DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

November 2015

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 18 and 19, 2015, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of August Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes from the August 2015 DoD P&T Committee meeting on October 30, 2015.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations (CFR) 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

Nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Alzheimer's Disease Agents: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric)

Memantine extended release (Namenda XR) is an N-methyl-D-aspartate (NMDA) receptor antagonist approved for once daily dosing in the treatment of moderate to severe Alzheimer's disease. The immediate release (IR) formulation of memantine (Namenda IR) is now available in a generic formulation. Namzaric is a fixed-dose combination product containing memantine extended release (ER) and donepezil (Aricept), the most commonly prescribed acetylcholinesterase inhibitor.

Although there are no well-conducted head-to-head studies that compare Namenda XR or Namzaric with other Alzheimer's drugs, the two new drugs appear similar to their IR and individual components in terms of efficacy and safety. Namenda XR and Namzaric provide a modest clinical benefit at best, and some efficacy endpoints in the clinical trials showed no benefit at all. While Namenda XR and Namzaric offer the convenience of once daily dosing, there is no data to support any additional clinical benefit of combining an NMDA receptor antagonist with an acetylcholinesterase inhibitor. There is no data available to support the fixed-dose combination improves adherence.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the main benefits for Namenda XR and Namzaric are their once daily dosing, which provides a convenience to caregivers or patients with swallowing difficulties. Aside from this factor, the memantine IR version and the individual components of memantine and donepezil are clinically interchangeable with the memantine ER version (Namenda XR) and combination product (Namzaric).

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: donepezil (Aricept, generics), memantine IR (Namenda, generics), galantamine (Razadyne, generic), donepezil orally dissolving tablet (Aricept ODT, generic), rivastigmine (Exelon, generic), galantamine ER (Razadyne ER), memantine ER (Namenda XR), memantine ER/donepezil (Namzaric), rivastigmine transdermal system (Exelon Patch).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) memantine ER (Namenda XR) and memantine ER/donepezil (Namzaric) be designated NF.

2. ***COMMITTEE ACTION: MN RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Namenda XR and Namzaric. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—Manual PA criteria were recommended at the August 2015 DoD P&T Committee meeting, with an implementation date of February 3, 2016. The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) maintaining the previously approved PA criteria for Namenda XR and Namzaric. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF, PA, AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first

Wednesday after a 90-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Attention Deficit Hyperactivity Disorder (ADHD): Stimulants

Background—The ADHD stimulants were reviewed for formulary placement. The full class, including the nonstimulants and wakefulness promoting agents, was previously reviewed in February 2012. New entrants to the class include amphetamine sulfate tablets (Evekeo), methylphenidate ER capsules (Aptensio XR), and dextroamphetamine tablets (Zenzedi). The only products that do not have generic equivalents include methylphenidate ER oral suspension (Quillivant XR), methylphenidate transdermal system (Daytrana), and lisdexamfetamine (Vyvanse).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- The new entrants to the class, Evekeo, Aptensio XR, and Zenzedi do not contain new chemical entities; they were approved by the FDA using data from previously approved drugs. There are no head-to-head studies between any of the new entrants and other ADHD stimulants. The active ingredients for the new drugs are available in generic formulations that are on the UF.
- Quillivant XR is the only long-acting methylphenidate oral suspension on the market and is approved for children as young as six years of age. Immediate release methylphenidate and dextroamphetamine oral solutions are therapeutic alternatives to Quillivant XR, but must be dosed twice daily.
- Daytrana is the only transdermal patch available for ADHD, but is associated with skin reactions.
- Vyvanse is currently designated NF and is approved for children and adults with ADHD. A review of Military Health System (MHS) prescribing habits shows that the vast majority of utilization for all the ADHD drugs, including Vyvanse, is in the population aged five to 14 years. Vyvanse has a new FDA-approved indication for binge eating disorder, but other therapies, including topiramate, zonisamide, and the selective serotonin reuptake inhibitors are also commonly used for this condition.
- For patients with swallowing difficulties, the following products can be used:

- Vyvanse is dissolvable in water.
- Ritalin LA, Metadate CD, Adderall XR, and Focalin XR capsules can be opened and their contents can be sprinkled on food.

- All the stimulants contain a black box warning for potential abuse and dependency.

Overall Relative Clinical Effectiveness Conclusion: There were no significant updates to the previous clinical conclusions from the February 2012 UF class review. The ADHD stimulants have a high degree of therapeutic interchangeability, although there are differences in the duration of action between products. The branded ADHD stimulants: Quillivant XR, Vyvanse, Daytrana, Zenzedi, Evekeo, and Aptensio XR offer no additional clinical advantages over the other stimulant agents on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results for brand-only agents showed that methylphenidate ER capsules (Aptensio XR) was the most cost-effective agent, followed by methylphenidate transdermal system (Daytrana), lisdexamfetamine (Vyvanse), methylphenidate ER oral suspension (Quillivant XR), and amphetamine tablets (Evekeo).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Aptensio XR, Quillivant XR, and Evekeo as formulary, with Daytrana and Vyvanse as NF, demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:
    - UF:
        - amphetamine sulfate tabs (Evekeo)
        - methylphenidate ER oral suspension (Quillivant XR suspension)
        - methylphenidate ER (Aptensio XR)
        - methamphetamine (Desoxyn, generic)
        - dextroamphetamine (Dexedrine spansule, Dextrostat tabs, ProCentra solution, generics; Zenzedi tabs)
        - mixed amphetamine salts ER (Adderall XR; generic)
        - mixed amphetamine salts IR (Adderall, generic)
        - methylphenidate osmotic controlled release oral delivery system (OROS) (Concerta; generic)
        - methylphenidate CD (Metadate CD; generic)
        - methylphenidate IR (Ritalin, generic)
        - methylphenidate LA (Ritalin LA, generic)
        - methylphenidate SR (Ritalin SR, generic)
        - methylphenidate ER (Metadate ER, Methylin ER, generic)

- methylphenidate chewable tablets, solution (Methylin, generic)
- dexmethylphenidate IR (Focalin; generic)

- NF
  - lisdexamfetamine (Vyvanse)
  - methylphenidate transdermal system (Daytrana)
  - dexmethylphenidate ER (Focalin XR, generic)

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:
   - Maintaining the following drugs on the BCF:
     - mixed amphetamine salts ER (Adderall XR; generic)
     - methylphenidate osmotic controlled release oral delivery system (OROS) (Concerta; generic)
   - Removing the following drugs from the BCF; they will remain UF
     - Methylphenidate ER (Ritalin LA, generic)
     - Methylphenidate IR (Ritalin IR, generic)

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) maintaining the current MN criteria for Daytrana and dexmethylphenidate ER (Focalin XR, generic). The P&T Committee also recommended updating the current MN criteria for Vyvanse. The MN criteria for Vyvanse will not include binge eating disorder. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: UF AND IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Antirheumatics: Injectable Methotrexate

Background—Methotrexate received FDA approval for the treatment of rheumatoid arthritis (RA) and psoriasis in 1959. Methotrexate is one of the most studied disease-modifying antirheumatic drugs (DMARD) and is a cornerstone of therapy for treating RA. Currently, injectable methotrexate is available in a generic 50 mg/2 mL vial formulation and two auto-injectors, Otrexup and Rasuvo. Injectable methotrexate products are administered subcutaneously.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- Methotrexate low-dose oral and injectable vial formulations:
    - Methotrexate absorption via the oral route is variable, especially at doses greater than 15 mg. In contrast, subcutaneous (SC) methotrexate injections are completely absorbed. Most patients prefer oral over SC methotrexate therapy.
    - Anecdotal observations report that some gastrointestinal toxicities may be avoided by administering methotrexate subcutaneously.
    - A 2014 Cochrane Review concluded there was moderate to high quality evidence demonstrating that oral methotrexate, in doses ranging between 5 mg to 25 mg, has a substantial clinical and statistically significant benefit in efficacy outcomes compared to placebo. There was a 16% discontinuation rate due to adverse events with oral methotrexate compared to 8% with placebo.
    - In 2008, a randomized controlled trial comparing the efficacy and safety of oral and SC methotrexate reported SC administration was significantly more effective than oral administration at the same dosage, with no difference in tolerability profiles.
- Methotrexate low-dose injectable vials and auto-injector formulations:
    - There are no head-to-head trials or systematic reviews comparing the different types of injectable methotrexate formulations.
    - The two new auto-injectors, Otrexup and Rasuvo, were FDA approved through 505(b)(2) applications by demonstrating bioequivalence to the generic injectable methotrexate vial formulations.
    - There are no clinical trials that demonstrate Otrexup or Rasuvo auto-injectors provide greater benefit to patients over oral or conventionally injected methotrexate using vials. There is no comparative effectiveness, safety, or tolerability data.
    - There is a high degree of therapeutic interchangeability for the injectable methotrexate delivery options.

Overall Relative Clinical Effectiveness Conclusion: Except for patient convenience, the methotrexate pre-filled auto-injector formulations of Otrexup and Rasuvo offer no additional clinical advantages over generic methotrexate vials. The benefit of the new products may be limited to a niche group of patients with limited vision, decreased finger dexterity, or impaired

cognition.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the injectable methotrexate products. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that injectable methotrexate in the vial formulation was the most cost-effective injectable agent, followed by Otrexup and Rasuvo.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating methotrexate injectable vials as formulary, with Otrexup and Rasuvo designated NF, demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

    - UF:
        - Methotrexate 50 mg/2 mL vials
    - NF:
        - Methotrexate auto-injector (Otrexup)
        - Methotrexate auto-injector (Rasuvo)

    NOTE: As part of this recommendation, generic methotrexate 2.5 mg tablets remain on the BCF in the Antirheumatics Drugs Class (pre-UF Rule decision).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for the methotrexate auto-injectors (Otrexup and Rasuvo). See Appendix B for the full criteria.
3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) PA criteria for the methotrexate auto-injectors (Otrexup and Rasuvo). See Appendix C for the full criteria.
4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) QLs for Otrexup and Rasuvo auto-injectors, consistent with the product labeling. See Appendix D for the QLs.
5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent)

1) an effective date of the first Wednesday after a 90-day implementation period in all points of service (POS); and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Acne Drugs: Oral Isotretinoins

Background—The oral isotretinoin acne agents were reviewed for formulary placement. All the products in the class have the same active ingredient, isotretinoin. The class is comprised of AB-rated generic formulations of Accutane, including Amnesteem, Claravis, Myorisan and Zenatane, and a branded product, Absorica.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- The oral isotretinoins, including Absorica, have the same FDA indication, labeling, efficacy, side effect profile, and drug interaction profile. As a subclass, the oral isotretinoins are effective in achieving a ≥70% reduction in total nodular lesion count when taken with meals for up to 20 weeks of therapy.
- Absorica is an oral isotretinoin product specifically formulated to allow for absorption regardless of meals. Absorica has a higher bioavailability in fasting conditions than the other oral isotretinoins. To ensure adequate absorption, the generic formulations must be taken with meals.
- In one head-to-head comparison study of Absorica and generic isotretinoin, there was no difference in efficacy outcomes or adverse reactions between the two products when taken under fed conditions.
- Potential advantages of Absorica include patient convenience due to administration without regard to meals, and the availability of two additional dosage strengths (25 mg and 35 mg) compared to generic oral isotretinoins. However, there are no published head-to-head trials that indicate better compliance or reduced relapse rates with Absorica compared to other isotretinoins.
- The oral isotretinoins are reserved for treating severe nodular recalcitrant acne, due to their significant adverse effects, including teratogenicity, pseudotumor cerebri, and psychiatric problems including suicide risk.
- All the oral isotretinoins, including Absorica, are rated as pregnancy category X, require mandatory enrollment in the Risk Evaluation and Mitigation Strategies (REMS) program iPLEDGE, and are limited to dispensing of a 30-day supply at one time.

- There is a high degree of therapeutic interchangeability among the oral isotretinoins and Absorica.

Overall Relative Clinical Effectiveness Conclusion: Other than the convenience of taking Absorica without regard to meals, it offers no additional clinical advantages over the other oral isotretinoins. Based on clinical issues alone, only one isotretinoin product is required on the UF.

Overall Relative Cost Effectiveness Conclusion: CMA and BIA were performed to evaluate oral isotretinoin agents. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that Myorisan and Amnesteem were the most cost-effective oral isotretinoins, followed by Zenatane, Claravis, and Absorica.
- BIA was performed to evaluate the potential impact of designating selected oral isotretinoins as formulary or NF on the UF. BIA results showed that designating Myorisan, Amnesteem, Zenatane, and Claravis as formulary, with Absorica as NF, demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:
    - UF oral isotretinoins:
        - Myorisan
        - Amnesteem
        - Zenatane
        - Claravis
    - NF oral isotretinoins:
        - Absorica

    NOTE: As part of this recommendation, no oral isotretinoin products were added to the BCF. The topical acne products tretinoin 0.25% and 0.05% (Retin A, generics) and clindamycin 1% and 2% (Cleocin T, generics) remain on the BCF (pre-UF Rule decision).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Absorica. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Absorica. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF, PA, AND IMPLEMENTATION PERIOD***
The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

D. Gastrointestinal-2 (GI-2) Miscellaneous Drugs

Background—The P&T Committee evaluated the GI-2 Miscellaneous Drugs. The drugs in the subclass include metronidazole (Flagyl, generic), oral vancomycin, fidaxomicin (Dificid), nitazoxanide (Alinia), oral neomycin, rifaximin (Xifaxan), alosetron (Lotronex), tegaserod (Zelnorm), linaclotide (Linzess), and lubiprostone (Amitiza). The FDA recently approved eluxadoline (Viberzi) and it will be reviewed as a newly-approved drug at an upcoming meeting. Tegaserod has been discontinued from the market.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following for the GI-2 Miscellaneous agents:

- There are no updates or changes from the previous clinical conclusions made at the November 2012 UF drug class review for the treatment of hepatic encephalopathy, travelers' diarrhea, *Clostridium difficile* associated diarrhea, and *Clostridium difficile* infection (CDI). (See the November 2012 P&T Committee meeting minutes at http://www.health.mil/PandT.)
- There are no head-to-head studies among any of the drugs in the GI-2 miscellaneous subclass for the indications of diarrhea-predominant irritable bowel syndrome (IBS-D), constipation-predominant IBS (IBS-C), or chronic idiopathic constipation. All of the clinical trials for IBS studies showed a significant placebo effect. Treatment for opioid-induced constipation was not a focus of this review.

Diarrhea-Predominant IBS (IBS-D)

- For rifaximin (Xifaxan), the studies for IBS-D are of moderate quality evidence. FDA approval for IBS-D was based on the unpublished TARGET 3 trial, which found that rifaximin was modestly more effective than placebo in relieving IBS-D symptoms but relapses were common. Rifaximin primarily relieves abdominal pain, but does not show a statistically significant improvement in stool consistency. It is also approved for travelers' diarrhea and to decrease the recurrence of hepatic encephalopathy.

- Use of alosetron (Lotronex) for IBS-D is restricted to women with severe refractory IBS-D. It is only available through an FDA-mandated REMS program due to the risk of severe adverse events, including death due to bowel obstruction.

Constipation-Predominant IBS (IBS-C)

- The FDA approved linaclotide (Linzess) for the treatment of IBS-C based on two placebo-controlled clinical trials. Linaclotide showed statistically significant improvements in both abdominal pain and an increase in number of bowel movements per week. The studies are rated as high quality evidence. It is generally well tolerated, although patients may experience diarrhea.
- The FDA approved lubiprostone (Amitiza) for the treatment of IBS-C based on two placebo-controlled trials that showed varying efficacy for IBS-C symptoms. The studies are of moderate quality evidence and were primarily conducted in Caucasian women.
    - The most common adverse events with lubiprostone (Amitiza) are nausea, headache, and diarrhea/abdominal pain. Limitations to use include its drug interaction profile and its FDA approval for use only in women for IBS.

Chronic Idiopathic Constipation (CIC)

- Both linaclotide (Linzess) and lubiprostone (Amitiza) are approved for treating CIC, and both drugs have shown increases in the number or frequency of bowel movements per week.
- Comparative efficacy between the two drugs for CIC cannot be made.

Overall relative clinical effectiveness conclusion: At this time, comparative efficacy statements between the drugs approved for treating IBS cannot be made due to their differing mechanisms of action, lack of head-to-head studies, lack of consistent diagnostic criteria, and variable endpoints. The P&T Committee concluded that even though the studies showed statistically significant results for treating IBS symptoms, whether the results are clinically meaningful remains to be determined due to the significant placebo response and lack of comparative studies.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results for the branded products, for all FDA-approved indications, showed that lubiprostone (Amitiza) and linaclotide (Linzess) were the most cost-effective agents, followed by alosetron (Lotronex), nitazoxanide (Alinia), rifaximin (Xifaxan), and fidaxomicin (Dificid).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF. BIA results showed that designating all agents in the GI-2 Miscellaneous Drug Subclass as formulary demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

   - UF
     - alosetron (Lotronex)
     - fidaxomicin (Dificid)
     - linaclotide (Linzess)
     - lubiprostone (Amitiza)
     - nitazoxanide (Alinia)
     - rifaximin (Xifaxan)
     - tegaserod (Zelnorm)—discontinued
     - metronidazole (Flagyl, generic)
     - neomycin
     - vancomycin

   - NF
     - None

   - Notes:
     - Fidaxomicin (Dificid) will continue to be excluded from the Mail Order Pharmacy due to the time constraints for treating acute *C. difficile* infection.
     - There were no changes to the BCF drugs in the class from the November 2012 meeting. Metronidazole 250 mg and 500 mg tablets will remain on the BCF.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Prior authorization was recommended for rifaximin, due to the potential for off-label uses for a wide range of conditions for which there is no supporting clinical data.

   The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

   - Applying new manual PA criteria for new users of rifaximin (Xifaxan) 550 mg tablets for treating IBS-D at a dosage of one tablet three times daily for 14 days. Up to two re-treatment courses will be allowed in six months, for a total of three total treatment courses. See Appendix C for the full criteria.
   - Continuing the existing manual PA criteria for rifaximin (Xifaxan) 550 mg tablets, for hepatic encephalopathy at a dosage of one tablet twice daily. (See November 2012 DoD P&T Committee meeting minutes for full criteria.)

- Continuing the current Prior Authorization for rifaximin 200 mg tablets for travelers' diarrhea, which requires a trial of a fluoroquinolone first. As part of this recommendation, the current quantity limits for rifaximin—200 mg tablets, one tablet three times daily for three days (a total of nine tablets), will be continued. (See November 2012 DoD P&T Committee meeting minutes for full criteria.)

3. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is March 30, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Targeted Immunomodulatory Biologics (TIBs): Adalimumab (Humira) Manual PA Criteria**—The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class. Adalimumab (Humira) was selected as the UF step-preferred agent. In September 2015, adalimumab (Humira) received FDA approval for treatment of moderate to severe hidradenitis suppurativa. The PA criteria were updated for Humira to reflect the new FDA indication.

   a) ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA) PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) revised manual PA criteria for Humira in new patients, consistent with the new FDA-approved product labeling for hidradenitis suppurativa. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) implementation of the PA for adalimumab become effective upon signing of the minutes.

2. **Anti-Malarial Drugs: Mefloquine Manual PA Criteria**—The P&T Committee discussed recent changes to the package insert for the antimalarial drug mefloquine (Lariam, generic) due to the risk of serious psychiatric and neurologic side effects. Mefloquine is primarily utilized as malaria prophylaxis. The P&T Committee has not reviewed the antimalarial drug class; most of the agents are available in generic formulations, with variability in malaria resistance patterns across the world.

   In April 2013, the Assistant Secretary of Defense for Health Affairs made changes to the malaria Force Health Protection program. Atovaquone-proguanil (Malarone, generic) and doxycycline are now first-line choices in areas other than Sub-Saharan Africa. In Sub-Saharan Africa, the first-line choice is atovaquone-proguanil, followed by doxycycline. Mefloquine is third line choice. In July 2013, the FDA added a black box warning to the mefloquine label due to risk of permanent adverse effects, including dizziness, loss of balance, and tinnitus. A Fiscal Year 2014 mefloquine drug utilization review revealed suboptimal documentation for contraindications and patient education in the available records.

   a) ***COMMITTEE ACTION: MEFLOQUINE MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for mefloquine in new users. The PA criteria are consistent with the FDA-approved product labeling to ensure safe and appropriate use of mefloquine. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: MEFLOQUINE PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is March 30, 2016.

3. **Hepatitis C Virus (HCV) Drugs: Direct Acting Antivirals (DAAs) Manual PA Criteria**—The HCV DAAs were reviewed by the P&T Committee in May 2015; manual PA criteria and QLs were recommended for the subclass. In July 2015, the FDA approved two new HCV DAAs for the treatment of HCV genotype 3 (GT3) and HCV genotype 4 (GT4): daclatasvir (Daklinza) and paritaprevir/ritonavir/ombitasvir (Technivie), respectfully. The P&T Committee reviewed the PA criteria and QLs for the DAAs due to the new entrants in the class, changes in the FDA package labeling, FDA drug safety communications, and updated treatment recommendations for HCV by the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA). Consult www.HCVguidelines.org for the most recent update from September 25, 2015.

   a) ***COMMITTEE ACTION: HCV DAAs MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) changes and/or new manual PA criteria for the following DAAs. See Appendix E for the full criteria.

(1) Removing the hepatitis B virus (HBV) co-infection contraindication from all the current HCV DAA manual PA criteria.

(2) Manual PA criteria for new users of paritaprevir/ritonavir/ombitasvir (Technivie). Technivie is contraindicated in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C) and is not indicated for use in patients with cirrhosis. It can cause serious liver injury in patients with underlying advanced liver disease. Prior authorization will expire after 12 weeks, based on the treatment regimen.

(3) Manual PA criteria for new users of daclatasvir (Daklinza). Prior authorization will expire after 12–24 weeks based on the treatment regimen.

(4) Revising the existing manual PA criteria for new users of sofosbuvir (Sovaldi). Prior authorization will expire after 12–48 weeks based on the treatment regimen.

(5) Revising the existing manual PA criteria for new users of paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak). Viekira Pak is contraindicated in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C) and can cause serious liver injury in patients with underlying advanced liver disease. Prior authorization will expire after 12–24 weeks based on the treatment regimen.

(6) Revising the existing manual PA criteria for new users of ledipasvir/sofosbuvir (Harvoni). Prior authorization will expire after 8–24 weeks based on the treatment regimen.

b) ***COMMITTEE ACTION: HCV DAAs QLs***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) QLs for both daclatasvir (Daklinza) and paritaprevir/ritonavir/ombitasvir (Technivie), limiting the quantity to a one-month supply. QLs apply to all the products in the HCV DAAs subclass and are consistent with recommended dosing and product packaging. See Appendix D for the QLs.

c) ***COMMITTEE ACTION: HCV DAAs MANUAL PA CRITERIA AND QLs IMPLEMENTATION PLAN***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) implementation for the manual PA criteria and QLs upon signing of the minutes.

4. **Female Hyposexual Desire Disorder (HSDD) Drugs: Flibanserin (Addyi) Manual PA Criteria**—Flibanserin is the first drug approved for treating HSDD in premenopausal women that is not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance.

The drug is available under a limited distribution program, requiring physician registration, due to the risk of adverse effects.

a) ***COMMITTEE ACTION: FLIBANSERIN (ADDYI) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for flibanserin (Addyi) in all new and current users, due to the risk of severe hypotension, especially if used concomitantly with alcohol. Prior authorization will be limited to the FDA-approved indication. Discontinuation of treatment is warranted if there is no improvement in symptoms after eight weeks. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: FLIBANSERIN (ADDYI) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

5. **Basal Insulins: Insulin Glargine 300 U/mL (Toujeo) Manual PA Criteria**—Toujeo is a long-acting human insulin analog indicated for improvement of glycemic control in adults with type 1 or type 2 diabetes mellitus. It contains a concentrated solution of insulin glargine, 300 U/mL. Insulin glargine under the brand name of Lantus has been available since 2000, at a concentration of 100 U/mL. The hemoglobin A1c-lowering effect of Toujeo is similar to Lantus. Other formulations of insulin glargine are expected in 2016.

   a) ***COMMITTEE ACTION: INSULIN GLARGINE 300 U/mL (TOUJEO) PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for Toujeo in all new and current users, to ensure appropriate use and to reduce the risk of insulin dosing errors. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: INSULIN GLARGINE 300 U/mL (TOUJEO) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

6. **Chronic Heart Failure Drugs: Ivabradine (Corlanor) Manual PA Criteria** Ivabradine (Corlanor) is approved to decrease the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure. The package insert states the drug should only be used in patients who have a left ventricular ejection fraction of less than 35%, who have a heart rate of at least 70 beats per minute, and who are receiving maximum tolerated doses of beta blockers, or who have a contraindication

to beta blockers. Corlanor decreases heart rate without affecting ventricular repolarization or myocardial contractility.

a) ***COMMITTEE ACTION: IVABRADINE (CORLANOR) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for new users of Corlanor, consistent with the FDA-approved product labeling. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: IVABRADINE (CORLANOR) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 4,2016.

7. **Second Generation Antihistamines: Desloratadine (Clarinex), desloratadine/pseudoephedrine (Clarinex-D), and levocetirizine (Xyzal) MN Criteria**—MN criteria apply to the NF second generation antihistamines Clarinex, Clarinex-D, and Xyzal. The current formulary alternatives listed on the MN form include fexofenadine (Allegra, generic) and fexofenadine/pseudoephedrine (Allegra-D). Several antihistamine formulations are now solely available over-the-counter, including fexofenadine, loratadine (Claritin, generics), and cetirizine (Zyrtec, generics).

   a) ***COMMITTEE ACTION: SECOND GENERATION ANTIHISTAMINES MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) revising the current second generation antihistamines MN criteria to remove fexofenadine as a formulary alternative, and to add generic loratadine and cetirizine with or without pseudoephedrine as appropriate formulary alternatives.

   b) ***COMMITTEE ACTION: SECOND GENERATION ANTIHISTAMINES MN CRITERIA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

B. QLs

1. Quantity limits were reviewed for five drugs: idelalisib (Zydelig) for chronic lymphocytic leukemia, gefitinib (Iressa) for metastatic non-small cell lung cancer, sonidegib (Odomzo) for advanced basal cell carcinoma, flibanserin (Addyi) for HSDD and isavuconazonium (Cresemba) for invasive aspergillosis and mucormycosis.

COMMITTEE ACTIONS: QLs—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) QLs for idelalisib (Zydelig), gefitinib (Iressa), sonidegib (Odomzo), flibanserin (Addyi), and isavuconazonium (Cresemba). See Appendix D for the QLs.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VII. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

The P&T Committee reviewed three drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with the FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity at military treatment facilities (MTFs). These NF drugs will remain available in the Mail Order POS without preauthorization.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following products be designated NF on the UF:

- Pari Respirator: tobramycin (Kitabis Pak), 300 mg/5 mL inhalation solution
- Libertas Pharm: doxycycline (Doryx), 200 mg delayed release tablet
- Gemini Labs: levothyroxine (Unithroid) 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 137 mcg, 150 mcg, 175 mcg, and 300 mcg tablets

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following preauthorization criteria for Kitabis Pak. Doryx, and Unithroid:

1. Obtaining the product by home delivery would be detrimental to the patient; and,
2. For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.

These preauthorization criteria do not apply to any other POS other than retail network pharmacies.

Note that the following drugs will not be available in the Mail Order Pharmacy:

- Kitabis Pak, 300 mg/5 mL inhalation solution, is only available in the Retail Network via a specialty distributor network of pharmacies.
- Unithroid 25 mcg and 100 mcg tablets are noncompliant with the Trade Agreements Act and, therefore, are only available in retail network pharmacies.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in the Retail Network; and 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. INNOVATOR DRUGS

Section 702 of the FY15 NDAA established new authority for the P&T Committee's review process of FDA newly-approved innovator drugs. The P&T Committee is provided up to 120 days to recommend tier placement for innovator drugs on the UF. During this period, innovator drugs will be assigned a classification pending status; they will be available under terms comparable to NF drugs, unless medically necessary, in which case they would be available under terms comparable to formulary drugs. For additional information, see the August 2015 DoD P&T Committee meeting minutes at http://www.health.mil/PandT.

Drugs subject to the Innovator Rule are defined as new drugs that are approved by the FDA under a Biologic License Application (BLA) or New Drug Application (NDA). The NDA innovator drugs will be further defined by their chemical types to include, but not limited to, new molecular entities, new active ingredients, and new combinations. The definition was further expanded to include new dosage formulations.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following regarding the innovator drugs:

A. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors—Evolocumab (Repatha)

- The PCSK9 inhibitors are a new class of biologic drugs that lower low-density lipoprotein (LDL) cholesterol and are administered by SC injection. The first product, alirocumab (Praluent), was approved on July 24, 2015, prior to implementation of the Innovator Rule on August 25, 2015. Evolocumab (Repatha) is the second PCSK9 inhibitor, and obtained FDA approval on August 27, 2015, after the Innovator Rule went into effect. An interim P&T Committee meeting held on September 3, 2015, recommended PA and MN criteria, and QLs for Repatha. (See August 2015 DoD P&T Committee meeting minutes, found at http://www.health.mil/PandT.)
- The product labeling for Repatha is similar to Praluent, with the exception that, in addition to patients with heterozygous familial hypercholesterolemia (HeFH) and clinical atherosclerotic cardiovascular disease (ASCVD), Repatha is also approved for treating patients with homozygous familial hypercholesterolemia (HoFH), including pediatric patients from ages 13 to 17 years.
- The PCSK9 inhibitors cause reductions in low-density lipoprotein cholesterol (LDL-C) ranging from 40% to 75%. Excluding the additional indication for HoFH, the LDL-lowering benefit for Repatha appears similar to Praluent, based on their individual trials.
- The effect of the PCSK9 inhibitors on cardiovascular (CV) morbidity and mortality has not been determined. CV outcomes studies are expected in 2017, and will aid in defining the clinical benefit of this drug class.
- Praluent is available on the UF and covers the same indication as Repatha. For patients with HoFH, patients can access Repatha via the previously approved PA and MN criteria.
- Relative cost-effectiveness of Repatha was reviewed by the P&T Committee.

B. Oral Oncologic Drugs—Trifluridine/Tipiracil (Lonsurf)

- Lonsurf is a last line, oral treatment for metastatic colorectal cancer. First line treatments are intravenously administered medications.
- Efficacy shows statistical significance for Lonsurf in terms of increased overall survival compared to placebo (7.1 months versus 5.3 months, respectively).
- Relative cost-effectiveness of Lonsurf was reviewed by the P&T Committee.

C. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Empagliflozin/Metformin IR (Synjardy)

- The SGLT2 inhibitors were reviewed in August 2015. Empagliflozin (Jardiance) and empagliflozin/linagliptin (Glyxambi) were designated formulary and step-preferred,

while the two other products and their combinations (canagliflozin and dapagliflozin with and without metformin) were designated NF and non step-preferred.

- Synjardy is the third available fixed-dose combination containing an SGLT2 inhibitor and metformin. There are no significant clinical differences between the three SGLT2 inhibitors in terms of effect on glycemic control, or changes in weight, blood pressure and lipid parameters.
- Empagliflozin/metformin offers the advantage of a fixed-dose combination with metformin. The parent compound is the step-preferred SGLT2 inhibitor.
- Relative cost-effectiveness of Synjardy was reviewed by the P&T Committee.

1. ***COMMITTEE ACTIONS: UF RECOMMENDATIONS***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

    - UF:
        - Oncology Drugs: tifluridine/tipiracil (Lonsurf)
        - SGLT2 Inhibitors: empagliflozin/metformin IR (Synjardy); Synjardy will be step-preferred. No changes were recommended for the previously approved step-therapy and manual PA criteria. See Appendices B, C, and D.
    - NF:
        - PCSK9 Inhibitor: evolocumab (Repatha). No changes were recommended for the previously approved manual PA criteria, MN criteria, or QLs. See Appendices B, C, and D.

2. ***COMMITTEE ACTION: UF IMPEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date upon signing of the minutes in all POS.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

IX. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM (EXPANDED MTF/MAIL PHARMACY INITIATIVE), AND NONFORMULARY (TIER 3) PHARMACEUTICALS AT MAIL ORDER

The Expanded MTF/Mail Pharmacy Initiative (EMMPI) medication program drug list is defined by the P&T Committee, which recommends additions and removals. The program, which began on October 1, 2015, requires that non-Active Duty beneficiaries initiating treatment with drugs on the EMMPI list must fill those prescriptions at MTFs or the Mail Order Pharmacy, following two courtesy fills at the Retail Network. The requirement can be waived based on individual patient needs and other appropriate circumstances. Additionally, recent statutory and regulatory changes mandate that NF pharmaceutical agents are generally not available at MTFs or the Retail Network, but are available in the Mail Order program. For additional information on these two programs, refer to the August 2015 DoD P&T Committee meeting minutes, available at http://www.health.mil/PandT.

The P&T Committee undertook a review of drug classes containing one or more medications currently on the EMMPI list or the list of NF (Tier 3) medications. The review had three purposes: 1) to recommend any additional exceptions to the requirement to fill NF (Tier 3) medications at mail order; 2) to recommend changes to the EMMPI list in order to apply Mail or MTF/Mail requirements consistently within drug classes; and, 3) to define drug classes to be added to the EMMPI list, whenever possible, enabling newly-approved branded, legend agents in those classes that are intended for chronic use to be added to the program automatically.

A. Expanded Maintenance Medication Program Drug List and NF (Tier 3) Medications Available at the Mail Order Pharmacy

- The P&T Committee did not identify any new exceptions to the NF (Tier 3) mail requirement, but did apply already defined exceptions (outlined in Appendix G).
- The P&T Committee also recommended temporarily deferring implementation of the Mail Order requirement for several medications or drug classes until outstanding questions regarding acute versus chronic use, availability at Mail Order, or the need for additional exceptions can be resolved, or until NF (Tier 3) status for medications that are now available in generic formulations can be reviewed. Major drug classes falling into the last category include the calcium channel blockers, proton pump inhibitors, and oral contraceptives.
- The P&T Committee recommended numerous additions to the EMMPI list, as outlined in Appendix G.
- The P&T Committee recommended establishing class definitions as outlined in Appendix G.

1. ***COMMITTEE ACTION: EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) changes to the EMMPI list and the establishment of class definitions applying to the EMMPI list, as outlined in Appendix G.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

X. ITEMS FOR INFORMATION

A. Beneficiary Advisory Panel Comments—The P&T Committee was briefed on comments from the Beneficiary Advisory Panel (BAP) members from the September 30, 2015, meeting regarding pre-authorization criteria for drugs not in compliance with FY08 NDAA, Section 703. Regarding the criterion written as,

> "For branded products with AB-rated generic availability, use of the generic product would be detrimental to the patient,"

the BAP recommended changing "would" to "could." The P&T Committee acknowledged the BAP's comments, but recommended maintaining the criterion as written, since the P&T Committee would have identified those Section 703 medications that may have a unique clinical requirement.

XI. ADJOURNMENT

The meeting adjourned at 1125 hours on November 19, 2015. The next meeting will be in February 2016.

Appendix A—Attendance: November 2015 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Hepatitis C Virus Drugs Prior Authorization Criteria

Appendix F—Table of Innovator Drugs: Formulary Recommendations

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug List and Nonformulary Medications Excluded from Mail Order Requirements

Appendix H—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary

Appendix I—Table of Abbreviations

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

R.C. Bono
VADM, MC, USN
Director

16 01 29
Date

Appendix A—Attendance: November 2015 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood for George Jones, PharmD, M.S.	Chief, DHA Operations Management Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
COL Jack Lewi, MC	Army, Internal Medicine Physician
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
CDR Karl Kronmann, MC	Navy, Physician at Large Alternate
MAJ Dausen Harker, MC	Army, Family Practice Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Shaun Carstairs, MC	Navy, Physician at Large
MAJ John Poulin, MC	Army, Physician at Large
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Guests	
CAPT Stephen Rudd	Indian Health Service
LT Teisha Robertson via DCS	DHA Purchased Care Operations
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
MAJ Michele Hudak via DCS	DHA Integrated Utilization Branch
Mr. Henry Gibbs via DCS	Chief, DHA Informatics Integration
Maj Richard Caballero	Defense Logistics Agency Troop Support
Mr. Alexander Quiñones	Defense Logistics Agency Troop Support
Mr. Bruce Mitterer	DHA Contract Operations Division
Ms. Chelsea Lavelle	DHA Contract Operations Division
Ms. Praise Stephenson	DHA Contract Operations Division
CPT Kenesha Pace	Army Medical Department Center and School
CPT Ryan Costantino	Winn Army Community Hospital, Ft. Stewart

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
CDR Marisol Martinez, USPHS	DHA Formulary Management Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MS	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
LTC Misty Carlson, MC	DHA Integrated Utilization Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Dr. David Meade via DCS	DHA Integrated Utilization Branch
Dr. Ingrid Svihla, PharmD, BCPS	DHA Integrated Utilization Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
Dr. Elizabeth Hearin, PharmD, BCPS	DHA Informatics Integration
Emily Griffin	University of North Carolina Eshelman School of Pharmacy Student

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Memantine ER (Namenda XR) • Memantine ER/Donepezil (Namzaric) **Alzheimer's Disease Agents**	• No alternative formulary agent—Patient requires once daily dosing or has difficulty swallowing, or multiple daily dosing causes undue burden to caregiver. **Formulary Alternatives:** memantine IR (Namenda), donepezil (Aricept), galantamine (Razadyne, generic), donepezil orally dissolving tablet (Aricept ODT, generic), rivastigmine (Exelon, generic), galantamine ER (Razadyne ER), memantine ER (Namenda XR), memantine/donepezil (Namzaric), and rivastigmine transdermal system (Exelon Patch)
• Lisdexamfetamine (Vyvanse) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	• Use of formulary ADHD stimulants is contraindicated • Patient has experienced significant adverse effects from formulary ADHD stimulants • Use of the formulary stimulants has resulted in therapeutic failure for ADHD. Note that the MN criteria does not include Binge Eating Disorder. **Formulary Alternatives:** methylphenidate ER and mixed amphetamine salts, Ritalin LA, Metadate CD, Concerta, Adderall XR
• Methylphenidate Transdermal System (Daytrana) • Dexmethylphenidate ER (Focalin XR) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	No changes to MN criteria recommended in February 2012. • Use of formulary ADHD stimulants is contraindicated • Patient has experienced significant adverse effects from formulary ADHD stimulants • Use of the formulary stimulants has resulted in therapeutic failure • No alternative formulary agent: For Daytrana only, the patient is unable to take oral medications **Formulary Alternatives:** Extended-release methylphenidate and mixed amphetamine salts, including Ritalin LA, Metadate CD, Concerta, Adderall XR
• Methotrexate auto-injector (Otrexup) • Methotrexate auto-injector (Rasuvo) **Antirheumatics: Injectable Methotrexate**	• No alternative formulary agent. Patient requires an auto-injector due to decreased finger dexterity, limited vision, or impaired cognition. **Formulary Alternatives:** generic methotrexate 50 mg/2 mL vials; generic methotrexate 2.5 mg tablets
• Isotretinoin (Absorica) **Acne Drugs: Oral Isotretinoins**	• No alternative formulary agent. Patient is unable to comply with dietary requirements associated with the formulary oral isotretinoins. **Formulary Alternatives:** Generic formulations of Amnesteem, Claravis, Zenatane, Myorisan
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	No changes to MN criteria recommended September 3, 2015. • Use of statins is contraindicated. The contraindication must be listed on the medical necessity form. • The patient has had an inadequate response to a statin, with an LDL > 100 mg/dL despite statin therapy at maximal tolerated doses. • The patient is intolerant of statins. • No alternative formulary agent. The patient has homozygous familial hypercholesterolemia and requires additional LDL-C lowering, despite maximal doses of statin or other therapies (e.g., ezetimibe, LDL apheresis). **Formulary Alternatives:** statins, ezetimibe

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Memantine ER (Namenda XR) **Alzheimer's Disease Agents**	Manual Prior Authorization criteria originally approved August 2015 with an implementation date of February 3, 2016. No changes recommended to PA criteria November 2015. Manual PA criteria apply to all new users of Namenda XR. Manual PA criteria—Namenda XR is approved if: • The patient is being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia), AND • Taking Namenda IR (memantine) twice daily causes undue burden to the patient or care provider, AND • The patient's functional status has not declined while receiving Namenda IR Prior Authorization does not expire.
• Memantine ER/ Donepezil (Namzaric) **Alzheimer's Disease Agents**	Manual Prior Authorization criteria originally approved August 2015 with an implementation date of February 3, 2016. No changes recommended to PA criteria November 2015. Manual PA criteria apply to all new users of Namzaric. Manual PA criteria—Namzaric is approved if: • The patient is being treated for moderate to severe dementia of the Alzheimer's type, AND • The patient is stabilized on one of the following regimens: o memantine IR 10 mg twice daily or memantine ER 28 mg once daily and donepezil hydrochloride 10 mg, OR o memantine IR 5 mg twice daily or ER 14 mg once daily and donepezil hydrochloride 10 mg, AND • The patient is unable to take Namenda (memantine) and Aricept (donepezil) separately, OR • The patient has progressive swallowing difficulties Prior Authorization does not expire.
• Methotrexate auto-injector (Otrexup) • Methotrexate auto-injector (Rasuvo) **Antirheumatics: Injectable Methotrexate**	Manual PA criteria apply to all new users of Otrexup and Rasuvo methotrexate auto-injectors. Manual PA criteria—Otrexup or Rasuvo are approved if: • The patient has experienced intolerance or significant adverse effects from generic injectable methotrexate vials OR • The patient has decreased finger dexterity, limited vision, or impaired cognition that results in the inability to utilize generic injectable methotrexate vials Prior authorization does not expire.
• Absorica **Acne Drugs: Oral Isotretinoins**	Manual PA criteria apply to all new users of Absorica. Manual PA criteria • Patient is unable to comply with the dietary requirements of an AB-rated generic oral isotretinoin Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Rifaximin (Xifaxan) 550 mg tablets **GI-2 Miscellaneous Drugs**	All new users of rifaximin 550 mg tablets are required to undergo manual prior authorization criteria. <u>Manual PA criteria</u> • Hepatic Encephalopathy: No changes from November 2012 o Patient is ≥18 years of age o Patient has a documented diagnosis of hepatic encephalopathy o Prior Authorization does not expire • Irritable Bowel Syndrome-Diarrhea Predominant (IBS-D) o Patient has clinically documented moderate to severe IBS-diarrhea type, without constipation, and has symptoms of moderate abdominal pain and bloating. AND o The patient has had failure, intolerance, or contraindication to at least one antispasmodic agent; e.g., dicyclomine (Bentyl), Librax, hyoscyamine (Levsin), Donnatal, loperamide (Imodium) AND o The patient has had failure, intolerance, or contraindication to at least one tricyclic antidepressant (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline o If yes to the above, then treatment will be approved for a single 14-day course of therapy (550 mg tablets, one tablet three times daily for 14 days) o For IBS-D, patients who experience recurrence of symptoms can be retreated up to two more times with the same regimen (total of three treatment courses in 6 months) if the following: • Patient has had a positive response to a previous 14-day course of rifaximin. o Prior authorization expires in 6 months • Non-FDA approved uses, including use of the 200 mg rifaximin tablets for travelers' diarrhea, *C. difficile* infection, inflammatory bowel disease, chronic abdominal pain, hepatitis, diabetes, rosacea, or any other non FDA-approved condition: o Prior Authorization is not approved • Use of rifaximin 200 mg tablets for travelers' diarrhea is subject to prior authorization. See November 2012 P&T Committee meeting minutes.
• Adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs)**	Prior Authorization criteria originally approved August 2014 and implemented February 18, 2015. November 2015 changes to PA criteria in bold. Manual PA criteria for hidradenitis suppurativa applies to new patients. Manual PA Criteria applies to all new users of adalimumab (Humira). Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate • Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade • Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

Drug / Drug Class	Prior Authorization Criteria
	• **Moderate to severe hidradenitis suppurativa (November 2015)** Pediatric patients with: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric patients: 2–17 years) • Moderate to severely active Crohn's disease (≥ 6 years) who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan) Prior Authorization does not expire.
• Mefloquine **Antimalarial Drugs**	Manual PA Criteria apply to all new users of mefloquine. Coverage approved for patients with the following: • Patients requiring mefloquine for malaria chemoprophylaxis. The PA is not intended for patients requiring treatment of acute malaria infections. • Patients with a contraindication or intolerance to both atovaquone-proguanil (Malarone) and doxycycline (e.g., pregnancy) • Patients do NOT have a major psychiatric disorder to include but not limited to o Active or recent history of depression o Generalized anxiety disorder o Psychosis or schizophrenia o Post-Traumatic Stress Disorder (PTSD) or Traumatic Brain Injury (TBI) • Patients do NOT have a history of seizures or vestibular disorders • Patients do NOT have a cardiac conduction abnormality AND • The total treatment duration (months) must be documented on the PA form. AND • The above information is documented in the medical record and the patient has been educated on mefloquine adverse effects and dosing. Prior Authorization expires after one continuous treatment course.
• Flibanserin (Addyi) **Female Hyposexual Desire Disorder Drugs**	Manual PA criteria apply to all new and current users of flibanserin (Addyi). <u>Manual PA criteria</u>—Flibanserin is approved if: • The drug is prescribed for a premenopausal female with HSDD not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance AND • The patient does not have current alcohol use • The patient does not have hepatic impairment (Child-Pugh score ≥6) • The patient is not receiving concomitant therapy with a moderate or strong CYP3A4 inhibitor (e.g., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil) AND • The prescription is written from a provider who is certified/enrolled in the flibanserin REMS program • Note that contraindications to the use of flibanserin include concurrent alcohol, moderate or strong CYP3A4 inhibitors, and hepatic impairment Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Insulin glargine 300 U/mL (Toujeo) **Basal Insulins**	Manual PA criteria apply to all new and current users of Toujeo. Manual PA criteria—Toujeo is approved if: • The patient is at least 18 years of age AND • The patient has diabetes and is using a minimum of 100 units of Lantus (insulin glargine) per day AND • The patient requires a dosage increase with Lantus and has experienced a clinically significant, severe hypoglycemia episode, despite splitting the Lantus dose AND • The patient has been counseled regarding the risk of dosing errors. • Note that the following are not acceptable reasons for Toujeo: o Non-adherence to previous insulin treatment o Patient or prescriber preference for the use of Toujeo o Patient or prescriber preference for a smaller injection volume Prior Authorization does not expire.
• Ivabradine (Corlanor) **Chronic Heart Failure Drugs**	Manual PA criteria apply to all new users of Corlanor. Manual PA criteria—Corlanor is approved if: • The drug is prescribed by a cardiologist or heart failure specialist. • The patient has a diagnosis of stable, symptomatic heart failure with left ventricular ejection fraction ≤35%, is in sinus rhythm, and has a resting heart rate >70 beats per minute. • The patient has heart failure symptoms despite maximal therapy of a beta blocker therapy that has been shown to have survival benefit in heart failure. o Note that acceptable heart failure beta blockers and target doses include the following: metoprolol succinate ER 200 mg QD; carvedilol 25 mg BID, or 50 mg BID if < 85 kg; carvedilol ER 80 mg QD; bisoprolol 10 mg QD (bisoprolol is not FDA-approved for heart failure but has proven efficacy in a large clinical trial) • OR the patient has a contraindication to beta blocker use o Note that the contraindication must be listed on the Prior Authorization form. Prior Authorization does not expire.
• Canagliflozin (Invokana) • Canagliflozin/metformin (Invokamet) • Dapagliflozin (Farxiga) • Dapagliflozin/metformin ER (Xigduo XR) • Empagliflozin (Jardiance) • **Empagliflozin/ Metformin IR (Synjardy)**	No changes to step therapy and manual PA criteria recommended August 2015; to be implemented February 3, 2016. All new users of an SGLT2 inhibitor are required to try metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin or a sulfonylurea (SU) and a DPP-4 inhibitor first. Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first. Automated PA criteria

Drug / Drug Class	Prior Authorization Criteria
Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors	• The patient has filled a prescription for metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. OR • The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria—If automated PA criteria are not met, Jardiance, Synjardy, or Glyxambi is approved (e.g., a trial of metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes are NOT required) if: • The patient has had an inadequate response to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has experienced a significant adverse effect from metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has a contraindication to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes. AND In addition to the above criteria regarding metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes, the following PA criteria would apply specifically to all new and current users of canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/ metformin ER (Xigduo XR): • The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance, Glyxambi, or Synjardy) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	No changes recommended for PA criteria from September 3, 2015, implemented October 30, 2015. Manual PA criteria apply to all new and current users of evolocumab (Repatha). Manual PA criteria—Evolocumab is approved if: • A cardiologist, lipidologist, or endocrinologist prescribes the drug. • The patient is at least 18 years of age for HeFH and clinical ASCVD. For HoFH, patients as young as 13 years of age can receive the drug. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally tolerated statin in combination

Drug / Drug Class	Prior Authorization Criteria
	with ezetimibe, OR o If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. – Contraindication to statin ▪ The contraindication must be defined. • Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 140 mg every 2 weeks, or o 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. • PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Repatha will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Methotrexate auto-injector (Otrexup) • Methotrexate auto-injector (Rasuvo) **Antirheumatics: Injectable Methotrexate**	▪ Retail Network: 4 auto-injectors per 30 days ▪ MTF and Mail Order Pharmacy: 12 auto-injectors per 90 days
• Paritaprevir/ritonavir/ombitasvir (Technivie) **Hepatitis C Drugs—DAAs**	▪ Retail Network, Mail Order Pharmacy and MTF: 1 monthly carton with 4 weekly cartons each containing a 7 daily dose pack with 2 paritaprevir/ritonavir/ombitasvir tablets / 28 days
• Daclatasvir (Daklinza) **Hepatitis C Drugs—DAAs**	▪ Retail Network, Mail Order Pharmacy and MTF: 28 tablets per 28 days
• Idelalisib (Zydelig) **Chronic Lymphocytic Leukemia; B-cell Non-Hodgkin Lymphoma; Small Lymphocytic Lymphoma**	▪ Retail Network: 60 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 120 tabs per 60 days
• Gefitinib (Iressa) **Metastatic Non-Small Cell Lung Cancer**	▪ Retail Network : 30 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 60 tabs per 60 days
• Sonidegib (Odomzo) **Advanced Basal Cell Carcinoma**	▪ Retail Network: 30 caps per 30 days ▪ MTF and Mail Order Pharmacy: 60 caps per 60 days
• Flibanserin (Addyi) **Hypoactive Sexual Desire Disorder**	▪ Retail Network: 30 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 60 tabs per 60 days
• Isavuconazonium (Cresemba) **Invasive Aspergillosis and Mucormycosis**	▪ Retail Network: 56 tabs per 28 days ▪ MTF and Mail Order Pharmacy: 112 tabs per 56 days
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	No changes recommended from September 3, 2015, implemented October 30, 2015. ▪ HeFH and ASCVD o Retail Pharmacy Network: 2 of the 140 mg syringes per 30 days o MTF and Mail Order Pharmacy: 6 of the 140 mg syringes per 90 days. ▪ HoFH o Retail Pharmacy Network: 3 of the 140 mg syringes per 30 days ▪ MTF and Mail Order Pharmacy: 9 of the 140 mg syringes per 90 days

Appendix E—Table of Hepatitis C Virus Drugs Prior Authorization Criteria

Prior Authorization Criteria

Paritaprevir/Ritonavir/Ombitasvir (Technivie)—New PA Criteria November 2015

Direct Acting Antiviral Subclass

- New users of paritaprevir/ritonavir/ombitasvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 4 infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Paritaprevir/ritonavir/ombitasvir (Technivie) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Does not have moderate or severe hepatic impairment (Child-Pugh Class B & C), or cirrhosis

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 12 weeks, based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for Paritaprevir/Ritonavir/Ombitasvir (Technivie)

Patient Population	Treatment	Duration
Genotype 4 without cirrhosis	TECHNIVIE + ribavirin	12 weeks*
For initial therapy of treatment naïve as well as retreatment of patient with GT4 who previously failed RBV + IFN * Technivie without ribavirin for 12 weeks may be considered for some treatment-naïve patients who cannot tolerate ribavirin		

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Prior Authorization Criteria

Daclatasvir (Daklinza)—New PA Criteria November 2015

Direct Acting Antiviral Subclass

- New users of daclatasvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 3 infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Daclatasvir (Daklinza) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Daclatasvir (Daklinza) is not prescribed as monotherapy

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 12 to 24 weeks, based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for Daclatasvir (Daklinza)

Genotype	Patient Population	Treatment	Duration
3	Treatment naïve or experienced[1] without cirrhosis	DACLATASVIR + SOFOSBUVIR	12 weeks
	Treatment naïve or experienced[1] with cirrhosis	DACLATASVIR + SOFOSBUVIR ± ribavirin	24 weeks
[1]Treatment experienced have failed with peginterferon alpha plus ribavirin			

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Prior Authorization Criteria

Sofosbuvir (Sovaldi)—November 2015 updates are bolded

Direct Acting Antiviral Subclass

- New users of sofosbuvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1, 2, 3, or 4 HCV infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Sofosbuvir (Sovaldi) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Sofosbuvir (Sovaldi) is not prescribed as monotherapy

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 12 to 24 week (up to 48 weeks in HCC awaiting transplants), based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for Sofosbuvir (Sovaldi)

HCV genotype	Treatment	Duration
Genotype 1	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks
	SIMEPREVIR 150 mg once daily + SOFOSBUVIR 400 mg once daily (treatment naïve or experienced without cirrhosis)	12 weeks
	SIMEPREVIR 150 mg once daily + SOFOSBUVIR 400 mg once daily (treatment naïve or experienced with cirrhosis)	24 weeks
Genotype 2	SOFOSBUVIR + ribavirin	12 weeks
	SOFOSBUVIR + ribavirin (cirrhotic or treatment experienced)	16 to 24 weeks
	SOFOSBUVIR + peginterferon alfa + ribavirin (treatment experienced)	**12 weeks**
Genotype 3	SOFOSBUVIR + ribavirin	24 weeks
	SOFOSBUVIR + peginterferon alfa + ribavirin (cirrhotic or treatment experienced)	12 weeks
	DACLATASVIR + SOFOSBUVIR (without cirrhosis)	**12 weeks**
	DACLATASVIR + SOFOSBUVIR + ribavirin (cirrhotic)	**24 weeks**
Genotype 4, 5, 6	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks
	SOFOSBUVIR + ribavirin	24 weeks
Hepatocellular carcinoma awaiting transplant	SOFOSBUVIR + ribavirin	up to 48 weeks or at transplant
Treatment-experienced patients who have failed treatment with peginterferon alfa plus ribavirin but not a HCV protease inhibitor		

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Prior Authorization Criteria

Paritaprevir/Ritonavir/Ombitasvir with Dasabuvir (Viekira Pak)—November 2015 updates are bolded

Direct Acting Antiviral Subclass

- New users of paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1 HCV infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- **Does not have moderate or severe hepatic impairment (Child-Pugh Class B & C), decompensated cirrhosis, or IL-28B T/T polymorphism**
- If co-infected with HIV, patient is on anti-retroviral therapy

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment and presence of cirrhosis.
- Prior authorization will expire after 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1 Patient Populations[1,2,3]	***Treatment***	***Duration***
GT1a without cirrhosis	Viekira Pak + ribavirin bid	12 weeks
GT1a with cirrhosis[4]	Viekira Pak + ribavirin bid	24 weeks
GT1b without cirrhosis	Viekira Pak	12 weeks
GT1b with cirrhosis	Viekira Pak	12 weeks
Liver transplant recipients with normal hepatic function and mild fibrosis (Metavir ≤2)	Viekira Pak + ribavirin bid	24 weeks

[1]Follow GT1a dosing recommendation in patients with an unknown GT1 or mixed GT1 infection

[2]Treatment naïve or treatment-experienced with peginterferon alpha plus ribavirin

[3]Contraindicated in moderate and severe hepatic impairment (Child-Pugh Class *B* & C)

[4] Avoid in GT1a patients with cirrhosis and prior null responder to peginterferon/ribavirin

Prior Authorization Criteria

Ledipasvir/Sofosbuvir (Harvoni)—November 2015 updates are bolded

Direct Acting Antiviral Subclass

- New users of ledipasvir/sofosbuvir (Harvoni) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1 or 4 infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Ledipasvir/sofosbuvir (Harvoni) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 8 weeks or 12 weeks or 24 weeks, based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for Daclatasvir (Daklinza)

Genotype 1 Patient Populations[1]	Treatment	Duration
Treatment naïve with or without cirrhosis	HARVONI	8-12 weeks[2]
Treatment experienced without cirrhosis	HARVONI	12 weeks
Treatment experienced with cirrhosis	**HARVONI + ribavirin**	**12 weeks**
Treatment experienced with cirrhosis	HARVONI	24 weeks
Genotype 4 Patient Population	**Treatment**	**Duration**
Treatment naïve or experienced with or without cirrhosis	**HARVONI**	**12 weeks**

[1]Treatment-experienced patients who have failed treatment with either (a) peginterferon alfa plus ribavirin or (b) HCV protease inhibitor plus peginterferon alfa plus ribavirin

[2]Consider treatment duration of 8 weeks in treatment-naïve patients without cirrhosis who have a pretreatment HCV RNA less than 6 million IU/mL

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Appendix F—Table of Innovator Drugs: Formulary Recommendations

Generic name, Brand name	DoD PEC Drug Class	FDA Approval Date	FDA Approval Type	FDA Indications	Formulary Alternatives	Recommended UF Status	Comments
Evolocumab (Repatha)	• Antilipidemics-1; PCSK9 Inhibitors	8/27/2015	BLA	Adjunct to diet and maximally tolerated statin therapy in adults with the following conditions, who require additional LDL lowering: • Heterozygous familial hypercholesterolemia (HeFH) • Homozygous familial hypercholesterolemia (HoFH) including pediatric patients ages 13-17 years • Clinical atherosclerotic cardiovascular disease (ASCVD)	• statins • ezetimibe • alirocumab (Praluent)*	▪NF	▪Prior Authorization and Medical Necessity criteria and QLs recommended at interim P&T Committee meeting September 3, 2015, and implemented on October 30, 2015 ▪No changes recommended to PA, MN, or QLs; see Appendices B, C, and D ▪PCSK9 inhibitors drug class not reviewed yet
Trifluridine/ tipiracil (Lonsurf)	• Oncological Agents	9/22/2015	NDA; 1	Metastatic Colorectal Cancer ▪ Patients previously treated with fluoropyrimidine-, oxaliplatin-and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy	• capecitabine (Xeloda), a fluoropyrimidine* • regorafenib (Stivarga)*	▪UF	▪Oral drugs for metastatic colorectal cancer not reviewed yet
Empagliflozin/ metformin IR (Synjardy)	• Non-Insulin Diabetes Drugs; SGLT2 Inhibitors	8/26/2015	NDA; 4	Type 2 diabetes ▪ Adjunct to diet and exercise to improve glycemic control in adults who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin.	• empagliflozin (Jardiance) • empagliflozin /linagliptin (Glyxambi)	▪UF; step-preferred	▪SGLT2 inhibitors reviewed in August 2015; empagliflozin products step-preferred ▪Prior Authorization criteria recommended at August 2015 P&T Committee meeting; implementation on February 3, 2016 ▪No changes recommended to PA criteria

NDA Chemical Types:
1: New molecular entity;
2: New active ingredients;
3: New dosage formulations;
4: New combinations
* Drug Class not previously reviewed for UF status

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug (EMMPI) List and Nonformulary Medications (Tier 3) Medications Excluded from Mail Order Requirements

Notes: This table shows the EMMPI list and the nonformulary (Tier 3) list side-by-side. Please note that the table omits classes where no action is recommended by the P&T Committee (no exceptions to the NF mail order requirement apply, no changes to the current EMMPI list are recommended, and no class definitions are recommended). It is not a complete list of EMMPI or nonformulary (Tier 3) medications. Formulary status is as of the November 2015 P&T Committee meeting.

Legend: capitalized drugs – brand name only; italicized drugs – generics available

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
Alzheimer's	Alzheimer's therapy, NMDA receptor antagonist (H1A) *Namenda* (memantine) **Add NAMENDA XR (memantine)**	-
	Alzheimer's therapy – NMDA receptor antagonists & cholinesterase inhibitors (H1C) **Add NAMZARIC (memantine/donepezil)**	-
	Cholinesterase inhibitors (J1B) *Aricept* (donepezil) *Razadyne, Razadyne ER* (galantamine) *Exelon* (rivastigmine) patch, capsule	*Aricept* (donepezil) 23 MG
	Class Definition – **RECOMMENDATION:** Branded, legend medications in GC3s H1A, H1C, or J1B and intended for chronic use to be added to the EMMPI list	
Androgens–anabolic steroids	Androgenic agents (F1A) - **Add all testosterone products to EMMPI list: FORTESTA, ANDRODERM, TESTIM, STRIANT, VOGELXO, NATESTO (nasal)**	ANDROGEL 1% gel pump and packets ANDROGEL 1.62% gel pump AXIRON transdermal solution
	Class Definition – **RECOMMENDATION**: Branded, legend testosterone products in GC3 F1A and intended for chronic use as testosterone replacement therapy be added to the EMMPI list	
Antibiotics	Aminoglycoside (W1F) Tobi (tobramycin for nebulization) **Add TOBI PODHALER**	ZMAX (azithromycin suspension) KETEK (telithromycin) **ZMAX and KETEK not suitable for mail; acute use exception applies**
Anticoagulants	Heparin and related (M9K) FRAGMIN (dalteparin) *Lovenox* (enoxaparin) *Arixtra* (fondaparinux)	-
	Thrombin inhibitors, selective, direct, reversible (M9T) PRADAXA (dabigatran)	-
	Direct Factor XA inhibitor (M9V) ELIQUIS (apixaban)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	XARELTO (rivaroxaban) SAVAYSA (edoxaban)	
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s M9K, M9T, or M9V and intended for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = SSRIs)	SSRIs – H2S (SSRIs) *Celexa, Lexapro, Prozac, Paxil, Pexeva, Zoloft* **Add Paxil CR (paroxetine 24H)**	*Prozac weekly* (90 mg) *Sarafem* (10,20 mg)
	SSRI & 5HTA partial agonist antidepressant (H8P) -	VIIBRYD (vilazodone)
	SSRI & 5HT receptor modulator (H8T) -	BRINTELLIX (vortioxetine)
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3s H2S, H8P, or H8T that are indicated for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = SNRIs)	SNRIs (H7C) & fibromyalgia agents SNRIs (H0G) *Effexor XR* (venlafaxine 24H) **Add Cymbalta (duloxetine)**	KHEDEZLA, PRISTIQ ER (desvenlafaxine 24H) FETZIMA (levomilnacipran) SAVELLA (milnacipran)
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3S H7C or H0G that are intended for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = MAOIs)	MAO inhibitor (H7H) -	EMSAM patch (selegiline)
	MAOIs-non-selective and irreversible (H7J) MARPLAN (isocarboxazid) *Nardil* (phenelzine) *Parnate* (tranylcypromine)	-
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3s H7H or H7J be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = NDRIs)	NDRIs (H7D) *Wellbutrin, Wellbutrin SR, Wellbutrin XL* (bupropion)	APLENZIN (bupropion HBr ER 24H) FORFIVO XL (bupropion HCl ER 24H)
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3 H7D that are intended for chronic use to be added to the EMMPI list; does not apply to products for smoking cessation	
Antidepressants / non-opioid pain (subclass = SARIs)	Serotonin-2 antagonist/reuptake inhibitor (SARIs) (H7E) -	*Oleptro ER (trazodone ER 24H)*
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3 H7E that are intended for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = tetracyclic antidepressants)	Alpha-2 receptor antagonist antidepressant (H7B) **Add *Remeron* (mirtazapine)**	-
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3 H7B that are intended for chronic use to be added to the EMMPI list	

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
Antiemetics - antivertigo	Antiemetic/ antivertigo agent (H6J) -	ANZEMET (dolasetron) SANCUSO (granisetron patch) ZUPLENZ (ondansetron film) DICLEGIS (doxylamine/pyridoxine) **Not suitable for mail; acute use exception applies**
Antifungals (subclass = topical antifungals)	Topical antifungals (Q5F) -	*Loprox* (ciclopirox) *Spectazole* (econazole) VUSION (miconazole/zinc oxide oint) OXISTAT (oxiconazole) ERTACZO (sertaconazole) EXELDERM (sulconazole) **Not suitable for mail; acute use exception applies**
Antigout (subclass = chronic agents)	Hyperuricemia tx – xanthine oxidase inhib (C7A) *Zyloprim* (allopurinol)	ULORIC (febuxostat)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 C7A that are intended for chronic use to be added to the EMMPI list	
Antihistamine-2 blockers/other antiulcer	Anti-ulcer preparation (D4E) *Pepcid* (famotidine) *Zantac* (ranitidine) *Cytotec* (misoprostol) *Carafate* (sucralfate)	
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 D4E that are intended for chronic use to be added to the EMMPI list	
Antihypertensives (misc)	Antihypertensives, vasodilator (A4A) -	-
	Antihypertensives, sympatholytic (A4B) *Catapres* (clonidine) patches, tabs *Clorpres* (clonidine/chlorthalidone)	-
	J7B Alpha-adrenergic *Minipress* (prazosin)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s A4A, A4B, and J7B that are intended for chronic use to be added to the EMMPI list	
Antilipidemics-1	M4D – HMG CoA reductase inhibitors *Lipitor* (atorvastatin) *Lescol* (lovastatin) *Pravachol* (pravastatin) CRESTOR (rosuvastatin) *Zocor* (simvastatin)	LESCOL XL (fluvastatin ER 24H) ALTOPREV (lovastatin ER 24H) LIVALO (pitavastatin)
	M4E – lipotropic *Niaspan* (niacin ER 24H) ZETIA (ezetimibe)	-
	M4I – HMG CoA & CCB *Caduet* (amlodipine/atorvastatin)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	M4L – HMG CoA & niacin -	ADVICOR (niacin/lovastatin) SIMCOR (niacin/simvastatin)
	HMG CoA & cholest AB inhibitor (M4M) -	LIPTRUZET (ezetimibe/atorvastatin) VYTORIN (ezetimibe/simvastatin)
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s M4D, M4E, M4I, M4L, or M4M that are intended for chronic use to be added to the EMMPI list	
Antilipidemics-2 (subclass = bile acid sequestrants)	Bile acid sequestrants (D7L) *Questran, Questran Light* (cholestyramine) *Colestid* (colestipol)	WELCHOL (colesevelam) (06)
Antilipidemics-2 (subclass = omega-3 fatty acids)	Lipotropic (M4E) Lovaza (omega-3 acid ethyl esters) **Add VASCEPA (icosapent ethyl)**	
Antilipidemics-2 (subclass = fenofibrates)	Lipotropic (M4E) *Lofibra*, FENOGLIDE, LIPOFEN (fenofibrate) *Tricor*, TRIGLIDE, (fenofibrate, nanocrystallized) *Lofibra* (fenofibrate, micronized) FIBRICOR (fenofibric acid) **Add ANTARA (fenofibrate, micronized),** ***Trilipix* (fenofibric acid (choline)**	-
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3 D7L or M4E that are intended for chronic use to be added to the EMMPI list	
Antiplatelet	Platelet aggregation inhibitor (M9P) AGGRENOX (aspirin/dipyridamole) *Pletal* (cilostazol) *Plavix* (clopidogrel) *Persantine* (dipyridamole) EFFIENT (prasugrel) BRILINTA (ticagrelor)	Zontivity (vorapaxar)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 M9P that are intended for chronic use to be added to the EMMPI list	
Antipsychotic agents	-	SAPHRIS (asenapine) FANAPT (iloperidone) LATUDA (lurasidone) **Not suitable for mail; antipsychotic exception applies**
ADHD (subclass = stimulants)	Treatment for ADHD /narcolepsy (H2V), adrenergics, aromatic, non-catecholamine (J5B) -	Focalin XR (dexmethylphenidate) DAYTRANA (methylphenidate transdermal system) QUILLIVANT XR (methylphenidate 24h susp) VYVANSE (lisdexamfetamine) **Not suitable for mail; C-II exception applies**
ADHD (subclass = wakefulness promoting)	Narcolepsy and sleep disorder therapy (H8Q) -	NUVIGIL (armodafinil)

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
BPH	BPH/micturition agents (Q9B) *Proscar* (finasteride) *Uroxatral* (alfuzosin) *Flomax* (tamsulosin)	AVODART (dutasteride) JALYN (dutasteride/tamsulosin) RAPAFLO (silodosin)
	Alpha-adrenergic blocking agent (J7B) *Cardura* (doxazosin)	CARDURA XL (doxazosin)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Q9B or J7B that are intended for chronic use to be added to the EMMPI list	
Beta blockers & diuretic combos	Alpha/beta adrenergic (J7A) *Coreg*, COREG CR (carvedilol)	
	Beta adrenergic (J7C) & combos (J7H) *Sectral* (acebutolol) *Tenormin* (atenolol), *Tenoretic* (atenolol/chlorthalidone) *Ziac* (bisoprolol/HCTZ) DUTOPROL (metoprolol succinate/HCTZ) *Lopressor HCT* (metoprolol tartrate/HCTZ) *Corgard* (nadolol), *Corzide* (nadolol/bendroflumethiazide) *Inderal LA*, INNOPRAN LA (propranolol) *Betapace, Betapace AF* (sotalol) *Tenoretic* (atenolol/chlorthalidone) *Ziac* (bisoprolol/HCTZ) **Add: Inderal XL (propranolol)**	BYSTOLIC (nebivolol)
CCBs	Calcium channel blocking agent (A9A) *Norvasc* (amlodipine) *Cardizem, Cardizem CD, Tiazac* (diltiazem) *Adalat CC, Procardia, Procardia XL* (nifedipine) *Calan, Calan SR* (verapamil)	*Cardizem LA, Matzim LA* (diltiazem) *Isradipine* *Nicardipine IR* CARDENE SR (nicardipine) *Sular* (nisoldipine) *Verelan, Verelan PM* (verapamil 24H)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 A9A that are intended for chronic use to be added to the EMMPI list	
Diabetes non-insulin	Alpha-glucosidases (C4M) *Precose* (acarbose) GLYSET (miglitol)	-
	Amylin agonist (C4H) SYMLINPEN 60, 120 (pramlintide)	-
	Biguanides (C4L) *Glucophage, Glucophage XR* (metformin) RIOMET solution (metformin)	*Fortamet*, GLUMETZA (metformin ER 24H)
	DPP-4s (C4J) and combos (C4C, C4M, C4W) TRADJENTA (linagliptan) JANUVIA (sitagliptan)	NESINA (alogliptan) ONGLYZA (saxagliptan)
	Dopamine agonists (C4V)	CYCLOSET (bromocriptine)

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug List and Nonformulary Medications Excluded from Mail Order Requirements

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	-	
	GLP-1s (C4I) BYDUREON (exenatide) **Add TANZEUM (albiglutide),** **BYDUREON PEN (exenatide)**	TRULICITY (dulaglutide) VICTOZA (liraglutide) BYETTA (exenatide)
	Meglitinides (C4K) and combos (C4S) *Starlix* (nateglinide) *Prandin* (repaglinide) *Prandimet* (repaglinide/metformin)	-
	SGLT2s (C4D) and combos (C4E) - Add GLYXAMBI (empagliflozin/linagliptan) Add JARDIANCE (empagliflozin)	INVOKANA (canaglifozin) FARXIGA (dapagliflozin) INVOKAMET (canaglifozin/metformin) XIGDUO XR (dapaglifozin/metformin)
	Sulfonylureas (C4K) & combos (C4S) *Amaryl* (glimepiride) Glucotrol, Glucotrol XL (glipizide) *Diabeta* (glyburide) *Glynase* (glyburide, micronized) *Glucovance* (glyburide/metformin)	-
	TZDs (C4N) & combos (C4R, C4T) Actos (pioglitazone) Duetact (pioglitazone/glimepiride) Actoplus Met, ACTOPLUS MET XR (pioglitazone/metformin)	AVANDIA (rosiglitazone) AVANDAMET (rosiglitazone/metformin)
	Class Definition – RECOMMENDATION: Branded, legend products in GC3s C4C, C4D,C4E, C4H, C4I, C4J, C4K, C4L, C4M, C4N, C4R, C4S, C4T, C4V, or C4W that are intended for chronic use to be added to the EMMPI list	
Diuretics	Carbonic anhydrase inhibitor (R1E) *Diamox Sequels* (acetazolamide) *Neptazane* (methazolamide)	-
	Thiazide & related (R1F) DIURIL oral suspension (chlorothiazide) *Microzide* (hydrochlorothiazide)	-
	Potassium-sparing diuretic (R1H) and combos (R1L) *Inspra* (eplerenone) *Aldactone* (spironolactone) DYRENIUM (triamterene) *Aldactazide* (spironolactone/HCTZ) *Dyazide, Maxzide, Maxzide-25mg* (triamterene/HCTZ)	-
	Loop (R1M) EDECRIN (ethacrynic acid) *Lasix* (furosemide) *Demadex* (torsemide)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s R1E, R1F, R1H, R1L, or R1M that are intended for chronic use to be added to the EMMPI list	
Electrolyte-mineral-trace element replacement	Potassium replacement (C1D) *Effer-K* (potassium bicarb/cit ac) *Klor-Con* (potassium chloride) 20, 25 mEq packet *K-tab ER* (potassium chloride) 10 mEq	-
	Other replacement products (calcium, magnesium salts, iron, iodine, misc) -	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 C1D that are intended for chronic use to be added to the EMMPI list	
Estrogens, combos (route = oral, topical or transdermal)	Estrogenic agents (G1A) *Alora, Climara*, MENOSTAR, *Minivelle, Vivelle-Dot* (estradiol patch) DIVIGEL, ELESTRIN, ESTROGEL (estradiol gel) *Estrace* (estradiol tablet) CLIMARA PRO, COMBIPATCH (estradiol/levonorgestrel patch) *Activella* (estradiol/norethindrone tablet) PREFEST (estradiol/norgestimate) PREMPHASE, PREMPRO (conjugated estrogen/m-progest acetate) PREMARIN (conjugated estrogens) ENJUVIA (conjugated estrogens, synthetic) MENEST (esterified estrogens) *FemHRT* (norethindrone/ethinyl estradiol) **Add EVAMIST transdermal spray (estradiol), *Lopreeza* tab (estradiol/norethindrone)**	--
	Estrogen & progestin with antimineralocorticoid (G1D) ANGELIQ (drospirenone/estradiol)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s G1A and G1D that are intended for chronic use to be added to the EMMPI list	
Estrogens, combos (route = vaginal)	Vaginal estrogen preparations (Q4K) ESTRACE cream, ESTRING vaginal ring, VAGIFEM vaginal tablet (estradiol) FEMRING vaginal ring (estradiol acetate) PREMARIN vaginal cream (conjugated estrogens)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Q4K that are intended for chronic use to be added to the EMMPI list	
GI-1 agents	Chronic inflammatory colon dx - 5-aminosalicylates (D6F) APRISO, DELZICOL, LIALDA (mesalamine) DIPENTUM (olsalazine) *Azulfidine* (sulfasalazine)	GIAZO (balsalazide) ASACOL HD, PENTASA (mesalamine)
	Chronic inflammatory colon dx, 5-aminosalicylates, rectal (Q3E) CANASA (mesalamine) rectal supp	-
	Glucocorticoids (P5A)	*Uceris* (budesonide) tablet

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	-	
	IBS agents – 5HT3 antagonists (D6C) *Lotronex* (alosetron)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s D6F, Q3E, and D6C that are intended for chronic use to be added to the EMMPI list	
Glaucoma	Q6G – miotics, other intraocular pressure reducer *Iopidine* (apraclonidine) LUMIGAN (bimatoprost) *Alphagan P* (brimonidine) COMBIGAN (brimonidine/timolol) *Trusopt* (dorzolamide) *Cosopt* (dorsolamide/timolol) COSOPT PF (dorzolamide/timolol/PF) PHOSPHOLINE IODIDE (echothiophate iodide) *Xalatan* (latanoprost) *Betagan* (levobunolol) *Isopto Carpine* (pilocarpine) *Timoptic, Timoptic XE,* TIMOPTIC OCUDOSE (timolol maleate) **Add SIMBRINZA (brinzolamide/brimonidine)**	Azopt (brinzolamide) ZIOPTAN (tafluprost) BETIMOL (timolol) 0.0025, ISTALOL (timolol maleate) Travatan Z (travoprost)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Q6G that are intended for chronic use to be added to EMMPI list	
Growth stimulating	Growth hormone (P1A) NORDITROPIN FLEXPRO, NUTROPIN AQ, NUTROPIN AQ NUSPIN **Add SEROSTIM, ZOMACTON, ZORBTIVE, NUTROPIN AQ NUSPIN (somatropin)**	GENOTROPIN, HUMATROPE, OMNITROPE, SAIZEN
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 P1A that are intended for chronic use to be added to EMMPI list	
Gynecological misc	Progestational agent (G2A) *Provera* (medroxyprogesterone) tablet *Aygestin* (norethindrone acetate) *Prometrium* (progesterone, micronized)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 G2A that are intended for chronic use to be added to EMMPI list	
Hepatitis C	Direct acting – various GC3s -	-
	Hep C treatment agent (W5G) PEGASYS (peginterferon alfa-2a) PEGINTRON, PEGINTRON REDIPEN (peginterferon alfa-2b) *Copegus, Rebetol* (ribavirin) INTRON A (interferon alfa-2b) **Add PEGASYS PROCLICK (peginterferon alfa-2a)**	Ribasphere RibaPak
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 W5G that are intended for chronic use to be added to EMMPI list	

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
Insulins (subclass = basal)	Insulin (C4G) LEVEMIR (insulin detemir) vial LANTUS (insulin glargine) vial LANTUS SOLOSTAR (insulin glargine) pen **Add Toujeo (insulin glargine 300 u/mL pen)**	LEVEMIR FLEXTOUCH (insulin detemir) pen
Insulins (subclass = combos)	Insulin (C4G) NOVOLOG MIX 70-30 vial, pen HUMULIN 70-30 vial, pen NOVOLIN 70-30 vial, pen HUMALOG MIX 50-50, 75-25 vial, pen	-
Insulins (subclass = intermediate-acting)	Insulin (C4G) HUMULIN N vial, pen NOVOLIN N vial, pen	-
Insulins (subclass = short-acting)	Insulin (C4G) NOVOLOG (insulin aspart) vial, pen, cartridge APIDRA (insulin glulisine) vial, pen HUMALOG (insulin lispro) vial, pen, cartridge **Add Afrezza (inhaled regular insulin)**	-
Insulins (subclass = misc)	Diabetic supplies (Y9A) -	VGO 20, 30, 40
Insulins	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 C4G that are intended for chronic use to be added to EMMPI list	
Leukotriene modifying	Z4B – Leukotriene receptor antagonist *Accolate* (zafirlukast) *Singulair* (montelukast)	ZYFLO, ZYFLO CR (zileuton)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Z4B that are intended for chronic use to be added to EMMPI list	
Migraine agents	H3F Antimigraine preparation -	*Axert* (almotriptan) FROVA (frovatriptan) *Amerge* (naratriptan) SUMAVEL DOSEPRO (sumatriptan needle-free injection) **Not suitable for mail; acute use exception applies**
MS agents	Agents to treat multiple sclerosis (H0E) COPAXONE, GLATOPA (glatiramer) AVONEX (interferon beta-1a) REBIF (interferon beta-1a) syringe BETASERON (interferon beta-1b) kit **Add REBIF REBIDOSE (interferon beta-1a) pen** **EXTAVIA (interferon beta-1b)**	PLEGRIDY, PLEGRIDY PEN (peginterferon beta-1a)
Mydriatics	Mydriatric (Q6J) ISOPTO ATROPINE (atropine sulfate) *Cyclogyl* (cyclopentolate) CYCLOMYDRIL (cyclopentolate/phenylephrine)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	Mydriacyl (tropicamide)	
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s Q6J that are intended for chronic use to be added to EMMPI list	
Narcotic analgesics and combinations	-	NUCYNTA (tapentadol) Ultram ER (tramadol ER 24H) ABSTRAL (fentanyl SL tab) FENTORA (fentanyl buccal) LAZANDA (fentanyl nasal) SUBSYS (fentanyl SL spray) **Not suitable for mail; acute use and/or C-II exceptions apply**
Ophthalmic-1 agents	-	Prolensa (bromfenac) **Not suitable for mail; acute use exception applies**
Osteoporosis agents	Bone resorption inhibitor (P4L) & bone resorption inhibitor & Vit D combos (P4N) Fosamax (alendronate) 70mg Boniva (ibandronate) 150mg Evista (raloxifene) **Add Duavee (conjugated estrogens/bazedoxifene)**	BINOSTO (alendronate 70mg eff tab) FOSAMAX PLUS D (alendronate/vit D3) *Atelvia* (risedronate DR) 35mg
	Bone formation stim agents – parathyroid (P4B) FORTEO (teriparatide)	Miacalcin (calcitonin, salmon, synthetic) nasal
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s P4L, P4N, P4B that are intended for chronic use to be added to EMMPI list	
Pain agents	Antimigraine preparation (H3F) -	CAMBIA (diclofenac potassium) powder pack – **Not suitable for mail; acute use exception applies**
	Nasal NSAIDs, COX non-selective (Q7K) -	SPRIX (ketorolac) - **Not suitable for mail; acute use exception applies**
	NSAID & H2 blocker (S2X) -	DUEXIS (ibuprofen/famotidine)
	NSAID & PPI (S2P) VIMOVO (naproxen/esomeprazole)	-
	NSAIDs, COX-2 selective (S2L) Celebrex (celecoxib)	-
	Salicylates (H3D) -	-
	Topical anti-inflammatory, NSAID (Q5E) Voltaren (diclofenac sodium) gel	PENNSAID (diclofenac sodium solution pump) FLECTOR (Diclofenac epolamine) **All above: Not suitable for mail; acute use exception applies** *diclofenac sodium drops* (topical)

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	NSAIDs (S2B) *Voltaren-XR* (diclofenac sodium ER 24H) *Nalfon* (fenoprofen calcium) *Mobic* (meloxicam) *EC-Naprosyn, Naprosyn* (naproxen) *Anaprox, Anaprox DS* (naproxen sodium) *Daypro* (oxaprozin) *Feldene* (piroxicam)	ZIPSOR (diclofenac potassium) ZORVOLEX (diclofenac micronized) PONSTEL (mefenamic acid) **All above: Not suitable for mail; acute use exception applies** Naprelan (naproxen sodium 24H)
Pancreatic enzyme agents	Pancreatic enzyme (D8A) - **RECOMMENDATION – add other pancreatic enzyme agents: CREON, ZENPEP, PANCREAZE, VIOKACE**	PERTYZE ULTRESA
	Class Definition – RECOMMENDATION: Branded, legend products in GC3 D8A that are intended for chronic use to be added to EMMPI list	
Parkinsons agents	C7B Decarboxylase inhibitor *Lodosyn* (carbidopa)	-
	Antiparkinsonism drugs, other (H6A) *Sinemet, Sinemet CR* (carbidopa/levodopa) *Stalevo* (carbidopa/levodopa/entacapone) *Comtan* (entacapone) *Mirapex, Mirapex ER* (pramipexole) AZILECT (rasagiline mesylate) *Requip, Requip XL* (ropinirole) NEUPRO (rotigotine) patch *Eldepryl* (selegiline) ZELAPAR (selegiline) 1.25 mg tab rapdis *Tasmar* (tolcapone)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s C7B and H6A that are intended for chronic use to be added to EMMPI list	
PDE-5 inhibitors (for ED)	Drugs to treat erectile dysfunction (F2A) VIAGRA (sildenafil)	CIALIS (tadalafil) LEVITRA, STAXYN (vardenafil) STENDRA (avanafil)
	Class Definition – RECOMMENDATION: Branded, legend products in GC3 F2A and that are intended for chronic use to be added to EMMPI list	
PPIs	Proton pump inhibitor (D4J) *Nexium* (esomeprazole) *Prilosec* (omeprazole) *Protonix* (pantoprazole)	DEXILANT (dexlansoprazole) *Prevacid* (lansoprazole) *Aciphex* (rabeprazole)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s D4J that are intended for chronic use to be added to EMMPI list	
Pulmonary-1 agents	ICS/LABA (J5G) ADVAIR DISKUS, HFA (fluticasone/salmeterol)	SYMBICORT (budesonide/formoterol) BREO ELLIPTA (fluticasone/vilanterol) DULERA (mometasone/formoterol)
	ICS (B6M) Pulmicort (budesonide) neb FLOVENT DISKUS, HFA (fluticasone)	QVAR (beclomethasone) PULMICORT FLEXHALER (budesonide) ALVESCO (ciclesonide) AEROSPAN (flunisolide) ASMANEX (mometasone)

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	Beta-adrenergic agents (J5D) Vospire ER (albuterol 12H tab)	PROVENTIL HFA, VENTOLIN HFA (albuterol) XOPENEX HFA (levalbuterol) **Not suitable for mail; acute use exception applies**
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s J5G, B6M that are intended for chronic use to be added to EMMPI list. Note: does not include albuterol and levalbuterol inhalers (J5D).	
Pulmonary-2 agents	Xanthines (A1B) -	-
	General bronchodilator agent (A1D) *Atrovent HFA* (ipratropium) TUDORZA PRESSAIR (aclidinium) SPIRIVA (tiotropium) INCRUSE ELLIPTA (umeclidinium)	
	Beta-adrenergic & anticholinergic (J5J) ANORO ELLIPTA (umeclidinium/vilanterol)	
	PDE-4 inhibitor (Z2X) -	
	Beta-adrenergic agent (J5D) BROVANA (arformoterol) FORADIL (formoterol) SEREVENT (salmeterol)	PERFOROMIST (formoterol neb) ARCAPTA (indacaterol)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s A1B, A1D, J5J, Z2X that are intended for chronic use to be added to EMMPI list.	
RBC stimulants	Erythropoiesis-stimulating agent (N1B) ARANESP (darbepoetin alfa) EPOGEN, PROCRIT (epoetin alfa)	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 N1B that are intended for chronic use to be added to EMMPI list	
Renin-angiotensin antihypertensives	ACEI (A4D) & ACE/thiazide (A4J) *Lotensin; Lotensin HCT* (benazepril) *Vasotec; Vaseretic* (enalapril) *Prinivil; Zestril; Zestoretic* (lisinopril) *Aceon* (perindopril) *Accupril;Accuretic* (quinapril) *Altace* (ramipril) *Mavik* (trandolapril)	-
	ACEI & CCB (A4K) *Tarka* (tradolapril/verapamil)	

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	ARB (A4F) & ARB/thiazide (A4I) EDARBI; EDARBYCLOR (azilsartan) *Atacand, Atacand HCT* (candesartan) *Avapro; Avalide* (irbesartan) *Cozaar; Hyzaar* (losartan) BENICAR; BENICAR HCT (olmesartan) *Micardis; Micardis HCT* (telmisartan) *Diovan, Diovan HCT* (valsartan)	
	ARB & CCB (A4H) or ARB/CCB/thiazide (A4V) AZOR(amlodipine/olmesartan) *Exforge; Exforge HCT* (amlodipine/valsartan) *Twynsta* (amlodipine/telmisartan) *Lotrel* (amlodipine/benazepril)	TRIBENZOR (amlodipine/olmesartan/HCTZ)
	Direct renin inhibitor (A4T) or DRI/CCB (A4X) or DRI/thiazide (A4U) TEKTURNA (aliskiren) TEKTURNA HCT (aliskiren/HCTZ)	TEKAMLO (aliskiren/amlodipine)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s A4J, A4K, A4I, A4V, A4T, A4X, A4U that are intended for chronic use to be added to EMMPI list	
Sedative hypnotic agents (newer)	-	EDLUAR, INTERMEZZO (zolpidem sublingual) ZOLPIMIST (zolpidem spray ROZEREM (ramelteon) BELSOMRA (suvorexant) – May 15 **All above: Not suitable for mail; acute use exception applies**
Self-monitoring blood glucose systems	-	Numerous **Not suitable for mail; previously defined exception applies**
Skeletal muscle relaxants & combos	Skeletal muscle relaxant (H6H) *Dantrium* (dantrolene sodium) *Zanaflex* (tiazanidine)	
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 H6H that are intended for chronic use to be added to EMMPI list	
TIBs (subclass = non-TNF inhibitors)	Anti-inflammatory, PDE-4 inhibitor (S2Z) OTEZLA (apremilast) oral	-
	Janus kinase inhibitor (Z2Z) XELJANZ (tofacitinib) oral	-
	Antipsoriatic agents systemic (L1A) CONSENTYX (secukinumab)	-
	Anti-inflam IL-1 antagonists (S2M) ARCALYST (Rilonacept)	KINERET (anakinra)
	Anti-inflam T-cell inhibitor (S2Q)	ORENCIA (abatacept)

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug List and Nonformulary Medications Excluded from Mail Order Requirements

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	-	
	IL-6 inhibitor (Z2V) -	ACTEMRA (tocilizumab SQ
	IL-12/23 inhibitor (Z2U) STELARA (ustekinumab)	-
	Tx chronic inflam dz of colon (D6A) -	CIMZIA (certolizumab)
TIBs (subclass = TNF inhibitors)	TNF inhibitors (S2J) HUMIRA (adalimumab) SIMPONI (golimumab)	ENBREL (etanercept)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s S2Z, Z2Z, L1A, S2M, S2Q, Z2V, Z2U, D6A, S2J that are intended for chronic treatment of RA, JRA, PsA, AS, psoriasis, Crohns disease, or ulcerative colitis to be added to EMMPI list	
Thyroid & antithyroid agents	Thyroid hormone (P3A) *Synthroid,* TIROSINT, *Unithroid* (levothyroxine) *Cytomel* (liothyronine) *Armour Thyroid* (thyroid, pork) *Tapazole* (methimazole)	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 P3A that are intended for chronic use to be added to EMMPI list	
Urinary misc	Urinary pH modifier (R1S) *Urocit-K* (potassium citrate)	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 R1S that are intended for chronic use to be added to EMMPI list	
WBC stimulants	Leukocyte (WBC) stimulant (N1C) NEUPOGEN (filgrastim) NEULASTA (pegfilgrastim) LEUKINE (sargramostim) **RECOMMENDATION: Add Granix (tbo-filgrastim)**	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 N1C that are intended for chronic use to be added to EMMPI list	

Appendix H—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2015	**Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	UF class review (previously reviewed Feb 2012)	▪ mixed amphetamine salts ER (Adderall XR; generic) ▪ methylphenidate osmotic controlled release oral delivery system (OROS) (Concerta; generic)	▪ amphetamine sulfate tabs (Evekeo) ▪ methylphenidate ER oral suspension (Quillivant XR suspension) ▪ methylphenidate ER (Aptensio XR) ▪ methamphetamine (Desoxyn, generic) ▪ dextroamphetamine (Dexedrine spansule, Dextrostat tabs, ProCentra solution, generics; Zenzedi tabs) ▪ methylphenidate CD (Metadate CD; generic) ▪ methylphenidate IR (Ritalin IR, generic) ▪ methylphenidate LA (Ritalin LA, generic) ▪ methylphenidate SR (Ritalin SR, generic) ▪ methylphenidate ER (Metadate ER, Methylin ER, generic) ▪ methylphenidate chewable tablets, solution (Methylin, generic) ▪ mixed amphetamine salts IR (Adderall, generic) ▪ dexmethylphenidate IR (Focalin; generic)	▪ lisdexamfetamine (Vyvanse) ▪ methylphenidate transdermal system (Daytrana) ▪ dexmethylphenidate ER (Focalin XR)	Pending singing of the minutes / 90 days The effective date is May 4, 2016.	▪ None	▪ Updated Medical Necessity for Vyvanse: does not include Binge Eating Disorder. (See Appendix B) ▪ Note that methylphenidate LA (Ritalin LA, generic) and methylphenidate IR (Ritalin IR, generic) are removed from the BCF

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2015	**Antirheumatics: Injectable Methotrexate Subclass**	UF class review	BCF: None (BCF selections from the Antirheumatics Drug Class include generic methotrexate 2.5 mg tablets)	▪ Generic methotrexate 50 mg/2 mL vials	▪ Methotrexate auto-injector (Otrexup) ▪ Methotrexate auto-injector (Rasuvo)	Pending singing of the minutes / 90 days The effective date is May 4, 2016.	▪Manual prior authorization applies to Otrexup and Rasuvo – see Appendix C ▪QLs apply – see Appendix D	
Nov 2015	**Acne Drugs: Oral Isotretinoins Subclass**	UF class review	BCF: None (BCF Acne drugs include topical acne products: tretinoin 0.025% and 0.05%, clindamycin 1% and 2%)	▪ Amnesteem ▪ Claravis ▪ Zenatane ▪ Myorisan	▪ Absorica	Pending signing of the minutes / 90 days The effective date is May 4, 2016.	▪Prior authorization applies to Absorica – see Appendix C	
Nov 2015	**GI-2 Miscellaneous Drug Subclass**	UF class review Previously reviewed Nov 2012 (GI-2 antibiotics) and Feb 2011 (GI-1)	▪ Metronidazole 250 mg and 500 mg tablets	▪ Alosetron (Lotronex) ▪ Fidaxomicin (Dificid) ▪ Linaclotide (Linzess) ▪ Lubiprostone (Amitiza) ▪ Nitazoxanide (Alinia) ▪ Rifaximin (Xifaxan) ▪ Tegaserod (Zelnorm) – discontinued ▪ Metronidazole (Flagyl, generics) ▪ Neomycin ▪ vancomycin	None	Pending signing of the minutes / 60 days The effective date is March 30, 2016.	▪Prior Authorization applies to rifaximin – see Appendix C	▪Dificid not available from the Mail Order Pharmacy

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2015	**Alzheimer's Disease Agents**	New Drug Class previously reviewed Nov 2005	• ECF: Donepezil (Aricept, generics)	• Memantine IR (Namenda, generics) • Galantamine (Razadyne, generic) • Galantamine ER (Razadyne ER) • Rivastigmine (Exelon, generic) • Rivastigmine transdermal system (Exelon Patch)	Nov 2015 • **Memantine ER (Namenda XR)** • **Memantine ER/donepezil (Namzaric)** • Donepezil 23 mg (Aricept 23 mg) – Feb 2011 • Tacrine– discontinued	Pending signing of the minutes / 90 days The effective date is May 4, 2016.	•Prior Authorization applies – see Appendix C	

TRICARE Formulary Search tool: http://tricare.mil/pharmacyformulary

BCF: Basic Core Formulary
ECF: Extended Core Formulary
ER: extended release
IR: immediate release

Appendix I—Table of Abbreviations

ADHD	attention deficit hyperactivity disorder
AE	adverse event
AASLD/IDSA	American Association for the Study of Liver Diseases/Infectious Diseases Society of America
ASCVD	atherosclerotic cardiovascular disease
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
CD	controlled delivery
CDI	*Clostridium difficile* infection
CIC	chronic idiopathic constipation
CFR	Code of Federal Regulations
CK	creatinine kinase
CMA	cost minimization analysis
CV	cardiovascular
DAAs	direct acting antivirals
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DM	diabetes mellitus
DMARD	disease-modifying antirheumatic drugs
DoD	Department of Defense
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FY	fiscal year
GI-2	Gastrointestinal-2 Miscellaneous Drugs
GT3	genotype 3 hepatitis virus infection
GT4	genotype 4 hepatitis virus infection
HBV	hepatitis B virus
HCV	hepatitis C virus
HDL	high-density lipoprotein
HeFH	heterozygous familial hypercholesterolemia
HF	heart failure
HoFH	homozygous familial hypercholesterolemia
HSDD	hyposexual desire disorder
IBS	irritable bowel syndrome
IBS-C	constipation-predominant irritable bowel syndrome
IBS-D	diarrhea-predominant irritable bowel syndrome
IR	immediate release
LDL	low-density lipoprotein
LDL-C	low-density lipoprotein cholesterol
LVEF	left ventricular ejection fraction

MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDA	New Drug Application
NDAA	National Defense Authorization Act
NF	nonformulary
NMDA	N-methyl-D-aspartate
OTC	over-the-counter
ODT	orally dissolving tablet
OROS	osmotic controlled release oral delivery system
P&T	Pharmacy and Therapeutics
PA	prior authorization
PCSK9	proprotein convertase subtilisin/kexin type 9 inhibitors
POS	points of service
RA	rheumatoid arthritis
REMS	Risk Evaluation and Mitigation Strategies
QD	once daily
QLs	quantity limits
SC	subcutaneous
SGLT2	sodium-glucose co-transporter 2 inhibitor
SVR	sustained virologic response
TFL	TRICARE for Life
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

August 2015

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 12 and 13, 2015, at the Defense Health Agency (DHA), Pharmacy Operations Division, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes from the May 2015 DoD P&T Committee meeting on July 20, 2015.

2. **Correction to the May 2015 Minutes**

   a) **Line Extension, Formulary Status Clarification—Testosterone Replacement Products: Testosterone Gel (Vogelxo)**

   At the May 2015 P&T Committee meeting, the formulary status of Vogelxo, an AB-rated generic to the proprietary product Testim, was presented as a line extension. Vogelxo was recommended to follow the same formulary placement and prior authorization criteria as its parent drug. The formulary status of Vogelxo was further clarified that it remain Uniform Formulary and non step-preferred, similar to the formulary status for Testim.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations (CFR) 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

Nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015. (See Section XII.)

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)

Umeclidinium (Incruse Ellipta) is an oral inhaler approved for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). There are no studies evaluating reduction in COPD exacerbations as a primary endpoint. Similar to tiotropium (Spiriva), umeclidinium has a long duration of action. The FDA-approved dose of 62.5 mcg was based on trials showing umeclidinium produced statistically and clinically significant improvements in the forced expiratory volume in one second (FEV_1). The safety profile is similar to the other LAMAs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that the main clinical benefits of umeclidinium are its one puff, once daily dosing, and the ease of use of the Ellipta device. Based on active controlled trials, the changes in FEV_1 with umeclidinium appear similar to that achieved with tiotropium.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that umeclidinium (Incruse Ellipta) was cost effective compared with other LAMA inhalers on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) umeclidinium (Incruse Ellipta) be designated formulary on the UF, based on clinical and cost effectiveness. Umeclidinium was not recommended for addition to the BCF.

2. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) QLs for umeclidinium (Incruse Ellipta), consistent with the FDA-approved package labeling. See Appendix D.

3. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE (TFL) BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding umeclidinium (Incruse Ellipta) to the maintenance drug list, due to the potential for additional cost avoidance and for consistency with other inhaled bronchodilators on the UF that are already included on the list.

4. ***COMMITTEE ACTION: UF AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the UF and Mail Order Pharmacy implementation become effective upon signing of the minutes.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)

Secukinumab (Cosentyx) is a first-in-class human interleukin-17A (IL-17A) receptor antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

The TIBs were previously reviewed for UF placement in August 2014; adalimumab (Humira) was selected as the BCF and step-preferred drug. Step therapy, manual prior authorization (PA), and QLs apply to all the TIBs. In February 2015, the P&T Committee recommended manual PA criteria and QLs for secukinumab, consistent with the class.

- Five TIBs are approved for treating psoriasis: adalimumab (Humira), etanercept (Enbrel), ustekinumab (Stelara), apremilast (Otezla), and secukinumab (Cosentyx).
- In clinical trials, secukinumab demonstrated superior efficacy to placebo, etanercept, and ustekinumab in treating moderate to severe plaque psoriasis based on the Psoriasis Area and Severity Index 75 (PASI 75) score, which measures the severity and extent of psoriasis. There are no head-to-head trials comparing secukinumab and adalimumab.
- Secukinumab is well tolerated. The rates of adverse events (AEs) do not differ significantly for secukinumab and other TIBs.
- The FDA-approved 300 mg dose requires administration of two 150 mg injections, which is a potential inconvenience to the patient.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent), despite its unique mechanism of action, secukinumab (Cosentyx) offers no clinically compelling advantages over the existing TIBs on the UF approved for plaque psoriasis.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that secukinumab (Cosentyx) was cost effective compared with other TIBs on the UF approved for treating plaque psoriasis.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following:

    - Secukinumab (Cosentyx) be designated formulary and non-preferred based on cost effectiveness and the previously accepted solicitation condition sets from the August 2014 P&T Committee TIBs Drug Class review. A trial of adalimumab (Humira) is required prior to use of Cosentyx.

- The current PA and QLs for Cosentyx, previously approved at the February 2015 P&T Committee meeting, be continued.

2. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding secukinumab (Cosentyx) to the maintenance medication drug list, as the other TIBs are included on the list.

3. ***COMMITTEE ACTION: UF AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the UF and Mail Order Pharmacy implementation become effective upon signing of the minutes.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

The SGLT2 inhibitors and their fixed-dose combinations with metformin and dipeptidyl dipeptidase-4 (DPP-4) inhibitors were reviewed for formulary placement. They are indicated as adjunctive therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- As a subclass, the SGLT2 inhibitors are effective in lowering hemoglobin A1c (A1c) by 0.4% to 1% when used as monotherapy and, when added on to other drugs, by 0.5% to 2% as part of dual therapy and by 0.3% to 1.3% as part of triple therapy.
- There are no head-to-head trials between any of the SGLT inhibitors, although there do not appear to be clinically relevant differences in their effects on lowering A1c when used as monotherapy or added on to other diabetes drugs.
- In addition to their effects on glycemic control, other actions of the SGLT2 inhibitors include a reduction in triglycerides and a modest increase in both low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol. The SGLT2 inhibitors also slightly decrease systolic blood pressure (by 4 mm Hg to 6 mm Hg) and body weight (reduction of 1.8 kg).

- The most common adverse drug reactions for all the SGLT2 inhibitors are female genital mycotic infections and urinary tract infections. The SGLT2 inhibitors are contraindicated in severe renal impairment, although empagliflozin and canagliflozin can be used in patients with estimated glomerular filtration rates as low as 45 mL/min. A recent FDA safety alert details the risk of ketoacidosis with the subclass. Patients with a history of bladder cancer should avoid use of dapagliflozin.
- Empagliflozin and dapagliflozin have a lower risk of drug-drug interactions than canagliflozin.
- The cardiovascular (CV) safety profile of SGLT2 inhibitors is currently unknown. At the time of the August 2015 DoD P&T Committee meeting, there were no published long-term CV outcomes trials.
- There is a high degree of therapeutic interchangeability between the SGLT2 inhibitors.
- The SGLT2 inhibitors have a limited role in treating T2DM due to a lack of clinically, compelling advantages over alternative therapies in lowering A1c, an unknown CV safety profile, and undesirable side effects, including genital mycotic and urinary tract infections.

Overall Relative Clinical Effectiveness Conclusion: Other than their potential for weight loss, the SGLT2 inhibitors offer no additional clinical advantages over the other non-insulin diabetes drugs on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analyses (BIA) were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that empagliflozin (Jardiance) and empagliflozin/linagliptin (Glyxambi) were the most cost-effective SGLT2 inhibitors, followed by dapagliflozin (Farxiga), dapagliflozin/metformin (Xigduo XR), and lastly followed by canagliflozin (Invokana) and canagliflozin/metformin (Invokamet).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary (and step-preferred) or NF (and non step-preferred) on the UF. BIA results showed that designating empagliflozin (Jardiance) and empagliflozin/ linagliptin (Glyxambi) as formulary and step-preferred resulted in the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following:
    - UF and step-preferred:
        - Empagliflozin (Jardiance)
        - Empagliflozin/linagliptin (Glyxambi)
    - NF and non step-preferred:
        - Canagliflozin (Invokana)
        - Canagliflozin/metformin (Invokamet)

- Dapagliflozin (Farxiga)
- Dapagliflozin/metformin extended release (Xigduo XR)

- This recommendation includes step therapy (automated PA), which requires a trial of empagliflozin or empagliflozin/metformin prior to use of the NF, non step-preferred SGLT2 inhibitors in all new and current users. PA criteria currently apply to the SGLT2 inhibitors subclass.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee did not recommend (16 for, 0 opposed, 1 abstained, 0 absent) any of the SGLT2 inhibitors for addition to the BCF. Several other drugs from the non-insulin diabetes drug subclasses are designated with BCF status, including metformin IR, metformin ER, glyburide, glyburide micronized, glipizide, sitagliptin (Januvia), and sitagliptin/metformin (Janumet).

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/metformin ER (Xigduo XR). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) AND MANUAL PA CRITERIA***—Existing automated PA (step therapy) requires a trial of metformin, a sulfonylurea, or a DPP-4 inhibitor prior to use of a SGLT2 inhibitor.

   Additionally, empagliflozin-containing products (Jardiance or Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users must try a preferred empagliflozin product before trying canagliflozin- or dapagliflozin-containing products.

   The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) modifying the existing PA criteria to require a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses prior to use of an SGLT2 inhibitor in new users. The P&T Committee also recommended step therapy criteria for Invokana, Invokamet, Farxiga, and Xigduo XR. See Appendix C for the full criteria.

5. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding the SGLT2 inhibitors to the maintenance medication drug list due to the potential for additional cost avoidance. Other non-insulin diabetes drug subclasses are

included on the list, including the DPP-4 inhibitors, thiazolidinediones, glucagon-like peptide-1 receptor agonists, and sulfonylureas.

6. ***COMMITTEE ACTION: UF, PA, AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)

The GLP1RA subclass includes exenatide once weekly (Bydureon), exenatide twice daily (Byetta), liraglutide (Victoza), albiglutide (Tanzeum), and dulaglutide (Trulicity). The GLP1RAs that are not indicated for treating diabetes were excluded from this review (i.e., liraglutide is also available under the trade name Saxenda for weight loss).

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following conclusions:

- Metformin remains the first-line treatment in all patients with T2DM, unless contraindications exist.
- The GLP1RAs are all indicated for monotherapy as an adjunct to diet and exercise to improve glycemic control in adult patients with T2DM. They are not first-line therapies.
- The GLP1RAs are self-injectable medications that differ in the frequency of administration. Trulicity, Tanzeum, and Bydureon have the advantage of once weekly dosing; Victoza is dosed once daily; and, Byetta is dosed twice daily (BID).
- The GLP1RAs decrease A1c on average approximately 1% to 2% from baseline, when used as monotherapy or in combination with other oral agents.
- The results of seven head-to-head trials between the GLP1RAs do not show clinically significant differences in effects on glycemic control.
- Weight loss was observed in all seven head-to-head studies. When used as monotherapy or as an add-on agent, a 2 kg to 3 kg weight loss is expected with the GLP1RAs.

- GLP1RAs either do not adversely impact or provide small improvements in blood pressure. The subclass may also improve lipid parameters.
- The reported incidence of hypoglycemia with GLP1RAs is low, ranging from 3% to 9%. However, when a GLP1RA is used concurrently with a sulfonylurea, the incidence increases from 13% to 40%. Albiglutide has the lowest incidence of hypoglycemia when used with a sulfonylurea or as monotherapy.
- Nausea is the most common AE among all the GLP1RAs. Tanzeum has the lowest incidence of nausea (11.1%) compared to Bydureon (14.4%), Victoza (22.7%), Trulicity (12.1 % to 21.1%), or Byetta (29.9%).
- All the GLP1RAs are contraindicated for use in patients with pancreatitis. All the GLP1RAs except Byetta carry black box warnings for medullary thyroid cancer and multiple endocrine neoplasia syndrome type 2.
- There are no completed trials with any FDA-approved GLP1RA that assess long-term CV outcomes; CV safety studies are underway.
- Tanzeum and Trulicity have an advantage in offering a smaller needle size for patient convenience.
- Trulicity, Byetta, and Victoza have an advantage as they do not require mixing prior to administration.

Overall Relative Clinical Effectiveness Conclusion—The GLP1RAs have a high degree of therapeutic interchangeability, with no clinically relevant differences between the individual products.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that exenatide twice daily (Byetta) was the most cost-effective GLP1RA, followed by albiglutide (Tanzeum), exenatide once weekly (Bydureon), dulaglutide (Trulicity), and liraglutide (Victoza).
- BIA was performed to evaluate the potential impact of designating selected agents as step-preferred, formulary, or NF on the UF. BIA results showed that designating exenatide once weekly (Bydureon) and albiglutide (Tanzeum) as formulary and step-preferred agents, with no grandfathering (i.e., step therapy would apply to all new and current users of a GLP1RA), demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 2 opposed, 2 abstained, 0 absent) the following:
    - UF and step-preferred:
        - Exenatide once weekly (Bydureon)
        - Albiglutide (Tanzeum)
    - NF and non step-preferred:

- Exenatide twice daily (Byetta)
- Dulaglutide (Trulicity)
- Liraglutide (Victoza)

- This recommendation includes step therapy (automated PA), which requires a trial of exenatide once weekly (Bydureon) and albiglutide (Tanzeum) prior to use of the NF, non-preferred GLP1RA drugs, in all new and current users. PA criteria currently apply to the GLP1RAs subclass.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding exenatide once weekly (Bydureon) to the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for exenatide twice daily (Byetta), dulaglutide (Trulicity), and liraglutide (Victoza). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) AND MANUAL PA CRITERIA***—Existing automated PA (step therapy) criteria for the GLP1RAs requires a trial of metformin or a sulfonylurea first, based on positive long-term outcomes data with metformin and the sulfonylureas.

   Additionally, exenatide once weekly (Bydureon) and albiglutide are now recommended as the preferred GLP1RAs. New and current users must try Bydureon and Tanzeum prior to using Byetta, Trulicity, or Victoza.

   The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) maintaining the existing PA criteria, requiring a trial of metformin or sulfonylurea prior to use of a GLP1RA in all current and new users. The P&T Committee also recommended step therapy criteria for Byetta, Trulicity, and Victoza. See Appendix C for the full criteria.

5. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding the GLP1RAs to the maintenance medication drug list due to the potential for additional cost avoidance.

6. ***COMMITTEE ACTION: UF, PA, AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

☑ Approved ☐ Disapproved

Director, DHA, Decision:

Approved, but modified as follows:

C. Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)

The tyrosine kinase inhibitors (TKIs) used for treating CML were reviewed by the P&T Committee.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Imatinib (Gleevec), nilotinib (Tasigna), and dasatinib (Sprycel) are approved in the United States for first-line therapy of chronic phase CML. Guidelines from the National Cancer Care Network and international guidelines also support the use of these three TKIs as first-line therapies
- Head-to-head trials between imatinib and the second generation TKIs found that dasatinib and nilotinib yield superior and more rapid hematologic, cytogenetic, and molecular responses in patients with chronic phase CML. However, to date, there are no statistically significant differences in overall survival between imatinib and the second generation TKIs.
- Imatinib advantages include pending generic availability, a well-known safety profile, and additional FDA indications other than CML. AEs include fatigue, myalgias, and fluid retention.
- Advantages of dasatinib and nilotinib compared to imatinib include fewer progressions to acute phase CML or blast phase CML. The second generation TKIs are preferred for use in moderate to high risk patients.
- Dasatinib (Sprycel) has been associated with pleural effusions and pulmonary arterial hypertension.
- Nilotinib (Tasigna) requires twice daily administration and a fasting window. It has a black box warning for QT interval prolongation, and has been associated with pancreatitis and hyperglycemia.

- Bosutinib (Bosulif) is currently limited to the second-line setting; it has not shown an advantage over imatinib when used as first-line therapy for chronic phase CML. It causes significant gastrointestinal toxicity, particularly diarrhea.
- Ponatinib (Iclusig) is the only TKI that is effective in patients with a specific mutation (T315I+). It has significant safety concerns, including vasoocclusive events, which led to its temporary removal from the market.

Overall Relative Clinical Effectiveness Conclusion: The P&T Committee concluded that the choice of CML drug depends on patient comorbidities, provider experience, continued response to initial treatment, prior treatment, and AE profiles.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed imatinib (Gleevec) was the most cost-effective TKI for CML.
- BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and formulary, non-preferred and formulary, and formulary without a step-therapy requirement. BIA results showed that all scenarios modeled were similar in projected cost avoidance to the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following:

    - UF (no-step scenario):
        - Imatinib (Gleevec)
        - Dasatinib (Sprycel)
        - Nilotinib (Tasigna)
        - Bosutinib (Bosulif)
        - Ponatinib (Iclusig)
    - NF: None

2. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding nilotinib (Tasigna) to the TFL Pharmacy Drug List. This is consistent with other CML agents included on the program that are not subject to a limited distribution process.

3. ***COMMITTEE ACTION: UF AND NILOTINIB (TASIGNA) AVAILABILITY THROUGH MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the UF and Mail Order Pharmacy implementation plans become effective upon signing of the minutes.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

D. Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics

The Narcotic Analgesic Drug Class was previously reviewed in February 2007, and included both immediate release (IR) and extended release (ER) products. The long acting high potency opioids subclass includes the extended release/long acting (ER/LA) generic and branded formulations of morphine sulfate, morphine/naltrexone, fentanyl transdermal system, hydrocodone, hydromorphone, oxymorphone, oxycodone, and tapentadol. Sustained release morphine sulfate (MS Contin, generics) is currently the BCF agent.

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following for the long acting narcotic analgesics:

- The long acting opioids are recognized as the mainstay of chronic pain management, with well-documented evidence of their efficacy in the short-term.
- Current guidelines do not state a preference for the use of one long acting high potency narcotic analgesic over another in the treatment of moderate to severe pain.
- Tapentadol ER (Nucynta ER) is the only long acting narcotic analgesic with an FDA-approved indication for the treatment of neuropathic pain associated with diabetic peripheral neuropathy.
- There is no new evidence regarding the comparative effectiveness of the long acting high potency narcotics. Clinical trials differ significantly in terms of study designs, patient characteristics, types of pain treated, and titration schedules.
- Meaningful conclusions cannot be drawn from indirect comparisons of the drugs. Two systematic reviews concluded that there is insufficient evidence to suggest clinically relevant differences in efficacy and safety among the long acting narcotics.
- In general, the long acting opioids share similar safety profiles. Common AEs, include constipation, nausea, vomiting, and dizziness.
- While abuse-deterrent formulations offer a potential barrier to abuse via intravenous and intranasal routes, they have yet to demonstrate the ability to

prevent abuse altogether. Abusers can still overcome the technologies in these formulations via over consumption.

- Several DoD resources for providers are available to help ensure safe opioid prescribing and include the Sole Provider Program, the Prescription Monitoring Program, "Do no harm" mandatory training, Project ECHO (Extension for Community Healthcare Outcomes), and the VA/DoD Clinical Practice Guidelines "Management of Opioid Therapy for Chronic Pain" Toolkit.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic sustained release morphine sulfate (MS Contin) was the most cost-effective ER/LA opioid.

- BIA was performed to evaluate the potential impact of scenarios designating selected ER/LA opioid agents as formulary or NF on the UF. BIA results showed that scenarios where all generic and branded formulations of the long acting high potency narcotic analgesics are designated formulary on the UF demonstrated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATIONS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

    - UF (no step scenario):
        - Fentanyl transdermal system (Duragesic, generics)
        - Hydrocodone ER (Hysingla ER)
        - Hydrocodone ER (Zohydro ER)
        - Hydromorphone ER (Exalgo, generics)
        - Morphine sulfate sustained release (MS Contin, generics)
        - Morphine ER (Avinza, Kadian, generics)
        - Morphine ER/naltrexone (Embeda)
        - Oxycodone controlled release (Oxycontin)
        - Oxymorphone ER (Opana ER, generics)
        - Tapentadol ER (Nucynta ER)

    - NF: None

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VI. BCF CLARIFICATION

A. Attention Deficit Hyperactivity Disorder (ADHD) Drugs—Methylphenidate LA (Ritalin LA)

The ADHD drugs were last reviewed in February 2012. At that time, Ritalin LA was added to the BCF, as it was the most cost-effective long acting methylphenidate formulation available at Military Treatment Facilities (MTFs). In July 2015, a new Ritalin LA dosage strength (60 mg) became available, which is significantly more costly than the other dosages. The Ritalin LA 60 mg dosage has the same FDA-approved indication as the other dosage strengths. There is currently low utilization of the other Ritalin LA dosages at the MTFs. The ADHD stimulants will be reviewed in November 2015.

1. ***COMMITTEE ACTION: BCF CLARIFICATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent), upon signing of the minutes, methylphenidate LA 60 mg (Ritalin LA) be excluded from the BCF; it will remain on the UF.

Director, DHA, Decision: ☐ Approved ☐ Disapproved

Approved, but modified as follows:

VII. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Alirocumab (Praluent) and Evolocumab (Repatha) PA Criteria**—The PCSK9 inhibitors are a new class of biologic drugs that lower LDL cholesterol. Alirocumab (Praluent) was approved on July 24, 2015, and is administered as biweekly subcutaneous injections. The second drug in the class and evolocumab (Repatha) is anticipated to obtain FDA approval on August 27, 2015.

   Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional LDL lowering. The product labeling states that the effect of Praluent on CV morbidity and mortality has not been determined. PA criteria were recommended for the PCSK9 inhibitors due to the lack of data on CV morbidity and mortality, unknown long-term safety profile, and anticipated high cost.

   a) ***COMMITTEE ACTION: PCSK9 INHIBITOR ALIROCUMAB (PRALUENT) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for alirocumab (Praluent) in

all new and current users. PA will be approved for patients with HeFH or patients with ASCVD with LDL levels greater than 100 mg/dL despite maximally tolerated statins doses (atorvastatin 40 mg to 80 mg and rosuvastatin 20 mg to 40 mg, or any statin at maximally tolerated doses in combination with ezetimibe). See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: ALIROCUMAB (PRALUENT) QLs***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) QLs for alirocumab (Praluent) of two syringes or pens per 30 days in the Retail Network and six syringes or pens per 90 days in the MTFs and Mail Order Pharmacy. See Appendix D.

c) ***COMMITTEE ACTION: PCSK9 INHIBITOR EVOLOCUMAB (REPATHA) PA CRITERIA***—Due to the impending FDA approval of evolocumab, the P&T Committee also recommended (16 for, 0 opposed, 1 abstained, 0 absent), contingent upon FDA approval, manual PA criteria for evolocumab (Repatha) in all new and current users. PA will be approved for the FDA-approved indications and age range as noted in the product labeling. If the FDA-approved indications for Repatha are similar to Praluent, than the same PA criteria will apply to Repatha. See Appendix C for the full criteria.

INTERIM P&T COMMITTEE MEETING—Following the August 2015 P&T Committee meeting, Repatha obtained FDA approval on August 27, 2015. Therefore, the DoD P&T Committee held an interim meeting on September 3, 2015, to confirm the PA criteria for Repatha, and determine QLs and MN criteria. The product labeling for Repatha is similar to Praluent, with the exception that, in addition to patients with HeFH and clinical ASCVD, Repatha is also approved for treating patients with homozygous familial hyper-cholesterolemia (HoFH), including pediatric patients from ages 13 to 17 years.

d) ***COMMITTEE ACTION: PCSK9 INHIBITOR EVOLOCUMAB (REPATHA) MN CRITERIA***—FDA approval of Repatha occurred on August 27, 2015, following the implementation of the "120-Day Innovator Drug Rule," which requires newly approved innovator drugs to be placed on the third tier of the UF until review by the P&T Committee. (See Section XI, Innovator Drugs, below.) The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Repatha. See Appendix B for the full criteria.

e) ***COMMITTEE ACTION: EVOLUCOMAB (REPATHA) QLs***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following QLs for evolocumab (Repatha):

- Patients with HeFH and ASCVD will be able to obtain two of the 140 mg syringes per 30 days in the Retail Network; and, six of the 140 mg syringes per 90 days in the MTFs and Mail Order POS. See Appendix D.
- Patients with HoFH will be able to obtain three of the 140 mg syringes per 30 days in Retail Network; and, nine of the 140 mg syringes per 90 days in the MTFs and Mail Order POS. See Appendix D.

f) ***COMMITTEE ACTION: PCSK9 INHIBITOR (PRALUENT AND REPATHA) PA, QLs, AND MN IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the PA, QLs, and MN implementation plans become effective upon signing of the minutes in all POS.

2. **Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA) PA Criteria**—The FDA approved Arnuity Ellipta and Asmanex HFA in August and April 2014, respectively. The ICS products were reviewed by the P&T Committee in May 2014 and automated PA (step therapy) and manual PA criteria were approved. Fluticasone propionate (Flovent Diskus and Flovent HFA) are the step-preferred ICS products; the remaining ICS products are non step-preferred.

   Arnuity Ellipta and Asmanex HFA are approved for treating asthma in patients 12 years of age and older; Flovent Diskus is approved in patients as young as four years of age. Arnuity Ellipta and Asmanex HFA were recommended to follow the same PA criteria as the other non step-preferred ICS products.

   a) ***COMMITTEE ACTION: ICS PRODUCTS FLUTICASONE FUROATE (ARNUITY ELLIPTA) AND MOMETASONE (ASMANEX HFA) STEP THERAPY AND PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) step therapy and manual PA criteria for all new users of Arnuity Ellipta and Asmanex HFA, consistent with the current PA for the other non step-preferred ICS products. See Appendix C for the full criteria.

3. **ICS and Long-Acting Beta2-Adrenergic Agonist (LABA) Combinations: Fluticasone furoate/vilanterol (Breo Ellipta) Manual PA Criteria**—Fluticasone furoate/vilanterol (Breo Ellipta) is indicated for the long-term treatment of COPD. In April 2015, the FDA-approved indication was further expanded to include the daily treatment of asthma in patients aged 18 years and older. The ICS/LABA products were reviewed by the P&T Committee in February 2014, where automated PA (step therapy) and manual PA criteria were approved for patients older than 12 years. Fluticasone propionate/salmeterol (Advair Diskus and Advair HFA) are the step-preferred ICS/LABA products; the remaining ICS/LABA products are non step-preferred.

a) ***COMMITTEE ACTION: ICS AND LABA COMBINATION PRODUCT FLUTICASONE FUROATE/VILANTEROL (BREO ELLIPTA) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) updating the manual PA criteria for Breo Ellipta to include the expanded FDA-approved indication for treating patients who are at least 18 years of age with asthma. See Appendix C for the full criteria.

4. **Insulin Drugs: Miscellaneous Insulin Delivery Devices (Valeritas V-Go) MN Criteria**—Manual PA criteria for the V-Go insulin delivery device were first recommended in August 2014. V-Go was designated with NF status at the November 2014 P&T Committee meeting. The P&T Committee recommended updating the current V-Go MN criteria to ensure that prior authorization has been determined. A PA form should be completed and approved before V-go is dispensed at any MHS point of service.

   a) ***COMMITTEE ACTION: V-GO INSULIN DELIVERY DEVICE MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding the requirement for completion of an approved PA form prior to MN determination. See Appendix B for the full criteria.

   b) ***COMMITTEE ACTION: V-GO INSULIN DELIVERY DEVICE PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) implementation upon signing of the minutes in all POS.

5. **Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet) PA Criteria**—Ofev and Esbriet are two oral drugs that were FDA-approved in October 2014 for treatment of idiopathic pulmonary fibrosis (IPF). Ofev and Esbriet improve symptoms in IPF, as measured by a reduction in the decline in forced vital capacity, but have not been shown to decrease mortality. Manual PA criteria were recommended to ensure appropriate use of the drug for IPF diagnoses. See Appendix C for the full criteria.

   a) ***COMMITTEE ACTION: PULMONARY FIBROSIS DRUGS NINTEDANIB (OFEV) AND PIRFENIDONE (ESBRIET) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Ofev and Esbriet, consistent with the FDA-approved product labeling for use in IPF. Prior authorization will expire after one year. See Appendix C for the full criteria.

6. **Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric) Manual PA Criteria**
   Namenda XR and Namzaric are both approved for treatment of patients with moderate to severe dementia of Alzheimer's disease. Namenda XR is an ER formulation of

memantine that is dosed once daily, in contrast to memantine IR, which is dosed twice daily. There are no studies addressing whether once daily therapy improves efficacy of memantine.

Namzaric contains a fixed-dose combination of memantine ER and donepezil (Aricept, generics). Memantine IR and donepezil are both available in low-cost generic formulations. FDA approval of Namzaric was based on bioequivalence studies and not clinical trial data. These two products will be reviewed as new drugs in November 2015. PA criteria were recommended to ensure appropriate use.

a) ***COMMITTEE ACTION: MEMANTINE (NAMENDA XR) AND MEMANTINE ER/DONEPEZIL (NAMZARIC) MANUAL PA CRITERIA*** The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Namenda XR and Namzaric in new users, consistent with the FDA-approved product labeling for Alzheimer's disease. See Appendix C for the full criteria.

7. **Sedative Hypnotics Drugs: Tasimelteon (Hetlioz) Renewal PA Criteria**—Hetlioz is approved for treatment of blind patients with non-24 hour sleep-wake disorder. The P&T Committee reviewed Hetlioz in February 2015 and designated it with NF status; PA and MN criteria were also established at that time. Currently, PA criteria expires after six months, as patients who do not respond after a six-month Hetlioz trial are unlikely to show therapeutic benefit. The P&T Committee recommended adding additional criteria to the existing PA to allow for the renewal of the PA after six months, based on patient response.

   a) ***COMMITTEE ACTION: TASIMELTEON (HETLIOZ) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) revising the manual PA criteria for Hetlioz to assess response after six months of therapy. See Appendix C for the full criteria.

8. **Cystic Fibrosis (CF) Drugs: Lumacaftor/Ivacaftor (Orkambi) Manual PA Criteria**—Orkambi is a fixed-dose combination product containing lumacaftor with ivacaftor (Kalydeco). Both drugs are potentiators of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Orkambi was FDA-approved in July 2015 for treatment of CF in patients at least 12 years of age who are homozygous for the F508del mutation in the CFTR gene. Currently, PA criteria apply to the ivacaftor component of Orkambi.

a) ***COMMITTEE ACTION: CF DRUG LUMACAFTOR/ IVACAFTOR (ORKAMBI) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Orkambi, consistent with the FDA-approved product labeling. See Appendix C for the full criteria.

9. **Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel) Manual PA Criteria**
Solaraze is FDA-approved for the topical treatment of actinic keratosis.

a) ***COMMITTEE ACTION: DICLOFENAC GEL (SOLARAZE 3% GEL) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Solaraze 3% Gel in all new users, consistent with the FDA-approved product labeling for use in actinic keratosis. See Appendix C for the full criteria.

10. **PA and MN Criteria Implementation Periods**

a) ***COMMITTEE ACTION: PA CRITERIA AND MN CRITERIA IMPLEMENTATION PLAN***—For all of the PA and MN criteria discussed above (with the exception of the PCSK9 inhibitors and the V-Go insulin delivery device), the P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

B. QLs—QLs were reviewed for four drugs—one from the COPD class, one drug for basal cell carcinoma, and two drugs used in compounded prescriptions. QLs already apply to other products in the COPD and oncology drug classes.

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) QLs for tiotropium/olodaterol (Stiolto Respimat), vismodegib (Erivedge), lidocaine 5% ointment, and lidocaine/prilocaine cream (Emla cream, generic). See Appendix D.

☒ Approved ☐ Disapproved

Director, DHA, Decision

Approved, but modified as follows:

VIII. COMPOUND PRESCRIPTIONS

A. PA Criteria—The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant, but decreasing. Compounded medications continue to have a high potential for inappropriate use.

The decrease in number of compounded prescriptions filled and cost of compounded prescriptions is due in part to the enforcement of Express Scripts Commercial Reject List that was signed into practice by Dr. Jonathon Woodson, Assistant Secretary of Defense for Health Affairs, in May 2015. Modifications to the existing compounded prescription PA criteria were proposed in an effort to decrease inappropriate use and ensure safety for beneficiaries.

1. ***COMMITTEE ACTION: COMPOUND PRESCRIPTIONS MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) that the current PA criteria should expire after one year. PA approval will last for 12 months, or for the duration of therapy, if less than 12 months

2. ***COMMITTEE ACTION: COMPOUND PRESCRIPTIONS MANUAL PA CRITERIA IMPLEMENTATION PLAN***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS; and DHA send a letter to all beneficiaries with a PA currently in place with the following

    a) Notification to beneficiaries of the one-year time limit on future PAs; and,

    b) Upon implementation, the one-year time limit will go into effect on existing approved PAs.

Based on the P&T Committee's recommendation, the effective date is January 6, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

IX. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

The P&T Committee reviewed one drug from a pharmaceutical manufacturer that was not included on a DoD Retail Refund Pricing Agreement; this drug was not in compliance with the FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity at the MTFs. These

NF drugs will remain available in the Mail Order POS without preauthorization.

A. ***COMMITTEE ACTION: DRUG DESIGNATED NF***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) the following product be designated NF on the UF:

- Neos Therapeutics: Hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) the following preauthorization criteria for hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL by Neos Therapeutics:

1. Obtaining the product by home delivery would be detrimental to the patient; and,
2. For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.

These preauthorization criteria do not apply to any other POS other than retail network pharmacies.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in the Retail Network; and 2) DHA send a letter to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

X. OVER-THE-COUNTER (OTC) DRUGS

Section 702 of the FY13 NDAA provides legislative authority for the OTC Drug Program. The Final Rule published in the Federal Register on July 27, 2015, establishes the process for identifying OTC products for coverage under the TRICARE pharmacy benefit and the rules for making these products available to eligible DoD beneficiaries. The Final Rule can be found at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy.

The approved OTC drugs will comply with the mandatory generic policy stated in 32 CFR 99.21(j)(2) and be available under terms similar for generic drugs, except that the need for a prescription and/or a co-payment may be waived in some circumstances. However, the P&T Committee may recommend waiver of copayments for particular OTC drugs in all POS. No cost-sharing for OTC drugs is required at any of the three POS for a uniformed service member on active duty.

A. OTC Drugs—Relative Cost-Effectiveness and Patient Access

The P&T Committee evaluated the relative cost-effectiveness and patient access considerations for the following OTC drugs currently covered as part of the OTC Demonstration Project: omeprazole 20 mg (Prilosec, Prilosec OTC, generics), loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics), and levonorgestrel 1.5 mg (Plan B, generics).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent):

    a) Remove coverage of branded omeprazole (Prilosec OTC), as it is not cost effective, relative to comparable generic and prescription proton pump inhibitors.

    b) Generic formulations of omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics), and levonorgestrel (Plan B, generics) will remain designated as UF.

2. ***COMMITTEE ACTION: COPAYMENT WAIVER***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent)

    a) Continuing the current copayment waiver for levonorgestrel 1.5mg (Plan B, generics). Copayments for levonorgestrel 1.5 mg (Plan B) will remain $0.

    b) Removing the current copayment waiver for generic omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), and cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics). Copayments will now be required for these medications.

3. ***COMMITTEE ACTION: PRESCRIPTION WAIVER***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent):

    a) Continuing the current waiver of the requirement for a prescription for levonorgestrel 1.5mg (Plan B, generics). Levonorgestrel will continue be covered without a prescription.

b) Removing the current waiver of the requirement for a prescription for generic omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), and cetirizine with or without pseudoephedrine (Zyrtec, Zyrtec D, generics). Prescriptions will now be required for these medications.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

XI. INNOVATOR DRUGS

New authority enacted in section 702 of the FY15 NDAA establishes authority for the P&T Committee's review process of newly approved innovator drugs. The Final Rule published in the Federal Register on July 27, 2015, clarified this process for formulary placement of newly approved innovator drugs brought to the market under a New Drug Application (NDA) approved by the FDA (available at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy). The P&T Committee is provided up to 120 days to recommend tier placement on the UF. During this period, new drugs will be assigned a classification pending status; they will be available under terms comparable to NF drugs, unless medically necessary, in which case they would be available under terms comparable to formulary drugs.

Drugs subject to the Innovator Rule are defined as new drugs that are approved by the FDA under a Biologic License Application (BLA) or NDA. The NDA innovator drugs will be further defined by the NDA chemical types to include, but are not limited to, new molecular entities, new active ingredients, and new combinations.

General MN criteria were recommended by the P&T Committee for these newly approved innovator drugs.

1. ***COMMITTEE ACTIONS: GENERAL MN CRITERIA FOR NEWLY APPROVED INNOVATOR DRUGS***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) general MN criteria for newly approved innovator drugs. In certain circumstances, specific MN criteria for these drugs may also established. The general criteria are as follows:

    - Use of the formulary agents is contraindicated.
    - The patient has experienced significant adverse effects from the formulary agents that are unlikely to occur with the NF agent.
    - The formulary agents have resulted in therapeutic failure.
    - There is no alternative formulary agent. A formulary agent is defined as a drug from the same drug class or used for the same indication as the NF drug.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

XII. AVAILABILITY OF DRUGS THROUGH NATIONAL MAIL ORDER PHARMACY PROGRAM

Until recently, the statute (10 USC 1074g) required availability of NF (Tier 3) drugs in at least one of three POS (MTFs, retail network, or the mail order program), while the regulation (32 CFR 199.21(e)(1)) stated that NF drugs would be generally unavailable at MTFs and generally available in the retail network and the mail order program. This prevented NF drugs from being included in the list of covered medications under the TFL Pilot Program.

Section 702 of the FY15 NDAA changed the requirement to specify that NF medications "shall be available through the national mail-order pharmacy program." This change was implemented via the Final Rule published in the Federal Register on July 27, 2015 (available at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy). The Final Rule clarifies that "non-formulary pharmaceutical agents are generally not available in military treatment facilities or in the retail point of service. They are available in the mail order program."

At the February 2015 meeting, the P&T Committee reviewed the criteria for waiving the requirement to use mail order and necessary exclusions of medications from the program, based on clinical considerations or operational feasibility. In addition to the exclusions from the program discussed in February 2015, the P&T Committee agreed that it would not be feasible to limit NF (Tier 3) blood glucose test strips to mail order. Not only are more than 150 different blood glucose test strips designated as NF, many are used by patients in very low volumes and cannot be efficiently handled by the mail order program.

1. ***COMMITTEE ACTIONS: NECESSARY EXCLUSIONS FROM THE NF-TO-MAIL REQUIREMENT***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) that the following categories or classes of NF (Tier 3) medications be excluded from the requirement to use mail order as the sole point of dispensing: medications for acute therapy, Schedule II controlled substances, antipsychotics, oncology agents, limited distribution drugs, and self-monitoring blood glucose system test strips.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

XIII. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM

In addition to increasing copayments (from $5/$17/$43 to $8/$20/$46 for Tiers 1, 2, and 3, respectively), the FY15 NDAA substantially expands the population of patients who "must generally refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program" to include all eligible covered beneficiaries (all beneficiaries except for Active Duty). As specified by the FY15 NDAA, the new program will begin October 1, 2015; the current TFL Pilot Program terminates on September 20, 2015. Regulations implementing the new program were published as an interim final rule in the Federal Register on August 6, 2015 (available at https://www.federalregister.gov/articles/2015/08/06/2015-19196/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-refills-of-maintenance).

The new program is similar in structure to the TFL Pilot Program, including procedures for allowing two initial fills at retail and for waiving the requirement for medications for acute care needs, prescriptions covered by other health insurance, or when necessary due to personal need or hardship, emergencies, and other special circumstances. Unlike the pilot program, there is no opt-out option.

A. Expanded Maintenance Medication Program Drug List

Drugs for the expanded Maintenance Medication Program must meet the following requirements:

- the medication is prescribed for a chronic, long-term condition that is taken on a regular, recurring basis;
- it is clinically appropriate to dispense the medication from the mail order pharmacy;
- it is cost effective to dispense the medication from the mail order pharmacy;
- the medication is available for an initial filling of a 30-day or less supply through retail pharmacies;
- the medication is generally available at MTF pharmacies for initial prescription fill and refills; and,
- the medication is available for refill through the mail order pharmacy.

1. ***COMMITTEE ACTION: EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the initial list of covered maintenance medications for the Expanded Maintenance Medication Program. See Appendix E.

The P&T Committee noted that the requirements under the program apply only to branded versions of the medications on the list. Many of these medications are available in generic formulations. In this case, the vast majority of prescriptions should be dispensed as generic versions of the products, consistent with TRICARE's mandatory generic policy, and would not be subject to the requirements of the program.

This list will be periodically revised and accessible on the TRICARE Pharmacy Program website and by telephone from the TRICARE Pharmacy Program Service Center.

XIV. ADJOURNMENT

The meeting adjourned at 1345 hours on August 13, 2015. The next meeting will be in November 2015.

Appendix A—Attendance: August 2015 P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Expanded Maintenance Medication Program Drug List
Appendix F—Table of Implementation Status of UF Recommendations/Decisions Summary
Appendix G—Table of Abbreviations

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

30 Oct 2015
Date

Appendix A—Attendance: August 2015 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood, USPHS for George Jones, PharmD, M.S.	DHA/POD Chief of Staff/ Operations Management Branch
CDR Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
COL Jack Lewi, MC	Army, Internal Medicine Physician
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
MAJ Dausen Harker, MC	Army, Family Practice Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Shaun Carstairs, MC	Navy, Physician at Large
MAJ John Poulin, MC	Army, Physician at Large
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. Bryan Wheeler	Acting General Counsel, DHA
Guests	
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
CAPT Matthew Baker	Indian Health Service
Mr. Matthew Halbe via DCS	DHA Contract Operations Division
LT Ebenezer Aniagyel	Customer Pharm Ops Center, Defense Logistics Agency

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
MAJ Aparna Raizada, MS	DHA Formulary Management Branch
LTC Misty Carlson, MC	DHA Integrated Utilization Branch
CDR Marisol Martinez, USPHS	DHA Formulary Management Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Deputy Chief, P&T Section, Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Teresa Anekwe, PharmD, BCPS	DHA Formulary Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
Dean Valibhai, PharmD, MBA	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
David Meade, PharmD, BCPS via phone	DHA Integrated Utilization Branch
Ms. Deborah Garcia	DHA Formulary Management Branch contractor
Mr. Kirk Stocker	DHA Formulary Management Branch contractor
Esmond Nwokeji, PhD	DHA Formulary Management Branch contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Canagliflozin (Invokana) • Canagliflozin/metformin (Invokamet) • Dapagliflozin (Farxiga) • Dapagliflozin/metformin XR (Xigduo XR) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	• Patient has experienced significant adverse effects from empagliflozin-containing products that are not expected to occur with canagliflozin- or dapagliflozin-containing products **Formulary Alternatives:** empagliflozin-containing product (Jardiance, Glyxambi)
• Liraglutide (Victoza) • Dulaglutide (Trulicity) • Exenatide BID (Byetta) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Patient has experienced significant adverse effects from the GLP1RA preferred products (Bydureon or Tanzeum) that are not expected to occur with Victoza, Trulicity, and Byetta. **Formulary Alternatives:** exenatide once weekly (Bydureon) and albiglutide (Tanzeum)
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	• Use of statins is contraindicated. The contraindication must be listed on the medical necessity form. • The patient has had an inadequate response to a statin, with an LDL > 100 mg/dL despite statin therapy at maximal tolerated doses. • The patient is intolerant of statins. • No alternative formulary agent. The patient has homozygous familial hypercholesterolemia and requires additional LDL-C lowering, despite maximal doses of statin or other therapies (e.g., ezetimibe, LDL apheresis). **Formulary Alternatives:** statins, ezetimibe
• Valeritas Insulin Delivery Device (V-Go) **Insulin–Miscellaneous Delivery Devices**	• A Prior Authorization form is completed and approved. AND • Formulary agents result or are likely to result in therapeutic failure. Lack of documentation of a PA form for V-Go will result in denial of the medical necessity criteria. • **Formulary alternatives:** Uniform Formulary insulin products (insulin glargine, insulin lispro, insulin aspart) pens and vials

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Canagliflozin (Invokana) • Canagliflozin/ metformin (Invokamet) • Dapagliflozin (Farxiga) • Dapagliflozin/ metformin ER (Xigduo XR) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	All new users of an SGLT2 inhibitor are required to try metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin or a sulfonylurea (SU) and a DPP-4 inhibitor first. Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first. Automated PA criteria • The patient has filled a prescription for metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Or • The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria—If automated PA criteria are not met, Jardiance or Glyxambi is approved (e.g., a trial of metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes are NOT required) if: • The patient has had an inadequate response to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has experienced a significant adverse effect from metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has a contraindication to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes. AND In addition to the above criteria regarding metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes, the following PA criteria would apply specifically to all new and current users of canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/ metformin ER (Xigduo XR): • The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance or Glyxambi) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.
• Exenatide twice daily (Byetta) • Dulaglutide (Trulicity) • Liraglutide (Victoza) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	All new users of Bydureon, Tanzeum, Byetta, Trulicity, and Victoza are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA. Patients currently taking a GLP-1RA must have had a trial of metformin or a sulfonylurea first. Additionally, Bydureon and Tanzeum are the preferred agents in the GLP-1RA subclass. New and current users of Byetta, Victoza and Trulicity must try Bydureon and Tanzeum first. Automated PA criteria: The patient has received a prescription for metformin or SU at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days,

Drug / Drug Class	Prior Authorization Criteria
	AND Manual PA criteria: If automated PA criteria are not met, Bydureon, Tanzeum, Byetta, Trulicity, or Victoza is approved (e.g., trial of metformin or SU is NOT required) if: • The patient has a confirmed diagnosis of Type 2 diabetes mellitus • The patient has experienced any of the following issues on metformin: o impaired renal function precluding treatment with metformin o history of lactic acidosis • The patient has experienced any of the following issues on a SU: o hypoglycemia requiring medical treatment • The patient has had inadequate response to metformin or a SU • The patient has a contraindication to metformin or a SU AND In addition to the above criteria regarding metformin and SU, the following PA criteria would apply specifically to new and current users of Byetta, Trulicity, and Victoza: • The patient has had an inadequate response to Bydureon and Tanzeum.
• Alirocumab (Praluent) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	Manual PA criteria apply to all new and current users of alirocumab (Praluent). Manual PA criteria—Alirocumab is approved if: • A cardiologist, lipidologist, or endocrinologist prescribes the drug. • The patient is at least 18 years of age. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR o If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. o Contraindication to statin

Drug / Drug Class	Prior Authorization Criteria
	▪ The contraindication must be defined. • Praluent is not approved for any indication other than HeFH or clinical ASCVD. • Praluent is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 75 mg every 2 weeks, or o 150 mg every 2 weeks. • PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Praluent will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/KexinType 9 (PCSK9) Inhibitor**	Manual PA criteria apply to all new and current users of evolocumab (Repatha). Manual PA criteria—Evolocumab is approved if: • A cardiologist, lipidologist, or endocrinologist prescribes the drug. • The patient is at least 18 years of age for HeFH and clinical ASCVD. For HoFH, patients as young as 13 years of age can receive the drug. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR o If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.

Drug / Drug Class	Prior Authorization Criteria
	– Contraindication to statin ▪ The contraindication must be defined. • Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 140 mg every 2 weeks, or o 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. • PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Repatha will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.
• Fluticasone furoate (Arnuity Ellipta) • Mometasone (Asmanex HFA) **Inhaled Corticosteroids (ICS)**	PA criteria apply to all new users of Arnuity Ellipta and Asmanex HFA who are older than 12 years of age. Automated PA criteria: The patient has filled a prescription for Flovent Diskus or Flovent HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Arnuity Ellipta and Asmanex HFA are approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if: • Patient has experienced any of the following issues with Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred ICS: o inadequate response to the step preferred drugs o contraindication o patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk
• Fluticasone furoate/vilanterol (Breo Ellipta) **Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs) Combinations**	Existing step therapy criteria apply to all new and current users of Breo Ellipta who are older than 12 years of age. **New PA criteria for Breo Ellipta will apply to patients who are at least 18 years of age for treating asthma.** Automated PA criteria: The patient has filled a prescription for Advair or Advair HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria 1. Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) if: • Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with the non-preferred ICS/LABA combination drug: o inadequate response to Advair Diskus or Advair HFA o intolerable adverse effects o contraindication

Drug / Drug Class	Prior Authorization Criteria
	○ patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk **2. Additionally, Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) in patients who are 18 years of age and older for treating asthma if:** • Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with Breo-Ellipta: ○ inadequate response to Advair Diskus or Advair HFA ○ intolerable adverse effects
• Nintedanib (Ofev) Pirfenidone (Esbriet) **Pulmonary Fibrosis**	Manual PA criteria will apply to all new and current users of nintedanib (Ofev) and pirfenidone (Esbriet). Manual PA criteria: Ofev or Esbriet is approved if: • The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND • The patient is being actively managed by a pulmonologist, AND • The patient is only receiving one therapy – either Ofev or Esbriet. The patient cannot receive both drugs concomitantly (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa). PA will expire after one year. Subsequent PA approval (Renewal PA) will require clinical documentation of efficacy, and will be limited to one year.
• Memantine ER (Namenda XR) **Alzheimer's Disease**	Manual PA criteria apply to all new users of Namenda XR. Manual PA criteria Namenda XR is approved: • The patient is being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia), AND • Taking Namenda IR (memantine) twice daily causes undue burden to the patient or care provider, AND • The patient's functional status has not declined while receiving Namenda IR.
• Memantine ER/donepezil (Namzaric) **Alzheimer's Disease**	Manual PA criteria apply to all new users of Namzaric. Manual PA criteria Namzaric is approved if: • The patient is being treated for moderate to severe dementia of the Alzheimer's type, AND • The patient is stabilized on one of the following regimens: ○ memantine IR 10 mg twice daily or memantine ER 28 mg once daily and donepezil hydrochloride 10 mg, OR ○ memantine IR 5 mg twice daily or ER 14 mg once daily and donepezil hydrochloride 10 mg, AND • The patient is unable to take Namenda (memantine) and Aricept (donepezil) separately, OR • The patient has progressive swallowing difficulties.

Drug / Drug Class	Prior Authorization Criteria
• Tasimelteon (Hetlioz) **Newer Sedative Hypnotics (SED-1s)**	For patients who have completed the initial 6-months trial of Hetlioz, renewal PA criteria will be determined. Renewal Manual PA criteria: Tasimelteon (Hetlioz) will be approved indefinitely if: • The patient is totally blind and has a documented diagnosis of non-24 sleep wake disorder AND • The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers) AND • The patient has been receiving Hetlioz for 6 months and has had a documented response to therapy. PA will not be approved if the patient has not had a documented response to therapy. If the patient has not responded after 6 months, they will be deemed a non-responder.
• Lumacaftor/Ivacaftor (Orkambi) **Cystic Fibrosis**	PA apply to all new and current users of Lumacaftor/ivacaftor (Orkambi). Manual PA criteria: Orkambi is approved if: • Orkambi is prescribed for the treatment of cystic fibrosis in an age-appropriate patient population according to the product label. AND • The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, detected by an FDA-approved test.
• Diclofenac Gel (Solaraze 3% Gel) **Topical Pain**	PA criteria apply to all new users of Solaraze 3% Gel. Manual PA criteria Diclofenac 3% topical gel (Solaraze Gel) is approved if: • The patient has a documented diagnosis of actinic keratosis.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Umeclidinium (Incruse Ellipta) **Long-Acting Muscarinic Agonists**	▪ Retail Network: 1 inhaler per 30 days ▪ MTF and Mail Order Pharmacy: 3 inhalers per 90 days ▪ Note that "institutional packs" of 7-day supply inhalers are limited to 1 inhaler at all points of service
• Tiotropium/olodaterol (Stiolto Respimat) **LAMA/LABA**	▪ Retail Network : One 28-metered actuations inhaler per 14 days OR ONE 60-metered actuations inhaler per 30 days ▪ MTF and Mail Order Pharmacy: Two 60-metered actuations inhalers per 60 days
• Alirocumab (Praluent) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	▪ Retail Network: 2 syringes or pens per 30 days ▪ MTF and Mail Order Pharmacy: 6 syringes or pens per 90 days
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/KexinType 9 (PCSK9) Inhibitor**	▪ HeFH and ASCVD o Retail Pharmacy Network: 2 of the 140 mg syringes per 30 days o MTF and Mail Order Pharmacy: 6 of the 140 mg syringes per 90 days. ▪ HoFH o Retail Pharmacy Network: 3 of the 140 mg syringes per 30 days o MTF and Mail Order Pharmacy: 9 of the 140 mg syringes per 90 days
• Vismodegib (Erivedge) **Oral Oncologic Drugs**	▪ Retail Network : 28 capsules per 28 days ▪ MTF and Mail Order Pharmacy: 56 capsules per 56 days
• Lidocaine 5% Ointment **Topical Anesthetic**	▪ Retail Network: No more than 300 grams in 30 days ▪ MTF and Mail Order Pharmacy: No more than 300 grams in 30 days
• Lidocaine-Prilocaine Cream (Emla cream, generic) **Topical Anesthetic**	▪ Retail Network: No more than 300 grams in 30 days ▪ MTF and Mail Order Pharmacy: No more than 300 grams in 30 days

Appendix E—Expanded Maintenance Medication Program Drug List

ALZHEIMERS AGENTS	
ARICEPT	NAMENDA
ARICEPT ODT	RAZADYNE
EXELON	RAZADYNE ER
ANTIARRHYTHMICS	
CORDARONE	NORPACE CR
MULTAQ	RYTHMOL
NORPACE	RYTHMOL SR
ANTIBIOTICS	
TOBI	
ANTICOAGULANTS	
ARIXTRA	PRADAXA
ELIQUIS	SAVAYSA
FRAGMIN	XARELTO
LOVENOX	
ANTIDEPRESSANTS AND NON-OPIOID PAIN SYNDROME AGENTS	
CELEXA	PAXIL
EFFEXOR XR	PEXEVA
LEXAPRO	PROZAC
LUVOX CR	WELLBUTRIN
MARPLAN	WELLBUTRIN SR
NARDIL	WELLBUTRIN XL
PARNATE	ZOLOFT
ANTIGOUT AGENTS	
ULORIC	ZYLOPRIM
ANTIHISTAMINE-2 BLOCKERS AND OTHER ANTIULCER AGENTS	
CARAFATE	PEPCID
CYTOTEC	ZANTAC
ANTIHYPERTENSIVE AGENTS	
CATAPRES	MINIPRESS
CATAPRES-TTS	TENEX
CLORPRES	
ANTILIPIDEMICS-1	
ALTOPREV	PRAVACHOL
CADUET	SIMCOR
CRESTOR	VYTORIN
LESCOL	ZETIA
LIPITOR	ZOCOR
NIASPAN	

ANTILIPIDEMICS-2

COLESTID	QUESTRAN
FENOGLIDE	QUESTRAN LIGHT
FIBRICOR	TRICOR
LIPOFEN	TRIGLIDE
LOFIBRA	TRILIPIX
LOVAZA	

ANTINEOPLASTIC AND PREMALIGNANT LESION AGENTS

TARGRETIN

ANTIPLATELET-HEMORRHELOGIC AGENTS

AGGRENOX	PERSANTINE
BRILINTA	PLAVIX
EFFIENT	PLETAL

ANTIRHEUMATICS

PLAQUENIL

BENIGN PROSTATIC HYPERPLASIA AGENTS

CARDURA	PROSCAR
FLOMAX	UROXATRAL

BETA BLOCKERS AND HYDROCHLOROTHIAZIDE COMBINATIONS

BETAPACE	INNOPRAN XL
BETAPACE AF	LOPRESSOR HCT
COREG	SECTRAL
COREG CR	TENORETIC
CORGARD	TENORMIN
CORZIDE	TRANDATE
DUTOPROL	ZIAC
INDERAL LA	

BINDERS-CHELATORS-ANTIDOTES-OVERDOSE AGENTS

PROGLYCEM

CALCIUM CHANNEL BLOCKING AGENTS

ADALAT CC	NORVASC
CALAN	PROCARDIA
CALAN SR	PROCARDIA XL
CARDIZEM	TIAZAC
CARDIZEM CD	

CARDIOVASCULAR AGENTS MISCELLANEOUS

BIDIL	LANOXIN
DILATRATE-SR	MINITRAN
ISORDIL	NITRO-DUR
ISORDIL TITRADOSE	RANEXA

CORTICOSTEROIDS-IMMUNE MODULATORS

CORTEF

DIABETES NON-INSULIN

ACTOPLUS MET	GLYSET
ACTOPLUS MET XR	JANUMET
ACTOS	JANUMET XR
AMARYL	JANUVIA
BYDUREON	JENTADUETO
BYETTA	PRANDIMET
DIABETA	PRANDIN
DUETACT	PRECOSE
GLUCOPHAGE	RIOMET
GLUCOPHAGE XR	STARLIX
GLUCOTROL	SYMLIN
GLUCOTROL XL	TRADJENTA
GLUCOVANCE	VICTOZA
GLYNASE	

DIURETICS

ALDACTAZIDE	EDECRIN
ALDACTONE	INSPRA
DEMADEX	LASIX
DIAMOX	MAXZIDE
DIURIL	MICROZIDE
DYAZIDE	NEPTAZANE
DYRENIUM	ZAROXOLYN

ELECTROLYTE-MINERAL-TRACE ELEMENT REPLACEMENT

EFFER-K	K-TAB ER
KLOR-CON	

ENDOCRINE AGENTS MISCELLANE(

DDAVP	STIMATE
HECTOROL	ZEMPLAR
SANDOSTATIN	

ESTROGENS AND ESTROGEN-ANDROGEN COMBINATIONS

ACTIVELLA	ESTROGEL
ALORA	FEMHRT
ANGELIQ	FEMRING
CLIMARA	MENEST
CLIMARA PRO	MENOSTAR
COMBIPATCH	MINIVELLE
DIVIGEL	PREFEST
ELESTRIN	PREMARIN
ENJUVIA	PREMPHASE
ESTRACE	PREMPRO
ESTRASORB	VAGIFEM
ESTRING	VIVELLE-DOT

GASTROINTESTINAL-1 AGENTS	
APRISO	DIPENTUM
AZULFIDINE	LIALDA
CANASA	LOTRONEX
DELZICOL	
GASTROINTESTINAL-2 AGENTS	
URSO	URSO FORTE
GLAUCOMA AGENTS	
ALPHAGAN P	LUMIGAN
BETAGAN	PHOSPHOLINE IODIDE
BETOPTIC S	TIMOPTIC
COMBIGAN	TIMOPTIC OCUDOSE
COSOPT	TIMOPTIC-XE
COSOPT PF	TRUSOPT
IOPIDINE	XALATAN
ISOPTO CARPINE	
GROWTH STIMULATING AGENTS	
NORDITROPIN FLEXPRO	NUTROPIN AQ NUSPIN
NUTROPIN	SAIZEN
NUTROPIN AQ	
GYNECOLOGICAL AGENTS MISCELLANEOUS	
AYGESTIN	PROVERA
PROMETRIUM	
HEMATOLOGICAL AGENTS MISCELLANEOUS	
AGRYLIN	
HEPATITIS C AGENTS	
COPEGUS	PEGINTRON
INTRON A	REBETOL
PEGASYS	
IMMUNOLOGICAL AGENTS MISCELLANEOUS	
NEUMEGA	
INSULINS	
APIDRA	LEVEMIR
APIDRA SOLOSTAR	NOVOLIN 70/30
HUMALOG	NOVOLIN 70-30
HUMALOG MIX 50-50	NOVOLIN N
HUMALOG MIX 75-25	NOVOLOG
HUMULIN 70/30	NOVOLOG MIX 70-30
HUMULIN N	RELION 70/30
LANTUS	RELION N
LANTUS SOLOSTAR	

LAXATIVES-CATHARTICS-STOOL SOFTENERS	
KRISTALOSE	
LEUKOTRIENE MODIFYING AGENTS	
ACCOLATE	SINGULAIR
LUTEINIZING HORMONE-RELEASING HORMONE AGONISTS-ANTAGONISTS	
ELIGARD	LUPRON DEPOT-PED
LUPRON DEPOT	TRELSTAR
METABOLIC REPLACEMENT AGENTS MISCELLANEOUS	
CARNITOR	
MULTIPLE SCLEROSIS AGENTS	
AVONEX	GLATOPA
BETASERON	REBIF
COPAXONE	
MYDRIATICS	
CYCLOGYL	ISOPTO ATROPINE
CYCLOMYDRIL	MYDRIACYL
NEUROLOGICAL AGENTS MISCELLANEOUS	
EVOXAC	MESTINON
EXELON	
ONCOLOGICAL AGENTS	
DAPSONE	TARCEVA
GLEEVEC	TARGRETIN
SPRYCEL	TEMODAR
SUTENT	XELODA
OPHTHALMIC AGENTS MISCELLANEOUS	
RESTASIS	
OSTEOPOROSIS AGENTS	
BONIVA	FOSAMAX
EVISTA	FOSAMAX PLUS D
FORTEO	
OVERACTIVE BLADDER AGENTS	
DETROL	DITROPAN XL
DETROL LA	VESICARE
PAIN AGENTS	
ANAPROX	MOBIC
ANAPROX DS	NALFON
CELEBREX	NAPROSYN
DAYPRO	VIMOVO
EC-NAPROSYN	VOLTAREN
FELDENE	VOLTAREN-XR

PARKINSONS AGENTS	
AZILECT	REQUIP
COMTAN	REQUIP XL
ELDEPRYL	SINEMET
LODOSYN	SINEMET CR
MIRAPEX	STALEVO
MIRAPEX ER	TASMAR
NEUPRO	ZELAPAR
PHOSPHODIESTERASE-5 INHIBITOI	
VIAGRA	
PROTON PUMP INHIBITORS	
NEXIUM	PROTONIX
PRILOSEC	
PULMONARY-1 AGENTS	
ADVAIR DISKUS	FLOVENT HFA
ADVAIR HFA	PULMICORT
FLOVENT DISKUS	VOSPIRE ER
PULMONARY-2 AGENTS	
ANORO ELLIPTA	LUFYLLIN
ATROVENT HFA	SEREVENT DISKUS
BROVANA	SPIRIVA
FORADIL	TUDORZA PRESSAIR
RED BLOOD CELL STIMULANTS	
ARANESP	PROCRIT
EPOGEN	
RENIN-ANGIOTENSIN ANTIHYPERTENSIVES	
ACCUPRIL	LOTENSIN
ACCURETIC	LOTENSIN HCT
ACEON	LOTREL
ALTACE	MAVIK
AMTURNIDE	MICARDIS
ATACAND	MICARDIS HCT
ATACAND HCT	PRINIVIL
AVALIDE	TARKA
AVAPRO	TEKTURNA
AZOR	TEKTURNA HCT
BENICAR	TEVETEN
BENICAR HCT	TEVETEN HCT
COZAAR	TWYNSTA
DIOVAN	UNIRETIC
DIOVAN HCT	UNIVASC
EDARBI	VASERETIC

RENIN-ANGIOTENSIN ANTIHYPERTENSIVES (Continued)	
EDARBYCLOR	VASOTEC
EXFORGE	ZESTORETIC
EXFORGE HCT	ZESTRIL
HYZAAR	
RESPIRATORY AGENTS MISCELLANEOUS	
PULMOZYME	
SKELETAL MUSCLE RELAXANTS AND COMBINATIONS	
DANTRIUM	ZANAFLEX
TARGETED IMMUNOMODULATORY BIOLOGICS	
HUMIRA	SIMPONI ARIA
KINERET	STELARA
OTEZLA	XELJANZ
SIMPONI	
THYROID AND ANTITHYROID AGEI	
ARMOUR THYROID	TAPAZOLE
CYTOMEL	TIROSINT
SYNTHROID	
URINARY AGENTS MISCELLANEOU	
UROCIT-K	
VITAMINS	
NASCOBAL	ROCALTROL
POTABA	
WHITE BLOOD CELL STIMULANTS	
LEUKINE	NEUPOGEN
NEULASTA	

Appendix F—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2015	**Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors Subclass**	UF class review	▪ BCF: None (BCF selections from the non-insulin diabetes drug classes include metformin IR, metformin ER, glipizide, glyburide, glyburide micronized, sitagliptin, and sitagliptin/ metformin)	Uniform Formulary and step-preferred: ▪ Empagliflozin (Jardiance) ▪ Empagliflozin/linagliptin (Glyxambi)	Nonformulary and non step-preferred: ▪ Canagliflozin (Invokana) ▪ Canagliflozin/ metformin (Invokamet) ▪ Dapagliflozin (Farxiga) ▪ Dapagliflozin/ metformin ER (Xigduo XR)	Pending singing of the minutes / 90 days	▪See comments	▪Must try metformin and at least one drug from 2 additional oral non-insulin diabetes drug classes first before any SGLT2 inhibitor in new users. ▪Must try an empagliflozin-containing product first before Invokana, Invokamet, Farxiga, or Xigduo XR in all new and current users. (See Appendix C)
Aug 2015	**Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	UF class review Previously reviewed Nov 2012	BCF and step preferred: ▪ Exenatide once weekly (Bydureon)	Uniform Formulary and step-preferred: ▪ Albiglutide (Tanzeum)	Nonformulary and non step-preferred: ▪ Liraglutide (Victoza) ▪ Dulaglutide (Trulicity) ▪ Exenatide BID (Byetta)	Pending singing of the minutes / 90 days	▪See comments	▪ Must try metformin or a sulfonylurea first before a GLP1RA. Must try Bydureon and Tanzeum first before Victoza, Trulicity, or Byetta in all new and current users. (See Appendix C)

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2015	**Chronic Myelogenous Leukemia (CML)**	UF class review	None	▪ Imatinib (Gleevec) ▪ Dasatinib (Sprycel) ▪ Nilotinib (Tasigna) ▪ Bosutinib (Bosulif) ▪ Ponatinib (Iclusig)	None	Pending signing of the minutes	N/A	-
Aug 2015	**Long Acting Narcotic Analgesics**	UF subclass review	▪ Morphine sulfate extended release (MS Contin, generics)	▪ Fentanyl transdermal system (Duragesic, generics) ▪ Hydrocodone ER (Hysingla ER, Zohydro ER) ▪ Hydromorphone ER (Exalgo, generics) ▪ Morphine ER (Avinza, Kadian, generics) ▪ Morphine ER/naltrexone (Embeda) ▪ Oxycodone (Oxycontin) ▪ Oxymorphone ER (Opana ER) ▪ Tapentadol ER (Nucynta ER)	▪ None	Pending singing of the minutes	▪ High potency opioid PA: patients receiving a high potency opioid cannot be opioid-naive	▪ This is the high potency subclass of the Narcotic Analgesics Drug Class, for which immediate release morphine sulfate (MSIR, generics) and controlled release morphine sulfate (MS Contin, generics) are designated BCF.

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2015	**Pulmonary II–Chronic Obstructive Pulmonary Disease: Long-Acting Muscarinic Agents**	New Drug Class previously reviewed May 2013	▪ Tiotropium (Spiriva HandiHaler)	**LAMAs** ▪ **Umeclidinium (Incruse Ellipta) Aug 2015** ▪ Aclidinium (Tudorza) May 2013 LAMA/LABAs ▪ Umeclidinium/ vilanterol (Anoro Ellipta) Nov 2014	▪ None	Pending signing of the minutes	QLs apply (See Appendix D)	-
Aug 2015	**Targeted Immunologic Biologics (TIBs)**	New Drug Class previously reviewed Aug 2014	▪ Adalimumab (Humira)	**Uniform Formulary and non step preferred** **August 2015** ▪ **Secukinumab (Cosentyx)** **August 2014** ▪ Apremilast (Otezla) ▪ Golimumab (Simponi) ▪ Tofacitinib (Xeljanz) ▪ Ustekinumab (Stelara)	Non formulary and Non step preferred **August 2014** ▪ Abatacept (Orencia) ▪ Anakinra (Kineret) ▪ Certolizumab (Cimzia) ▪ Etanercept (Enbrel) ▪ Tocilizumab (Actemra)	Pending singing of the minutes	▪Step therapy required; see comments ▪Quantity Limits apply; see Formulary Search Tool	▪ Must try Humira first in all new users before the other TIBs. (See Appendix C) ▪ See TRICARE Formulary Search Tool for Cosentyx PA criteria ▪ TIBs are no longer an ECF class; Humira now BCF

TRICARE Formulary Search tool: *https://www.express-scripts.com/static/formularySearch/2.0.4/#/formularySearch/drugSearch?accessLink=FSTResults*
IR: immediate release
ER: extended release

Appendix G—Table of Abbreviations

A1c	hemoglobin A1c
ADHD	attention deficit hyperactivity disorder
AE	adverse event
ASCVD	atherosclerotic cardiovascular disease
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
CF	cystic fibrosis
CFR	Code of Federal Regulations
CFTR	cystic fibrosis transmembrane conductance regulator
CK	creatinine kinase
CMA	cost minimization analysis
CML	chronic myelogenous leukemia
COPD	chronic obstructive pulmonary disease
CV	cardiovascular
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DM	diabetes mellitus
DoD	Department of Defense
DPN	diabetic peripheral neuropathy
DPP-4	dipeptidyl dipeptidase-4 inhibitor
ECF	Extended Core Formulary
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FEV_1	forced expiratory volume in one second
FY	fiscal year
GLP1RA	glucagon-like peptide-1 receptor agonist
HDL	high-density lipoprotein
HeFH	heterozygous familial hypercholesterolemia
HoFH	homozygous familial hypercholesterolemia
ICS	Inhaled Corticosteroids Drug Class
IPF	idiopathic pulmonary fibrosis
IL-17A	interleukin-17A
IR	immediate release
LA	long acting
LABA	long-acting beta2-adrenergic agonist
LAMA	long-acting muscarinic antagonist
LDL	low-density lipoprotein
LDL-C	low-density lipoprotein cholesterol
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDA	New Drug Application
NDAA	National Defense Authorization Act

NF	nonformulary
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PCSK9	proprotein convertase subtilisin/kexin type 9 inhibitors
PMP	Prescription Monitoring Program
POS	points of service
Project ECHO	Extension for Community Healthcare Outcomes
QLs	quantity limits
SC	subcutaneous
SGLT2	sodium-glucose co-transporter 2 inhibitor
SL	sublingual
SU	sulfonylurea
T2DM	type 2 diabetes mellitus
TFL	TRICARE for Life
TIBs	targeted immunomodulatory biologics
TKIs	tyrosine kinase inhibitors
TZD	thiazolidinedione
UF	Uniform Formulary
ULN	upper limit of normal

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

May 2015

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 13 and 14, 2015, at the Defense Health Agency (DHA) Formulary Management Branch, Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of February Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes from the February 2015 DoD P&T Committee meeting on May 5, 2015.

2. **Correction to the February 2015 Minutes**

   a) Compound Prescriptions—On May 8, 2015, Dr. Jonathan Woodson, Assistant Secretary of Defense for Health Affairs, signed the Decision Paper on Implementing ESI Commercial Reject List and Prior Authorization for all Compound Medication Prescriptions. As of May 1, 2015, Express Scripts will screen all TRICARE compound drug claims to ensure each ingredient is safe, effective and covered by TRICARE. Prescribers/beneficiaries may request prior authorization for compound claims that do not pass the initial screen, and file an appeal using the regular TRICARE appeal process if prior authorization is not granted.

   Adopting the ESI "commercial reject list" would protect access to legitimate compound medications while further restricting those attempting to exploit the system. Implementation of the ESI commercial reject list will occur as soon as operationally possible.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the

clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Newer Sedative Hypnotics (SED-1s): Suvorexant (Belsomra)

Background—Suvorexant (Belsomra) is a first-in-class orexin receptor antagonist indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or maintenance. Its mechanism of action antagonizes orexin receptors, which turns off the wakefulness signal in the brain.

- There are no head-to-head studies with suvorexant and other sedative hypnotic drugs.
- Suvorexant reduced the time to sleep onset by approximately 10 minutes and increased the total sleep time by approximately 30 minutes compared to placebo.
- The 5 mg dose has not been studied in clinical trials and is meant for patients with drug interaction concerns.
- Suvorexant is generally well tolerated. The most common adverse effects include next-day somnolence, headache, and fatigue.
- Somnolence was more common in the non-elderly treatment group, was mild to moderate, and occurred earlier in the course of therapy.
- Similar to other agents in the class, suvorexant is a controlled substance (Schedule IV), has several drug interactions, and carries the same warnings regarding sleep-related behaviors.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) despite its unique mechanism of action, suvorexant (Belsomra) offers no clinically compelling advantages over the existing newer sedative hypnotic agents on the UF. Other SED-1 drugs on the UF also have the same FDA-approved indications as suvorexant (Belsomra).

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed to evaluate suvorexant (Belsomra) with other agents on the UF used in the treatment of insomnia. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that suvorexant was not cost effective.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) suvorexant (Belsomra) be designated NF, due to the lack of compelling clinical advantages and cost disadvantage compared to the existing sedative hypnotics on the UF.
2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for suvorexant (Belsomra). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA***—Existing automated PA criteria (step therapy) for the SED-1s requires a trial of immediate release zolpidem or zaleplon. The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that the existing automated PA criteria for the SED-1s apply to suvorexant (Belsomra). All new users of suvorexant will undergo the PA process. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service (POS); and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is October 21, 2015.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Multiple Sclerosis (MS) Drug: Peginterferon Beta-1a (Plegridy)

Background—Peginterferon beta-1a (Plegridy) is a new pegylated interferon that is dosed every two weeks and administered subcutaneously. It is a disease-modifying agent approved for patients with relapsing forms of MS. There are no head-to-head trials comparing Plegridy with oral or injectable drugs for MS.

- Compared to interferon beta-1a (Avonex), Plegridy offers the advantage of less frequent dosing (every 2 weeks instead of once weekly dosing) and subcutaneous administration, instead of intramuscular (IM) dosing. However, Avonex is now available in an autoinjector, which can ease IM administration.
- Plegridy's safety profile is similar to that of established interferons on the market, but it has a higher incidence of injection-site reactions than Avonex or placebo.
- While Plegridy offers the patient the convenience of every two-weeks administration, there is no data in patients who have received long-term prior treatment with another beta interferon or an oral agent.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that the place in therapy for peginterferon beta-1a (Plegridy) is limited because the oral MS agents and the other disease-modifying drugs for MS, including Avonex, are on the UF and available to patients. Peginterferon beta-1a (Plegridy) should be reserved for those patients who are not able to tolerate the currently available oral medications or injectables for MS.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate peginterferon beta-1a (Plegridy) with other injectable disease-modifying agents that are used to treat MS. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that peginterferon beta-1a (Plegridy) was not cost effective.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) peginterferon beta-1a (Plegridy) be designated NF based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for peginterferon beta-1a (Plegridy). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is October 21, 2015.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Antiemetics/Antivertigo Agents: Doxylamine Succinate and Pyridoxine Hydrochloride (Diclegis)

Background—Diclegis is a delayed-release product containing doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, or vitamin B6. Diclegis is indicated for treatment of nausea and vomiting during pregnancy (NVP) in women who do not respond to conservative therapies.

- The individual components of Diclegis are available over-the-counter (OTC) in inexpensive formulations of the sleep aid Unisom and vitamin B6.
- The components of Diclegis were previously available in a formulation known as Bendectin, which was approved in 1956. Bendectin was voluntarily removed from the market in 1983 due to litigation concerns. The FDA New Drug Application for Diclegis references the data for Bendectin. Since the market withdrawal of Bendectin, OTC doxylamine and vitamin B6 continue to be available and are frequently used for NVP.
- Current treatment guidelines from the American College of Obstetrics and Gynecology state vitamin B6 or use of doxylamine with vitamin B6 are safe and effective, and are

the recommended first-line treatments for NVP. Other treatments, including acupressure and ginger, other antihistamines, and ondansetron are also recommended.

- In the 15-day small clinical trial used to obtain FDA approval, Diclegis showed a statistically significant benefit over placebo in emesis but the clinical difference was small.
- A 2013 Cochrane review found that there was limited evidence to support use of vitamin B6, antihistamines, and other antiemetics for mild to moderate nausea and vomiting during pregnancy. However, there are no significant head-to-head trials available to compare the agents currently used for NVP.
- No studies have suggested a definitive link between fetal malformations and the drugs typically used for treating NVP, including Diclegis, the equivalent OTC components, or the other commonly used antiemetics.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the combination prescription product of doxylamine succinate and pyridoxine hydrochloride (Diclegis) offers no clinically compelling advantages when compared to the individual OTC components or other antiemetic available on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) Diclegis is more costly than the individual OTC components and the formulary agents used in the treatment of nausea and vomiting during pregnancy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) doxylamine succinate and pyridoxine hydrochloride (Diclegis) be designated NF due to the lack of compelling clinical advantages, aside from its pregnancy Category A rating, and its cost disadvantage when compared to the individual OTC components and the formulary agents available to treat NVP.
2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for doxylamine succinate and pyridoxine hydrochloride (Diclegis). See Appendix B for the full criteria.
3. ***COMMITTEE ACTION: PA CRITERIA***—Manual PA criteria were recommended at the February 2013 DoD P&T Committee meeting and implemented in August 2013 for doxylamine succinate and pyridoxine hydrochloride (Diclegis), requiring a trial of nonpharmacologic interventions and OTC pyridoxine, and consideration of alternate antiemetics. The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) maintaining the current PA criteria for doxylamine succinate and pyridoxine hydrochloride (Diclegis). See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is October 21, 2015.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Hepatitis C Virus (HCV) Drugs: Direct Acting Antivirals (DAAs)

Background—Simeprevir (Olysio), sofosbuvir (Sovaldi), ledipasvir/sofosbuvir (Harvoni), and ombitasvir/paritaprevir/ritonavir/dasabuvir co-packaged tablets (Viekira Pak) are DAAs with FDA indications for the treatment of genotype 1 chronic HCV in adults. Additionally, sofosbuvir is indicated for the treatment of adults with genotypes 2, 3, and 4 chronic HCV. Boceprevir (Victrelis) is a first generation DAA and is no longer the standard of care; market withdrawal is expected in December 2015.

Due to the rapidly evolving HCV field, use of the DAAs outside of their FDA-labeled indications is not uncommon. The American Association for the Study of Liver Diseases/ Infectious Diseases Society of America (AASLD/IDSA) updated the HCV treatment guidelines on April 8, 2015. The AASLD/IDSA HCV treatment guidelines recommend all-oral, (interferon-free) options whenever feasible for patients with HCV. Harvoni and Viekira Pak are now prominently featured in the guidelines as recommended regimens for patients with genotype 1 and 4 chronic HCV. Sovaldi in combination with Olysio is also a recommended regimen in patients with genotype 1 HCV. Sovaldi with ribavirin is recommended for patients with non-genotype 1 chronic HCV, in most situations. Consult the guidelines for the most up-to-date recommendations at: www.HCVguidelines.org.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 against, 0 abstained, 1 absent) the following:

- There are no studies directly comparing Harvoni, Sovaldi in combination with Olysio, or Viekira Pak. In general, when making indirect comparisons across similar patient populations, efficacy (assessed as sustained virologic response at 12 weeks (SVR12), the primary endpoint) appears similar among these products.
- In general, the rate of SVR12 across clinical trials in patients with genotype 1 chronic HCV treated with any DAA except Victrelis is > 90%. With Harvoni and Viekira Pak, SVR12 rates are > 95% in most instances.

- Harvoni and Viekira Pak represent all-oral (interferon-free) therapies that have demonstrated high rates of clinical cure (SVR12) in large populations across Phase III clinical trials.
- Sovaldi, when used with Olysio, represents an all-oral option for patients with genotype 1 chronic HCV; however, data are limited to one small Phase IIa study.
- Harvoni is the only one of these three regimens (Harvoni, Sovaldi with Olysio, and Viekira Pak) that has been studied in previous HCV protease inhibitor treatment failures.
- Viekira Pak with ribavirin was evaluated in HCV genotype 1 patients with liver transplant and patients co-infected with HIV. There is a potential for significant drug-drug interactions with Viekira Pak.
- Sovaldi remains as an important therapy that allows for interferon-free options in patients with genotypes 2 or 3 chronic HCV.
- In the absence of head-to-head trials, HCV treatment should be based on current AASLD/IDSA treatment guideline recommendations, individual patient characteristics, likelihood of adherence, and patient preferences, as well as cost.

Relative Cost-Effectiveness Analysis and Conclusion—A cost-effectiveness analysis (CEA) and Budget Impact Analysis (BIA) were performed to evaluate the HCV drugs. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CEA results showed that all DAA agents were within a range considered cost-effective to the MHS.
- BIA was performed to evaluate the potential impact of designating selected agents as step-preferred, formulary, or NF on the UF. BIA results showed that designating all agents UF, with no step-therapy, demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 1 opposed, 1 abstained, 1 absent) the following:
   - UF:
     - Ledipasvir/sofosbuvir (Harvoni)
     - Paritaprevir/ritonavir/ombitasvir + dasabuvir (Viekira Pak)
     - Sofosbuvir (Sovaldi)
     - Simeprevir (Olysio)
     - Boceprevir (Victrelis), until market withdrawal in December 2015
   - NF: None

2. ***COMMITTEE ACTION: EXTENDED CORE FORMULARY (ECF)***
   As the recommended AASLD/IDSA treatment guidelines are continually updated and changing, the P&T Committee recommended (16 for, 0

opposed, 1 abstained, 1 absent) to not add an HCV DAA drug to the ECF. For the HCV class, ribavirin 200 mg capsules and peginterferon alfa-2a (Pegasys) were designated ECF in November 2012.

3. ***COMMITTEE ACTION: SOFOSBUVIR (SOVALDI) PA CRITERIA***
Manual PA criteria for the individual DAAs were recommended previously. The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) minor revisions to the Sovaldi manual PA criteria to include the table of the recommended treatments for each HCV genotype and duration of therapy. See Appendix D for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the UF and PA implementation become effective upon signing of the minutes in all POS.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Oral Anticoagulants

Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of the oral anticoagulant drugs, which is comprised of the following:

- **Target-Specific Oral Anticoagulants (TSOACs)**: apixaban (Eliquis), dabigatran (Pradaxa), edoxaban (Savaysa), and rivaroxaban (Xarelto)

- **Vitamin K Antagonists**: warfarin (Coumadin, generic)

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following conclusions:

- **Non-valvular Atrial Fibrillation (NVAF):**
  - In NVAF, dabigatran and apixaban were superior to not optimally controlled warfarin, while edoxaban and rivaroxaban were non-inferior.
  - Intracranial bleeding was lower with all four TSOACs compared with warfarin in the major trials used to obtain FDA approval for apixaban, dabigatran, edoxaban, and rivaroxaban.
  - Edoxaban advantages include once daily dosing and an overall lower rate of bleeding versus warfarin. Disadvantages include a higher rate of

gastrointestinal (GI) bleeding, and a higher risk of stroke in patients with normal renal function (creatinine clearance greater than 95 mL/min).

- Dabigatran was the only TSOAC to show superior ischemic stroke reduction, but it has a higher incidence of GI bleeding than warfarin, causes dyspepsia, and is highly dependent on renal clearance.
- Rivaroxaban advantages include once daily dosing, but it has an increased incidence of GI bleeding and major bleeding compared to warfarin. The patient population studied with rivaroxaban had more comorbidities than the other three TSOACs.
- Apixaban had significantly less major bleeding than warfarin, and was the only TSOAC to show a reduction in mortality, but the confidence interval approached one. The point estimates and confidence intervals for all the TSOACs are similar for mortality.

- **Venous Thromboembolism (VTE)**
  - For acute VTE, no overlap with low-molecular weight heparin (LMWH) is required with apixaban or rivaroxaban. All four TSOACs were non-inferior to LMWH and/or warfarin for the composite endpoint of recurrent VTE, nonfatal pulmonary embolism (PE), or death.
  - Apixaban and rivaroxaban had significantly less major bleeding than LMWH and/or warfarin.
- **VTE Prevention following Orthopedic Surgery (Hip or Knee Replacement)**
  - The TSOACs offer a convenience to patients in that LMWH injections are not required.
  - Rivaroxaban and apixaban are FDA approved, while edoxaban and dabigatran are not approved for this use.

Overall Relative Clinical Effectiveness Conclusion: Due to a lack of head-to-head trials, the P&T Committee concluded there is insufficient evidence to determine if one TSOAC has advantages over the others. The TSOACs have advantages of predictable anticoagulant effect, fixed dosing, fewer drug interactions, and lack of laboratory monitoring and dietary restrictions, compared to warfarin. However, overall warfarin remains a viable therapy option due to its large number of FDA-approved indications, long history of use, preferred choice for patients with severe renal dysfunction, and availability of an antidote.

Relative Cost-Effectiveness Analysis and Conclusion—CMA, CEA, and BIA were performed to evaluate the oral anticoagulants. The P&T Committee concluded (17 for, 0 opposed, 1 abstained, 0 absent) the following:

- CMA and CEA results showed generic warfarin was the most cost-effective oral anticoagulant, followed by all branded TSOACs (apixaban, dabigatran, edoxaban and rivaroxaban).

- BIA was performed to evaluate the potential impact of designating selected TSOACs with formulary or NF status on the UF. BIA results showed that modeled scenarios where generic warfarin is BCF, with all other branded TSOACs designated as formulary on the UF, demonstrated greater cost avoidance for the MHS compared to the current baseline formulary status.

1. ***COMMITTEE ACTION: UF RECOMMENDATIONS***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) the following:

   - UF:
     - Warfarin (Coumadin; generic)
     - Apixaban (Eliquis)
     - Dabigatran (Pradaxa)
     - Edoxaban (Savaysa)
     - Rivaroxaban (Xarelto)
   - NF: None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) generic warfarin remain designated with BCF status.

3. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) adding edoxaban (Savaysa) to the maintenance medication drug list, as the other TSOACs are on the program. Implementation will occur upon signing of the minutes.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Testosterone Replacement Therapy (TRT): Testosterone Nasal Gel (Natesto)** Natesto is a new formulation of testosterone that is administered intranasally. It is dosed as one pump actuation per nostril, three times daily, six to eight hours apart. The TRT products were reviewed by the P&T Committee in August 2012 and automated PA (step therapy) and manual PA criteria were recommended for the class

(implemented March 2013).

a) ***COMMITTEE ACTION: TESTOSTERONE NASAL GEL (NATESTO) STEP THERAPY AND PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) step therapy and manual PA criteria for testosterone nasal gel (Natesto), consistent with the rest of the class and its FDA-approved indication. See Appendix C for the full criteria.

2. **Cystic Fibrosis (CF) Drugs: Ivacaftor (Kalydeco)**—Ivacaftor (Kalydeco) is indicated for the treatment of CF. PA criteria were recommended at the February 2012 meeting, updated in May 2014 and December 2014 to reflect the FDA-approved indication for various mutations in the CF transmembrane conductance regulator gene. In March 2015, the FDA-approved indication was further expanded to include pediatric patients aged 2 years and older. Along with this expanded indication, a new dosage form was launched in the form of oral granules that are mixed with either soft food or liquid every 12 hours for weight-based pediatric dosing.

   a) ***COMMITTEE ACTION: IVACAFTOR (KALYDECO) PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) updated manual PA criteria for Kalydeco to include the expanded FDA-approved indication. See Appendix C for the full criteria.

3. **Renin Angiotensin Antihypertensives (RAAs): Perindopril/Amlodipine (Prestalia)** The FDA recently approved the combination product perindopril and amlodipine (Prestalia). It is indicated for the treatment of hypertension as monotherapy or as initial therapy in patients requiring multiple drugs to achieve their blood pressure goals. The RAAs class was reviewed in August 2010; step therapy was implemented in January 2011 and applies to all drugs in the class.

   a) ***COMMITTEE ACTION: PERINDOPRIL/AMLODIPINE (PRESTALIA) PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) step therapy criteria for perindopril/amlodipine (Prestalia), consistent with the current criteria for the RAAs class. See Appendix C for the full criteria.

4. **Inhaled Insulin (Afrezza)**—Afrezza is rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with Type 1 or Type 2 diabetes mellitus. It is available as single-use cartridges of 4, 8, and 12 units, administered via oral inhalation at the beginning of a meal. Dosing must be individualized. Manual PA criteria were recommended to ensure appropriate use of the drug in Type 1 and Type 2 diabetic patients, including failure of or inability to tolerate an adequate trial (90 days) of a rapid or short-acting subcutaneous insulin product. See Appendix C for the full criteria.

   a) ***COMMITTEE ACTION: INHALED INSULIN (AFREZZA) PA CRITERIA*** The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent)

manual PA criteria for Afrezza, consistent with the FDA-approved product labeling for use in Type 1 and Type 2 diabetic patients. See Appendix C for the full criteria.

5. **Self-Monitoring Blood Glucose System (SMBGS) Test Strips: ACCU-CHEK Aviva Plus Test Strips**—The SMBGS test strips were evaluated at the November 2014 P&T Committee Meeting. Step therapy and MN criteria were recommended with an implementation date of August 5, 2015. PA and MN criteria allow for use of a non-preferred, NF test strip if the patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter.

   The ACCU-CHEK Aviva Plus test strips are designated non-preferred and NF. However, the ACCU-CHEK Aviva Plus test strips are used in the ACCU-CHEK Combo meter, which communicates wirelessly with the ACCU-CHEK Spirit Combo insulin pump.

   a) ***COMMITTEE ACTION: ACCU-CHEK AVIVA PLUS SMBGS TEST STRIPS MANUAL PA CRITERIA AND MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstain, 0 absent) adding the ACCU-CHEK Aviva Plus test strips to the SMBGS Test Strips PA criteria and MN criteria for patients using the ACCU-CHEK Aviva Combo meter with the ACCU-CHEK Spirit Combo pump. See Appendices B and C for full criteria.

B. QUANTITY LIMITS (QLs)—QLs were reviewed for three oral oncologic drugs. QLs already apply to products in the Oral Oncology Drug Class.

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) QLs for palbociclib (Ibrance), panobinostat (Farydak), lenvatinib (Lenvima), consistent with the product labeling and packaging. See Appendix E for QLs.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VII. LINE EXTENSIONS

A. Formulary Status Clarification—The P&T Committee clarified the formulary status for two product line extensions ("follow-on products") by the original manufacturers. Line extensions have the same FDA indications as the "parent" drug.

Nuvigil was reviewed for formulary placement in 2012 and designated NF at that time with a manual PA implemented. A 200 mg Nuvigil dose was approved in February 2014 and has been on the UF since its launch. Vogelxo is an AB-rated generic to Testim, which was designated NF and placed behind the TRT step in May 2013.

1. ***COMMITTEE ACTION: LINE EXTENSIONS FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent vote) clarifying the formulary status of armodafinil (Nuvigil) 200 mg and testosterone gel (Vogelxo).

    - Armodafinil (Nuvigil) 200 mg: Designated NF and subject to the same manual PA as the other marketed strengths of Nuvigil
    - Testosterone Gel (Vogelxo): Designated NF and placed behind the TRT step along with its parent drug, Testim

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. ADJOURNMENT

The meeting adjourned at 1020 hours on May 14, 2015. The next meeting will be in August 2015.

Appendix A—Attendance: May 2015 P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Prior Authorization Criteria for Hepatitis C Drugs
Appendix E—Table of Quantity Limits
Appendix F—Table of Implementation Status of UF Recommendations/Decisions Summary
Appendix G—Table of Abbreviations

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH

Lieutenant General, USAF, MC, CFS
Director

20 July 2015
Date

Appendix A—Attendance: May 2015 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood for George Jones, PharmD, M.S.	Chief, DHA Operations Management Branch
CAPT Walter Downs, MC	Chief, DHA Formulary Management Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
LTC Kevin Tiller, BSC	Air Force, Pharmacy Officer Alternate
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer Alternate
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
CPT Danika Alexander, MC for MAJ John Poulin, MC	Army, Physician at Large
COL Michael Wynn, MC	Army, Family Practice Physician
Col James Jablonski, MC	Air Force, Physician at Large
LCDR Adam Deising, MC for CDR Brian King, MC	Navy, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
COL Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. Bryan Wheeler	Acting General Counsel, DHA
Guests	
Mr. Bill Davies via DCO	DHA Pharmacy Operations Division
LTC Kevin Ridderhoff, MS	DHA, Pharmacy Operations Division
MAJ Randall Sweeney	Defense Logistics Agency Troop Support
MAJ Richard Caballero	Defense Logistics Agency Troop Support
CDR Matthew Baker	Indian Health Service
Mr. Matthew Halbe	DHA Contract Operations Division
Ms. Patricia Legra	DHA Contract Operations Division
Capt Nina Tachikawa	Air Force, Pharmacy Officer

Appendix A—Attendance (continued)

Others Present	
LCDR Marisol Martinez, USPHS	DHA Pharmacy Operations Division
LTC Misty Carlson, MC	DHA Pharmacy Operations Division
Maj David Folmar, BSC	DHA Pharmacy Operations Division
Lt Col Ronald Khoury, MC	DHA Pharmacy Operations Division
CDR Edward Vonberg, BSC	DHA Pharmacy Operations Division
Angela Allerman, PharmD, BCPS	DHA Pharmacy Operations Division
Shana Trice, PharmD, BCPS	DHA Pharmacy Operations Division
Amy Lugo, PharmD, BCPS via DCO	DHA Pharmacy Operations Division
Teresa Anekwe, PharmD, BCPS via DCO	DHA Pharmacy Operations Division
Eugene Moore, PharmD, BCPS	DHA Pharmacy Operations Division
Brian Beck, PharmD, BCPS	DHA Pharmacy Operations Division
Dean Valibhai	DHA Pharmacy Operations Division
David Meade, PharmD, BCPS via phone	DHA Pharmacy Operations Division
Ms. Deborah Garcia	DHA Pharmacy Operations Division contractor
Mr. Kirk Stocker	DHA Pharmacy Operations Division contractor
Esmond Nwokeji, PhD	DHA Pharmacy Operations Division contractor
Daniel DeLeon	Incarnate Word Pharmacy student

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Suvorexant (Belsomra) **Newer Sedative Hypnotics (SED-1s)**	• Use of the formulary agent is contraindicated **Formulary alternatives:** zolpidem IR, zaleplon, zolpidem ER (Ambien CR), eszopiclone (Lunesta), and doxepin (Silenor)
• Peginterferon beta-1a (Plegridy) **Multiple Sclerosis (MS) Drugs**	• No alternative formulary agent. Patient requires Peginterferon beta-1a and cannot be treated with Avonex or Rebif. **Formulary alternatives**: Avonex, Rebif, Copaxone, Betaseron, Extavia, and the oral agents
• Doxylamine succinate and pyridoxine hydrochloride (Diclegis) **Antiemetics/Antivertigo Agents**	• No alternative formulary agent. Patient cannot swallow two tablets separately and must take a fixed-dose combination product. **Formulary Alternatives:** over-the-counter vitamin pyridoxine, over-the-counter doxylamine, metoclopramide, ondansetron
• ACCU-CHEK Aviva Plus Test Strips **Self-Monitoring Blood Glucose (SMBGS) Test Strips**	No alternative formulary agent: • Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter: o CONTOUR NEXT strip with CONTOUR NEXT Link meter for Medtronic pump. o Nova Max strip with Nova Max Link meter for Medtronic pump. o **ACCU-CHEK Aviva Plus test strips with the ACCU-CHEK Combo meter for the ACCU-CHEK Spirit Combo pump.** o For Retail Network Only: OneTouch Ultra test strips with OneTouch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump. o For Retail Network Only: OneTouch Ultra test strips with OneTouch Ping meter and using the OneTouch Ping insulin pump

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Suvorexant (Belsomra) **Newer Sedative Hypnotics (SED-1s)**	A trial of generic zolpidem IR or zaleplon is required for new users of Belsomra Automated PA • The patient has filled a prescription for zolpidem IR or zaleplon at any Military Health System pharmacy point of service (Military Treatment Facility, retail network pharmacies, or mail order) during the previous 180 days. Manual PA criteria • The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.
• Doxylamine succinate and pyridoxine hydrochloride (Diclegis) **Antiemetics/Antivertigo Agents**	All new users of Diclegis are required to try a nonpharmacologic method for management of nausea and vomiting during pregnancy AND over-the-counter pyridoxine before receiving doxylamine succinate and pyridoxine hydrochloride (Diclegis). Manual PA criteria—Doxylamine succinate and pyridoxine hydrochloride (Diclegis) is approved if: • The patient has not had relief of symptoms after trying a nonpharmacologic method to manage nausea and vomiting during pregnancy, AND • The patient has not had relief of symptoms after trying over-the-counter pyridoxine for management of nausea and vomiting during pregnancy. • Providers are encouraged to consider an alternate antiemetic (e.g., ondansetron) prior to prescribing doxylamine succinate and pyridoxine hydrochloride (Diclegis). Prior Authorization will expire after 9 months.
• Testosterone nasal gel (Natesto) **Testosterone Replacement Therapy (TRTs)**	PA criteria apply to all new and current users of Natesto. Automated PA criteria: The patient has filled a prescription for transdermal 2% gel pump (Fortesta) at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days **AND** Manual PA criteria: If automated criteria are not met, coverage is approved for Natesto if: • Contraindications exist to Fortesta (hypersensitivity to a component) • Inadequate response to Fortesta (minimum of 90 days **AND** failed to achieve testosterone levels above 400 ng/dL **AND** denied improvement in symptoms) • Clinically significant adverse reactions to Fortesta not expected with Natesto **AND** Coverage approved for male patients aged 17 years or older with: • A diagnosis of hypogonadism evidenced by 2 or more morning testosterone levels in the presence of symptoms usually associated with hypogonadism Coverage for use in women or in adolescent males under the age of 17 is not approved and will be considered upon appeal only.

Drug / Drug Class	Prior Authorization Criteria
• Ivacaftor (Kalydeco) **Cystic Fibrosis (CF) Drugs**	Manual PA Criteria apply to all new and current users of Ivacaftor (Kalydeco). • Coverage will be approved for the treatment of CF patients aged **2 years and older** who have a G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R or for R117H mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, detected by an FDA-approved test. • Coverage is not approved for patients who are homozygous for the F508del mutation in the CFTR gene.
• Perindopril/amlodipine (Prestalia) **Renin Angiotensin Antihypertensives (RAAs)**	PA criteria apply to all new and current users of Prestalia. Automated PA criteria—The patient has filled a prescription for one of the preferred agents (generic ACE inhibitors, generic losartan, losartan/HCTZ, Diovan, Diovan HCT, Exforge, Exforge HCT, Micardis, Micardis HCT, or Twynsta) at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days **AND** Manual PA criteria—If automated criteria are not met, coverage is approved for Prestalia if: • Contraindications exist to one step-preferred RAA agent not expected to occur with Prestalia • Inadequate response to one step-preferred RAA agent • Inability to tolerate due to adverse effects to one step-preferred RAA agent
• Inhaled Insulin (Afrezza) **Insulins**	Manual PA criteria apply to all new and current users of Afrezza. Coverage is approved for non-smoking patients with either: **Type 1 Diabetes Mellitus (diagnosed)** • Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting subcutaneous (SC) insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin • Afrezza is used as adjunctive treatment to current basal insulin therapy • Spirometry testing [baseline forced expiratory volume in the first second (FEV1) upon initiation with repeated FEV1 at 6 months after initiation and repeated annually thereafter] has been performed **Type 2 Diabetes Mellitus (diagnosed)** • Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting SC insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin • Failure of or clinically significant adverse effect to two oral anti-diabetic agents [i.e. sulfonylurea, thiazolidinedione (TZD), or dipeptidyl peptidase-4 inhibitor (DPP-4 inhibitor)] if metformin is contraindicated • Spirometry testing (baseline FEV1 upon initiation with repeated FEV1 at 6 months after initiation and repeated annually thereafter) has been performed Contraindications to the use of Afrezza: hypoglycemia, chronic lung disease (asthma, COPD), hypersensitivity to regular human insulin, or any Afrezza excipients
• ACCU-CHEK Aviva Plus test strips **Self-Monitoring Blood Glucose System Test Strips**	New and current users of the nonformulary test strips are required to try FreeStyle Lite or Precision Xtra. See November 2014 P&T Committee Meeting minutes for full class PA criteria. Manual PA Criteria—Non-preferred test strip allowed if: patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter • CONTOUR NEXT strip with CONTOUR NEXT Link meter for Medtronic pump • Nova Max strip with Nova Max Link meter for Medtronic pump • ACCU-CHEK Aviva Plus test strip with the ACCU-CHEK Combo meter for the ACCU-CHEK Spirit Combo pump

Appendix D—Table of Prior Authorization (PA) Criteria for Hepatitis C Drugs

Prior Authorization Criteria

Sofosbuvir (Sovaldi)
Direct Acting Antiviral Subclass

- New users of sofosbuvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV infection
- Has laboratory evidence of HCV genotype 1, 2, 3, or 4 HCV infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Sofosbuvir (Sovaldi) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Sofosbuvir (Sovaldi) is not prescribed as monotherapy

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 12 to 24 weeks, based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for Sofosbuvir (Sovaldi)

HCV genotype	Treatment	Duration
Genotype 1	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks
	SIMEPREVIR 150 mg once daily + SOFOSBUVIR 400 mg once daily (treatment naïve or experienced* without cirrhosis)	12 weeks
	SIMEPREVIR 150 mg once daily + SOFOSBUVIR 400 mg once daily (treatment naïve or experienced* with cirrhosis)	24 weeks
Genotype 2	SOFOSBUVIR + ribavirin	12 weeks
	SOFOSBUVIR + ribavirin (cirrhotic or treatment experienced)	16 weeks
Genotype 3	SOFOSBUVIR + ribavirin	24 weeks
	SOFOSBUVIR + peginterferon alfa + ribavirin (cirrhotic or treatment experienced)	12 weeks
Genotype 4, 5, 6	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks
Hepatocellular carcinoma awaiting transplant	SOFOSBUVIR + ribavirin	up to 48 weeks or at transplant

***Treatment-experienced patients who have failed treatment with peginterferon alfa plus ribavirin but not a HCV protease inhibitor**

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates and guidelines.

Appendix E—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Palbociclib (Ibrance) **Oral Oncologic Drugs**	▪ Retail Network : 21 capsules per 28 days ▪ MTF and Mail Order Pharmacy: 42 capsules per 56 days
• Panobinostat (Farydak) **Oral Oncologic Drugs**	▪ Retail Network : 6 capsules per 28 days ▪ MTF and Mail Order Pharmacy: 12 capsules per 56 days
• Lenvatinib (Lenvima) **Oral Oncologic Drugs**	▪ Retail Network: 1 carton per 30 days ▪ MTF and Mail Order Pharmacy: 2 cartons per 60 days

Appendix F—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2015	**Hepatitis C Virus (HCV) Agents – Direct Acting Agents (DAAs) Subclass**	UF class review Previously reviewed Nov 2012	▪ ECF: No DAA selected ▪ Peginterferon alfa-2a (Pegasys) ▪ Ribavirin 200 mg capsules (generics); excludes Ribapak formulation	▪ Sofosbuvir (Sovaldi) ▪ Simeprevir (Olysio) ▪ Ledipasvir/Sofosbuvir (Harvoni) ▪ Paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak) ▪ Note: Victrelis will remain UF until withdrawn from the market in December 2015	▪ None	Pending singing of the minutes	▪ Manual PA required ▪ QLs also apply; 28-day supply	-
May 2015	**Oral Anticoagulants**	UF class review Previously reviewed Feb 2013	▪ Generic warfarin	▪ Apixaban (Eliquis) ▪ Dabigatran (Pradaxa) ▪ Edoxaban (Savaysa) ▪ Rivaroxaban (Xarelto)	▪ None	Pending singing of the minutes	-	-
May 2015	**Newer Sedative Hypnotics (SED-1s)**	New Drug	▪ Zolpidem immediate release (IR)	*Step preferred* ▪ Zaleplon (Sonata) *Non step-preferred* ▪ Zolpidem ER (Ambien CR) ▪ Eszopiclone (Lunesta) ▪ Doxepin (Silenor)	▪ **Suvorexant (Belsomra) May 2015** ▪ Ramelteon (Rozerem) ▪ Zolpidem SL (Edluar) ▪ Zolpidem SL (Intermezzo) ▪ Tasimelteon (Hetlioz) Feb 2015	Pending signing of the minutes / 90 days	▪ Step therapy (automated PA); requires a trial of zolpidem IR or zaleplon for all SED-1 agents except tasimelteon	▪ BCF, UF, and NF drugs are designated for the SED-1s. There are 2 step-preferred agents: zolpidem IR and zaleplon. See DoD P&T Minutes for May 2012 and Feb. 2013. ▪ See Appendix C for Manual PA criteria.

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2015	**Multiple Sclerosis Drugs**	New Drug	▪ Interferon beta-1b SC (Betaseron)	**Injectables** ▪ Interferon beta-1a SC (Rebif and Rebif Rebidose) ▪ Interferon beta-1a IM (Avonex) ▪ Interferon beta-1b SC (Extavia) **Orals** ▪ Dalfampridine (Ampyra) ▪ Teriflunomide (Aubagio) ▪ Glatiramer (Copaxone) ▪ Fingolimod (Gilenya) ▪ Dimethyl fumarate (Tecfidera)	▪ **PEG interferon beta-1a SC (Plegridy) May 2015**	Pending signing of the minutes / 90 days	-	-
May 2015	**Antiemetics/ Antivertigo Agents**	New Drug	Older Antiemetics (May 2006) ▪ Promethazine oral and rectal (generics)	Newer Antiemetics (Nov 2005) ▪ Granisetron tablets (generics) ▪ Ondansetron oral tablets (generics) ▪ Aprepitant (Emend) Older Antiemetics (May 2006) ▪ Dronabinol (Marinol) ▪ Meclizine (Antivert, generics) ▪ Prochloperazine (Compazine, generics) ▪ Thiethylperazine (Torecan) ▪ Trimethobenzamide (Tigan, generics) ▪ Transdermal scopolamine (Transderm Scop)	▪ **Doxylamine succinate/ pyridoxine hydrochloride (Diclegis) May 2015** Newer Antiemetics ▪ Ondansetron soluble film (Zuplenz) ▪ Dolasetron (Anzemet) ▪ Granisetron patch (Sancuso)	Pending signing of the minutes / 90 days	PA criteria recommended at Aug 2013 meeting	-

TRICARE Formulary Search tool: http://tricare.mil/pharmacyformulary

IR: immediate release
ER: extended release

Appendix G—Table of Abbreviations

AASLD/IDSA	American Association for the Study of Liver Diseases/Infectious Diseases Society of America
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	cost-effectiveness analysis
CFR	Code of Federal Regulations
CMA	cost minimization analysis
DAAs	direct acting antivirals
DCO	Defense Connect Online
DHA	Defense Health Agency
DoD	Department of Defense
ECF	Extended Core Formulary
ER	extended release
FDA	U.S. Food and Drug Administration
GI	gastrointestinal
HCV	hepatitis C virus
IM	intramuscular
IR	immediate release
LMWH	low-molecular weight heparin
MHS	Military Health System
MN	medical necessity
MS	multiple sclerosis
MTF	Military Treatment Facility
NF	nonformulary
NVAF	non-valvular atrial fibrillation
NVP	nausea and vomiting during pregnancy
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PE	pulmonary embolism
POS	points of service
QLs	quantity limits
RAAs	renin angiotensin antihypertensive
SED-1s	Sedative Hypnotic-1s Drug Class
SMBGS	self-monitoring blood glucose system
SC	subcutaneous
SL	sublingual
SVR	sustained virologic response
SVR12	sustained virologic response at 12 weeks
TRT	testosterone replacement therapy
TSOACs	target-specific oral anticoagulants
UF	Uniform Formulary
VTE	venous thromboembolism

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

February 2015

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 11 and 12, 2015, at the Defense Health Agency (DHA) Formulary Management Branch, Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes from the November 2014 DoD P&T Committee meeting on February 3, 2015.

2. **Correction to the November 2014 Minutes**

   a) Self-Monitoring Blood Glucose Test Strips—The November minutes were corrected to state the implementation period for the self-monitoring blood glucose test strips will be 180 days, instead of 120 days. The implementation date is August 5, 2015.

   b) Compound Prescriptions—The Director's decision is final regarding the manual prior authorization (PA) criteria for all new and current users of compound prescriptions. Coverage will be approved if the prescriber provides the information listed in the March 11, 2015 signed Determination Letter on Compounds and implementation of the PA will occur no later than May 1, 2015.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Newer Sedative Hypnotics Agents (SED-1s): Tasimelteon (Hetlioz)

Background—Tasimelteon (Hetlioz) is a melatonin receptor agonist indicated solely for treatment of the non-24 sleep wake disorder, a circadian rhythm disorder sometimes found in blind patients.

Only two placebo-controlled trials in patients with non-24 sleep wake disorder are available; no head-to-head or active comparator studies are available. Many limitations exist with these two studies, including the small numbers of patients enrolled (less than 100 patients), the inclusion of patients shown to previously respond to tasimelteon (RESET trial), and the high patient discontinuation rate (SET trial).

One study in sighted patients with insomnia showed improvements in sleep parameters, but other products on the UF [e.g., zolpidem, eszopiclone (Lunesta)] should be prescribed for insomnia instead of tasimelteon.

Two agents with a similar structure as tasimelteon [melatonin supplement and ramelteon (Rozerem)] are marketed to treat insomnia caused by difficulties with sleep onset.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that other than its unique indication for treating blind patients with non-24 sleep wake disorder, tasimelteon offers no clinically compelling advantages over the existing SED-1 drugs on the UF that are used to treat sleep disorders.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) tasimelteon (Hetlioz) is more costly than the formulary and nonformulary SED-1 agents and melatonin.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) tasimelteon (Hetlioz) be designated NF due to the lack of compelling clinical advantages, other than its unique indication, and cost disadvantage compared to SED-1 agents on the UF.
2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for tasimelteon (Hetlioz). See Appendix B for the full criteria.
3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA*** Automated (step therapy) and manual PA criteria were recommended at the August 2014 DoD P&T Committee meeting and implemented December 10, 2014 for tasimelteon, requiring a trial of zolpidem immediate release (IR) or zaleplon first, and a diagnosis of blindness. The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) updating the PA criteria for tasimelteon, including removing the step therapy requirement, and requiring all new patients to undergo the manual PA process. See Appendix C for the full criteria.
4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent)

1) an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS); and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is July 15, 2015.

5. ***COMMITTEE ACTION: EXCLUDE FROM 2015 NDAA SECTION 702 REQUIREMENT FOR NF MEDICATIONS AVAILABLE AT MAIL ORDER ONLY***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) tasimelteon be excluded from the requirement that NF drugs be solely available from the ~~TRICARE~~ Mail Order Pharmacy. See Section VIII.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors: Empagliflozin (Jardiance)

Background—Empagliflozin (Jardiance) is the third FDA-approved SGLT2 inhibitor. The drug is effective in lowering hemoglobin A1c (A1c) by about 0.65%–0.8% when used as monotherapy, by about 0.5%–0.8% as part of dual therapy, and by about 0.6%–1.3% as part of triple or quadruple therapy. It is similar to canagliflozin (Invokana) and dapagliflozin (Farxiga) in terms of its effects on increasing low-density lipoprotein cholesterol, increasing high-density lipoprotein cholesterol, and decreasing systolic blood pressure and body weight.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) empagliflozin offers no clinically compelling advantages over the existing UF non-insulin diabetes drugs, given the modest decrease in A1c, risk of adverse reactions, including female genital mycotic infections and urinary tract infections, and unknown long-term cardiovascular safety profile.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate empagliflozin (Jardiance) with other oral products on the UF used in the treatment of diabetes. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed empagliflozin (Jardiance) was not cost effective compared to existing formulary agents in the non-insulin diabetes class including metformin, sulfonylureas, thiazolidinediones, and dipeptidyl-dipeptidase-4 (DPP-4) inhibitors.
- Current costs for empagliflozin (Jardiance) show it was comparable to canagliflozin (Invokana) and dapagliflozin (Farxiga), the other agents available in the SGLT2 subclass.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent)

empagliflozin (Jardiance) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes, and cost disadvantage compared to the oral UF products used for treating diabetes.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for empagliflozin (Jardiance). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) a trial of metformin or a sulfonylurea and a DPP-4 inhibitor in all new and current users of empagliflozin (Jardiance), consistent with the PA requirements in place for canagliflozin and dapagliflozin. See Appendix C for full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD*** The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

Director, DHA, Decision ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Antiplatelet Agents: Vorapaxar (Zontivity)

Background—Vorapaxar (Zontivity) is a new antiplatelet with a novel mechanism of action [protease-activated receptor-1 antagonist] that inhibits thrombin-induced platelet activation. It is approved in the setting of secondary prevention for the reduction of cardiovascular (CV) events (including CV death, myocardial infarction (MI), and stroke) in patients with a history of MI or with peripheral artery disease. Vorapaxar must be used with aspirin and or clopidogrel. It remains unknown whether adding vorapaxar to aspirin and or clopidogrel offers benefits similar to that seen with other antiplatelet agents.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that clinically, the place in therapy for vorapaxar is limited due to the significantly increased bleeding risk. Vorapaxar should be reserved for those patients with stable atherosclerotic disease who have failed other antiplatelet therapies.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate vorapaxar (Zontivity) with other oral antiplatelet agents on the UF. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that vorapaxar (Zontivity) was not cost effective compared to other oral antiplatelet agents on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) vorapaxar (Zontivity) be designated NF based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for vorapaxar (Zontivity). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

D. Phosphodiesterase-5 (PDE-5) Inhibitors for Erectile Dysfunction (ED): Avanafil (Stendra)

Background—Avanafil (Stendra) is the fourth PDE-5 inhibitor for ED to enter the market. There are no head-to-head clinical trials comparing avanafil with the other PDE-5 inhibitors for treating ED. However, the change in efficacy endpoints for ED with avanafil and the safety profile appears similar to the other PDE-5 inhibitors. In one study, the higher doses of avanafil were effective in improving ED after prostatectomy, compared to placebo.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that although avanafil differs from the other PDE-5 inhibitors in that it has a 15-minute onset of action, only one PDE-5 is required on the UF to meet the needs of the Military Health System (MHS).

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) avanafil (Stendra) was more costly than the other UF and NF PDE-5 inhibitors.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) avanafil (Stendra) be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the BCF, step-preferred product, sildenafil (Viagra).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for avanafil (Stendra). See Appendix B for the full criteria.

3. ***COMMTTEE ACTION: PA CRITERIA***—Existing automated (step therapy) PA criteria for the PDE-5 inhibitors used for the treatment of ED requires a trial of sildenafil (Viagra) first, prior to receiving another PDE-5 inhibitor. The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) PA criteria for all current users of avanafil (Stendra), similar to the existing PA criteria for the class. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) QLs for avanafil (Stendra), consistent with the FDA-approved package labeling and the QLs in place for the other PDE-5s used in for the treatment of ED. See Appendix E for QLs.

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

Director, DHA, Decision: ☐ Approved ☐ Disapproved

Approved, but modified as follows:

E. Proton Pump Inhibitors (PPIs): Esomeprazole Strontium

Background—Esomeprazole strontium (no brand name) is the eighth PPI to reach the market. It was approved via section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act using efficacy and safety data primarily obtained from information contained in the package insert for esomeprazole magnesium (Nexium).

There are no clinical trials assessing efficacy. Esomeprazole strontium has the same indications as Nexium, with the exception that it is not approved for children. The FDA concluded that that daily dose of strontium contained in the product is not a significant risk to bone health.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that esomeprazole strontium offers no clinically compelling advantages compared to esomeprazole magnesium (Nexium) or the other PPIs.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that esomeprazole strontium is not cost effective compared to other PPIs on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) esomeprazole strontium be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the other PPIs on the UF.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for esomeprazole strontium. See Appendix B for the full criteria.

3. ***COMMTTEE ACTION: PA CRITERIA***—Existing automated (step therapy) PA criteria for the PPIs requires a trial of Nexium or omeprazole first, prior to receiving another PPI. The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) PA criteria for all new and current users of esomeprazole strontium similar to the existing PA criteria for the class. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

Director, ~~DHA~~, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Pulmonary Arterial Hypertension (PAH) Agents

Background—The P&T Committee reviewed the clinical effectiveness of the PAH Agents, which is divided into the three subclasses outlined below. The intravenous prostacyclins (e.g., Flolan and Remodulin) and PDE-5 inhibitors indicated for ED (e.g., Viagra, Cialis, and Levitra) were not included in the review.

- **Prostacyclins**: treprostinil nebulized solution (Tyvaso), treprostinil oral tablets [Orenitram extended release (ER)], and iloprost nebulized solution (Ventavis);

- **Endothelin Receptor Antagonists (ERAs)**: bosentan (Tracleer), ambrisentan (Letairis), and macitentan (Opsumit);
- **Nitric Oxide Drugs**: the soluble guanylate cyclase stimulator, riociguat (Adempas); and, the PDE-5 inhibitors, sildenafil generic, sildenafil brand (Revatio), and tadalafil (Adcirca).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following for the PAH agents:

1. There are no head-to-head comparisons among the PAH drugs; therefore, no evidence-based first-line treatment can be proposed.
2. For the PDE-5 inhibitors, there was no new data to change the conclusion from the previous UF review (November 2009).
    - Sildenafil and tadalafil show similar improvements in 6-minute walking distance (6MWD), based on indirect comparisons of clinical trial results.
    - The product labeling for the two drugs is similar with regard to contraindications, precautions, and warnings.
    - Tadalafil (Adcirca) is dosed once daily, which is more convenient compared to the three-times daily dosing required with sildenafil (Revatio).
3. In one systematic review (CHEST 2014), all the PAH drugs increased the 6MWD by 27.9 meters to 39.9 meters when compared to placebo; however, comparisons between agents are inconclusive. Of note, the minimal clinically important difference for the 6MWD is a distance of at least 33 meters.
4. Monotherapy with the ERAs or PDE-5-inhibitors showed decreased hospitalization rates. There is insufficient information to determine whether ERAs or the PDE-5 inhibitors decrease mortality.
5. The CHEST 2014 systematic review did not include treprostinil (Orenitram ER), macitentan (Opsumit) and riociguat (Adempas). In their individual trials, Orenitram ER, Opsumit, and Adempas caused statistically significant improvements in the 6MWD compared to placebo. The improvement in 6MWD was clinically significant with Adempas. Orenitram ER and Adempas have not shown mortality benefits. Orenitram ER showed a significant reduction in the endpoint of time to clinical worsening. Adempas has an additional indication for chronic thromboembolic pulmonary hypertension (CTEPH).
6. Within and among the subclasses, the PAH drugs have distinct adverse reaction profiles. The ERAs and riociguat are pregnancy category X.

Overall relative clinical effectiveness conclusion: The P&T Committee concluded the choice of drug for PAH depends on a variety of factors including indication, product labeling, mechanism of action, route of administration, side effect profile, drug interactions, patient preference, and physician experience.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) was performed to evaluate the PAH subclasses. BIA was performed to evaluate

the potential impact of designating selected agents in various formulary scenarios. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

ERAs:

- CMA results showed that ambrisentan (Letairis) was the most cost-effective agent in this subclass, followed by macitentan (Opsumit) and bosentan (Tracleer).
- BIA results showed that the scenario with Letairis, Opsumit, and Tracleer designated with UF status and no step requirement yielded the lowest budget impact for the MHS.

Prostacyclins:

- CMA results showed that treprostinil tablets (Orenitram ER) was the most cost-effective agent in this subclass, followed by treprostinil nebulized solution (Tyvaso) and iloprost (Ventavis).
- BIA results showed that the scenario with Orenitram ER, Tyvaso, and Ventavis designated with UF status and no step requirement yielded the lowest budget impact for the MHS.

Nitric Oxide Drugs:

- CMA results showed that sildenafil generic was the most cost-effective agent in this subclass, followed by tadalafil (Adcirca), sildenafil brand (Revatio), and riociguat (Adempas).
- BIA results showed that the scenario with sildenafil generic and sildenafil brand (Revatio) as step-preferred and formulary on the UF, with tadalafil (Adcirca) and riociguat (Adempas) as non step-preferred and formulary on the UF, yielded the lowest budget impact for the MHS.

a) ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) the following:

- ERAs: designate bosentan (Tracleer), ambrisentan (Letairis), and macitentan (Opsumit) as UF.
- Prostacyclins: designate treprostinil nebulized solution (Tyvaso), treprostinil tablets (Orenitram ER), and iloprost (Ventavis) as UF.
- Nitric Oxide Drugs:
    - UF and step-preferred: sildenafil 20mg generic and sildenafil brand (Revatio)
    - UF and non step-preferred: tadalafil (Adcirca) and riociguat (Adempas)

- This recommendation includes step therapy, which requires a trial of sildenafil 20 mg generic or sildenafil brand (Revatio) in all new users of tadalafil (Adcirca) or riociguat (Adempas).

b) ***COMMITTEE ACTION: EXTENDED CORE FORMULARY (ECF) RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) adding sildenafil 20mg generic and sildenafil brand (Revatio) tabs to the ECF.

c) ***COMMITTEE ACTION: NITRIC OXIDE DRUGS PA CRITERIA*** Existing manual PA criteria apply to sildenafil 20 mg (Revatio) or tadalafil (Adcirca) for patients with primary PAH. The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) criteria for all new users of the non-preferred nitric oxide PAH drugs [tadalafil (Adcirca) and riociguat (Adempas)], requiring a trial of sildenafil 20 mg generic or sildenafil brand (Revatio) first. See Appendix C for the full criteria.

d) ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Oral Oncology Drugs—Prostate Cancer

Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of the Prostate Cancer drugs, which is comprised of the following:

- **Subclass I (Anti-Androgen Agents)**: bicalutamide (Casodex; generic), flutamide (Eulexin; generic), and nilutamide (Nilandron)

- **Subclass II (Survival-Prolonging Drugs)**: enzalutamide (Xtandi) and abiraterone (Zytiga)

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following conclusions for the Prostate Cancer drugs:

- **Subclass I (Anti-Androgen Agents):**
    1. The American Society of Clinical Oncologists/Cancer Care Ontario 2014 Guidelines found only limited data regarding clinical benefits of the Subclass I agents (bicalutamide, flutamide, and nilutamide). The guidelines also stated that the three anti-androgens demonstrate unknown survival and quality of life benefit.
    2. In one head-to-head trial, bicalutamide was as effective as flutamide. There was no significant difference between the two drugs in the median time to progression of disease or median time to death.
    3. Flutamide has a higher incidence of gastrointestinal side effects than bicalutamide, and has warnings for hepatotoxicity. Nilutamide has a black box warning for pulmonary toxicity and delays visual light-to-dark adaptation that can limit its use.
    4. Bicalutamide is considered the initial drug of choice when used for complete androgen blockage, based on its dosing frequency (once daily dosing, compared to three times daily dosing with flutamide), toxicity profile, and clinical trial data.
    5. Although nilutamide has no compelling advantages compared with flutamide or bicalutamide and has the least favorable safety profile, it is required on the UF due to its unique indication for use in combination with surgical castration.

- **Subclass II (Survival Prolonging Drugs):**
    1. For the Subclass II agents, abiraterone (Zytiga) and enzalutamide (Xtandi) have independently been shown to improve overall survival and progression-free survival when compared to placebo, both in the post-chemotherapy and chemotherapy-naïve settings. There is no data to guide sequencing.
    2. Zytiga requires the co-administration of prednisone to help mitigate the mineralocorticoid excess that can result from its mechanism of action. Xtandi does not require concomitant administration of steroids, but 30%–47% of patients were receiving some form of steroids therapy in the two phase 3 studies that led to its FDA approval.
    3. The Subclass II agents have differing safety profiles. Zytiga can cause adrenocortical insufficiency, hypertension, hypokalemia, and edema, which requires close monitoring for these complications. Xtandi has been associated with seizures as well as hypertension when compared to placebo.

Overall relative clinical effectiveness conclusion: The P&T Committee concluded the choice of prostate cancer agent depends on clinical considerations, patient preferences, prior treatment, presence or absence of visceral disease, patient symptoms, and drug side effect profiles.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the Prostate Cancer drugs. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that in Subclass I, bicalutamide was the most cost-effective agent, followed by flutamide and nilutamide. In Subclass II, abiraterone (Zytiga) was more cost effective than enzalutamide (Xtandi).
- BIA results showed that designating all the prostate cancer drugs as formulary on the UF, with no step-preferred agents in either subclass, demonstrated significant cost avoidance for the MHS.

a) ***COMMITTEE ACTION: UF RECOMMENDATIONS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
  - Flutamide (Eulexin; generic)
  - Bicalutamide (Casodex; generic)
  - Nilutamide (Nilandron)
  - Abiraterone (Zytiga)
  - Enzalutamide (Xtandi)
- NF: None

b) ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) bicalutamide (Casodex) be designated with BCF status.

c) ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Manual PA criteria currently apply to enzalutamide (Xtandi) and abiraterone (Zytiga). The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the current PA criteria for Xtandi and Zytiga. The P&T Committee also recommended manual PA criteria for all new users of nilutamide (Nilandron) due to its limited indication. See Appendix C for full criteria.

d) ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

Director, DHA Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. Transmucosal IR Fentanyl Products (TIRFs)

Relative Clinical Effectiveness—The TIRF subclass is comprised of the following formulations of transmucosal fentanyl: oral lozenge (Actiq, generics), buccal tablet (Fentora), sublingual tablet (Abstral), nasal spray (Lazanda), and sublingual spray (Subsys). The soluble buccal film (Onsolis) is no longer marketed. The TIRFs are a subclass of the narcotic analgesics.

All of the TIRFs are indicated for the management of breakthrough cancer pain in patients who are already receiving opioids, and who are tolerant to around-the-clock therapy for their underlying persistent cancer pain. Short-acting opioids also remain a viable option for the treatment of breakthrough cancer pain.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following for the TIRF formulations:

1. No head-to-head comparisons of the various TIRF formulations have been conducted to date. Indirect comparisons are difficult to make, due to differences in patient selection criteria, severity of breakthrough pain episodes, and titration as well as repeat dosing protocols.
2. Evidence from a network meta-analysis and a Cochrane systematic review demonstrate that all the TIRFs provide rapid onset of analgesia, with clinically meaningful differences in pain intensity achieved after 30 minutes following administration.
3. Minor pharmacokinetic differences (such as bioavailability and onset of analgesia) do not result in clinically relevant differences in pain relief.
4. Adverse effects are similar for all the TIRFs and are consistent with opioid therapy in cancer patients. Unique application site reactions include dental caries with the lozenge (Actiq) and nasal irritation with the nasal spray (Lazanda).
5. Unique advantages of the products include the following: administration of the lozenge (Actiq) can be interrupted in case of toxicity and it is approved for adolescents 16 years and older. The sublingual tablet (Abstral) and spray (Subsys) have faster dissolution rates than the lozenge (Actiq) and buccal (Fentora) formulations. The nasal spray (Lazanda) is convenient and can be administered by caregivers.
6. Unique disadvantages include the following: the sugar content in the lozenge (Actiq) may cause formation of dental caries and subsequent tooth loss. Lazanda may be unsuitable for patients with respiratory illnesses. Co-administration of Lazanda with a vasoconstrictive nasal decongestant (e.g., oxymetazoline) may lead to reduced fentanyl plasma concentrations.

Overall Clinical-Effectiveness Conclusion—In the absence of direct comparative trials, TIRF selection should be based on individual patient characteristics, likelihood of adherence, and patient preferences.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the TIRF subclass. The P&T Committee concluded (14 for, 0 opposed, 1 abstained, 1 absent) the following:

- CMA results showed that generic fentanyl citrate lozenge (Actiq) was the most cost-effective TIRF, followed by Fentora, Lazanda, and Abstral. Subsys was the least cost effective.
- BIA results showed that all modeled scenarios demonstrated a cost avoidance for the MHS, compared to the current baseline formulary status. The scenario with generic fentanyl lozenge (Actiq) with no step requirement and formulary on the UF, and all other branded agents NF, demonstrated a cost avoidance for the MHS, with the smallest impact to patients from disruption in therapy.

a) ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (9 for, 5 opposed, 1 abstained, 1 absent) the following:

- UF: fentanyl transmucosal lozenge (Actiq, generics)
- NF:
  - Fentanyl sublingual tablet (Abstral)
  - Fentanyl buccal tablet (Fentora)
  - Fentanyl nasal spray (Lazanda)
  - Fentanyl sublingual spray (Subsys)

b) ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) not to add a TIRF to the BCF; morphine sulfate IR will remain the BCF selection for the narcotic analgesics class.

c) ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for Abstral, Fentora, Lazanda, and Subsys. See Appendix B for the full criteria.

d) ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

e) ***COMMITTEE ACTION: EXCLUDE FROM 2015 NDAA SECTION 702 REQUIREMENT FOR NF MEDICATIONS AVAILABLE AT MAIL ORDER***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) that the TIRFs recommended for NF status (Abstral, Fentora, Lazanda, and Subsys) be excluded from the requirement that NF drugs be solely available from the TRICARE Mail Order Pharmacy. See Section VIII.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VI. UTILIZATION MANAGEMENT

A. PAs and MN Criteria

1. **Hepatitis C Virus (HCV) Agents, Direct Acting Antivirals (DAAs): Paritaprevir/Ritonavir/Ombitasvir with Dasabuvir (Viekira Pak) Manual PA Criteria**—The combination product Viekira Pak contains paritaprevir 75 mg, ritonavir 50 mg, and ombitasvir 12.5 mg (dosed two tablets once daily), packaged with dasabuvir 250 mg (dosed twice daily). Viekira Pak was approved by the FDA in December 2014 and is the third FDA-approved interferon-free regimen indicated to treat HCV genotype 1. The hepatitis C drugs will be reviewed at an upcoming meeting.

   a) ***COMMITTEE ACTION: VIEKIRA PAK MANUAL PA CRITERIA***—PA criteria currently apply to the DAAs. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users of paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak), consistent with FDA-approved labeling. Prior authorization will expire after 12–24 weeks, based on the treatment regimen. See Appendix C for the full criteria.

2. **Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)** Secukinumab (Cosentyx) is a new TIB indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class (implemented on December 17, 2014).

   a) ***COMMITTEE ACTION: SECUKINUMAB (COSENTYX) PA CRITERIA*** The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria and step therapy for secukinumab (Cosentyx), consistent with the FDA-approved indication. See Appendix C for the full criteria.

3. **Topical Antifungals: Efinaconazole 10% (Jublia) and Tavaborole 5% (Kerydin) Topical Solutions**—Jublia and Kerydin are indicated for the topical treatment of toenail onychomycosis. Both products are dosed once daily for 48 weeks. The P&T Committee reviewed the current recommended treatment guidelines, FDA-approved indications, efficacy data, safety information, and utilization and cost data for the topical antifungals for toenail onychomycosis.

    a) ***COMMITTEE ACTION: EFINACONAZOLE 10% (JUBLIA) AND TAVABORALE 5% (KERYDIN) MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for efinaconazole 10% (Jublia) and tavaborole 5% (Kerydin) in all new and current users of the products. PA criteria were recommended due to the modest efficacy of the products, lack of head-to-head clinical trials, limited efficacy and safety data, and high cost. See Appendix C for the full criteria.

    b) ***COMMITTEE ACTION: EFINACONAZOLE 10% (JUBLIA) AND TAVABORALE 5% (KERYDIN)) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the PA. Based on the P&T Committee's recommendation, the effective date is August 19, 2015.

4. **Cystic Fibrosis Drugs: Ivacaftor (Kalydeco)**—Ivacaftor (Kalydeco) is indicated for the treatment of cystic fibrosis. PA criteria were recommended at the February 2012 meeting, updated in May 2014, and reflect the FDA-approved indication for various mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. In December 2014, Kalydeco received an additional indication for the R117H mutation in the CFTR gene.

    a) ***COMMITTEE ACTION: IVACAFTOR (KALYDECO) MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updated manual PA criteria for Kalydeco to include the expanded FDA-approved indication. See Appendix C for the full criteria.

5. **Non-Insulin Diabetes Mellitus Drugs: Glucagon-Like Peptide-1 Receptor Agonist (GLP1RAs); Exenatide Once Weekly Pen (Bydureon Pen)**—Exenatide (Bydureon) is now available in a pre-filled pen in addition to the original vial formulation. Manual PA criteria were recommended at the November 2014 P&T Committee meeting due to the significant price difference between the Bydureon Pen formulation and the Bydureon vials. The cost of the Bydureon pen is now comparable to the vial formulation.

a) ***COMMITTEE ACTION: EXENATIDE PEN (BYDUREON PEN) REMOVAL OF PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) to remove the manual PA criteria for the Bydureon pen, requiring use of Bydureon vials first. The existing step therapy PA, requiring a trial of metformin or a sulfonylurea first, will remain for the formulation.

6. **Nasal Allergy Drugs: Mometasone (Nasonex) and Fluticasone Furoate (Veramyst) Nasal Inhalers**—The Nasal Allergy Drugs were reviewed by the P&T Committee in May 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class, requiring a trial of generic fluticasone propionate (Flonase) azelastine 137 mcg, flunisolide, or ipratropium. Step therapy does not apply to patients younger than age four. Nasonex and Veramyst were recommended for NF and non step-preferred status. Both drugs are approved for treating symptoms of allergic rhinitis in patients as young as two years of age, while generic Flonase is approved in children as young as four years of age. The P&T Committee recommended updating the MN criteria to reflect the pediatric indications for Nasonex and Veramyst.

   a) ***COMMITTEE ACTION: MOMETASONE (NASONEX) AND FLUTICASONE FUROATE (VERAMYST) MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) revised MN criteria for Nasonex and Veramyst, consistent with the FDA-approved product labeling for use in children as young as two years of age. See Appendix B for the full criteria.

B. QLs—QLs were reviewed for several drugs from the Hepatitis C drugs, inhaled corticosteroids, nasal allergy drugs, antiemetics, and oral chemotherapy drug classes. QLs apply to products in these respective drug classes.

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) QLs for paritaprevir/ritonavir/ombitasvir dasabuvir (Viekira Pak), fluticasone furoate inhaler (Arnuity Ellipta), beclomethasone hydrofluoroalkane (HFA) pediatric 40 mcg/spray (QNASL), netupitant/palonosetron (Akynzeo), and olaparib (Lynparza), consistent with the product labeling. See Appendix E for QLs.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VII. LINE EXTENSIONS

A. Formulary Status Clarification—The P&T Committee clarified the formulary status for one product line extension ("follow-on product") by the original manufacturer. Line extensions have the same FDA indications and pricing as the "parent" drug.

1. ***COMMITTEE ACTION: LINE EXTENSIONS FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of beclomethasone HFA nasal spray 40 mcg/spray (Children's QNASL). The 40 mcg/spray is a new formulation approved for children aged 4–11 years. Children's QNASL is recommended to have the same formulary status as the 80 mcg/spray formulation (QNASAL), which is indicated for adults and children older than 12 years. Implementation will occur upon signing of the minutes.

    - Beclomethasone HFA nasal spray 40 mcg/spray (Children's QNASL): NF and non step-preferred, similar to beclomethasone HFA nasal spray 80 mcg/spray (QNASL). The same step therapy criteria and manual PA criteria will apply.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. 2015 National Defense Authorization Act (NDAA) Section 702

A. NF Medications Available at Mail Order Pharmacy Only—The P&T Committee was briefed on the following four components in 2015 NDAA Section 702 impacting the pharmacy benefit:

- co-pay changes,
- generic drugs to NF tier,
- termination of the TRICARE For Life pilot, subsequently making the program permanent and expanding to under 65, and
- NF medications available at the Mail Order Pharmacy only.

The 2015 NDAA, signed in December 2014, restricts the availability of NF drugs to one point of service, the Mail Order Pharmacy. Beneficiaries with medical necessity will be able to obtain NF drugs at other points of service at the UF co-pay.

This law takes effect with decisions made during the 2015 P&T Committee meetings. Drugs designated with NF status by the P&T Committee will be restricted to the Mail Order Pharmacy. However, an additional vote by the P&T Committee is required for certain drugs (including those for acute therapy, schedule II controlled substances, antipsychotics, oncology agents, and limited distribution drugs) to be excluded from the requirement that NF drugs be

solely available from the Mail Order Pharmacy. Emergent overrides (e.g., drug shortages, special circumstances or emergencies, natural disasters) will be allowed.

PA criteria were recommended to ensure patient safety. Additionally, the P&T Committee requested a 90-day PA expiration for patients meeting the titration criteria listed in (c), below. This request will be evaluated and implemented when operationally feasible.

1. ***COMMITTEE ACTION: NF PRESCRIPTIONS MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for all new NF prescriptions. Coverage will be approved if the prescriber provides the following information listed below.

   a) Does the patient reside in a long-term care facility?

   b) Does the patient have barriers to receiving medications by mail (e.g., no permanent mail address, resides in a rural setting)?

   c) Is the patient not on a stable dose of medication or is the medication currently being titrated?

Director, DHA Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

IX. ITEMS FOR INFORMATION

A. New Drugs Go to Third Tier—The current 32 Code of Federal Regulations (CFR) Part 199 statute states that new FDA-approved drugs are immediately placed on the Second Tier (formulary brand-name drugs).

The Proposed Pharmacy TRICARE Rule, published in the CFR on September 19, 2014, clarifies the process for formulary placement of newly approved innovator drugs brought to market under a New Drug Application approved by the FDA. The proposed rule provides the P&T Committee up to 120 days to recommend tier placement on the UF. During this 120-day period, new drugs would be assigned a "pending status" and be available in the Retail Network and Mail Order Pharmacy under terms comparable to NF (Third Tier) drugs. Tier classification will normally occur at the next P&T Committee meeting following FDA approval. The rule is available at http://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22276.pdf.

X. ADJOURNMENT

The meeting adjourned at 1130 hours on February 12, 2015. The next meeting will be in May 2015.

Appendix A—Attendance: February 2015 P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Prior Authorization Criteria for Hepatitis C Drugs
Appendix E—Table of Quantity Limits
Appendix F—Table of Implementation Status of UF Recommendations/Decisions Summary
Appendix G—Table of Abbreviations

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

5 May 2015
Date

Appendix A—Attendance: February 2015 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood	Chief of Staff, DHA Pharmacy Operations Division
CAPT Walter Downs, MC	Chief, DHA Formulary Management Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer Alternate
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
MAJ John Poulin, MC	Army, Physician at Large
Col Michael Wynn, MC	Army, Family Practice Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
COL Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Voting Members Absent	
George Jones, PharmD, M.S.	Chief, DHA Pharmacy Operations Division
Col Michael Spilker, BSC	DHA Deputy Chief, Pharmacy Operations Division
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Guests	
Mr. Bill Davies via DCO	DHA Pharmacy Operations Division
MAJ Kevin Ridderhoff, MS	DHA, Pharmacy Operations Division
Lt Col Ann McManis via DCO	DHA, Pharmacy Operations Division
LCDR Robert Selvester, MC	VA/DoD Evidence-Based Practice Guideline Work Group
Mr. Matthew Lechtenberg	VA Pharmacy Benefit Management

Appendix A—Attendance (continued)

Guests	
Mr. Alexander Quinones	Defense Logistics Agency Troop Support
MAJ Randall Sweeney	Defense Logistics Agency Troop Support
CDR Matthew Baker	Indian Health Service
Mr. Emmett Larson	DHA Contract Operations Division
Mr. Matthew Gilger	DHA Contract Operations Division
Others Present	
LTC Robert Conrad, MS via phone	DHA Pharmacy Operations Division
LCDR Marisol Martinez, USPHS	DHA Pharmacy Operations Division
LTC Misty Cowan, MC	DHA Pharmacy Operations Division
Maj David Folmar, BSC	DHA Pharmacy Operations Division
Maj Ronald Khoury, MC	DHA Pharmacy Operations Division
CDR Edward Vonberg, BSC	DHA Pharmacy Operations Division
Angela Allerman, PharmD, BCPS	DHA Pharmacy Operations Division
Shana Trice, PharmD, BCPS	DHA Pharmacy Operations Division
Amy Lugo, PharmD, BCPS via DCO	DHA Pharmacy Operations Division
Teresa Anekwe, PharmD, BCPS via DCO	DHA Pharmacy Operations Division
Brian Beck, PharmD, BCPS	DHA Pharmacy Operations Division
David Meade, PharmD, BCPS via phone	DHA Pharmacy Operations Division
Ms. Deborah Garcia	DHA Pharmacy Operations Division contractor
Mr. Kirk Stocker	DHA Pharmacy Operations Division contractor
Esmond Nwokeji, PhD	DHA Pharmacy Operations Division contractor
Maj Ellen Roska	University of Texas PhD student
Brittny Wolda	Incarnate Word Pharmacy student

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Tasimelteon (Hetlioz) **Sedative Hypnotic-1s (SED-1s)**	• No alternative formulary agent – patient is blind and has non-24 sleep wake disorder **Formulary alternatives:** melatonin supplement, zolpidem IR, zaleplon, eszopiclone
• Empagliflozin (Jardiance) **Sodium-Glucose Co-transporter 2 (SGLT2) Inhibitors**	• Use of the formulary agent is contraindicated **Formulary alternatives:** metformin, sulfonylureas, sitagliptin (Januvia, Janumet), linagliptin (Tradjenta, Jentadueto), GLP1RAs, pioglitazone, insulin
• Vorapaxar (Zontivity) **Antiplatelet Agents**	• Formulary agents result or are likely to result in therapeutic failure. **Formulary alternatives:** clopidogrel, cilostazol, pentoxifylline, dipyridamole, Aggrenox, prasugrel, ticagrelor
• Avanafil (Stendra) **PDE-5 Inhibitors for Erectile Dysfunction**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary alternative:** sildenafil (Viagra)
• Esomeprazole Strontium **Proton Pump Inhibitors (PPIs)**	• Use of ALL formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from ALL formulary agents • All formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and esomeprazole magnesium (Nexium)
• Fentanyl sublingual tablet (Abstral) • Fentanyl buccal tablet (Fentora) • Fentanyl nasal spray (Lazanda) • Fentanyl sublingual spray (Subsys) **Transmucosal Immediate Release Fentanyl Products (TIRFs)**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents o For example, dental caries with Actiq or uncontrolled diabetic patients requiring sugar-free formulations • Patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk o For example, patient has xerostomia or mucositis and requires non-oral route of administration • **Formulary alternatives:** fentanyl citrate lozenge, morphine sulfate IR, oxycodone IR, oxymorphone IR, hydromorphone IR

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Tasimelteon (Hetlioz) **Newer Sedative Hypnotics (SED-1s)**	The previous automated (step therapy) criteria for tasimelteon (Hetlioz) (requiring a trial of zolpidem IR or zaleplon) no longer apply. Manual PA criteria apply to all new users of tasimelteon (Hetlioz). Manual PA criteria: Tasimelteon (Hetlioz) is approved if: i. The patient is totally blind and has a documented diagnosis of non-24 sleep wake disorder AND ii. The patient has had a trial of melatonin and either failed or had an adverse event AND iii. The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers) PA Criteria will expire after 6 months (if patient has not responded after 6 months, they will be deemed a non-responder)
• Empagliflozin (Jardiance) **Sodium-Glucose Co-transporter 2 (SGLT2) Inhibitors**	All new and current users of empagliflozin (Jardiance) are required to try metformin or a sulfonylurea (SU), and a dipeptidyl-dipeptidase-4 (DPP-4) inhibitor before empagliflozin (Jardiance). Automated PA criteria: The patient has filled a prescription for metformin or a SU, AND a DPP-4 inhibitor at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, empagliflozin (Jardiance) is approved (e.g., trial of metformin or SU AND a DPP-4 inhibitor is NOT required) if: • The patient has experienced any of the following issues on metformin: o impaired renal function precluding treatment with metformin o history of lactic acidosis • The patient has experienced any of the following issues on a sulfonylurea: o hypoglycemia requiring medical treatment • The patient has had inadequate response to metformin or a SU or a DPP-4 inhibitor • The patient has a contraindication to metformin or a SU or DPP-4 inhibitor

Drug / Drug Class	Prior Authorization Criteria
• Avanafil (Stendra) **PDE-5 Inhibitors for Erectile Dysfunction (ED)**	PA criteria apply to all current users of avanafil. Automated PA criteria: Coverage approved for treatment of ED if: a) The patient has received a prescription for sildenafil (Viagra) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days, AND b) The patient is a male aged 40 years or older. Manual PA criteria: A trial of sildenafil (Viagra) is not required if: • Patient has tried sildenafil (Viagra) and has had an inadequate response or was unable to tolerate treatment due to adverse effects. • Treatment with sildenafil (Viagra) is contraindicated. • Patient is between 18 and 39 years of age and is being treated for ED of organic or mixed organic/psychogenic origin. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in a) or b).] • Patient is between 18 and 39 years of age and is being treated for drug-induced ED where the causative drug cannot be altered or discontinued. [Must try sildenafil (Viagra) first or indicate inability to due to reasons stated above in a) or b).] Coverage is approved for the following non-ED uses requiring daily therapy: • Use of sildenafil, tadalafil, or avanafil (Stendra) for preservation/restoration of erectile dysfunction after prostatectomy. PA expires after one year.
• Esomeprazole Strontium **Proton Pump Inhibitors (PPIs)**	PA criteria apply to all new and current users of esomeprazole strontium. Automated PA criteria: The patient has filled a prescription for omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), or esomeprazole magnesium (Nexium) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order), during the previously 180 days. AND Manual PA criteria: A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), or esomeprazole magnesium (Nexium) is NOT required if: • The patient has tried omeprazole, pantoprazole tablets, and esomeprazole magnesium (Nexium) and had an inadequate response. • The patient has tried omeprazole, pantoprazole tablets, and esomeprazole magnesium (Nexium) and was unable to tolerate it due to adverse effects. • Treatment with omeprazole, pantoprazole tablets, and esomeprazole magnesium (Nexium) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency).

Drug / Drug Class	Prior Authorization Criteria
• Sildenafil 20mg generic • Sildenafil brand (Revatio) • Tadalafil (Adcirca) • Riociguat (Adempas) **Pulmonary Arterial Hypertension Agents (PAH) – Nitric Oxide Drugs Subclass**	PA criteria apply to all new users of Adempas and Adcirca. Automated PA criteria: The patient has filled a prescription for sildenafil 20mg generic or sildenafil brand (Revatio) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Adempas and Adcirca is approved (e.g., a trial of sildenafil is NOT required) if: • For Adempas: o Patient has a documented diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) o Patient has tried a PDE-5 inhibitor and failed or did not respond to therapy o Patient has experienced significant adverse effects from the PDE-5 inhibitor • For Adcirca: o Patient has tried a sildenafil 20 mg generic or sildenafil brand (Revatio) and failed or did not respond to therapy • For both Adempas and Adcirca: o Patient is not taking a nitrate drug.
• Enzalutamide (Xtandi) **Prostate Cancer Drugs Subclass II – Survival Prolonging Drugs**	Coverage is approved if: • Documented diagnosis of metastatic castration-resistant prostate cancer No expiration date for the PA
• Abiraterone (Zytiga) **Prostate Cancer Drugs Subclass II – Survival Prolonging Drugs**	Coverage is approved if: • Documented diagnosis of metastatic castration-resistant prostate cancer AND • Patient is receiving concomitant therapy with prednisone. No expiration date for the PA
• Nilutamide (Nilandron) **Prostate Cancer Subclass I – Anti-Androgens**	Manual PA criteria: PA criteria apply to all new users of nilutamide. Nilutamide is approved if any of the following: • Patient has experienced significant adverse effects or contraindication from bicalutamide or flutamide; or • Patient has experienced therapeutic failure with bicalutamide or flutamide; or • Patient has a diagnosis of metastatic prostate cancer (stage D2) disease and the patient has undergone orchiectomy.

Drug / Drug Class	Prior Authorization Criteria
• Secukinumab (Cosentyx) **Targeted Immunomodulatory Biologics (TIBs)**	PA criteria apply to all new and current users of Cosentyx. Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days AND Manual PA criteria: If automated criteria are not met, coverage is approved for Cosentyx if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB AND Coverage approved for patients > 18 years with: • Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy Coverage is NOT provided for concomitant use with other TIBs.
• Efinaconazole 10% (Jublia) and tavaborole 5% (Kerydin) Topical Solutions **Topical Antifungals**	PA criteria apply to all new and current users of Jublia and Kerydin. Manual PA criteria: Jublia and Kerydin are approved if all of the following criteria apply: 1. The patient must have diagnostically confirmed onychomycosis by either KOH preparation, fungal culture, nail biopsy, or other assessment to confirm diagnosis. 2. The patient is immunocompromised, has diabetes mellitus, or peripheral vascular disease and has swelling and/or redness in the surrounding nail tissue or pain in affected nail(s). 3. The patient has history of one of the following (therapeutic failure, contraindication or adverse events, or intolerance) to one of the following antifungals: itraconazole, terbinafine, or ciclopirox • therapeutic failure • contraindication (e.g., renal impairment, pre-existing liver disease, or evidence of ventricular dysfunction such as CHF) • adverse event/intolerance to one of the following antifungal agents 4. Treatment is requested due to a medical condition and not for cosmetic purposes. Examples include the following: • patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis • diabetic patients with additional risk factors for cellulitis • patients who experience pain/discomfort associated with the infected nail 5. The patient's condition is causing debility or a disruption in their activities of daily living. 6. Jublia or Kerydin have not been used in the previous 24 months. PA nilutamide expires after 1 year.

Drug / Drug Class	Prior Authorization Criteria
• Ivacaftor (Kalydeco) **Cystic Fibrosis Drugs**	Manual PA Criteria apply to all new and current users of Ivacaftor (Kalydeco). 1. Coverage will be approved for the treatment of CF patients aged 6 years and older who have a G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R or for R117H mutation in the CFTR gene, detected by an FDA-approved test. 2. Coverage is not approved for patients who are homozygous for the F508del mutation in the CFTR gene.
• Exenatide once weekly pen (Bydureon pen) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	Manual PA criteria from the November 2014 meeting recommended to be removed. Exenatide once weekly (Bydureon pen) • Coverage approved if patient has first tried Bydureon 2mg vial/cartridge first AND • Patient has dexterity issues and cannot assemble the Bydureon vial/cartridge

Appendix D—Table of Prior Authorization (PA) Criteria for Hepatitis C Drugs

Prior Authorization Criteria

Paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak)
Direct Acting Antiviral Subclass

- New users of paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their Viekira Pak prescriptions.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1 infection
    1. State the HCV genotype and HCV RNA viral load on the PA form
- Paritaprevir/ritonavir/ombitasvir + dasabuvir (Viekira Pak) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with Hepatitis B virus (HBV).

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1 Patient Populations[1,2]	***Treatment***	***Duration***
GT1a without cirrhosis	Viekira Pak + ribavirin bid	12 weeks
GT1a with cirrhosis	Viekira Pak + ribavirin bid	24 weeks[3]
GT1b without cirrhosis	Viekira Pak	12 weeks
GT1b with cirrhosis	Viekira Pak + ribavirin bid	12 weeks
Liver transplant recipients with normal hepatic function and mild fibrosis (Metavir ≤2)	Viekira Pak + ribavirin bid	24 weeks

[1]Follow GT1a dosing recommendation in patients with an unknown GT1 or mixed GT1 infection
[2]Treatment naïve or treatment-experienced with peginterferon alpha plus ribavirin
[3]For treatment naïve OR prior IFN+RBV relapser/partial responder, consider 12 weeks

Appendix E—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Avanafil (Stendra) **PDE-5 Inhibitors**	• Retail and MTF Network: 6 tablets per 30 days (collective of all PDE-5 inhibitors) • Mail Order Pharmacy: 18 tablets per 90 days (collective of all PDE-5 inhibitors)
• Paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak) **Hepatitis C Drugs**	• Retail Network, Mail Order and MTF: 4 Paks /28 days • Each Viekira Pak contains 7 individual packages and provides for daily dosing for one week • Individual packages contain 2 paritaprevir/ritonavir/ombitasvir tablets and 2 dasabuvir tablets
• Fluticasone furoate oral inhaler (Arnuity Ellipta) **Inhaled Corticosteroid**	• Retail: 60 blisters (1 Diskus)/30 days • MTF and Mail: 180 blisters (3 Diskus)/90 days
• Beclomethasone HFA pediatric nasal spray (QNASL) 40 mcg **Nasal Allergy Drug**	• Retail: 1 canister/30 days • MTF and Mail: 3 canisters/90 days
• Netupitant/palonosetron (Akynzeo) 300 mg/0.5 mg cap **Antiemetic**	• Retail: 2 boxes/30 days • MTF and Mail: 6 boxes/90 days
• Olaparib (Lynparza) 50 mg cap **Oral Oncology Drug (Ovarian Cancer)**	• Retail: 448 caps (4 bottles)/28 days • MTF and Mail: 896 caps (8 bottles)/56 days

Appendix F—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2015	**Pulmonary Arterial Hypertension (PAH) Agents**	UF class review Not previously reviewed (PDE-5 inhibitors for PAH reviewed Nov 2009)	▪ ECF: Sildenafil 20 mg (generic) and sildenafil brand (Revatio)	*Nitric oxide pathway:* *Step preferred:* ▪ sildenafil 20mg generic ▪ sildenafil brand (Revatio) *Non step-preferred* ▪ tadalafil (Adcirca) ▪ riociguat (Adempas) *Endothelin receptor antagonists:* ▪ bosentan (Tracleer) ▪ ambrisentan (Letairis) ▪ macitentan (Opsumit) *Prostacyclins:* ▪ treprostinil nebulized solution (Tyvaso) ▪ treprostinil tabs (Orenitram ER) ▪ iloprost nebulized solution (Ventavis)	▪ None	Pending singing of the minutes / 90 days	▪Step therapy required for the nitric oxide agents; see comments	▪ For the nitric oxide pathway drugs, a trial of sildenafil 20 mg generic or sildenafil brand (Revatio) is required prior to Adcirca or Adempas. See Appendix C. ▪ Adcirca was previously NF, but now is UF, and non step-preferred.
Feb 2015	**Prostate Cancer Drugs**	UF class review	▪ Bicalutamide (Casodex)	▪ Flutamide (Eulexin) ▪ Nilutamide (Nilandron) ▪ Enzalutamide (Xtandi) ▪ Abiraterone (Zytiga)	▪ None	Pending singing of the minutes / 90 days	▪PA required for nilutamide (See Appendix C)	▪ Bicalutamide is now BCF. ▪ No change recommended for the current PA for Zytiga and Xtandi

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2015	**Transmucosal Immediate Release Fentanyl Products (TIRFs)**	UF subclass review Not Previously reviewed	▪ None (see Comments)	▪ Fentanyl transmucosal lozenge (Actiq, generics)	▪ Fentanyl sublingual tablet (Abstral) ▪ Fentanyl buccal tablet (Fentora) ▪ Fentanyl nasal spray (Lazanda) ▪ Fentanyl sublingual spray (Subsys)	Pending singing of the minutes / 90 days	▪ High opioid safety edit in place	▪ No BCF selection for this subclass ▪ This is a subclass of the High Potency narcotic drugs; morphine sulfate IR and controlled release morphine sulfate (MS Contin, generics) are designated BCF
Feb 2015	**Newer Sedative Hypnotics (SED-1s)**	New Drug	▪ Zolpidem immediate-release	*Step preferred* ▪ Zaleplon (Sonata) *Non step-preferred* ▪ Zolpidem ER (Ambien CR) ▪ Eszopiclone (Lunesta) ▪ Doxepin (Silenor)	▪ **Tasimelteon (Hetlioz) February 2015** ▪ Ramelteon (Rozerem) ▪ Zolpidem SL (Edluar) ▪ Zolpidem SL (Intermezzo)	Pending signing of the minutes / 60 days	▪ Step therapy (automated PA); requires a trial of zolpidem IR or zaleplon for all SED-1 agents except tasimelteon	▪ All new users of Hetlioz will undergo a manual PA process ▪ See Appendix C for Manual PA criteria.

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2015	**Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	New Drug	▪ None (see comments)	▪ None (see comments)	▪ **Empagliflozin (Jardiance) February 2015** ▪ Dapagliflozin (Farxiga) May 2014 ▪ Canagliflozin (Invokana)	Pending signing of the minutes / 90 days	▪ Step therapy (automated PA); requires a trial of metformin, or sulfonylureas (SUs), and a DPP-4 inhibitor in all new and current users of a SGLT2 inhibitor.	▪ BCF, UF, and NF drugs are designated for metformin, SUs, DPP-4 inhibitors, GLP-1RAs, TZDs, meglitinides, and alpha glucosidase inhibitors. See DoD P&T Minutes for Nov 2010, Aug 2012, and Nov 2012.
Feb 2015	**Antiplatelet Agents**	New Drug Review	▪ Clopidogrel (Plavix)	▪ Prasugrel (Effient) ▪ Ticagrelor (Brilinta) ▪ Aspirin/dipyridamole ER (Aggrenox) ▪ Ticlopidine (Ticlid, generics) ▪ Cilostazol (Pletal, generics) ▪ Dipyridamole (Persantine, generics) ▪ Pentoxifylline (Trental, generics)	▪ **Vorapaxar (Zontivity) February 2015**	Pending signing of the minutes / 90 days	▪ N/A	▪ None

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2015	**PDE-5 Inhibitors for Erectile Dysfunctions**	New Drug Review	▪ Sildenafil (Viagra)	▪ None for Erectile Dysfunction	▪ **Avanafil (Stendra) February 2015** ▪ Tadalafil (Cialis) ▪ Vardenafil (Levitra, Staxyn)	Pending singing of the minutes / 90 days	▪PA required for Stendra (See Appendix C) ▪QL apply – see Appendix E	▪ Viagra is the BCF and step-preferred PDE-5 inhibitor for erectile dysfunction.
Feb 2015	**Proton Pump Inhibitors**	New Drug Review	▪ Omeprazole (Prilosec, generic) excludes 40mg Prilosec capsule ▪ Esomeprazole (Nexium)	▪ Prilosec 40mg (brand) ▪ Pantoprazole (Protonix, generic) tablets	▪ **Esomeprazole strontium (February 2015)** ▪ Lansoprazole (Prevacid) ▪ Omeprazole NaHCO3 (Zegerid) ▪ Rabeprazole (Aciphex) ▪ Dexlansoprazole (Dexilant)	Pending signing of the minutes / 90 days	▪PA applies (See Appendix C)	▪ See DoD P&T Minutes for Nov 2012, May 2009, Feb 2008, & May 2007

TRICARE Formulary Search tool: *http://www.pec.ha.osd.mil/formulary_search.php*

Appendix G—Table of Abbreviations

6MWD	6-minute walking distance
A1c	hemoglobin A1c
AASLD/IDSA	American Association for the Study of Liver Diseases/Infectious Diseases Society of America
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	cost-effectiveness analysis
CFR	Code of Federal Regulations
CFTR	cystic fibrosis transmembrane conductance regulator
CMA	cost minimization analysis
CTEPH	chronic thromboembolic pulmonary hypertension
CV	cardiovascular
DAAs	direct acting antivirals
DCO	Defense Connect Online
DHA	Defense Health Agency
DoD	Department of Defense
DPP-4	dipeptidyl dipeptidase-4 inhibitors
ECF	Extended Core Formulary
ED	erectile dysfunction
ER	extended release
ERA	endothelin receptor agonists
FDA	U.S. Food and Drug Administration
GLP1RA	glucagon-like peptide-1 receptor agonist
HCV	hepatitis C virus
HFA	hydrofluoroalkane
IR	immediate release
MHS	Military Health System
MI	myocardial infarction
MN	medical necessity
MTF	Military Treatment Facility
NF	nonformulary
NDAA	National Defense Authorization Act
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAH	Pulmonary Arterial Hypertension Drug Class
PDE-5	Phosphodiesterase-5 Inhibitors Drug Class
PPIs	proton pump inhibitors
POS	points of service
QLs	quantity limits
SED-1s	Sedative Hypnotic-1s Drug Class
SGLT2	Sodium-Glucose Co-Transporter 2 Inhibitors Drug Class
TIBs	targeted immunomodulatory biologics
TIRFs	transmucosal IR fentanyl products
UF	Uniform Formulary