

EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP)

April 1, 2020

UNIFORM FORMULARY DRUG CLASS REVIEWS

I. UF CLASS REVIEWS—Pain Agents: Nonsteroidal Anti-Inflammatory Drug (NSAID) Subclass

A. Pain Agents: NSAID Subclass—UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (12 for, 5 opposed, 0 abstained, 1 absent) the following:

- UF
 - a) celecoxib
 - b) diclofenac/misoprostol
 - c) diclofenac potassium
 - d) diclofenac sodium
 - e) diflunisal
 - f) etodolac
 - g) flurbiprofen
 - h) ibuprofen 400 mg, 600 mg & 800 mg
 - i) indomethacin IR 25 mg & 50 mg
 - j) indomethacin ER 75 mg
 - k) indomethacin rectal suppository
 - l) ketorolac tablets
 - m) meloxicam 7.5 mg & 15 mg
 - n) nabumetone
 - o) naproxen 250 mg & 500 mg
 - p) naproxen 125mg/5ml oral suspension
 - q) naproxen IR 375 mg
 - r) naproxen delayed release (DR) 375 mg & 500 mg
 - s) naproxen sodium 275 mg & 550 mg
 - t) oxaprozin
 - u) piroxicam
 - v) sulindac
 - w) mefenamic acid 250 mg (generic Ponstel) (*moves from NF to UF*)
 - x) Note that the older non-FDA-approved products, salsalate and choline magnesium trisalicylate will remain UF

- NF
 - a) diclofenac potassium powder packets 50 mg (Cambia)
 - b) fenoprofen tablets (*moves from UF to NF*)
 - c) indomethacin oral suspension (*moves from UF to NF*)
 - d) ketoprofen (*moves from UF to NF*)
 - e) ketorolac nasal spray (Sprix)
 - f) meclufenamate (*moves from UF to NF*)
 - g) meloxicam ODT (Qmiiz)
 - h) naproxen sodium ER (Naprelan, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card
 - i) tolmetin (*moves from UF to NF*)

- Tier 4/Not Covered
 - a) amlodipine/celecoxib (Consensi)
 - b) diclofenac potassium liquid-filled capsules (Zipsor)
 - c) diclofenac submicronized (Zorvolex)
 - d) fenoprofen capsules (*moves from UF to Tier 4*)
 - e) ibuprofen/ famotidine tablets (Duexis)
 - f) indomethacin submicronized (Tivorbex)
 - g) meloxicam submicronized (Vivlodex)
 - h) naproxen/esomeprazole (Vimovo) (*remains Tier 4*)

Committee members with opposing votes were not opposed to the agents being considered for their respective formulary status as recommended, noting they wanted the recommendation to include more agents for Tier 4 status. The Committee commented and considered Cambia powder packets, Qmiiz, Naprelan, and Sprix nasal spray as potential additional Tier 4 candidates. The opinion to move all these additional agents to Tier 4 was not unanimous.

When considering the NSAID candidates for Tier 4/Not Covered status, the P&T Committee considered the information outlined in the interim rule, Section 702(b)(10) of the NDAA 2018 published on December 11, 2018, and found at <https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms>. The interim rule allows for complete exclusion of drugs from TRICARE pharmacy benefit coverage when certain criteria are met. Tier 4/Not Covered status will apply to all users of the recommended candidates.

For the eight NSAIDs recommended for Tier 4/Not Covered status, The P&T Committee concluded that they provide very little to no additional clinical effectiveness relative to the other NSAIDs. Overall, the P&T Committee felt that the needs of TRICARE beneficiaries could be met by the formulary NSAIDs. Formulary alternatives for the Tier 4 candidates include generic NSAIDs.

B. Pain Agents: NSAID Subclass—Manual PA Criteria

Existing PA criteria currently apply to Naprelan brand and generic from the November 2018 meeting, and for Qmiiz, when it was reviewed as an innovator in May 2019. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated manual PA criteria for new users of Naprelan brand and generic, and Qmiiz. Additionally, new manual PA criteria for all new and current users of Cambia, was recommended, limiting use to patients with a contraindication, therapeutic failure or intolerance to a triptan and who have failed two previous NSAIDs.

The PA criteria are as follows:

1. diclofenac potassium powder packets 50 mg (Cambia)

Manual PA criteria apply to all new and current users of diclofenac potassium powder (Cambia). Note that multiple formulary NSAIDs and triptans are available without a PA including ibuprofen, indomethacin, naproxen, diclofenac potassium tablets, sumatriptan, rizatriptan, and zolmitriptan.

Manual PA Criteria: Cambia is approved if all criteria are met:

- Patient is ≥ 18 years of age
- Patient has a diagnosis of migraine
- Prescription is written by or in consultation with a Neurologist
- Patient has tried and failed at least two formulary NSAIDs including diclofenac potassium tablets (Cataflam generic)
- Patient has tried and failed or has a contraindication to at least one formulary triptan (e.g., sumatriptan, rizatriptan, and zolmitriptan)

2. meloxicam ODT (Qmiiz)

Manual PA criteria apply to all new users of meloxicam ODT (Qmiiz). Note that multiple formulary NSAIDs, including meloxicam oral tablets, are available for DoD beneficiaries without a PA.

Manual PA Criteria: Qmiiz is approved if all criteria are met:

- Provider must explain why the patient requires meloxicam ODT and cannot take any of the formulary NSAIDs.

3. naproxen sodium controlled release (CR) (Naprelan brand and generic)

Manual PA criteria apply to all new users of naproxen CR (Naprelan). Note that multiple formulary NSAIDs are available without a PA including ibuprofen, indomethacin, meloxicam, naproxen, and celecoxib.

Manual PA Criteria: naproxen CR is approved if all criteria are met:

- Provider must provide clinical rationale of why patient cannot take any of the formulary NSAIDs.

C. Pain Agents: NSAID Subclass—UF/Tier 4/Not Covered PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent): 1) an effective date of the first Wednesday 120 days after signing of the P&T minutes at all points of service (POS); 2) DHA send letters to beneficiaries affect by the NF recommendations; and 3) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation.

Summary of Physician's Perspective:

- We reviewed the NSAIDs back in 2011, and since then, new branded products have been approved that contain active ingredients that are already available in generic formulations.
- There are over 50 products in the class, however, the top 10 most frequently used NSAIDs account for approximately 99% of the utilization and contribute to 66% of the overall cost. The remaining 1% of the utilization accounts for 33% of the overall NSAID cost.
- Out of the nine products recommended for non-formulary status, four are currently designated nonformulary. The other five products (ketoprofen, fenoprofen tablets, meclofenamate, tolmetin, and indomethacin suspension) are old drugs which do not have any unique use or place in therapy.
- For the NF and Tier 4 candidates, we did reach out to providers for their input. Providers in general were supportive of the NSAIDs recommended for Tier 4 and NF status.
- For Cambia, neurologist feedback did support keeping it as NF, but only for a limited patient population (those with a triptan contraindication or intolerance who have failed other NSAIDs), which is reflected in the PA. Providers were concerned that if Cambia was made Tier 4, patients would be faced with paying nearly \$1,000 in out-of-pocket expenses.
- Sprix nasal spray will also remain NF. This drug is not typically used in the emergency department setting, as Committee members commented that in the ER, either IM or IV ketorolac is commonly used to relieve acute pain. Feedback from emergency department specialists widely supported Tier 4

status, but the majority of the Committee recommended keeping Sprix as NF because of potential opioid-sparing effect.

- Vimovo (naproxen with esomeprazole) was one of the first Tier 4 drugs, which was implemented in August 2019. This is also the first Tier 4 drug where we have gone back to re-evaluate whether it should return back to UF status. For all the Tier 4 selections, we will systematically go back and do a similar re-analysis.
- For the innovator drug Consensi (amlodipine with celecoxib), the Committee felt strongly that this product could be detrimental to patients, since those who are partially compliant to their pain management are at risk for having suboptimal management of their hypertension. Additionally, Consensi costs 40 times more than the individual ingredients given separately, and several commercial health plans don't cover Consensi.
- The Committee did acknowledge the opioid sparing effect of the NSAIDs. Out of the 21 distinct active ingredients, the formulary recommendation will result in 17 remaining on the UF. For the Tier 4 recommendations, all of the active ingredients are available either on the formulary, or OTC.
- In the MHS, approximately 800,000 unique patients received an NSAID over the past year. The NF and Tier 4 candidates will affect about 1,300 beneficiaries. If you consider that at some point every beneficiary will need an NSAID, this action will not impact 99.9% of our beneficiaries.
- The Committee members who voted against the formulary recommendation wanted four additional products to be designated Tier 4. The committee members in favor of adding more agents to the Tier 4 category were unconvinced that these agents added any benefit to those currently available on the Formulary.

Summary of Panel Questions and Comments:

Mr. Hostettler asked if the Meloxicam ODT has any efficacy or safety benefits over the naproxen suspension, indomethacin suspension, and the indomethacin suppositories.

LCDR Hall responded the Meloxicam ODT was recommended for the Non-Formulary status. It is an orally disintegrating tablet and would be another option for patients who are unable to swallow.

Mr. Hostettler repeated, does the Meloxicam have any better safety or efficacy benefits than the three (3) product previously mentioned? Maybe it should be included in the list of UF products.

LCDR Hall responded the NSAIDs do have variable GI and cardiovascular safety profiles across the different NSAIDs. I think the purpose of that list purpose was provide an example. It says non-tablet or capsule dosage forms but it's not by any means all-inclusive. But that was from our initial perspective. We were looking at some of the options that we wanted to capture, we did end up keeping Qmiiz ODT as an option in the Non-Formulary status.

Mr. Hostettler asked if UF included both Tier 1 and Tier 2 drugs.

LCDR Hall responded yes, it does.

Mr. Hostettler stated that he does not know which Tier 2 are.

LCDR Hall responded the Tier 2 products branded products only and Tier 1 would be generics.

Mr. Hostettler responded that the committee has made exceptions to that brand/generic policy in past recommendations to allow the generic or lower co-pay. When this happens, please note it in the discussions.

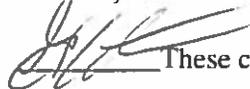
LCDR Hall responded we will. We are not recommending any changes for ones that received Tier 1 copays for this class.

There were no more Panel questions or comments. The Chair called for a vote on the UF/Tier 4/Not Covered Recommendation, Manual PA Criteria, UF/Tier 4/Not Covered and PA Implementation Plan, for the Pain Agents: NSAIDS.

- **Pain Agents: NSAID—UF/Tier 4/Not Covered Recommendation**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

- **Pain Agents: NSAID Subclass—Manual PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

- **Pain Agents: NSAID—UF/Tier 4/Not Covered and PA Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

II. UF CLASS REVIEWS—Pain Agents: Topical Pain Subclass

A. Pain Agents: Topical Pain Subclass—UF/Tier 4/Not Covered Recommendation

P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - a) diclofenac 1% gel (Voltaren generic)
 - b) diclofenac 1.5% solution (Pennsaid 1.5% generic)
 - c) lidocaine 5% patch (Lidoderm generic)
- NF
 - a) None
- Tier 4/Not Covered
 - a) diclofenac 2% solution (Pennsaid 2%)
 - b) diclofenac 1.3% patch (Flector)
 - c) lidocaine 5% patch (Lidoderm generic)

When considering the candidates for Tier 4/not covered status, the P&T Committee considered the information previously stated in section II. C on page 7.

For the three products recommended for Tier 4/Not Covered status, Pennsaid 2%, Flector and ZTlido, the P&T Committee concluded that they provide very little to no additional benefit relative to the other topical pain agents. Overall, the P&T Committee felt that the needs of TRICARE beneficiaries could be met by the formulary topical pain drugs. Formulary alternatives for the Tier 4 candidates also include the generic oral NSAIDs.

B. Paint Agents: Topical Pain Subclass—UF/Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 120-day implementation period in all points of service and, 2) DHA send letters to beneficiaries who are affected by the UF/Tier 4 recommendations at 30 and 60 days prior to implementation.

Summary of Physician's Perspective:

- This class is divided up into the topical NSAIDs and topical lidocaine products. For the topical NSAIDs, even though these products are not given orally, they still have the same warnings for GI toxicity and cardiovascular side effects.
- The four topical NSAIDs all contain diclofenac as the active ingredient; they just vary in their concentration and dosage formulation.
- Flector patch was recommended for Tier 4 status. Due to its size, it's not practical to use on the fingers or knees. Utilization showed that although the package insert for Flector limits it to 2 weeks use, some patients appear to be receiving these patches regularly. This is not the intended length of time for this prescription, and is inconsistent with the package insert labeling.
- For Flector, the majority of the MHS providers surveyed agreed with recommending Tier 4 status, with one commenting that they didn't see much utility for the patches considering their cost, especially since lidocaine patches are available. Two commercial healthcare plans have the Flector patch as not covered, and several others have it as non-preferred and requiring a PA, even though it is used for acute pain.
- For the Pennsaid 2% pump, providers mentioned that it does not have major advantages compared to the Voltaren gel. Other comments were that they would use the 1% solution instead of the 2% pump, due to its cost, and that there was no need to have both the 1% solution and 2% pump available.
- For the branded lidocaine product, ZT Lido, provider feedback overwhelmingly said this formulation was not needed, and that the generic Lidoderm patch would meet the needs of their patients.
- Even though there are three Tier 4 candidates, there are alternative products, including generic Voltaren gel and Lidoderm, along with the oral NSAIDs. For the class, generic Voltaren gel is used by about 60% of the patients currently receiving a topical NSAID, and 30% of patients are on the generic Lidoderm patch.

- We have about 220,000 patients in the class, and about 3,200 patients would be affected by this formulary recommendation. The three Tier 4 drugs will affect only 1.5% of overall Topical Pain users.
- The three products remaining on the formulary (Voltaren gel, Pennsaid 1.5% drops, and Lidoderm 5% patch) are generic and will remain at the Tier 1 copay.

Summary of Panel Questions and Comments:

There were no Panel questions or comments. The Chair called for a vote on the UF/Tier 4/Not Covered, UF/Tier4/Not Covered and PA Implementation Plan Recommendations for the Pain Agents: Topical Pain Subclass.

- **Paint Agents: Topical Pain Subclass—UF/Tier 4/Not Covered Recommendation**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

- **Paint Agents: Topical Pain Subclass—UF/Tier 4/Not Covered and PA Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

III. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

- A. **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4/Not Covered Recommendation**

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
 - benralizumab injection (Fasenra Pen) — Miscellaneous Pulmonary 1 Agent in a new self-administered pen for eosinophilic and severe asthma

- elxacaftor/tezacaftor/ivacaftor (Trikafta) — Cystic Fibrosis triple fixed-dose combination
 - pegfilgrastim-bmez injection (Ziextenzo) — Hematological Agents: White Blood Cell Stimulants; another biosimilar for Neulasta
 - pretomanid — Antitubercular drug for extensively drug-resistant (XDR) or treatment intolerant/nonresponsive multidrug-resistant (MDR) tuberculosis
 - voxelotor (Oxbryta) — Sickle cell anemia agent for sickle cell disease
 - zanubrutinib (Brukinsa) — Oral oncologic agent for mantle cell lymphoma
- NF
 - Asenapine transdermal system (Secuado) — New patch formulation of asenapine for schizophrenia in adults
 - Baclofen oral solution (Ozobax) — New oral solution formulation of baclofen for spasticity associated with multiple sclerosis
 - Colchicine oral solution (Gloperba) — Anti-Gout Agents; a new oral solution formulation of colchicine
 - Diroximel fumarate (Vumerity) — Multiple Sclerosis Agents; another methyl fumarate formulation
 - Minocycline 4% foam (Amzeeq) — Topical Acne and Rosacea Agents; a new formulation of minocycline
 - Testosterone undecanoate capsules (Jatenzo) — Testosterone Replacement Therapy (TRT) in an oral capsule
 - Trifarotene 0.005% cream (Aklief) — Topical Acne and Rosacea agents; a new retinoid
- Tier 4/Not Covered
 - a) albuterol dry powder inhaler (ProAir Digihaler) — Pulmonary-1: Short Acting Beta Agonist (SABA) for asthma
 - 1) ProAir Digihaler was recommended for Tier 4 status as it has no clinical benefit relative to other agents approved for treating asthma symptoms and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to ProAir Digihaler include albuterol MDI (ProAir HFA), albuterol DPI (ProAir Respiclick), albuterol MDI (Proventil HFA), albuterol MDI (Ventolin HFA), and levalbuterol MDI (Xopenex HFA).
 - b) benzoyl peroxide 9.8% foam (Enzoclear) — Keratolytic for acne vulgaris

1) Enzoclear was recommended for Tier 4 status as it is not an FDA-approved drug, has no clinical benefit relative to other agents approved for acne vulgaris, and the needs of TRICARE beneficiaries are met by alternative agents.

- Formulary alternatives to Enzoclear include clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics), clindamycin/ benzoyl peroxide 1% - 5% gel (Benzaclin, generics), and clindamycin/benzoyl peroxide 1% - 5% gel kit (Duac CS Kit)

c) omeprazole magnesium/amoxicillin/rifabutin (Talia) - Miscellaneous Anti-infective for *Helicobacter pylori* salvage therapy

1) Talia was recommended for Tier 4 status as it has no clinical benefit relative to other agents approved for *H. pylori* and the needs of TRICARE beneficiaries are met by alternative agents.

- Formulary alternatives to Talia include amoxicillin, omeprazole, rifabutin, clarithromycin, metronidazole, and tetracycline.

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- TRTs: Applying the same manual PA criteria in new and current users of Jatenzo, as is currently in place for the other non-step-preferred TRT products. Patients must first try generic Fortesta or generic Androgel 1%. Also for Jatenzo, additional safety requirements are included in the PA to exclude patients with uncontrolled hypertension or those at high risk for CV adverse events.
- Applying manual PA criteria to new and current users of Akliel, Amzeeq, Fasentra Pen, Oxbryta, Vumerity, and Trikafta.
- Applying manual PA criteria to new users of Brukinsa, Gloperba, and Ozobax.

Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5)

1. baclofen oral solution (Ozobax)

Manual PA criteria apply to all new users of Ozobax.

Manual PA criteria: Ozobax is approved if all criteria are met:

- Ozobax will be used for the treatment of spasticity
- Patient requires baclofen and cannot use the tablet formulation or crushed tablet due to a documented medical condition such as dysphagia, oral candidiasis, or systemic sclerosis, and not due to convenience
- Presence of an NG/J-tube alone is not a reason for approval

Non-FDA approved uses are not approved including nystagmus, trigeminal neuralgia, hiccups, GERD, alcohol abstinence in alcoholic liver disease, and low back pain.

PA does not expire

2. benralizumab injection (Fasenra Pen)

Manual PA is required for all new and current users of Fasenra Pen.

Manual PA Criteria: Fasenra Pen is approved if all criteria are met:

- The patient has a diagnosis of severe persistent eosinophilic asthma
- Patient must be ≥ 12 years
- The drug is prescribed by an allergist, immunologist, or pulmonologist
- Patient must have an eosinophilic phenotype asthma as defined as either
 - a) Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids OR
 - b) Eosinophils ≥ 300 cells/mcL
- Patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following:
 - a) Hospitalization for asthma in past year
 - b) Two courses oral corticosteroids in past year
 - c) Daily high-dose inhaled corticosteroids with inability to taper off
- The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid:

- a) LABA (e.g., formoterol, salmeterol), LAMA (tiotropium), or leukotriene receptor antagonist

Non-FDA-approved uses are not approved.

PA does not expire

3. colchicine oral solution (Gloperba)

Manual PA is required for all new users of Gloperba. Note that other formulations of colchicine (e.g. Colcrys) do not require PA

Manual PA Criteria: Gloperba is approved if all criteria are met:

- Provider must explain why the patient requires liquid colchicine and cannot take colchicine capsules or tablets.

Non-FDA-approved uses are not approved.

PA does not expire.

4. diroximel fumarate (Vumerity)

Manual PA criteria apply to all new and current users of Vumerity.

Manual PA Criteria: Vumerity approved if all criteria are met:

- Documented diagnosis of a relapsing form of Multiple Sclerosis (MS)
- Patient must have had at least a two-week trial of Tecfidera and either
 - a) Have failed therapy OR
 - b) Continues to have GI side effects not expected to occur with Vumerity
- Complete blood count drawn within six months prior to initiation of therapy, due to risk of lymphopenia
- Coverage is NOT provided for concomitant use with other disease-modifying drugs of MS

Non-FDA-approved uses are not approved.

PA does not expire.

5. **elexacaftor/tezacaftor/ivacaftor (Trikafta)**

Manual PA is required for all new and current users of Trikafta.

Manual PA Criteria: Trikafta is approved if all criteria are met

- Prescribed by or in consultation with a pulmonologist
- Prescribed for the treatment of cystic fibrosis (CF) for an FDA-approved age
- Patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test
- Not approved in combination therapy with Symdeko, Orkambi or Kalydeco

Non-FDA-approved uses are not approved

PA does not expire.

6. **minocycline 4% foam (Amzeeq)**

Manual PA is required for all new and current users of Amzeeq. Note: Amzeeq is not included in the automated step therapy for the topical acne and rosacea agents

Note: Adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination gel), and tretinoin (cream and gel) are available without a PA; providers are encouraged to consider changing the prescription to one of these agents.

Manual PA Criteria: Amzeeq is approved if all criteria are met:

- Patient has a diagnosis of acne vulgaris
- This agent has been identified as having cost-effective alternatives. The provider must explain why the patient requires Amzeeq and cannot take the formulary alternatives. _____(blank write-in)

Non-FDA approved uses (including rosacea) are not approved.

PA does not expire.

7. testosterone undecanoate capsules (Jatenzo)

Manual PA criteria apply to all new and current users of Jatenzo.

Manual PA Criteria: Jatenzo is approved if all criteria are met:

- Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions
 - a) Patient is a male age > 18 years
 - b) Patient has a diagnosis of deficiency or absence of endogenous testosterone associated with structural or genetic etiologies
 - c) Patient is experiencing signs and symptoms usually associated with hypogonadism
 - d) Patient has tried testosterone 2% gel (Fortesta) OR testosterone 1% gel (AndroGel generic) for a minimum of 90 days AND failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after use of the agent) AND without improvement in symptoms

OR

- Patient has a contraindication to or has experienced a clinically significant adverse reaction to Fortesta OR generic testosterone 1% gel, that is not expected to occur with Jatenzo
- The patient requires a testosterone replacement therapy (TRT) that has a low risk of skin-to-skin transfer between family members

OR

- The requested medication is being used for female-to-male gender reassignment (endocrinologic masculinization)
 - a) Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND
 - b) Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to the most current edition of the DSM; AND
 - c) Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that

have not been stabilized with treatment); AND

- d) Patient has a documented minimum of three months of real- life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria;

AND

- e) For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding.

- Patient does not have any of the following:
 - a) Hypogonadism conditions not associated with structural or genetic etiologies, carcinoma of the breast or suspected carcinoma of the prostate
 - b) Uncontrolled hypertension or is at risk for cardiovascular events prior to start of Jatenzo therapy or during treatment (based on the product's boxed warning of increased risk of major adverse cardiovascular events and hypertension)
- Jatenzo is not approved for concomitant use with other testosterone products.

Non-FDA-approved uses are not approved.

PA does not expire.

8. trifarotene 0.005% cream (Aklief)

Manual PA is required for all new and current users of Aklief.

Note: Adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination gel), and tretinoin (cream and gel) are available without a PA; providers are encouraged to consider changing the prescription to one of these agents.

Manual PA Criteria: Aklief is approved if all criteria are met:

- Patient has a diagnosis of acne vulgaris
- This agent has been identified as having cost-effective alternatives. The provider must explain why Aklief is required and the patient cannot take the formulary alternatives. _____ (blank write-in).

Non-FDA-approved uses are not approved

Prior authorization expires in 1 year.

Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA

9. voxelotor (Oxbryta)

Manual PA applies to new and current users of Oxbryta.

Manual PA Criteria: Oxbryta is approved if all criteria are met:

- Patient meets FDA-indicated age requirements for Oxbryta
- Patient has a diagnosis of sickle cell disease
- Patient has had at least one vaso-occlusive crisis in the last 12 months AND has a hemoglobin between 5.5 g/dL and 10.5 g/dL
- Patient has had an inadequate treatment response to a 3 month trial of hydroxyurea
- Drug is prescribed by or in consultation with a hematologist
- For patients on a strong or moderate CYP3A4 inducer (e.g. carbamazepine, phenytoin, rifampin, etc.):
 - a) Provider acknowledges that prior to starting Oxbryta patient should be switched to a drug that does not interact with Oxbryta. If, and only if, this is not possible, provider should continue the CYP3A4 inducer and increase the dose of Oxbryta per the package insert.

Non-FDA-approved uses are not approved.

PA expires after 1 year.

Renewal PA criteria: PA will be approved indefinitely if:

- There is documented improvement in Hb by ≥ 1 g/dL from baseline
- OR
- The patient has demonstrated a decreased number of vaso-occlusive crises by ≥ 1 crisis/year from baseline in past 12 months

10. zanubrutinib (Brukinsa)

Manual PA criteria apply to all new users of Brukinsa.

Manual PA Criteria: Brukinsa will be approved if all criteria are met:

- Patient is \geq 18 years
- Prescribed by or in consultation with a hematologist/oncologist
- Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL).
- Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias
- Patient will use sun protection in sun-exposed areas
- Female patients of childbearing age and are not pregnant confirmed by (-) HCG.
- Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment
- Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment
- The diagnosis Is NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis:
_____.

Non-FDA approved uses are not approved.

PA does not expire.

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- **New Drugs Recommended for UF or NF Status, and PA criteria:** An effective date upon the first Wednesday two weeks after signing of the minutes in all POS.
- **New Drugs Recommended for Tier 4 Status:** 1) An effective date of the first Wednesday after a 120-day implementation period at all POS; and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation.

Summary of Physician’s Perspective:

- The Committee reviewed 16 new drugs, of which six were recommended for UF status, with seven recommended for NF status, and three Tier 4 candidates.
- Prior authorization criteria will apply to 10 of the drugs. These new drugs all belong in classes where PA is already required. “No grandfathering,” where both new and current users will be affected by the PA, is recommended for seven of the drugs.
- The three drugs recommended for Tier 4 status all contain active ingredients that are on the UF, and the Committee was unanimous in the vote here.
 - a) ProAir Digihaler is an albuterol formulation that has a Bluetooth connection to an App that tracks use of the inhaler and shows weather and pollen reports. However, no clinical studies were conducted with this product. Also there is no evidence that use of the App leads to improved clinical outcomes.
 - b) Enzoclear contains benzoyl peroxide foam in a prescription formulation, however it is not an FDA-approved drug, and has no additional clinical benefit relative to other agents for acne. The manufacturer can choose to market products as requiring a prescription, without undergoing the rigorous new drug application process for FDA-approved drugs. Although OTC benzoyl peroxide products are not part of the TRICARE pharmacy benefit, there are several prescription acne products on the formulary that have combinations of benzoyl peroxide with clindamycin.
 - c) Talicia is a triple-ingredient product (two antibiotics with a PPI) which is approved as a salvage regimen for treating *H. pylori* infections. Taking the individual products separately actually results in a lower tablet burden. Also it is less expensive for the patient to pay three generic co-pays rather than one nonformulary copay. We did receive input from GI specialists and internal medicine physicians who supported Tier 4 status.

Summary of Panel Questions and Comments:

Mr. Hostettler asked for clarification on the language “when the PA expires, the next fill/refill will require submission of a PA” for the trifarotene 0.005% cream (Aklief). Does that mean that the next time it’s going to be filled, it’s going to require a PA? Or is that the end of the prescription that they’re currently on, has to be re-written, and that’s when it hits the PA?

LCDR Hall: It would be after that one year that it would require the resubmission of the PA. So it wouldn’t be with each fill, it would be after that initial year.

The Panel had no more questions or comments. The Chair called for a vote on the UF Recommendation, PA Criteria and UF and PA Implantation Plan for the Newly Approved Drugs per 32 CFR 199.21(g)(5).

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:

 These comments were taken under consideration prior to my final decision.

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:

 These comments were taken under consideration prior to my final decision.

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:

 These comments were taken under consideration prior to my final decision.

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

A. New Manual PA Criteria—Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for new and current users of sulfacetamide and combination products other than Klaron, Rosanil, Avar or generics; venlafaxine HCL ER 24 hr. tablets; and Zalvit (regardless of the woman's age), due to significant cost differences compared with the numerous available alternative agents. The details are discussed below.

1) Acne: Topical Acne and Rosacea Subclass—Sulfacetamide and sulfacetamide/sulfur products

Sulfacetamide sodium is an antibacterial agent used for acne and rosacea that exhibits a bacteriostatic effect. The addition of sulfur is theorized to increase effectiveness. Rosacea treatment guidelines list sulfacetamide/sulfur as a second-line agent for mild to moderate rosacea, and as a third-line agent for moderate to severe rosacea. Acne treatment guidelines differ in their recommendations with regard to the efficacy of sulfacetamide sodium; however, there is a lack of evidence for sulfur.

There are various strengths and formulations of sulfacetamide alone (i.e. cream, foam, lotion, shampoo), as well as other combination products with sulfur and other ingredients, but none of these products are FDA-approved. The only FDA-approved product is a 10% lotion/suspension of sulfacetamide available under the trade name of Klaron; this is the most cost-effective single ingredient product, and the one most commonly used in the MHS. The most cost-effective combination product is sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar generics). The Committee recommended adding a manual PA to encourage use of the most common strengths of sulfacetamide 10% lotion/suspension (Klaron, generics) and sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar, generics), and to discourage use of all nonstandard dose sulfacetamide products. PA is not required for branded or generic formulations of Klaron, Rosanil, or Avar.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of sulfacetamide and sulfacetamide combination products.

Note: sulfacetamide 10% lotion/suspension (Klaron, generics) and sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar, generics) are available without requiring PA. Providers are encouraged to consider changing the

prescription to these preferred sulfacetamide formulations.

Manual PA Criteria: Coverage for sulfacetamide and sulfacetamide combination products is approved if all criteria are met:

This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives _____ (blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

**2) Antidepressants and Non-opioid Pain Syndrome Agents—
Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets**

Venlafaxine HCL ER 24 hr. tablets were first approved in 2008. There are various generic manufacturers and the ER 24 hr. tablets are all significantly more costly than the ER 24 hr. capsules or immediate-release (IR) tablets. The venlafaxine ER 24 hr. tablets have fewer indications than the venlafaxine ER 24 hr. capsule (Effexor XR, generic) formulation. Equal doses of venlafaxine HCL ER 24 hr. tablets are bioequivalent to venlafaxine HCL ER 24 hr. capsules when administered under fed conditions but they do not carry an “AB-rating” for interchangeability to each other. The cost-effective venlafaxine formulations, HCL ER capsules (Effexor XR, generics) and venlafaxine HCL IR tablets, are available to patients without a PA. Manual PA was recommended for the venlafaxine HCL ER tablets, based on cost effectiveness.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of venlafaxine HCL ER 24 hr. tablets.

Note: venlafaxine ER capsules and venlafaxine IR tablets are available without requiring PA; providers are encouraged to consider changing the prescription to the preferred venlafaxine formulations: venlafaxine ER capsules, or venlafaxine IR tablets.

Manual PA Criteria: Coverage for venlafaxine HCL ER 24 hr. tablets is approved if all criteria are met:

This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives _____(blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

3) **Vitamin: Prenatal—Prenatal Vitamin (Zalvit)**

Zalvit is a prenatal dietary supplement manufactured by a single manufacturer and requires a prescription prior to dispensing. The primary ingredients of Zalvit are 13 mg of iron and 1 mg of folic acid (similar to Azesco presented at August 2019 P&T Committee meeting). Certain prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than age 45 and do not require prior authorization criteria. This agent was identified as having numerous cost-effective alternatives (including Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin Plus Low Iron, and Prenatal Plus DHA) that are available on the UF, where a PA is not required.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of Zalvit, regardless of the woman's age.

Note: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco and Zalvit and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant.

Manual PA Criteria: Coverage for Azesco or Zalvit is approved if all criteria are met:

This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives _____(blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

B. New Manual PA Criteria—Insulins: Rapid Acting Agents—generic insulin aspart (authorized generic for Novolog)

The Rapid Acting Insulins were reviewed for formulary status in November 2019, and branded Novolog is now step-preferred.

An authorized generic for Novolog entered the market in January 2020. An “authorized generic” is the brand company’s own product repackaged and marketed without the trade name. An authorized generic is considered therapeutically equivalent to the name brand drug because it is the same drug. The FDA does not consider authorized generics as AP-rated generic formulations. The insulin aspart authorized generic is less cost effective than the branded Novolog.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for new and current users requiring a trial of branded Novolog or branded Humalog, due to cost-effectiveness. The PA requirement will be removed when it is no longer cost advantageous.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of authorized generic insulin aspart.

Note: Brand Novolog or brand Humalog are the preferred rapid acting insulins and do not require PA.

Manual PA Criteria: Coverage for authorized generic insulin aspart is approved if all criteria are met:

The provider explains a patient-specific justification as to why the brand Novolog or brand Humalog product cannot be used (blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

C. New Manual PA Criteria—Respiratory Agents Miscellaneous—epinephrine auto injector (Auvi-Q)

The Auvi-Q device includes audible voice instructions and has a needle that automatically retracts following injection. The Auvi-Q formulary status is Uniform Formulary. Manual PA criteria were recommended at the February 2017 P&T Committee meeting for all epinephrine devices, including Auvi-Q. Although Auvi-Q is significantly more expensive than both branded and generic Epi-Pen, the manual PA requirements were temporarily lifted at the August 2018 P&T Committee meeting due to national shortages of Epi-Pen, and

intermittent availability of generic epinephrine auto-injectors. It now appears that the shortages of brand and generic Epi-Pen have resolved, and another product, a pre-filled syringe (Symjepi) was launched in May 2019. All we are recommending here is to re-instate the PA that was previously had on the Auvi Q.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) re- instating the manual PA criteria for epinephrine (Auvi-Q) auto-injector that were previously in place. The PA criteria will apply to new users only.

The manual PA criteria are as follows:

Manual PA criteria apply to all new users of epinephrine (Auvi-Q) auto-injector.

Note: Auvi-Q has been identified as having cost-effective alternatives including EpiPen, EpiPen generic, and Symjepi. These agents do not require PA.

Manual PA Criteria: Coverage for Auvi-Q is approved if all criteria are met:

The provider documents a patient-specific reason as to why the patient cannot use the formulary alternatives (blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

D. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the following implementation periods:

- (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for sulfacetamide and combination products, venlafaxine HCL ER 24 hr. tablets, and the prenatal vitamin Zalvit will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.
- (16 for, 0 opposed, 0 abstained, 2 absent) Implementing the new PA for the authorized generic for insulin aspart will become effective upon signing of the minutes.
- (16 for, 0 opposed, 0 abstained, 2 absent) Re-instating the previous PA criteria for Auvi-Q in new users will become effective the first Wednesday 30-days after the signing of the minutes.

Summary of Physician's Perspective:

There were five drugs from four classes where new PA criteria were recommended.

- **Topical Acne and Rosacea Subclass—Sulfacetamide and sulfacetamide/sulfur products:** Sulfacetamide-sulfur is available in several formulations, including topical suspensions, lotions, cleansers, creams, foams, and cleansing pads. Some of these formulations are very expensive. The Committee will not require a PA for the three most commonly used products, which are available in cleansers and a lotion. The PA will apply to all new and current users, with the provider explaining why the patient can't take the formulary alternatives. We will be mailing letters to the patients who will be affected by the new PA.
- **Antidepressants and Non-opioid Pain Syndrome Agents—Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets** This is another example of new formulations reaching the market that are significantly more costly than the original product, which in this case is Effexor extended release capsules or generic immediate release tablets. The intent of the PA is to encourage use of the cost-effective ER caps and IR tabs, and to discourage use of the expensive ER tabs. We will also be mailing letters to patients.
- **Prenatal Vitamin (Zalvit) -** This product is a prescription prenatal vitamin that is significantly more expensive than the other prescription prenatal vitamins. Prescription prenatal vitamins are part of the TRICARE pharmacy benefit, so having the PA is the most appropriate option to ensure this product is not used in the DoD. As of February 2020 we haven't had any utilization of Zalvit, and there are several formulary prenatal vitamins available.
- **Rapid Acting Insulins—generic insulin aspart (authorized generic for Novolog)**
 - a) We just reviewed the rapid acting insulins at the November 2019 P&T Committee meeting. The recommendation here is to prefer the branded Novolog product over the authorized generic. The authorized generic and the branded product all come from the same manufacturer, however the branded Novolog product is more cost effective than the authorized generic.
 - b) If the prescription is written for Novolog, the patient will receive Novolog. The patient will only be subject to the PA if the prescription is written for the authorized generic as "insulin aspart". Both of these products are charged at the Tier 2 (brand) copay.
- **Epinephrine auto injector (Auvi-Q):** For Auvi-Q we are re-instating the PA that we originally had when the drug was marketed in 2017. The epi-pen

shortage appears to have mostly resolved, and now there is another epinephrine injection on the market (Symjepi). Any patient currently receiving Auvi-Q will be grandfathered, so the PA will only apply to new patients.

Summary of Panel Questions and Comments:

Dr. Bertin commented that the discussion raises questions about procedure or process. In many of the cases, it states that the prescriber is required to provide an explanation as to why the product that was originally prescribed is necessary. Do the people who review these PAs have a specific list of acceptable reasons that can be used or some that are considered to be unacceptable? Or is it a subjective judgement call? Are these decisions made by trained health professionals? Can you give a little more explanation as to the review process that goes on?

Dr. Allerman responded it depends on the individual drug as to what patients fit the criteria and where it would be applicable. Did you have a specific case for a specific drug?

Dr. Bertin responded not necessarily. In general, do I assume that there are a bunch of different people who review these applications? I am just curious to the extent of the consistency that may or may not occur when the prescriber is simply providing a narrative rationale.

Dr. Allerman commented it is patient specific. It's hard to give generalities for all these different types of drugs that specifically fall under other drug classes. The individual Pharmacists reviewing the PA criteria will be able to look at the criteria submitted by the Physician. Based on their clinical skills and information, they will be able to make the recommendation to approve or deny.

Dr. Bertin clarified, it's a pharmacist who's making that decision?

Dr. Allerman responded, that is correct sir. These will all be reviewed by pharmacists.

Mr. Hostettler asked questions about the recommendation to put the PA for Auvi-Q back in place. The PA applies to new users only. Will patients prescribed Auvi-Q during the shortage remain on Auvi-Q indefinitely?

Dr. Allerman responded, that is correct sir. During the shortage when there is no prior authorization for Auvi-Q, any patient who is on Auvi-Q can stay on it indefinitely. It would just be a new patient who would be subject to the prior authorization.

Mr. Hostettler responded I work at a retail pharmacy and in my opinion, I don't believe the shortage has been resolved. I am skeptical about stating that the

shortage has been resolved when my retail pharmacy has been placed on back-order twice when we placed orders for this product. Please elaborate on the process to monitor and quickly resolve the issue if shortages become a reoccurring problem.

Dr. Allerman responded the majority of the utilization is actually at the MTF and the mail order. We probably reach out daily to the Defense Logistics Agency (DLA) regarding this issue. In our opinion, the shortage mostly appears to be resolved. If we do find that there are procurement problems, we would actually act quickly and remove the PA requirement for Auvi-Q. As this action does not require BAP review and consideration, the BAP would be updated after it is done. We would not wait for approval to remove the PA in the situation of a shortage.

Mr. Hostettler repeated that he is not sure the problem has been resolved. The process/environment is a bit different for a patient receiving products at a MTF and those filling prescriptions at a retail pharmacy. What recourse does a pharmacist have if a patient fills a prescription at the retail pharmacy and the PA is still in place for Auvi-Q? As previously stated, I work in a retail pharmacy and we use the same wholesaler as the MTF in town uses. When the retail pharmacy experiences problems getting drugs, I assume the MTF is experiencing the same problem. I am concerned the problem is not resolved and I encourage the P&T Committee to closely monitor the situation on the Auvi-Q. There were no more Panel Questions of Comments. The Chair called for a vote on the New Manual PA Criteria and New Manual PA Criteria Implementation Plan.

- **New Manual PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

- **New Manual PA Criteria—Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

V. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

DR. ALLERMAN

P&T Comments

A. Updated Manual PA Criteria

Updates to the manual PA criteria and step therapy for several drugs were recommended due to a variety of reasons, including clinical trial data, new dosing for FDA indications, age indications, new FDA-approved indications, and cost-effective alternative treatments being available. The updated PAs and step therapy outlined below will apply to new users with the exception of doxycycline (Oracea) which will apply to new and current users.

The updates are as follows:

- 1) Migraine Agents: Calcitonin Gene-related Peptide (CGRP) Preventatives—erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm (Emgality)**—Manual PA criteria for Aimovig, Ajovy, and Emgality were originally recommended at the August 2018 and November 2018 P&T meetings. The PAs for all the CGRP inhibitors were updated at the February 2019 P&T meeting and do not allow concurrent use with botulinum toxin; additionally the patient must not have received a botulinum toxin injection within 2 months of receiving a CGRP inhibitor.

The Committee considered whether to remove the prohibition of concurrent use with botulinum toxin. The Committee reviewed the data, which included comments from the American Migraine Foundation, the 2018 American Headache Society Consensus Statement on Initiation of CGRP antagonists, and a Neurology Times article. The available adverse event (AE) data suggests that there are minimal interactions between CGRPs and botulinum toxin. There is limited information on the effectiveness of concurrent use of CGRPs with botulinum toxin, as a portion of the patients experienced some benefit and others demonstrated no benefit or even an increased frequency of migraines. More data is needed to make a definitive conclusion on the benefit or harm of concurrent use. The service specialists were also contacted, and their recommendation was to remove this particular criterion. The Manual PA criteria for Aimovig, Ajovy, and Emgality were updated to remove the requirement to not allow concurrent use with botulinum toxin.

- 2) Antilipidemic 2's-omega-3 fatty acids—icosapent ethyl (Vascepa)**—Manual PA criteria for Vascepa were updated to reflect a new indication for CV outcome reduction (i.e., to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization). Patients will be required to meet the study inclusion criteria from the

REDUCE-IT trial published in the New England Journal of Medicine. For patients with hypertriglyceridemia and triglyceride (TG) levels ≥ 500 mg/dL, who have tried and failed generic Lovaza prior to use of Vascepa. Concurrent use of Vascepa with Lovaza will not be allowed. PA criteria will apply to all new users of Vascepa.

- 3) **Targeted Immunomodulatory Biologics (TIBs): tofacitinib (Xeljanz XR)**—Manual PA criteria for Xeljanz and Xeljanz XR were updated to reflect the new dosage strengths of 11 mg XR and 22 mg XR tablets administered once daily for treatment of ulcerative colitis (UC). Previously the only approved dosing regimens were 5 mg and 10 mg twice daily.
- 4) **Pulmonary 1's-Pulmonary Miscellaneous: mepolizumab (Nucala)**—Manual PA criteria for Nucala were updated to remove the age requirement for the eosinophilic asthma indication. The FDA recently lowered the age indication to ≥ 6 years for patients with eosinophilic asthma. The Manual PA criteria and age indication for eosinophilic granulomatosis with polyangiitis (EPGA) will not change and will remain limited to patients ≥ 18 years, consistent with the package insert.
- 5) **Basal Insulins: insulin glargine U-300 (Toujeo)**—Manual PA criteria for Toujeo were updated to reflect a new pediatric indication to improve glycemic control in patients with diabetes mellitus ≥ 6 years.
- 6) **Corticosteroids: Immune Modulators—deflazacort (Emflaza)**—Manual PA criteria for Emflaza were updated to reflect a lowered age indication to ≥ 2 years for patients with Duchenne muscular dystrophy (DMD).
- 7) **Acne Agents: Tetracyclines—doxycycline monohydrate IR/ER 40 mg capsules (Oracea)**—Manual PA criteria for Oracea were last updated during the Tetracyclines class review at the February 2017 P&T Committee meeting. Treatment guidelines for papulopustular rosacea list oral doxycycline as a second-line therapy option following topical medications. Oracea branded and generic formulations are much less cost effective than the immediate release (IR) formulation of doxycycline. The FDA-approved label for Oracea also states that efficacy beyond 16 weeks and safety beyond 9 months have not been established. The Oracea PA was updated to require the provider to document why the patient cannot be treated with the cost-effective formulary alternatives.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the updates to the manual PA criteria for Aimovig, Ajovy, Emgality, Xeljanz, Xeljanz XR, Nucala, Toujeo, Emflaza, Vascepa, and Oracea.

B. Updated Manual PA Criteria—Implementation Plan

The P&T Committee recommended the following implementation periods:

- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria for Aimovig, Ajovy, Emgality, Xeljanz, Xeljanz XR, Nucala, Toujeo, Emflaza, and Vascepa in new users will become effective the first Wednesday 60-days after the signing of the minutes.
- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria for Oracea brand and generics in new and current users will become effective the first Wednesday 90-days after the signing of the minutes.

Summary of Physician’s Perspective:

- At every meeting, we present updates to drugs with existing PAs to ensure the latest FDA indications or safety updates are included in our criteria. These updates to the existing PAs will only affect new patients, with one exception, Oracea. Here, we had updates for seven drug classes; most of the changes were to allow use in expanded patient populations, for example pediatric patients for four drugs.
- For the fish oil product (Vascepa), the PA will be similar to the patient enrollment criteria from the study that was used to gain FDA approval for reducing cardiovascular outcomes. For patients who do not meet the criteria for CV outcomes, they will be required to try Lovaza first, to reduce triglyceride levels.
- For the acne drug Oracea, we are strengthening the PA, because the generics are significantly less costly, and there is no difference in efficacy or safety. We are taking the approach of changing the PA, rather than making this a Tier 4 product for now. Both new and current users are affected, so patients will be receiving letters.

Summary of Panel Questions and Comments

Mr. Hostettler asked what are the formulary alternatives for Oracea?

LCDR Hall responded we do have some different versions of doxycycline that are generic including the 100 mg dose. We also have a 20 mg IR dose that can be used. So the thought is there is dosing for Oracea where you use a lower dose of sub anti-microbial dosing. That can be achieved either with the Oracea 40 mg once daily or using the other 20mg twice daily and then the traditional dosing is 50-100 mg twice daily is another option as well.

Mr. Hostettler asked if the 50 and 100 mg have the indication.

LCDR Hall responded they are used commonly with guidelines. A lot of professionals do use these doxycycline products for these indications. They may be using them off label but it is a common practice.

Mr. Hostettler commented there appears to be no consistent process or guidance for following the indication. There are times when the indications are strictly followed and in other situations they are not.

LCDR Hall thanked Mr. Hostettler for the comments. I know some of these medications are older may not go back and seek out other indications later but I do appreciate your comments.

Mr. Hostettler noted that the 90-day implementation plan but it does not state that letters will be sent to new and current users of Oracea. How many patients are impacted by the recommendation?

LCDR Hall apologized because the number was add to the last table. It's about 994 patients would be affected.

There were no more questions or comments from the Panel. The Chair called for a vote on PA Criteria and Implementation Plan for the Updated PA Criteria.

- **Updated PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

- **Updated PA Criteria—Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

VI. RE-EVALUATION OF NONFORMULARY GENERICS

DR. ALLERMAN

P&T Comments

Background—The DHA Pharmacy Operations Division (POD) Formulary

Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The P&T Committee's process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, TRICARE Management Agency (TMA), on July 24, 2007. A summary of the criteria is available in Appendix E of the November 2012 P&T Committee minutes.

A. Antidepressant-1s (AD-1s) and Non-Opioid Pain Syndrome Drugs: pregabalin (Lyrica)

Lyrica has been designated as NF and non-step-preferred since the AD-1 drug class review in November 2011. Step therapy requires a trial of gabapentin (generic Neurontin) and duloxetine (generic Cymbalta) prior to use of Lyrica. The P&T Committee re-evaluated the formulary status of Lyrica due to price reductions in generic pregabalin formulations available across all three points of service. New clinical information comparing pregabalin with gabapentin was reviewed. Current utilization trends, numbers of generic products on the market, and relative cost-effectiveness, including the weighted average cost per unit for generic pregabalin (Lyrica) were also reviewed. The unit cost of generic pregabalin formulations has dropped significantly from the previous generic and brand cost, and the generic supply appears stable, as 13 manufacturers are producing product.

Pregabalin (Lyrica) Formulary Status, PA recommendation and implementation—

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- Returning pregabalin (Lyrica, generics) to formulary status.
- Removing the current step-therapy and manual PA requirements for pregabalin.
- An effective date the first Wednesday 30 days after signing of the minutes

B. AD-1s: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs): desvenlafaxine succinate ER (Pristiq) and desvenlafaxine ER

Desvenlafaxine succinate ER (Pristiq) and desvenlafaxine ER are NF, with step therapy requiring an initial trial of venlafaxine ER. The Desvenlafaxine ER product was approved under a New Drug Application (NDA) and is considered a brand agent, with no generics available; a previously available desvenlafaxine ER product (Khedezla) has been discontinued. As of Nov 2019, generic desvenlafaxine succinate ER is available from multiple manufacturers and the weighted average cost across DoD POS is lower than that for venlafaxine ER. The P&T Committee also noted that, although the weighted average cost for the branded Desvenlafaxine ER products was much higher than venlafaxine ER or desvenlafaxine succinate ER (generic Pristiq),

utilization was very low (fewer than 300 30-day equivalent Rxs over a 90-day period)

Desvenlafaxine succinate ER (Pristiq) Formulary Status, PA

recommendation and implementation—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- Returning desvenlafaxine succinate ER (Pristiq, generics) to UF status.
- Making no changes to the formulary status for the branded Desvenlafaxine ER product, which will remain NF.
- Removing the step therapy requirement for both desvenlafaxine succinate ER (Pristiq, generics) and Desvenlafaxine ER.
- An effective date the first Wednesday 30 days after signing of the minutes at all points of service.

Summary of Physician’s Perspective:

- For Lyrica, generic formulations were launched in July 2019, but the pricing has now dropped enough to return it to formulary status. We are also removing the PA requirements for this drug. With this action, approximately 29,000 beneficiaries will now see their copay decrease, and new patients will not have to complete the PA.
- The same applies to Pristiq, as it will move back to formulary status, without a PA. This action will benefit the 7,500 patients currently on this drug.
- Both of these drugs are examples where we continually monitor pricing when generics become available for non-formulary drugs, and respond accordingly. This will result in patients only having to pay the generic copay, and providers will not have the hassle of the PA.

Summary of Panel Questions and Comments:

- Mr. Hostettler clarified the generics for pregabalin came on the market in the summer of 2019.
- Dr. Allerman responded that is correct. Unfortunately, sometimes it would take several months for the generics to have a significant decrease in price. We have been monitoring the price of generics for several months and now they have dropped significantly. We will recommend returning it to formulary status.
- Mr. Hostettler clarified it wasn’t one of those authorized generics holding the price down?

- Dr. Allerman responded is not a situation of an authorized generic. There's at least 13 different manufacturers available, so it is a stable supply and it's cost-effective.
- Mr. Hostettler responded I wanted to commend you on getting that to the beneficiaries as soon as you possibly can.

There were no more questions or comments from the Panel. The Chair called for a vote on the Pregabalin (Lyrica) and desvenlafaxine succinate ER (Pristiq) formulary status, PA recommendation and implementation plan for the Re-evaluation of Nonformulary Generics.

- **Pregabalin (Lyrica) and desvenlafaxine succinate ER (Pristiq) formulary status, PA recommendation and implementation plan.**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:



These comments were taken under consideration prior to my final decision.

VII. INFORMATIONAL ITEM—PRENATAL LEGEND VITAMINS MOVING TO OTC STATUS

DR. ALLERMAN

In November 2019, First Databank moved several legend Prenatal Vitamin preparations to the status of legend Multivitamin preparations. Prenatal vitamins are required to have ingredients containing folic acid 400 mcg; vitamin D 10 mcg/400 units; and iron 27mg (or Low/No iron products with 0 to 26 mg of iron). Several vitamin combinations that do not contain the adequate ingredients for classification as prenatal vitamins or are not labeled as prenatal vitamins are affected. Due to the CFR 199.4 regulations for coverage of vitamins, the products moving to multivitamin status will no longer be covered under the TRICARE pharmacy benefit.

Patients impacted by this change at the Mail, Retail, and MHS GENESIS sites will receive letters in February 2020, and the products will be removed from the Pharmacy Benefit on April 1, 2020.

Summary of Panel Questions and Comments:

Mr. Hostettler inquired about the number of patients impacted by the recommendation for the information provided on the prenatal vitamins. Will they receive a letter notifying them of the change?

Dr. Allerman stated there were approximately 400 patients impacted by the decision. Those patients did receive a letter back in February regarding this change.

(Note that BAP Comments are not required for the informational item)

Closing Remarks

Dr. Khoury provides a summary of the meeting. We reviewed three subclasses, 16 new drugs, and several utilization management actions. Overall, these NF and Tier 4 recommendations will impact 0.04% of our 9.5M beneficiaries, while we expect several actions to result in over 36K beneficiaries experiencing a copay reduction.

Mr. Ostrowski thanked Col Hoerner and everyone for participating as well as Lt Col Khoury for his comments. This was a great day and a challenging one but we did it.

Appendices:

- Appendix I – Brief list of Acronyms used in this Summary
- Appendix II – Information Item – Summary of Recommendations and Beneficiary Impact

BRIEF LISTING OF ACRONYMS USED IN THIS SUMMARY

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in the Panel discussions are listed below for easy reference. The term “Pan” in this summary refers to the “Uniform Formulary Beneficiary Panel,” the group who’s meeting in the subject of this report.

- AAOS – American Academy of Orthopedic Surgeons
- AD-1s – Antidepressant
- AHRQ – Agency for Healthcare Research and Quality
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- CMA – Cost- Minimization Analysis
- CR – Controlled Release
- CV – Cardiovascular
- FDA – Food and Drug Administration
- FMB – Formulary Management Branch
- GI – Gastrointestinal
- MHS – Military Health System
- MS – Multiple Sclerosis
- NCCN – National Comprehensive Cancer Network
- NF – Nonformulary
- NICE – National Institutes for Health and Care Excellence
- NSAID – Nonsteroidal Anti-inflammatory Drugs
- OARSI – Osteoarthritis Research Society International
- ODT – Orally Disintegrating Tablet
- PA – Prior Authorization
- POD – Pharmacy Operation Division
- PPI – Proton Pump Inhibitor
- RLE – Real-Life Experience
- TMA – Tricare Management Agency
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- XR – Extended Release

INFORMATION ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT

Table of implementation Status of UF Recommendations/Decisions Summary February 2020

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
Pain Agents: Nonsteroidal Anti-Inflammatory Drug Subclass	<ul style="list-style-type: none"> ▪ celecoxib ▪ diclofenac/misoprostol ▪ diclofenac potassium ▪ diclofenac sodium ▪ diflunisal ▪ etodolac ▪ flurbiprofen ▪ ibuprofen 400 mg, 600 mg & 800 mg ▪ indomethacin IR 25 mg & 50 mg ▪ indomethacin ER 75mg ▪ indomethacin rectal suppository ▪ ketorolac tablets ▪ meloxicam 7.5 mg & 15 mg ▪ nabumetone ▪ naproxen 250 mg & 500 mg ▪ naproxen 125mg/5ml oral suspension ▪ naproxen IR 375 mg ▪ naproxen delayed release (DR) 375 mg & 500 mg ▪ naproxen sodium 275 mg & 550 mg ▪ oxaprozin ▪ piroxicam ▪ sulindac ▪ mefenamic acid 250 mg (generic Ponstel) (moves from NF to UF) 	<ul style="list-style-type: none"> ▪ diclofenac potassium powder packets 50 mg (Cambia) ▪ fenoprofen tablets (moves from UF to NF) ▪ indomethacin oral suspension (moves from UF to NF) ▪ ketoprofen (moves from UF to NF) ▪ ketorolac nasal spray (Sprix) ▪ meclofenamate (moves from UF to NF) ▪ meloxicam ODT (Qmiiz) ▪ naproxen sodium ER (Naprelan, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card ▪ tolmetin (moves from UF to NF) 	<ul style="list-style-type: none"> ▪ amlodipine/c celecoxib (Consensi) ▪ diclofenac potassium liquid-filled capsules (Zipsor) ▪ diclofenac submicronized (Zorvolex) ▪ fenoprofen capsules (moves from UF to Tier 4) ▪ ibuprofen/famotidine tablets (Duexis) ▪ indomethacin submicronized (Tivorbex) 	Pending signing of the minutes / 120 days	<p><u>Unique Users Affected (NF candidates) Mail – 90</u> MTF – 5 Retail – 166 Total – 261</p> <p><u>Unique Users Affected (Tier 4 candidates) Mail – 447</u> MTF – 38 Retail – 559 Total – 1,044</p> <p>NF and Tier 4 candidates represent 0.16% of all NSAID UUs</p>
Pain Agents: Topical Pain Subclass	<ul style="list-style-type: none"> ▪ diclofenac 1% gel (Voltaren generic) ▪ diclofenac 1.5% solution (Pennsaid 1.5% generic) ▪ lidocaine 5% patch (Lidoderm generic) 	<ul style="list-style-type: none"> ▪ None 	<ul style="list-style-type: none"> ▪ diclofenac 2% solution (Pennsaid 2%) ▪ diclofenac 1.3% patch (Flector) ▪ lidocaine 1.8% patch (ZTlido) 	Pending signing of the minutes / 120 days	<p><u>Unique Users Affected (Tier 4 candidates) Mail – 946</u> MTF – 379 Retail – 1871 Total – 3197</p> <p>Tier 4 candidates represent 1.5% of all Topical Pain UUs</p>

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
Prenatal vitamin (Zalvit)	0	0	0	0
Acne: Topical Acne and Rosacea subclass— Sulfacetamide and sulfacetamide/sulfur products	252	616	1,562	2,430
Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets	775	2,598	1,996	5,369
Insulins: Rapid Acting Agents—generic insulin aspart (authorized generic for Novolog)	0	0	0	0

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
April 1, 2020
Remote Access Virtual Session

Present Panel Members

- Mr. Jon Ostrowski, Non Commissioned Officers Association, Chairperson
- Dr. Richard Bertin, Commissioned Officer Association of the US Public Health Service
- Dr. Karen Dager, Health Net Federal Services
- Mr. John Du Teil, US Army Warrant Officers Association
- Mr. Charles Hostettler, AMSUS, The Society of Federal Health Professionals
- Dr. Joseph McKeon, Humana
- Dr. Jay Peloquin, Express Scripts, Inc.

Absent Panel Members

- None

The meeting was held remotely as a virtual session and Col Paul Hoerner called the meeting to order at 12:00 P.M.

Agenda

The agenda for agenda for the meeting of the Panel is as follows.

- **Welcome and Opening Remarks**
- **Public Citizen Comments**
- **Therapeutic Class Reviews**

Members of the DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) will present relative clinical and cost-effective analyses along with the DoD Pharmacy & Therapeutics Committee (P&T) recommendations for the Uniform Formulary (UF) and any recommended Tier 4/Not Covered candidates. The P&T Committee made recommendations for the following drugs/drug classes during the February 2020 meeting:

- **Drug Class Reviews**
 - *Pain Agents: Nonsteroidal Anti-Inflammatory Drug (NSAID) Subclass*
 - *Pain Agents: Topical Pain Subclass*

➤ **Newly Approved Drugs per 32 CFR 199.21(g)(5)**

- *albuterol dry powder inhaler (ProAir Digihaler) — Pulmonary-I: Short Acting Beta Agonist (SABA) for asthma*
- *asenapine transdermal system (Secuado) — New patch formulation of asenapine for schizophrenia in adults*
- *baclofen oral solution (Ozobax) — New oral solution formulation of baclofen for spasticity associated with multiple sclerosis*
- *benralizumab injection (Fasenra Pen) — Miscellaneous Pulmonary I Agent in a new formulation of a self-administered pen for eosinophilic and severe asthma*
- *benzoyl peroxide 9.8% foam (Enzoclear) — Keratolytic for acne vulgaris*
- *colchicine oral solution (Gloperba) — Anti-Gout Agent in a new oral solution formulation of colchicine*
- *diroximel fumarate (Vumerity) — Multiple Sclerosis Agents; a new methyl fumarate formulation*
- *elexacaftor/tezacaftor/ivacaftor (Trikafta) — Cystic Fibrosis triple fixed-dose combination*
- *minocycline 4% foam (Amzeeq) — Topical Acne and Rosacea Agents; new formulation of minocycline*
- *omeprazole magnesium/amoxicillin/rifabutin (Talicia) - Miscellaneous Anti-infective for Helicobacter pylori salvage therapy*
- *pegfilgrastim-bmez injection (Ziextenzo) — Hematological Agents: White Blood Cell Stimulants; another biosimilar for Neulasta*
- *pretomanid — Antitubercular drug for extensively drug resistant tuberculosis (XDR TB)*
- *testosterone undecanoate capsules (Jatenzo) — Testosterone Replacement Therapy (TRT)*
- *trifarotene 0.005% cream (Aklief) — Topical Acne and Rosacea Agents in a new retinoid formulation*
- *voxelotor (Oxbryta) — Sickle cell anemia agent for sickle cell disease*
- *zanubrutinib (Brukinsa) — Oral oncologic agent for mantle cell lymphoma*

➤ **Utilization Management Issues**

➤ ***Prior Authorization Criteria—New Manual PA Criteria***

- *Acne: Topical Acne and Rosacea subclass—Sulfacetamide and sulfacetamide/sulfur products*
- *Antidepressants and Non-opioid Pain Syndrome Agents—Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets*
- *Vitamin: Prenatal—Prenatal vitamin (Zalvit)*
- *Insulins: Rapid Acting Agents—generic insulin aspart (authorized generic for Novolog)*
- *Respiratory Agents Miscellaneous—epinephrine auto injector (Auvi-Q)*

➤ ***Prior Authorization Criteria—Updated PA***

- *Migraine Agents: Calcitonin Gene-related Peptide (CGRP) Preventatives—erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm (Emgality)*
- *Antilipidemic 2's-omega-3 fatty acids: icosapent ethyl (Vascepa)*
- *Targeted Immunomodulatory Biologics (TIBs): tofacitinib (Xeljanz XR)*
- *Pulmonary 1's-Pulmonary Miscellaneous: mepolizumab (Nucala)*
- *Basal Insulins: insulin glargine U-300 (Toujeo)*
- *Corticosteroids: Immune Modulators—deflazacort (Emflaza)*
- *Acne Agents: Tetracyclines—doxycycline monohydrate IR/ER 40 mg capsules (Oracea)*

➤ **Re-Evaluation of NF Generics**

- *Antidepressant-1s (AD-1s) and Non-Opioid Pain Syndrome Drugs: pregabalin (Lyrica)*
- *AD-1s: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs): desvenlafaxine succinate ER (Pristiq) and desvenlafaxine ER*

➤ **Items for Information: Prenatal Legend Vitamins Moving to OTC Status**

➤ **Panel Discussions**

The Beneficiary Advisory Panel members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will discuss the recommendations and vote to accept or reject them. The Panel will provide comments on their vote as directed by the Panel Chairman.

Opening Remarks

Col Paul Hoerner introduced himself as the Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP). The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on February 4 – 5, 2020.

Col Hoerner indicated Title 10, United States, (U.S.C.) section 1074g, subsection b requires the Secretary of Defense to establish a DoD Uniform Formulary (UF) of the pharmaceutical agent and established the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

In addition, 10 U.S.C. Section 1074g, subsection c, also requires the Secretary to establish a UF Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The Panel includes members that represent non- governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. The Panel's comments must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF.

The Panel's meetings are conducted in accordance of the Federal Advisory Committee Act (FACA).

The duties of the Uniform Formulary Beneficiary Advisory Panel include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and subsequently recommending changes. Comments to the Director of the DHA regarding recommended formulary status, pre-authorizations and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.
- To hold quarterly meetings in an open forum. The panel may not hold meetings except at the call or with the advance approval of the DFO and in consultation with the chairperson of the Panel.
- To prepare minutes of the proceedings and prepared comments of the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website, and comments will be prepared for the Director of DHA. As guidance to the Panel regarding this meeting, Col Hoerner said the role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the department appreciates that the BAP may be interested in the drug class they selected for review, drugs recommended for the basic core formula (BCF) or specific pricing data, these items do not fall under the purview of the BAP.

- The P&T Committee met for approximately 16 hours conducting this review of the drug class recommendation presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information as presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website. Detailed minutes of this meeting are being prepared. The BAP minutes, the DoD P&T Committee minutes, and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO provided ground rules for conducting the meeting:

- Due to travel restrictions and guidance regarding COVID-19, this meeting will be conducted in a remote access format.
- Audience participation is limited to private citizen comments received in writing prior to the meeting.
- Members of the public attending this meeting will be joined in listen mode only.
- To ensure there will be no disruptions to discussions, as a precaution, attendees are asked to mute their phones
- This meeting is being recorded. Please speak clearly.
- All discussions take place in this open public forum. There is to be no committee discussion outside the room or during breaks.
- Members of the Formulary Management Branch and P&T Committee are available to answer questions related to the BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure the minutes accurately reflect relevant facts, regulations, or policy.

Panel and Presenter Guidance:

- When asking or responding to questions, panel members are asked to state their name prior to making comments and asking questions.
- Presenters or anyone respond to a question are asked to state their name when responding.

Voting Procedures:

- A list of panel members will be provided to the chair person. The chair person will request the panel vote after each recommendation. The chair person will state the panel member's name. The panel member will respond, concur or non-concur, with the recommendation.

Technical Difficulties:

- If for any reason committee members are disconnected from the call, please dial in to reconnect. Ask for summary of discussion and comment, if appropriate.

Registration procedure:

- Participants and attendees are encouraged to send an email for attendance to the following inbox: dha.ncr.j-6.mbx.baprequests@mail.mil. Please include your name, organization, and title. In the email, please reference “UF BAP - April 1st, 2020 Meeting” in the subject.

Col Hoerner introduced the individual Panel members (see list above) and noted house-keeping considerations.

Written Statements:

- Written statements received in accordance with the guidance in the Federal Register Notice were submitted to the Panel for their consideration.
- Written statements not received within the specified timeline were forwarded to the DFO and a summary provided to the Panel members for their consideration.

Chairman's Opening Remarks

Mr. Ostrowski welcomed all panel members and thanked everyone for taking the time during this crisis in our nation for being a part of this panel and to take care of business. Mr. Ostrowski welcomed all participants and wished everyone to be safe during this crisis.

DRUG CLASS REVIEW PRESENTATION

LT COL KHOURY

GOOD MORNING. I am Lieutenant Colonel Ronald Khoury, Chief of the Formulary Management Branch (FMB) of the DHA Pharmacy Operations Division. Doctor and retired Army Colonel John Kugler, the Chairman of the Pharmacy and Therapeutics Committee is also here “virtually”. Joining us virtually are two clinical pharmacists from the Formulary Management Branch, LCDR Elizabeth Hall and Dr. Angela Allerman. I would also like to recognize Mr. Bryan Wheeler, Deputy General Counsel.

The DoD Formulary Management Branch supports the DoD P&T Committee by conducting the relative clinical effectiveness analyses and relative cost effectiveness analyses of the drugs and drug classes under review and consideration by the DoD P&T Committee for the Uniform Formulary (relative meaning in comparison to the other agents defined in the same class).

We are here to present an overview of the analyses presented to the P&T Committee. 32 Code of Federal Regulations (CFR) establishes procedures for inclusion of pharmaceutical agents on the Uniform Formulary based upon both relative clinical effectiveness and relative cost effectiveness. Additionally, all TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018.

The goal of this presentation is not to provide you with the same in-depth analyses presented to the DoD P&T Committee but a summary of the processes and analyses presented to the DoD P&T Committee. These include:

- 1) A brief overview of the relative clinical effectiveness analyses considered by the DoD P&T Committee. All reviews include but are not limited to the sources of information listed in 32 CFR 199.21 (e)(1) and (g)(5). Also note that 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.
- 2) A brief general overview of the relative cost effectiveness analyses. This overview will be general in nature since we are unable to disclose the actual costs used in the economic models. This overview will include the factors used to evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes.
- 3) The DoD P&T Committee’s Uniform Formulary recommendation is based upon the Committee’s collective professional judgment when considering the analyses from both the relative clinical and relative cost effectiveness evaluations.

The Committee reviewed the following:

1) Two Uniform Formulary Drug Classes:

- a) Pain Agents: Nonsteroidal Anti-Inflammatory Drug (NSAID) Subclass and
- b) Pain Agents: Topical Pain Subclass – including the Topical NSAIDs and topical lidocaine products

A summary table of the UF drug class recommendations and the numbers of affected utilizers is found on pages 38-39 of the background document.

2) The P&T Committee also evaluated 16 newly approved drugs per 32 CFR 199.21(g)(5), which are currently in pending status and available under terms comparable to Nonformulary drugs.

And,

3) We also discussed prior authorizations (PAs) for **28** drugs in **11** drug classes.

- a) Acne – 16 drugs from 2 subclasses
- b) Antidepressants and Non-Opioid Pain Drugs
- c) Prenatal Vitamins
- d) Rapid-Acting Insulins
- e) Miscellaneous Respiratory Agents
- f) Calcitonin Gene-Related Peptides for Migraine Headache – 3 drugs
- g) Antilipidemic 2 Drugs – Omega-3 fatty acids
- h) TIBs
- i) Pulmonary 1 – Miscellaneous
- j) Basal Insulins
- k) Immune Modulators

The DoD P&T Committee will make a recommendation as to the effective date of the agents being changed from the Uniform Formulary (UF) tier to Nonformulary (NF) tier. Based on 32 CFR 199.21, such change will not be longer than 180 days from the final decision date but may be less.

Before we start with the first Drug Class Review, I'd like to give you a bottom line up front regarding the committee's actions at this meeting. We will review three subclasses, 16 drugs, and a number of utilization management actions. We predict that we will impact 0.04% of our 9.5M beneficiaries through these recommendation, while we expect several actions to result in over 36K beneficiaries experiencing a copay reduction.

UNIFORM FORMULARY CLASS REVIEWS

I. UF CLASS REVIEWS—Pain Agents: Nonsteroidal Anti-Inflammatory Drug (NSAID) Subclass

LCDR HALL

P&T Comments

A. Pain Agents: NSAID Subclass Relative Clinical Effectiveness Analysis and Conclusion

Background—The NSAIDs were last reviewed for formulary status in August 2011. There are approximately 50 different marketed products in the class, comprised of 21 individual chemical entities. Since the last review, five branded products were reviewed as new drugs. Data published since the August 2011 meeting was evaluated for the efficacy and safety review.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- There was no new data to change the previous clinical conclusion that the NSAIDs do not have clinically relevant differences in efficacy in treating a wide range of indications. The NSAIDs are highly therapeutically interchangeable.
- Evidence from several sources, including clinical practice guidelines from five organizations (for acute gout, primary dysmenorrhea, ankylosing spondylitis, juvenile arthritis, and headache), four Cochrane Reviews (for rheumatoid arthritis, osteoarthritis, low back pain, and axial spondyloarthritis), and an Agency for Healthcare Research and Quality (AHRQ) report for osteoarthritis do not distinguish between the NSAIDs for efficacy. Although a few trials and systematic reviews showed improved efficacy for individual products, overall for most disease states there is insufficient evidence to recommend any one NSAID based on efficacy alone.
- The August 2011 P&T safety conclusions remain largely unchanged. The NSAIDs as a class have an increased risk of serious gastrointestinal (GI) and cardiovascular (CV) adverse events, and all the products include black box warnings to this effect in their Food and Drug Administration (FDA) labeling. Using the lowest effective dose for the shortest amount of time possible is recommended to decrease the risk of adverse events, particularly in elderly patients.

- Individual NSAIDs are associated with varying risk of GI and CV adverse events.
 - a) In terms of GI adverse events, ibuprofen and celecoxib have the lowest risk, diclofenac and naproxen have moderate risk, and ketorolac and piroxicam are high-risk NSAIDs. For GI protection, the following strategies are listed in order from most effective to least effective: administering a COX-2 inhibitor with a proton pump inhibitor (PPI), a COX-2 inhibitor alone, an NSAID with a PPI, an NSAID with misoprostol, and an NSAID with an H2-blocker.
 - b) In terms of CV adverse events, diclofenac is associated with higher CV risk while naproxen has lower CV risk. Although there is some mixed data for celecoxib and ibuprofen, their CV risk falls between that of diclofenac and naproxen.
- The P&T Committee considered twelve formulations for Tier 4 status. Clinical factors considered for not covered status were based on comparative pharmacokinetic profiles, efficacy and safety, data from FDA summary reviews and published primary literature, formulary status from commercial health plans, and Military Health System (MHS) provider feedback.
- Diclofenac potassium liquid filled capsule (Zipsor) is the only NSAID available in a liquid-filled formulation. Head-to-head clinical trials with other NSAIDs are lacking. The potentially faster onset of action of Zipsor compared to generic diclofenac potassium is negated if Zipsor is taken with food. Two generic formulations of diclofenac are currently on the formulary, the sodium salt (generic Voltaren) and the potassium salt (generic Cataflam). Over 95% of the MHS market share for diclofenac is for the sodium salt.
- Diclofenac potassium powder packet (Cambia) is the only prescription NSAID with a specific FDA indication for treating migraine headache. However, other prescription and over-the-counter (OTC) NSAIDs are widely accepted and used for treating migraines, including diclofenac 50 mg and 100 mg tablets, naproxen, ibuprofen, and aspirin/acetaminophen/caffeine (Excedrin).
- Submicronized formulations of diclofenac (Zorvolex), indomethacin (Tivorbex), and meloxicam (Vivlodex) were designed to have a greater extent of absorption than standard versions of these drugs, but the FDA summary review noted that the manufacturer failed to demonstrate this. These three products offer no compelling clinical advantage over existing generic formulary medications.
- Ketorolac nasal spray (Sprix) is indicated for the short-term management of moderate to moderately severe pain that requires analgesia at the opioid level. It poses a significant risk if used beyond the labeling for five days, including

nephrotoxicity and GI toxicity. Committee members commented that in the emergency department setting, IM ketorolac is commonly used to relieve acute pain. Feedback from emergency department specialists widely supported Tier 4 status.

- Meloxicam orally disintegrating tablet (ODT) (Qmiiz) was previously reviewed as a new drug and designated as NF in May 2019. No new clinical trials were used to gain FDA approval, and Qmiiz is limited for use only in adults and pediatric patients who weigh at least 60 kg. The FDA review noted that Qmiiz has comparable efficacy and safety as the referenced drug, generic meloxicam.
- Naproxen sodium controlled release (Naprelan, generics) provides a convenience to the patient, as this formulation is dosed once daily, rather than twice daily. Other NSAIDs, including nabumetone, are dosed once daily. One head-to-head trial showed similar efficacy and safety between Naprelan and nabumetone. Trials comparing Naprelan with generic naproxen show no difference in efficacy, however, varying safety results were shown, as two trials found weak evidence of an improved GI adverse event profile with Naprelan.
- Ibuprofen/famotidine (Duexis) contains a fixed dose combination of an NSAID and an H2-blocker; these active ingredients are available OTC. A 2016 GI Safety Network Analysis found that the combination of an NSAID with an H2-blocker was the least effective strategy for providing GI protection, compared to other GI protective strategies.
- Naproxen/esomeprazole (Vimovo) contains components that are readily available as generic drugs already included on the uniform formulary. Vimovo was designated Tier 4 at the February 2019 DoD P&T meeting, which was implemented on August 29, 2019. There is no new data to support changing Vimovo's Tier 4 status.
- Celecoxib/amlodipine (Consensi) was approved in December 2019 for adults in whom treatment with the calcium channel blocker amlodipine (generic Norvasc) for hypertension and celecoxib for osteoarthritis are appropriate. There is minimal data available with this formulation. Other than patient convenience, this particular fixed dose combination has limited clinical utility, due to a narrow potential patient population, difficulty with titrating patients, and risk of long-term safety concerns.
- Fenoprofen (Nalfon and generics) has very limited MHS market share (less than 0.08%), and a literature review did not identify any unique indications. Currently, both tablets and capsules are marketed.

- Ketoprofen (generic Orudis), indomethacin rectal suppositories, meclofenamate sodium (generic Meclomen) and tolmetin (generic Tolectin) do not provide any compelling clinical advantages over the other NSAIDs, are infrequently prescribed in the MHS, and were identified by prescribers as potential options for NF status and Prior Authorization.
- Although the efficacy of the NSAIDs is similar from a population perspective, individual patient response to a particular drug may vary. Providers must also consider relative safety when selecting an NSAID for an individual patient.
- In order to meet the needs of MHS beneficiaries, a wide range of NSAIDs is required on the formulary, to account for differences in COX-2 selectivity, frequency of dosing, GI and CV safety profiles, and to allow for individual variability in patient response. At a minimum, one generic formulation of celecoxib, diclofenac sodium, ibuprofen, meloxicam, and naproxen are required, as these are the NSAIDs with the highest MHS utilization, comprising 94% of the NSAID market share. Additionally, a few alternative dosage forms are necessary for patients with swallowing difficulties, with the options including naproxen suspension, indomethacin suspension, or indomethacin suppositories.

B. Pain Agents: NSAID Subclass—Relative Cost-Effectiveness Analysis and Conclusion

A cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA showed that generic formulations in the class were the most cost-effective agents, with Qmiiz, fenoprofen, tolmetin, Naprelan, ketoprofen, Vivlodex, Tivorbex, Zorvolex, meclofenamate, Zipsor, Vimovo, Duexis, Consensi, Cambia and Sprix as substantially less cost-effective than the other NSAIDs.
- A BIA was performed to evaluate the potential financial impact of various formulary placement scenarios for the NSAIDs, designating selected NSAID agents as Tier 4, NF, and UF. The BIA results showed that designating fenoprofen capsules, Vimovo, Duexis, Zipsor, Zorvolex, Tivorbex, Vivlodex, and Consensi as Tier 4; and Cambia, Sprix, Naprelan brand and generic, Qmiiz, fenoprofen tablets, tolmetin, ketoprofen, and meclofenamate as NF; with the remaining NSAID agents in the class as UF, demonstrated significant cost avoidance for the MHS.

C. Pain Agents: NSAID Subclass—UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (12 for, 5 opposed, 0 abstained, 1 absent) the following:

- UF
 - a) celecoxib
 - b) diclofenac/misoprostol
 - c) diclofenac potassium
 - d) diclofenac sodium
 - e) diflunisal
 - f) etodolac
 - g) flurbiprofen
 - h) ibuprofen 400 mg, 600 mg & 800 mg
 - i) indomethacin IR 25 mg & 50 mg
 - j) indomethacin ER 75 mg
 - k) indomethacin rectal suppository
 - l) ketorolac tablets
 - m) meloxicam 7.5 mg & 15 mg
 - n) nabumetone
 - o) naproxen 250 mg & 500 mg
 - p) naproxen 125mg/5ml oral suspension
 - q) naproxen IR 375 mg
 - r) naproxen delayed release (DR) 375 mg & 500 mg
 - s) naproxen sodium 275 mg & 550 mg
 - t) oxaprozin
 - u) piroxicam
 - v) sulindac
 - w) mefenamic acid 250 mg (generic Ponstel) (*moves from NF to UF*)
 - x) Note that the older non-FDA-approved products, salsalate and choline magnesium trisalicylate will remain UF

- NF
 - a) diclofenac potassium powder packets 50 mg (Cambia)
 - b) fenoprofen tablets (*moves from UF to NF*)
 - c) indomethacin oral suspension (*moves from UF to NF*)
 - d) ketoprofen (*moves from UF to NF*)
 - e) ketorolac nasal spray (Sprix)
 - f) meclufenamate (*moves from UF to NF*)
 - g) meloxicam ODT (Qmiiz)
 - h) naproxen sodium ER (Naprelan, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card
 - i) tolmetin (*moves from UF to NF*)

- Tier 4/Not Covered
 - a) amlodipine/celecoxib (Consensi)
 - b) diclofenac potassium liquid-filled capsules (Zipsor)
 - c) diclofenac submicronized (Zorvolex)
 - d) fenoprofen capsules (*moves from UF to Tier 4*)
 - e) ibuprofen/ famotidine tablets (Duexis)
 - f) indomethacin submicronized (Tivorbex)
 - g) meloxicam submicronized (Vivlodex)
 - h) naproxen/esomeprazole (Vimovo) (*remains Tier 4*)

Committee members with opposing votes were not opposed to the agents being considered for their respective formulary status as recommended, noting they wanted the recommendation to include more agents for Tier 4 status. The Committee commented and considered Cambia powder packets, Qmiiz, Naprelan, and Sprix nasal spray as potential additional Tier 4 candidates. The opinion to move all these additional agents to Tier 4 was not unanimous.

When considering the NSAID candidates for Tier 4/Not Covered status, the P&T Committee considered the information outlined in the interim rule, Section 702(b)(10) of the NDAA 2018 published on December 11, 2018, and found at <https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms>. The interim rule allows for complete exclusion of drugs from TRICARE pharmacy benefit coverage when certain criteria are met. Tier 4/Not Covered status will apply to all users of the recommended candidates.

For the eight NSAIDs recommended for Tier 4/Not Covered status, The P&T Committee concluded that they provide very little to no additional clinical effectiveness relative to the other NSAIDs. Overall, the P&T Committee felt that the needs of TRICARE beneficiaries could be met by the formulary NSAIDs. Formulary alternatives for the Tier 4 candidates include generic NSAIDs.

D. Pain Agents: NSAID Subclass—Manual PA Criteria

Existing PA criteria currently apply to Naprelan brand and generic from the November 2018 meeting, and for Qmiiz, when it was reviewed as an innovator in May 2019. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated manual PA criteria for new users of Naprelan brand and generic, and Qmiiz. Additionally, new manual PA criteria for all new and current users of Cambia, was recommended, limiting use to patients with a contraindication, therapeutic failure or intolerance to a triptan and who have failed two previous NSAIDs.

The PA criteria are as follows:

1. diclofenac potassium powder packets 50 mg (Cambia)

Manual PA criteria apply to all new and current users of diclofenac potassium powder (Cambia). Note that multiple formulary NSAIDs and triptans are available without a PA including ibuprofen, indomethacin, naproxen, diclofenac potassium tablets, sumatriptan, rizatriptan, and zolmitriptan.

Manual PA Criteria: Cambia is approved if all criteria are met:

- Patient is ≥ 18 years of age
- Patient has a diagnosis of migraine
- Prescription is written by or in consultation with a Neurologist
- Patient has tried and failed at least two formulary NSAIDs including diclofenac potassium tablets (Cataflam generic)
- Patient has tried and failed or has a contraindication to at least one formulary triptan (e.g., sumatriptan, rizatriptan, and zolmitriptan)

2. meloxicam ODT (Qmiiz)

Manual PA criteria apply to all new users of meloxicam ODT (Qmiiz). Note that multiple formulary NSAIDs, including meloxicam oral tablets, are available for DoD beneficiaries without a PA.

Manual PA Criteria: Qmiiz is approved if all criteria are met:

- Provider must explain why the patient requires meloxicam ODT and cannot take any of the formulary NSAIDs.

3. naproxen sodium controlled release (CR) (Naprelan brand and generic)

Manual PA criteria apply to all new users of naproxen CR (Naprelan). Note that multiple formulary NSAIDs are available without a PA including ibuprofen, indomethacin, meloxicam, naproxen, and celecoxib.

Manual PA Criteria: naproxen CR is approved if all criteria are met:

- Provider must provide clinical rationale of why patient cannot take any of the formulary NSAIDs.

E. Pain Agents: NSAID Subclass—UF/Tier 4/Not Covered PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent): 1) an effective date of the first Wednesday 120 days after signing of the P&T minutes at all points of service (POS); 2) DHA send letters to beneficiaries affect by the NF

recommendations; and 3) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation.

F. Physician's Perspective

- We reviewed the NSAIDs back in 2011, and since then, new branded products have been approved that contain active ingredients that are already available in generic formulations.
- There are over 50 products in the class, however, the top 10 most frequently used NSAIDs account for approximately 99% of the utilization and contribute to 66% of the overall cost. The remaining 1% of the utilization accounts for 33% of the overall NSAID cost.
- Out of the nine products recommended for non-formulary status, four are currently designated nonformulary. The other five products (ketoprofen, fenoprofen tablets, meclofenamate, tolmetin, and indomethacin suspension) are old drugs which do not have any unique use or place in therapy.
- For the NF and Tier 4 candidates, we did reach out to providers for their input. Providers in general were supportive of the NSAIDs recommended for Tier 4 and NF status.
- For Cambia, neurologist feedback did support keeping it as NF, but only for a limited patient population (those with a triptan contraindication or intolerance who have failed other NSAIDs), which is reflected in the PA. Providers were concerned that if Cambia was made Tier 4, patients would be faced with paying nearly \$1,000 in out-of-pocket expenses.
- Sprix nasal spray will also remain NF. This drug is not typically used in the emergency department setting, as Committee members commented that in the ER, either IM or IV ketorolac is commonly used to relieve acute pain. Feedback from emergency department specialists widely supported Tier 4 status, but the majority of the Committee recommended keeping Sprix as NF because of potential opioid-sparing effect.
- Vimovo (naproxen with esomeprazole) was one of the first Tier 4 drugs, which was implemented in August 2019. This is also the first Tier 4 drug where we have gone back to re-evaluate whether it should return back to UF status. For all the Tier 4 selections, we will systematically go back and do a similar re-analysis.
- For the innovator drug Consensi (amlodipine with celecoxib), the Committee felt strongly that this product could be detrimental to patients, since those who are partially compliant to their pain management are at risk for having

suboptimal management of their hypertension. Additionally, Consensi costs 40 times more than the individual ingredients given separately, and several commercial health plans don't cover Consensi.

- The Committee did acknowledge the opioid sparing effect of the NSAIDs. Out of the 21 distinct active ingredients, the formulary recommendation will result in 17 remaining on the UF. For the Tier 4 recommendations, all of the active ingredients are available either on the formulary, or OTC.
- In the MHS, approximately 800,000 unique patients received an NSAID over the past year. The NF and Tier 4 candidates will affect about 1,300 beneficiaries. If you consider that at some point every beneficiary will need an NSAID, this action will not impact 99.9% of our beneficiaries.
- The Committee members who voted against the formulary recommendation wanted four additional products to be designated Tier 4. The committee members in favor of adding more agents to the Tier 4 category were unconvinced that these agents added any benefit to those currently available on the Formulary.

G. Panel's Questions and Comments:

Mr. Hostettler asked if the Meloxicam ODT has any efficacy or safety benefits over the naproxen suspension, indomethacin suspension, and the indomethacin suppositories.

LCDR Hall responded the Meloxicam ODT was recommended for the Non-Formulary status. It is an orally disintegrating tablet and would be another option for patients who are unable to swallow.

Mr. Hostettler repeated, does the Meloxicam have any better safety or efficacy benefits than the three (3) product previously mentioned? Maybe it should be included in the list of UF products.

LCDR Hall responded the NSAIDs do have variable GI and cardiovascular safety profiles across the different NSAIDs. I think the purpose of that list purpose was provide an example. It says non-tablet or capsule dosage forms but it's not by any means all-inclusive. But that was from our initial perspective. We were looking at some of the options that we wanted to capture, we did end up keeping Qmiiz ODT as an option in the Non-Formulary status.

Mr. Hostettler asked if UF included both Tier 1 and Tier 2 drugs.

LCDR Hall responded yes, it does.

Mr. Hostettler stated that he does not know which Tier 2 are.

LCDR Hall responded the Tier 2 products branded products only and Tier 1 would be generics.

Mr. Hostettler responded that the committee has made exceptions to that brand/generic policy in past recommendations to allow the generic or lower co-pay. When this happens, please note it in the discussions.

LCDR Hall responded we will. We are not recommending any changes for ones that received Tier 1 copays for this class.

There were no more Panel questions or comments. The Chair called for a vote on the UF/Tier 4/Not Covered Recommendation, Manual PA Criteria, UF/Tier 4/Not Covered and PA Implementation Plan, for the Pain Agents: NSAIDS.

- **Pain Agents: NSAID—UF/Tier 4/Not Covered Recommendation**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Pain Agents: NSAID Subclass—Manual PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Pain Agents: NSAID—UF/Tier 4/Not Covered and PA Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

II. UF CLASS REVIEWS—Pain Agents: Topical Pain Subclass

DR. ALLERMAN

P&T Comments

A. Pain Agents: Topical Pain Subclass Relative Clinical Effectiveness Analysis and Conclusion

Background—The Topical Pain drugs were previously reviewed at the February 2013 DoD P&T Committee meeting. The subclass is comprised of topical NSAIDs (diclofenac preparations) and lidocaine patches. Since the last class review, several products are now available in generic formulations, and currently only diclofenac 2% solution (Pennsaid 2%) and lidocaine 1.8% patch (ZTlido) remain branded products. Manual PA criteria apply to both Pennsaid 2% and ZTlido, requiring a trial of the generics first.

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

Topical diclofenac

- There was no new data to change the clinical conclusions from the February 2013 formulary review that the topical diclofenac products are highly interchangeable, effective for treating superficial musculoskeletal pain, and are similar in efficacy to oral diclofenac.
- Professional treatment guidelines from several organizations, including the UK National Institutes for Health and Care Excellence (NICE), the Osteoarthritis Research Society International (OARSI) and the American Academy of Orthopaedic Surgeons (AAOS) state that topical NSAIDs are appropriate for treating osteoarthritis affecting the knee and hand joints. Topical NSAIDs may be interchanged with oral NSAIDs when oral NSAIDs are not appropriate (e.g., geriatric population).
- The 2014 VA/DoD Clinical Practice Guidelines comment that topical NSAIDs have a decreased absolute risk of GI adverse events compared to oral diclofenac but note that there is insufficient evidence to compare topical versus oral diclofenac in terms of serious GI events (perforation, ulcers, or bleeding), CV events, renal impairment, and hepatotoxicity.
- The FDA package labeling for the topical diclofenac products still carries warnings about GI and CV risks and includes recommendations for liver function monitoring, similar to the oral NSAIDs.
- **Diclofenac 1% gel (Voltaren generic)** is the highest utilized topical NSAID in the MHS. Advantages include easy application to multiple joints, including the fingers, and FDA approval for osteoarthritis of both the hand and knees.
- **The diclofenac 1.5% topical solution (Pennsaid 1.5% generic)** FDA-approved indication is limited to treating osteoarthritis of the knee. Clinical usefulness may also be limited by the multiple daily dosing (four times daily) and the need to count out 40 drops for application.
- **The diclofenac 2% solution (Pennsaid 2%)** is bioequivalent to the 1.5% solution. The only difference between the products is that the 2% solution is available in a pump and has a slightly more viscous consistency. Provider comments noted that only one diclofenac solution is required on the formulary. Other than patient convenience, Pennsaid 2% offers no compelling advantages over diclofenac 1% gel or the 1.5% solution.
- **Diclofenac 1.3% patch (Flector, generic)** is the only topical NSAID approved for treating acute pain due to musculoskeletal injuries; it does not have approval

for treating osteoarthritis. A 2017 Cochrane review showed that diclofenac is effective for acute pain lasting for less than 7 days. Disadvantages to Flector include the large size, making it difficult to apply to small joints. Additionally only one patch can be applied at a time. Providers commented that there are many alternatives to Flector including oral NSAIDs and other topical NSAIDs.

Lidocaine Patches

- The clinical conclusions from February 2013 remain unchanged, finding that lidocaine patches are probably effective for treating postherpetic neuralgia (PHN), likely effective for neuropathic pain, and lacking in evidence for musculoskeletal pain. The most common adverse event for the lidocaine patch is application site reactions, specifically pruritus.
- **Lidocaine 5% patch (Lidoderm, generic)** has the highest utilization of all the topical pain drugs in the MHS. Advantages include that up to three patches can be used at a time and patches can be cut to size. There are three generic manufacturers on the market, so patients can try different products if there are adhesion issues.
- **Lidocaine 1.8% patch (ZTlido)** is a new formulation of lidocaine that is bioequivalent to the Lidoderm 5% patch, delivering the same amount of lidocaine to the patient. Although the manufacturer claims that ZTlido has improved adhesion over Lidoderm, FDA reviewers questioned the supporting evidence for this claim. There was no new data to change the conclusions from the ZTlido new drug review in November 2018 that it is a candidate for Tier 4 status.
- In order to meet the needs of MHS beneficiaries, one topical diclofenac product and one lidocaine patch are required on the formulary.

B. Pain Agents: Topical Pain Subclass—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate the topical pain agents. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that the following agents were substantially less cost-effective than the remainder of the class: diclofenac 1.3% patch (Flector, generics), diclofenac 2% solution (Pennsaid 2%), and lidocaine 1.8% patch (ZTlido).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating diclofenac 1% gel (Voltaren, generics), diclofenac 1.5% drops (generics), and lidocaine 5% patch (Lidoderm, generics) as UF, and diclofenac

1.3% patch (Flector, generics), diclofenac 2% solution (Pennsaid 2%), and lidocaine 1.8% patch (ZTlido) as Tier 4 demonstrated significant cost avoidance for the MHS.

C. Paint Agents: Topical Pain Subclass—UF/Tier 4/Not Covered Recommendation

P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - a) diclofenac 1% gel (Voltaren generic)
 - b) diclofenac 1.5% solution (Pennsaid 1.5% generic)
 - c) lidocaine 5% patch (Lidoderm generic)
- NF
 - a) None
- Tier 4/Not Covered
 - a) diclofenac 2% solution (Pennsaid 2%)
 - b) diclofenac 1.3% patch (Flector)
 - c) lidocaine 5% patch (Lidoderm generic)

When considering the candidates for Tier 4/not covered status, the P&T Committee considered the information previously stated in section II. C on page 7.

For the three products recommended for Tier 4/Not Covered status, Pennsaid 2%, Flector and ZTlido, the P&T Committee concluded that they provide very little to no additional benefit relative to the other topical pain agents. Overall, the P&T Committee felt that the needs of TRICARE beneficiaries could be met by the formulary topical pain drugs. Formulary alternatives for the Tier 4 candidates also include the generic oral NSAIDs.

D. Paint Agents: Topical Pain Subclass—UF/Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 120-day implementation period in all points of service and, 2) DHA send letters to beneficiaries who are affected by the UF/Tier 4 recommendations at 30 and 60 days prior to implementation.

E. Physician's Perspective

- This class is divided up into the topical NSAIDs and topical lidocaine products. For the topical NSAIDs, even though these products are not given orally, they still have the same warnings for GI toxicity and cardiovascular side effects.
- The four topical NSAIDs all contain diclofenac as the active ingredient; they just vary in their concentration and dosage formulation.
- Flector patch was recommended for Tier 4 status. Due to its size, it's not practical to use on the fingers or knees. Utilization showed that although the package insert for Flector limits it to 2 weeks use, some patients appear to be receiving these patches regularly. This is not the intended length of time for this prescription, and is inconsistent with the package insert labeling.
- For Flector, the majority of the MHS providers surveyed agreed with recommending Tier 4 status, with one commenting that they didn't see much utility for the patches considering their cost, especially since lidocaine patches are available. Two commercial healthcare plans have the Flector patch as not covered, and several others have it as non-preferred and requiring a PA, even though it is used for acute pain.
- For the Pennsaid 2% pump, providers mentioned that it does not have major advantages compared to the Voltaren gel. Other comments were that they would use the 1% solution instead of the 2% pump, due to its cost, and that there was no need to have both the 1% solution and 2% pump available.
- For the branded lidocaine product, ZT Lido, provider feedback overwhelmingly said this formulation was not needed, and that the generic Lidoderm patch would meet the needs of their patients.
- Even though there are three Tier 4 candidates, there are alternative products, including generic Voltaren gel and Lidoderm, along with the oral NSAIDs. For the class, generic Voltaren gel is used by about 60% of the patients currently receiving a topical NSAID, and 30% of patients are on the generic Lidoderm patch.
- We have about 220,000 patients in the class, and about 3,200 patients would be affected by this formulary recommendation. The three Tier 4 drugs will affect only 1.5% of overall Topical Pain users.
- The three products remaining on the formulary (Voltaren gel, Pennsaid 1.5% drops, and Lidoderm 5% patch) are generic and will remain at the Tier 1 copay.

G. Panel Questions and Comments.

There were no Panel questions or comments. The Chair called for a vote on the UF/Tier 4/Not Covered, UF/Tier4/Not Covered and PA Implementation Plan Recommendations for the Pain Agents: Topical Pain Subclass.

- **Paint Agents: Topical Pain Subclass—UF/Tier 4/Not Covered Recommendation**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Paint Agents: Topical Pain Subclass—UF/Tier 4/Not Covered and PA Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

III. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

LCDR HALL

P&T Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Relative Clinical Effectiveness and relative Cost-Effectiveness Conclusions

The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
 - benralizumab injection (Fasenra Pen) — Miscellaneous Pulmonary 1 Agent in a new self-administered pen for eosinophilic and severe asthma
 - elexacaftor/tezacaftor/ivacaftor (Trikafta) — Cystic Fibrosis triple fixed-dose combination
 - pegfilgrastim-bmez injection (Ziextenzo) — Hematological Agents: White Blood Cell Stimulants; another biosimilar for Neulasta

- pretomanid — Antitubercular drug for extensively drug-resistant (XDR) or treatment intolerant/nonresponsive multidrug-resistant (MDR) tuberculosis
 - voxelotor (Oxbryta) — Sickle cell anemia agent for sickle cell disease
 - zanubrutinib (Brukinsa) — Oral oncologic agent for mantle cell lymphoma
- NF
 - Asenapine transdermal system (Secuado) — New patch formulation of asenapine for schizophrenia in adults
 - Baclofen oral solution (Ozobax) — New oral solution formulation of baclofen for spasticity associated with multiple sclerosis
 - Colchicine oral solution (Gloperba) — Anti-Gout Agents; a new oral solution formulation of colchicine
 - Diroximel fumarate (Vumerity) — Multiple Sclerosis Agents; another methyl fumarate formulation
 - Minocycline 4% foam (Amzeeq) — Topical Acne and Rosacea Agents; a new formulation of minocycline
 - Testosterone undecanoate capsules (Jatenzo) — Testosterone Replacement Therapy (TRT) in an oral capsule
 - Trifarotene 0.005% cream (Aklief) — Topical Acne and Rosacea agents; a new retinoid
 - Tier 4/Not Covered
 - a) albuterol dry powder inhaler (ProAir Digihaler) — Pulmonary-1: Short Acting Beta Agonist (SABA) for asthma
 - 1) ProAir Digihaler was recommended for Tier 4 status as it has no clinical benefit relative to other agents approved for treating asthma symptoms and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to ProAir Digihaler include albuterol MDI (ProAir HFA), albuterol DPI (ProAir Respiclick), albuterol MDI (Proventil HFA), albuterol MDI (Ventolin HFA), and levalbuterol MDI (Xopenex HFA).
 - b) benzoyl peroxide 9.8% foam (Enzoclear) — Keratolytic for acne vulgaris
 - 1) Enzoclear was recommended for Tier 4 status as it is not an FDA-approved drug, has no clinical benefit relative to other agents approved for acne vulgaris, and the needs of TRICARE beneficiaries are met by alternative agents.

- Formulary alternatives to Enzoclear include clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics), clindamycin/ benzoyl peroxide 1% - 5% gel (Benzaclin, generics), and clindamycin/benzoyl peroxide 1% - 5% gel kit (Duac CS Kit)
- c) omeprazole magnesium/amoxicillin/rifabutin (Talicia) - Miscellaneous Anti-infective for *Helicobacter pylori* salvage therapy
 - 1) Talicia was recommended for Tier 4 status as it has no clinical benefit relative to other agents approved for *H. pylori* and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to Talicia include amoxicillin, omeprazole, rifabutin, clarithromycin, metronidazole, and tetracycline.

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- TRTs: Applying the same manual PA criteria in new and current users of Jatenzo, as is currently in place for the other non-step-preferred TRT products. Patients must first try generic Fortesta or generic Androgel 1%. Also for Jatenzo, additional safety requirements are included in the PA to exclude patients with uncontrolled hypertension or those at high risk for CV adverse events.
- Applying manual PA criteria to new and current users of Akliief, Amzeeq, Fasentra Pen, Oxbryta, Vumerity, and Trikafta.
- Applying manual PA criteria to new users of Brukinsa, Gloperba, and Ozobax.

Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5)

1. baclofen oral solution (Ozobax)

Manual PA criteria apply to all new users of Ozobax.

Manual PA criteria: Ozobax is approved if all criteria are met:

- Ozobax will be used for the treatment of spasticity
- Patient requires baclofen and cannot use the tablet formulation or

crushed tablet due to a documented medical condition such as dysphagia, oral candidiasis, or systemic sclerosis, and not due to convenience

- Presence of an NG/J-tube alone is not a reason for approval

Non-FDA approved uses are not approved including nystagmus, trigeminal neuralgia, hiccups, GERD, alcohol abstinence in alcoholic liver disease, and low back pain.

PA does not expire

2. **benralizumab injection (Fasenra Pen)**

Manual PA is required for all new and current users of Fasenra Pen.

Manual PA Criteria: Fasenra Pen is approved if all criteria are met:

- The patient has a diagnosis of severe persistent eosinophilic asthma
- Patient must be ≥ 12 years
- The drug is prescribed by an allergist, immunologist, or pulmonologist
- Patient must have an eosinophilic phenotype asthma as defined as either
 - a) Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids OR
 - b) Eosinophils ≥ 300 cells/mcL
- Patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following:
 - a) Hospitalization for asthma in past year
 - b) Two courses oral corticosteroids in past year
 - c) Daily high-dose inhaled corticosteroids with inability to taper off
- The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid:
 - a) LABA (e.g., formoterol, salmeterol), LAMA (tiotropium), or leukotriene receptor antagonist

Non-FDA-approved uses are not approved.

PA does not expire

3. colchicine oral solution (Gloperba)

Manual PA is required for all new users of Gloperba. Note that other formulations of colchicine (e.g. Colcrys) do not require PA

Manual PA Criteria: Gloperba is approved if all criteria are met:

- Provider must explain why the patient requires liquid colchicine and cannot take colchicine capsules or tablets.

Non-FDA-approved uses are not approved.

PA does not expire.

4. diroximel fumarate (Vumerity)

Manual PA criteria apply to all new and current users of Vumerity.

Manual PA Criteria: Vumerity approved if all criteria are met:

- Documented diagnosis of a relapsing form of Multiple Sclerosis (MS)
- Patient must have had at least a two-week trial of Tecfidera and either
 - a) Have failed therapy OR
 - b) Continues to have GI side effects not expected to occur with Vumerity
- Complete blood count drawn within six months prior to initiation of therapy, due to risk of lymphopenia
- Coverage is NOT provided for concomitant use with other disease-modifying drugs of MS

Non-FDA-approved uses are not approved.

PA does not expire.

5. elexacaftor/tezacaftor/ivacaftor (Trikafta)

Manual PA is required for all new and current users of Trikafta.

Manual PA Criteria: Trikafta is approved if all criteria are met

- Prescribed by or in consultation with a pulmonologist
- Prescribed for the treatment of cystic fibrosis (CF) for an FDA-approved age
- Patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test
- Not approved in combination therapy with Symdeko, Orkambi or Kalydeco

Non-FDA-approved uses are not approved

PA does not expire.

6. minocycline 4% foam (Amzeeq)

Manual PA is required for all new and current users of Amzeeq. Note: Amzeeq is not included in the automated step therapy for the topical acne and rosacea agents

Note: Adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination gel), and tretinoin (cream and gel) are available without a PA; providers are encouraged to consider changing the prescription to one of these agents.

Manual PA Criteria: Amzeeq is approved if all criteria are met:

- Patient has a diagnosis of acne vulgaris
- This agent has been identified as having cost-effective alternatives. The provider must explain why the patient requires Amzeeq and cannot take the formulary alternatives. _____ (blank write-in)

Non-FDA approved uses (including rosacea) are not approved.

PA does not expire.

7. testosterone undecanoate capsules (Jatenzo)

Manual PA criteria apply to all new and current users of Jatenzo.

Manual PA Criteria: Jatenzo is approved if all criteria are met:

- Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions
 - a) Patient is a male age > 18 years
 - b) Patient has a diagnosis of deficiency or absence of endogenous testosterone associated with structural or genetic etiologies
 - c) Patient is experiencing signs and symptoms usually associated with hypogonadism
 - d) Patient has tried testosterone 2% gel (Fortesta) OR testosterone 1% gel (AndroGel generic) for a minimum of 90 days AND failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after use of the agent) AND without improvement in symptoms

OR

- Patient has a contraindication to or has experienced a clinically significant adverse reaction to Fortesta OR generic testosterone 1% gel, that is not expected to occur with Jatenzo
- The patient requires a testosterone replacement therapy (TRT) that has a low risk of skin-to-skin transfer between family members

OR

- The requested medication is being used for female-to-male gender reassignment (endocrinologic masculinization)
 - a) Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND
 - b) Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to the most current edition of the DSM; AND
 - c) Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment); AND
 - d) Patient has a documented minimum of three months of real- life

experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria;
AND

- e) For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding.
- Patient does not have any of the following:
 - a) Hypogonadism conditions not associated with structural or genetic etiologies, carcinoma of the breast or suspected carcinoma of the prostate
 - b) Uncontrolled hypertension or is at risk for cardiovascular events prior to start of Jatenzo therapy or during treatment (based on the product's boxed warning of increased risk of major adverse cardiovascular events and hypertension)
- Jatenzo is not approved for concomitant use with other testosterone products.

Non-FDA-approved uses are not approved.

PA does not expire.

8. trifarotene 0.005% cream (Aklief)

Manual PA is required for all new and current users of Aklief.

Note: Adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination gel), and tretinoin (cream and gel) are available without a PA; providers are encouraged to consider changing the prescription to one of these agents.

Manual PA Criteria: Aklief is approved if all criteria are met:

- Patient has a diagnosis of acne vulgaris
- This agent has been identified as having cost-effective alternatives. The provider must explain why Aklief is required and the patient cannot take the formulary alternatives. _____ (blank write-in).

Non-FDA-approved uses are not approved

Prior authorization expires in 1 year.

Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA

9. voxelotor (Oxbryta)

Manual PA applies to new and current users of Oxbryta.

Manual PA Criteria: Oxbryta is approved if all criteria are met:

- Patient meets FDA-indicated age requirements for Oxbryta
- Patient has a diagnosis of sickle cell disease
- Patient has had at least one vaso-occlusive crisis in the last 12 months AND has a hemoglobin between 5.5 g/dL and 10.5 g/dL
- Patient has had an inadequate treatment response to a 3 month trial of hydroxyurea
- Drug is prescribed by or in consultation with a hematologist
- For patients on a strong or moderate CYP3A4 inducer (e.g. carbamazepine, phenytoin, rifampin, etc.):
 - a) Provider acknowledges that prior to starting Oxbryta patient should be switched to a drug that does not interact with Oxbryta. If, and only if, this is not possible, provider should continue the CYP3A4 inducer and increase the dose of Oxbryta per the package insert.

Non-FDA-approved uses are not approved.

PA expires after 1 year.

Renewal PA criteria: PA will be approved indefinitely if:

- There is documented improvement in Hb by ≥ 1 g/dL from baseline
- OR
- The patient has demonstrated a decreased number of vaso-occlusive crises by ≥ 1 crisis/year from baseline in past 12 months

10. zanubrutinib (Brukinsa)

Manual PA criteria apply to all new users of Brukinsa.

Manual PA Criteria: Brukinsa will be approved if all criteria are met:

- Patient is \geq 18 years
- Prescribed by or in consultation with a hematologist/oncologist
- Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL).
- Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias
- Patient will use sun protection in sun-exposed areas
- Female patients of childbearing age and are not pregnant confirmed by (-) HCG.
- Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment
- Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment
- The diagnosis Is NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis:
_____.

Non-FDA approved uses are not approved.

PA does not expire.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- **New Drugs Recommended for UF or NF Status, and PA criteria:** An effective date upon the first Wednesday two weeks after signing of the minutes in all POS.
- **New Drugs Recommended for Tier 4 Status:** 1) An effective date of the first Wednesday after a 120-day implementation period at all POS; and 2)

DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation.

E. Physician's Perspective

- The Committee reviewed 16 new drugs, of which six were recommended for UF status, with seven recommended for NF status, and three Tier 4 candidates.
- Prior authorization criteria will apply to 10 of the drugs. These new drugs all belong in classes where PA is already required. “No grandfathering,” where both new and current users will be affected by the PA, is recommended for seven of the drugs.
- The three drugs recommended for Tier 4 status all contain active ingredients that are on the UF, and the Committee was unanimous in the vote here.
 - a) ProAir Digihaler is an albuterol formulation that has a Bluetooth connection to an App that tracks use of the inhaler and shows weather and pollen reports. However, no clinical studies were conducted with this product. Also there is no evidence that use of the App leads to improved clinical outcomes.
 - b) Enzoclear contains benzoyl peroxide foam in a prescription formulation, however it is not an FDA-approved drug, and has no additional clinical benefit relative to other agents for acne. The manufacturer can choose to market products as requiring a prescription, without undergoing the rigorous new drug application process for FDA-approved drugs. Although OTC benzoyl peroxide products are not part of the TRICARE pharmacy benefit, there are several prescription acne products on the formulary that have combinations of benzoyl peroxide with clindamycin.
 - c) Talicia is a triple-ingredient product (two antibiotics with a PPI) which is approved as a salvage regimen for treating *H. pylori* infections. Taking the individual products separately actually results in a lower tablet burden. Also it is less expensive for the patient to pay three generic co-pays rather than one nonformulary copay. We did receive input from GI specialists and internal medicine physicians who supported Tier 4 status.

G. Panel's Questions and Comments.

Mr. Hostettler asked for clarification on the language “when the PA expires, the next fill/refill will require submission of a PA” for the trifarotene 0.005% cream (Aklief). Does that mean that the next time it’s going to be filled, it’s going to require a PA? Or is that the end of the prescription that they’re currently on, has to be re-written, and that’s when it hits the PA?

LCDR Hall: It would be after that one year that it would require the resubmission of the PA. So it wouldn't be with each fill, it would be after that initial year.

The Panel had no more questions or comments. The Chair called for a vote on the UF Recommendation, PA Criteria and UF and PA Implantation Plan for the Newly Approved Drugs per 32 CFR 199.21(g)(5).

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

DR. ALLERMAN

P&T Comments

A. New Manual PA Criteria—Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for new and current users of sulfacetamide and combination products other than Klaron, Rosanil, Avar or generics; venlafaxine HCL ER 24 hr. tablets; and Zalvit (regardless of the woman's age), due to significant cost differences compared with the numerous available alternative agents. The details are discussed below.

1) Acne: Topical Acne and Rosacea Subclass—Sulfacetamide and sulfacetamide/sulfur products

Sulfacetamide sodium is an antibacterial agent used for acne and rosacea that exhibits a bacteriostatic effect. The addition of sulfur is theorized to increase effectiveness. Rosacea treatment guidelines list sulfacetamide/sulfur as a second-line agent for mild to moderate rosacea, and as a third-line agent for moderate to severe rosacea. Acne

treatment guidelines differ in their recommendations with regard to the efficacy of sulfacetamide sodium; however, there is a lack of evidence for sulfur.

There are various strengths and formulations of sulfacetamide alone (i.e. cream, foam, lotion, shampoo), as well as other combination products with sulfur and other ingredients, but none of these products are FDA-approved. The only FDA-approved product is a 10% lotion/suspension of sulfacetamide available under the trade name of Klaron; this is the most cost-effective single ingredient product, and the one most commonly used in the MHS. The most cost-effective combination product is sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar generics). The Committee recommended adding a manual PA to encourage use of the most common strengths of sulfacetamide 10% lotion/suspension (Klaron, generics) and sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar, generics), and to discourage use of all nonstandard dose sulfacetamide products. PA is not required for branded or generic formulations of Klaron, Rosanil, or Avar.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of sulfacetamide and sulfacetamide combination products.

Note: sulfacetamide 10% lotion/suspension (Klaron, generics) and sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar, generics) are available without requiring PA. Providers are encouraged to consider changing the prescription to these preferred sulfacetamide formulations.

Manual PA Criteria: Coverage for sulfacetamide and sulfacetamide combination products is approved if all criteria are met:

This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives
_____ (blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

**2) Antidepressants and Non-opioid Pain Syndrome Agents—
Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets**

Venlafaxine HCL ER 24 hr. tablets were first approved in 2008. There are

various generic manufacturers and the ER 24 hr. tablets are all significantly more costly than the ER 24 hr. capsules or immediate-release (IR) tablets. The venlafaxine ER 24 hr. tablets have fewer indications than the venlafaxine ER 24 hr. capsule (Effexor XR, generic) formulation. Equal doses of venlafaxine HCL ER 24 hr. tablets are bioequivalent to venlafaxine HCL ER 24 hr. capsules when administered under fed conditions but they do not carry an “AB-rating” for interchangeability to each other. The cost-effective venlafaxine formulations, HCL ER capsules (Effexor XR, generics) and venlafaxine HCL IR tablets, are available to patients without a PA. Manual PA was recommended for the venlafaxine HCL ER tablets, based on cost effectiveness.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of venlafaxine HCL ER 24 hr. tablets.

Note: venlafaxine ER capsules and venlafaxine IR tablets are available without requiring PA; providers are encouraged to consider changing the prescription to the preferred venlafaxine formulations: venlafaxine ER capsules, or venlafaxine IR tablets.

Manual PA Criteria: Coverage for venlafaxine HCL ER 24 hr. tablets is approved if all criteria are met:

This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives _____ (blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

3) Vitamin: Prenatal—Prenatal Vitamin (Zalvit)

Zalvit is a prenatal dietary supplement manufactured by a single manufacturer and requires a prescription prior to dispensing. The primary ingredients of Zalvit are 13 mg of iron and 1 mg of folic acid (similar to Azesco presented at August 2019 P&T Committee meeting). Certain prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than age 45 and do not require prior authorization criteria. This agent was identified as having numerous cost-effective alternatives (including Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin Plus Low Iron, and Prenatal Plus DHA) that are available on the UF, where a PA is not required.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of Zalvit, regardless of the woman's age.

Note: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco and Zalvit and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant.

Manual PA Criteria: Coverage for Azesco or Zalvit is approved if all criteria are met:

This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives
_____ (blank
write- in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

B. New Manual PA Criteria—Insulins: Rapid Acting Agents—generic insulin aspart (authorized generic for Novolog)

The Rapid Acting Insulins were reviewed for formulary status in November 2019, and branded Novolog is now step-preferred.

An authorized generic for Novolog entered the market in January 2020. An “authorized generic” is the brand company’s own product repackaged and marketed without the trade name. An authorized generic is considered therapeutically equivalent to the name brand drug because it is the same drug. The FDA does not consider authorized generics as AP-rated generic formulations. The insulin aspart authorized generic is less cost effective than the branded Novolog.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for new and current users requiring a trial of branded Novolog or branded Humalog, due to cost-effectiveness. The PA requirement will be removed when it is no longer cost advantageous.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of authorized generic insulin aspart.

Note: Brand Novolog or brand Humalog are the preferred rapid acting insulins and do not require PA.

Manual PA Criteria: Coverage for authorized generic insulin aspart is approved if all criteria are met:

The provider explains a patient-specific justification as to why the brand Novolog or brand Humalog product cannot be used (blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

**C. New Manual PA Criteria—Respiratory Agents Miscellaneous—
epinephrine auto injector (Auvi-Q)**

The Auvi-Q device includes audible voice instructions and has a needle that automatically retracts following injection. The Auvi-Q formulary status is Uniform Formulary. Manual PA criteria were recommended at the February 2017 P&T Committee meeting for all epinephrine devices, including Auvi-Q. Although Auvi-Q is significantly more expensive than both branded and generic Epi-Pen, the manual PA requirements were temporarily lifted at the August 2018 P&T Committee meeting due to national shortages of Epi-Pen, and intermittent availability of generic epinephrine auto-injectors. It now appears that the shortages of brand and generic Epi-Pen have resolved, and another product, a pre-filled syringe (Symjepi) was launched in May 2019. All we are recommending here is to re-instate the PA that was previously had on the Auvi Q.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) re- instating the manual PA criteria for epinephrine (Auvi-Q) auto-injector that were previously in place. The PA criteria will apply to new users only.

The manual PA criteria are as follows:

Manual PA criteria apply to all new users of epinephrine (Auvi-Q) auto-injector.

Note: Auvi-Q has been identified as having cost-effective alternatives including EpiPen, EpiPen generic, and Symjepi. These agents do not require PA.

Manual PA Criteria: Coverage for Auvi-Q is approved if all criteria are met:

The provider documents a patient-specific reason as to why the patient cannot use the formulary alternatives (blank write-in)

Non-FDA-approved uses are NOT approved.

PA does not expire.

D. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the following implementation periods:

- (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for sulfacetamide and combination products, venlafaxine HCL ER 24 hr. tablets, and the prenatal vitamin Zalvit will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.
- (16 for, 0 opposed, 0 abstained, 2 absent) Implementing the new PA for the authorized generic for insulin aspart will become effective upon signing of the minutes.
- (16 for, 0 opposed, 0 abstained, 2 absent) Re-instating the previous PA criteria for Auvi-Q in new users will become effective the first Wednesday 30-days after the signing of the minutes.

E. Physician's Perspective

There were five drugs from four classes where new PA criteria were recommended.

- **Topical Acne and Rosacea Subclass—Sulfacetamide and sulfacetamide/sulfur products:** Sulfacetamide-sulfur is available in several formulations, including topical suspensions, lotions, cleansers, creams, foams, and cleansing pads. Some of these formulations are very expensive. The Committee will not require a PA for the three most commonly used products, which are available in cleansers and a lotion. The PA will apply to all new and current users, with the provider explaining why the patient can't take the formulary alternatives. We will be mailing letters to the patients who will be affected by the new PA.
- **Antidepressants and Non-opioid Pain Syndrome Agents—Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets** This is another example of new formulations reaching the market that are significantly more costly than the original product, which in this case is Effexor extended release capsules or generic immediate release tablets. The intent of the PA is to encourage use of the cost-effective ER caps and IR tabs, and to discourage use of the expensive ER tabs. We will also be mailing letters to patients.

- **Prenatal Vitamin (Zalvit)** - This product is a prescription prenatal vitamin that is significantly more expensive than the other prescription prenatal vitamins. Prescription prenatal vitamins are part of the TRICARE pharmacy benefit, so having the PA is the most appropriate option to ensure this product is not used in the DoD. As of February 2020 we haven't had any utilization of Zalvit, and there are several formulary prenatal vitamins available.
- **Rapid Acting Insulins—generic insulin aspart (authorized generic for Novolog)**
 - a) We just reviewed the rapid acting insulins at the November 2019 P&T Committee meeting. The recommendation here is to prefer the branded Novolog product over the authorized generic. The authorized generic and the branded product all come from the same manufacturer, however the branded Novolog product is more cost effective than the authorized generic.
 - b) If the prescription is written for Novolog, the patient will receive Novolog. The patient will only be subject to the PA if the prescription is written for the authorized generic as “insulin aspart”. Both of these products are charged at the Tier 2 (brand) copay.
- **Epinephrine auto injector (Auvi-Q):** For Auvi-Q we are re-instating the PA that we originally had when the drug was marketed in 2017. The epi-pen shortage appears to have mostly resolved, and now there is another epinephrine injection on the market (Symjepi). Any patient currently receiving Auvi-Q will be grandfathered, so the PA will only apply to new patients.

G. Panel's Questions and Comments

Dr. Bertin commented that the discussion raises questions about procedure or process. In many of the cases, it states that the prescriber is required to provide an explanation as to why the product that was originally prescribed is necessary. Do the people who review these PAs have a specific list of acceptable reasons that can be used or some that are considered to be unacceptable? Or is it a subjective judgement call? Are these decisions made by trained health professionals? Can you give a little more explanation as to the review process that goes on?

Dr. Allerman responded it depends on the individual drug as to what patients fit the criteria and where it would be applicable. Did you have a specific case for a specific drug?

Dr. Bertin responded not necessarily. In general, do I assume that there are a bunch of different people who review these applications? I am just curious to the extent of the consistency that may or may not occur when the prescriber is simply providing a narrative rationale.

Dr. Allerman commented it is patient specific. It's hard to give generalities for all these different types of drugs that specifically fall under other drug classes. The individual Pharmacists reviewing the PA criteria will be able to look at the criteria submitted by the Physician. Based on their clinical skills and information, they will be able to make the recommendation to approve or deny.

Dr. Bertin clarified, it's a pharmacist who's making that decision?

Dr. Allerman responded, that is correct sir. These will all be reviewed by pharmacists.

Mr. Hostettler asked questions about the recommendation to put the PA for Auvi-Q back in place. The PA applies to new users only. Will patients prescribed Auvi-Q during the shortage remain on Auvi-Q indefinitely?

Dr. Allerman responded, that is correct sir. During the shortage when there is no prior authorization for Auvi-Q, any patient who is on Auvi-Q can stay on it indefinitely. It would just be a new patient who would be subject to the prior authorization.

Mr. Hostettler responded I work at a retail pharmacy and in my opinion, I don't believe the shortage has been resolved. I am skeptical about stating that the shortage has been resolved when my retail pharmacy has been placed on back-order twice when we placed orders for this product. Please elaborate on the process to monitor and quickly resolve the issue if shortages become a reoccurring problem.

Dr. Allerman responded the majority of the utilization is actually at the MTF and the mail order. We probably reach out daily to the Defense Logistics Agency (DLA) regarding this issue. In our opinion, the shortage mostly appears to be resolved. If we do find that there are procurement problems, we would actually act quickly and remove the PA requirement for Auvi-Q. As this action does not require BAP review and consideration, the BAP would be updated after it is done. We would not wait for approval to remove the PA in the situation of a shortage.

Mr. Hostettler repeated that he is not sure the problem has been resolved. The process/environment is a bit different for a patient receiving products at a MTF and those filling prescriptions at a retail pharmacy. What recourse does a pharmacist have if a patient fills a prescription at the retail pharmacy and the PA is still in place for Auvi-Q? As previously stated, I work in a retail pharmacy and we use the same wholesaler as the MTF in town uses. When the retail pharmacy experiences problems getting drugs, I assume the MTF is experiencing the same problem. I am concerned the problem is not resolved and I encourage the P&T Committee to closely monitor the situation on the Auvi-Q. There were no more Panel Questions of Comments. The Chair called for a vote

on the New Manual PA Criteria and New Manual PA Criteria Implementation Plan.

- **New Manual PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **New Manual PA Criteria—Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

V. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

DR. ALLERMAN

P&T Comments

A. Updated Manual PA Criteria

Updates to the manual PA criteria and step therapy for several drugs were recommended due to a variety of reasons, including clinical trial data, new dosing for FDA indications, age indications, new FDA-approved indications, and cost-effective alternative treatments being available. The updated PAs and step therapy outlined below will apply to new users with the exception of doxycycline (Oracea) which will apply to new and current users.

The updates are as follows:

- 1) **Migraine Agents: Calcitonin Gene-related Peptide (CGRP) Preventatives—erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm (Emgality)**—Manual PA criteria for Aimovig, Ajovy, and Emgality were originally recommended at the August 2018 and November 2018 P&T meetings. The PAs for all the CGRP inhibitors were updated at the February 2019 P&T meeting and do not allow concurrent use with botulinum toxin; additionally the patient must not have received a botulinum toxin injection within 2 months of receiving a CGRP inhibitor.

The Committee considered whether to remove the prohibition of concurrent use with botulinum toxin. The Committee reviewed the data, which included comments from the American Migraine Foundation, the 2018 American Headache Society Consensus Statement on Initiation of CGRP antagonists, and a Neurology Times article. The available adverse event (AE) data suggests

that there are minimal interactions between CGRPs and botulinum toxin. There is limited information on the effectiveness of concurrent use of CGRPs with botulinum toxin, as a portion of the patients experienced some benefit and others demonstrated no benefit or even an increased frequency of migraines. More data is needed to make a definitive conclusion on the benefit or harm of concurrent use. The service specialists were also contacted, and their recommendation was to remove this particular criterion. The Manual PA criteria for Aimovig, Ajovy, and Emgality were updated to remove the requirement to not allow concurrent use with botulinum toxin.

- 2) Antilipidemic 2's-omega-3 fatty acids—icosapent ethyl (Vascepa)—** Manual PA criteria for Vascepa were updated to reflect a new indication for CV outcome reduction (i.e., to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization). Patients will be required to meet the study inclusion criteria from the REDUCE-IT trial published in the New England Journal of Medicine. For patients with hypertriglyceridemia and triglyceride (TG) levels ≥ 500 mg/dL, who have tried and failed generic Lovaza prior to use of Vascepa. Concurrent use of Vascepa with Lovaza will not be allowed. PA criteria will apply to all new users of Vascepa.
- 3) Targeted Immunomodulatory Biologics (TIBs): tofacitinib (Xeljanz XR)—** Manual PA criteria for Xeljanz and Xeljanz XR were updated to reflect the new dosage strengths of 11 mg XR and 22 mg XR tablets administered once daily for treatment of ulcerative colitis (UC). Previously the only approved dosing regimens were 5 mg and 10 mg twice daily.
- 4) Pulmonary 1's-Pulmonary Miscellaneous: mepolizumab (Nucala)—** Manual PA criteria for Nucala were updated to remove the age requirement for the eosinophilic asthma indication. The FDA recently lowered the age indication to ≥ 6 years for patients with eosinophilic asthma. The Manual PA criteria and age indication for eosinophilic granulomatosis with polyangiitis (EPGA) will not change and will remain limited to patients ≥ 18 years, consistent with the package insert.
- 5) Basal Insulins: insulin glargine U-300 (Toujeo)—** Manual PA criteria for Toujeo were updated to reflect a new pediatric indication to improve glycemic control in patients with diabetes mellitus ≥ 6 years.
- 6) Corticosteroids: Immune Modulators—deflazacort (Emflaza)—** Manual PA criteria for Emflaza were updated to reflect a lowered age indication to ≥ 2 years for patients with Duchenne muscular dystrophy (DMD).
- 7) Acne Agents: Tetracyclines—doxycycline monohydrate IR/ER 40 mg capsules (Oracea)—** Manual PA criteria for Oracea were last updated during the Tetracyclines class review at the February 2017 P&T Committee meeting.

Treatment guidelines for papulopustular rosacea list oral doxycycline as a second-line therapy option following topical medications. Oracea branded and generic formulations are much less cost effective than the immediate release (IR) formulation of doxycycline. The FDA-approved label for Oracea also states that efficacy beyond 16 weeks and safety beyond 9 months have not been established. The Oracea PA was updated to require the provider to document why the patient cannot be treated with the cost-effective formulary alternatives.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the updates to the manual PA criteria for Aimovig, Ajoyv, Emgality, Xeljanz, Xeljanz XR, Nucala, Toujeo, Emflaza, Vascepa, and Oracea.

B. Updated Manual PA Criteria—Implementation Plan

The P&T Committee recommended the following implementation periods:

- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria for Aimovig, Ajoyv, Emgality, Xeljanz, Xeljanz XR, Nucala, Toujeo, Emflaza, and Vascepa in new users will become effective the first Wednesday 60-days after the signing of the minutes.
- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria for Oracea brand and generics in new and current users will become effective the first Wednesday 90-days after the signing of the minutes.

C. Physician's Perspective

- At every meeting, we present updates to drugs with existing PAs to ensure the latest FDA indications or safety updates are included in our criteria. These updates to the existing PAs will only affect new patients, with one exception, Oracea. Here, we had updates for seven drug classes; most of the changes were to allow use in expanded patient populations, for example pediatric patients for four drugs.
- For the fish oil product (Vascepa), the PA will be similar to the patient enrollment criteria from the study that was used to gain FDA approval for reducing cardiovascular outcomes. For patients who do not meet the criteria for CV outcomes, they will be required to try Lovaza first, to reduce triglyceride levels.
- For the acne drug Oracea, we are strengthening the PA, because the generics are significantly less costly, and there is no difference in efficacy or safety. We are taking the approach of changing the PA, rather than making this a Tier 4 product for now. Both new and current users are affected, so patients will be receiving letters.

G. Panel's Questions and Comments

Mr. Hostettler asked what are the formulary alternatives for Oracea?

LCDR Hall responded we do have some different versions of doxycycline that are generic including the 100 mg dose. We also have a 20 mg IR dose that can be used. So the thought is there is dosing for Oracea where you use a lower dose of sub anti-microbial dosing. That can be achieved either with the Oracea 40 mg once daily or using the other 20mg twice daily and then the traditional dosing is 50-100 mg twice daily is another option as well.

Mr. Hostettler asked if the 50 and 100 mg have the indication.

LCDR Hall responded they are used commonly with guidelines. A lot of professionals do use these doxycycline products for these indications. They may be using them off label but it is a common practice.

Mr. Hostettler commented there appears to be no consistent process or guidance for following the indication. There are times when the indications are strictly followed and in other situations they are not.

LCDR Hall thanked Mr. Hostettler for the comments. I know some of these medications are older may not go back and seek out other indications later but I do appreciate your comments.

Mr. Hostettler noted that the 90-day implementation plan but it does not state that letters will be sent to new and current users of Oracea. How many patients are impacted by the recommendation?

LCDR Hall apologized because the number was add to the last table. It's about 994 patients would be affected.

There were no more questions or comments from the Panel. The Chair called for a vote on PA Criteria and Implementation Plan for the Updated PA Criteria.

- **Updated PA Criteria**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Updated PA Criteria—Implementation Plan**

Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

VI. RE-EVALUATION OF NONFORMULARY GENERICS

DR. ALLERMAN

P&T Comments

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The P&T Committee's process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, TRICARE Management Agency (TMA), on July 24, 2007. A summary of the criteria is available in Appendix E of the November 2012 P&T Committee minutes.

A. Antidepressant-1s (AD-1s) and Non-Opioid Pain Syndrome Drugs: pregabalin (Lyrica)

Lyrica has been designated as NF and non-step-preferred since the AD-1 drug class review in November 2011. Step therapy requires a trial of gabapentin (generic Neurontin) and duloxetine (generic Cymbalta) prior to use of Lyrica. The P&T Committee re-evaluated the formulary status of Lyrica due to price reductions in generic pregabalin formulations available across all three points of service. New clinical information comparing pregabalin with gabapentin was reviewed. Current utilization trends, numbers of generic products on the market, and relative cost-effectiveness, including the weighted average cost per unit for generic pregabalin (Lyrica) were also reviewed. The unit cost of generic pregabalin formulations has dropped significantly from the previous generic and brand cost, and the generic supply appears stable, as 13 manufacturers are producing product.

Pregabalin (Lyrica) Formulary Status, PA recommendation and implementation—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- Returning pregabalin (Lyrica, generics) to formulary status.
- Removing the current step-therapy and manual PA requirements for pregabalin.
- An effective date the first Wednesday 30 days after signing of the minutes

B. AD-1s: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs): desvenlafaxine succinate ER (Pristiq) and desvenlafaxine ER

Desvenlafaxine succinate ER (Pristiq) and desvenlafaxine ER are NF, with step therapy requiring an initial trial of venlafaxine ER. The Desvenlafaxine ER product

was approved under a New Drug Application (NDA) and is considered a brand agent, with no generics available; a previously available desvenlafaxine ER product (Khedezla) has been discontinued. As of Nov 2019, generic desvenlafaxine succinate ER is available from multiple manufacturers and the weighted average cost across DoD POS is lower than that for venlafaxine ER. The P&T Committee also noted that, although the weighted average cost for the branded Desvenlafaxine ER products was much higher than venlafaxine ER or desvenlafaxine succinate ER (generic Pristiq), utilization was very low (fewer than 300 30-day equivalent Rxs over a 90-day period)

Desvenlafaxine succinate ER (Pristiq) Formulary Status, PA recommendation and implementation—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- Returning desvenlafaxine succinate ER (Pristiq, generics) to UF status.
- Making no changes to the formulary status for the branded Desvenlafaxine ER product, which will remain NF.
- Removing the step therapy requirement for both desvenlafaxine succinate ER (Pristiq, generics) and Desvenlafaxine ER.
- An effective date the first Wednesday 30 days after signing of the minutes at all points of service.

C. Physician's Perspective

- For Lyrica, generic formulations were launched in July 2019, but the pricing has now dropped enough to return it to formulary status. We are also removing the PA requirements for this drug. With this action, approximately 29,000 beneficiaries will now see their copay decrease, and new patients will not have to complete the PA.
- The same applies to Pristiq, as it will move back to formulary status, without a PA. This action will benefit the 7,500 patients currently on this drug.
- Both of these drugs are examples where we continually monitor pricing when generics become available for non-formulary drugs, and respond accordingly. This will result in patients only having to pay the generic copay, and providers will not have the hassle of the PA.

D. Panel Questions and Comments.

- Mr. Hostettler clarified the generics for pregabalin came on the market in the summer of 2019.

- Dr. Allerman responded that is correct. Unfortunately, sometimes it would take several months for the generics to have a significant decrease in price. We have been monitoring the price of generics for several months and now they have dropped significantly. We will recommend returning it to formulary status.
- Mr. Hostettler clarified it wasn't one of those authorized generics holding the price down?
- Dr. Allerman responded is not a situation of an authorized generic. There's at least 13 different manufacturers available, so it is a stable supply and it's cost-effective.
- Mr. Hostettler responded I wanted to commend you on getting that to the beneficiaries as soon as you possibly can.

There were no more questions or comments from the Panel. The Chair called for a vote on the Pregabalin (Lyrica) and desvenlafaxine succinate ER (Pristiq) formulary status, PA recommendation and implementation plan for the Re-evaluation of Nonformulary Generics.

- **Pregabalin (Lyrica) and desvenlafaxine succinate ER (Pristiq) formulary status, PA recommendation and implementation plan.**

Concur: 7

Non-Concur: 0

Abstain: 0

Absent: 0

VII. INFORMATIONAL ITEM—PRENATAL LEGEND VITAMINS MOVING TO OTC STATUS

DR. ALLERMAN

In November 2019, First Databank moved several legend Prenatal Vitamin preparations to the status of legend Multivitamin preparations. Prenatal vitamins are required to have ingredients containing folic acid 400 mcg; vitamin D 10 mcg/400 units; and iron 27mg (or Low/No iron products with 0 to 26 mg of iron). Several vitamin combinations that do not contain the adequate ingredients for classification as prenatal vitamins or are not labeled as prenatal vitamins are affected. Due to the CFR 199.4 regulations for coverage of vitamins, the products moving to multivitamin status will no longer be covered under the TRICARE pharmacy benefit.

Patients impacted by this change at the Mail, Retail, and MHS GENESIS sites will receive letters in February 2020, and the products will be removed from the Pharmacy Benefit on April 1, 2020.

Panel Questions and Comments

Mr. Hostettler inquired about the number of patients impacted by the recommendation

for the information provided on the prenatal vitamins. Will they receive a letter notifying them of the change?

Dr. Allerman stated there were approximately 400 patients impacted by the decision. Those patients did receive a letter back in February regarding this change.

(Note that BAP Comments are not required for the informational item)

Closing Remarks

Dr. Khoury provides a summary of the meeting. We reviewed three subclasses, 16 new drugs, and several utilization management actions. Overall, these NF and Tier 4 recommendations will impact 0.04% of our 9.5M beneficiaries, while we expect several actions to result in over 36K beneficiaries experiencing a copay reduction.

Mr. Ostrowski thanked Col Hoerner and everyone for participating as well as Lt Col Khoury for his comments. This was a great day and a challenging one but we did it.

Meeting Adjourned at 2:40 p.m.



Mr. Jon Ostrowski
UF BAP Co-Chairperson

Appendices:

- Appendix I – Brief list of Acronyms used in this Summary
- Appendix II – Information Item – Summary of Recommendations and Beneficiary Impact

BRIEF LISTING OF ACRONYMS USED IN THIS SUMMARY

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in the Panel discussions are listed below for easy reference. The term “Pan” in this summary refers to the “Uniform Formulary Beneficiary Panel,” the group who’s meeting in the subject of this report.

- AAOS – American Academy of Orthopedic Surgeons
- AD-1s – Antidepressant
- AHRQ – Agency for Healthcare Research and Quality
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- CMA – Cost- Minimization Analysis
- CR – Controlled Release
- CV – Cardiovascular
- FDA – Food and Drug Administration
- FMB – Formulary Management Branch
- GI – Gastrointestinal
- MHS – Military Health System
- MS – Multiple Sclerosis
- NCCN – National Comprehensive Cancer Network
- NF – Nonformulary
- NICE – National Institutes for Health and Care Excellence
- NSAID – Nonsteroidal Anti-inflammatory Drugs
- OARSI – Osteoarthritis Research Society International
- ODT – Orally Disintegrating Tablet
- PA – Prior Authorization
- POD – Pharmacy Operation Division
- PPI – Proton Pump Inhibitor
- RLE – Real-Life Experience
- TMA – Tricare Management Agency
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- XR – Extended Release

INFORMATION ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT

Table of implementation Status of UF Recommendations/Decisions Summary February 2020

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
Pain Agents: Nonsteroidal Anti-Inflammatory Drug Subclass	<ul style="list-style-type: none"> ▪ celecoxib ▪ diclofenac/misoprostol ▪ diclofenac potassium ▪ diclofenac sodium ▪ diflunisal ▪ etodolac ▪ flurbiprofen ▪ ibuprofen 400 mg, 600 mg & 800 mg ▪ indomethacin IR 25 mg & 50 mg ▪ indomethacin ER 75mg ▪ indomethacin rectal suppository ▪ ketorolac tablets ▪ meloxicam 7.5 mg & 15 mg ▪ nabumetone ▪ naproxen 250 mg & 500 mg ▪ naproxen 125mg/5ml oral suspension ▪ naproxen IR 375 mg ▪ naproxen delayed release (DR) 375 mg & 500 mg ▪ naproxen sodium 275 mg & 550 mg ▪ oxaprozin ▪ piroxicam ▪ sulindac ▪ mefenamic acid 250 mg (generic Ponstel) (moves from NF to UF) 	<ul style="list-style-type: none"> ▪ diclofenac potassium powder packets 50 mg (Cambia) ▪ fenoprofen tablets (moves from UF to NF) ▪ indomethacin oral suspension (moves from UF to NF) ▪ ketoprofen (moves from UF to NF) ▪ ketorolac nasal spray (Sprix) ▪ meclofenamate (moves from UF to NF) ▪ meloxicam ODT (Qmiiz) ▪ naproxen sodium ER (Naprelan, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card ▪ tolmetin (moves from UF to NF) 	<ul style="list-style-type: none"> ▪ amlodipine/c celecoxib (Consensi) ▪ diclofenac potassium liquid-filled capsules (Zipsor) ▪ diclofenac submicronized (Zorvolex) ▪ fenoprofen capsules (moves from UF to Tier 4) ▪ ibuprofen/famotidine tablets (Duexis) ▪ indomethacin submicronized (Tivorbex) 	Pending signing of the minutes / 120 days	<p><u>Unique Users Affected (NF candidates) Mail – 90</u> MTF – 5 Retail – 166 Total – 261</p> <p><u>Unique Users Affected (Tier 4 candidates) Mail – 447</u> MTF – 38 Retail – 559 Total – 1,044</p> <p>NF and Tier 4 candidates represent 0.16% of all NSAID UUs</p>
Pain Agents: Topical Pain Subclass	<ul style="list-style-type: none"> ▪ diclofenac 1% gel (Voltaren generic) ▪ diclofenac 1.5% solution (Pennsaid 1.5% generic) ▪ lidocaine 5% patch (Lidoderm generic) 	<ul style="list-style-type: none"> ▪ None 	<ul style="list-style-type: none"> ▪ diclofenac 2% solution (Pennsaid 2%) ▪ diclofenac 1.3% patch (Flector) ▪ lidocaine 1.8% patch (ZTlido) 	Pending signing of the minutes / 120 days	<p><u>Unique Users Affected (Tier 4 candidates) Mail – 946</u> MTF – 379 Retail – 1871 Total – 3197</p> <p>Tier 4 candidates represent 1.5% of all Topical Pain UUs</p>

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
Prenatal vitamin (Zalvit)	0	0	0	0
Acne: Topical Acne and Rosacea subclass— Sulfacetamide and sulfacetamide/sulfur products	252	616	1,562	2,430
Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets	775	2,598	1,996	5,369
Insulins: Rapid Acting Agents—generic insulin aspart (authorized generic for Novolog)	0	0	0	0