DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA), on formulary status, prior authorization, pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS—RENIN-ANGIOTENSIN ANTIHYPERTENSIVES (RAAs)

P&T Comments

A. RAAs: Sacubitril/Valsartan (Entresto)—Relative Clinical Effectiveness and Conclusion

Entresto is a fixed-dose combination product approved for treating patients with chronic heart failure with reduced ejection fraction. It contains the angiotensin receptor blocker (ARB) valsartan (Diovan, generic) with sacubitril, a neprilysin inhibitor.

FDA approval was based on the results of the PARADIGM trial, which compared Entresto with the angiotensin converting enzyme (ACE) inhibitor enalapril (Vasotec, generic) in over 8,000 patients for 27 months. Treatment with Entresto resulted in a significant 20% relative risk reduction in the rate of death due to cardiovascular causes or hospitalization for heart failure compared to enalapril. The relative risk of all-cause death was reduced by 16% with Entresto.

Limitations to the PARADIGM study included the strict entry criteria (patients who could not tolerate target doses of ARBs or ACE inhibitors, and those with hypotension, reduced renal function, or a history of angioedema were excluded) and the enrollment of small numbers of African Americans and women.

Adverse effects associated with Entresto that occurred more frequently than enalapril were angioedema, particularly in African Americans, and hypotension. Theoretical risks of Entresto contributing to dementia are unknown at this time; the manufacturer is required to conduct studies in this area.

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that Entresto showed benefit in the limited patient population studied in the PARADIGM trial. Whether patients with chronic heart failure who are currently stabilized on ACE inhibitors/ARBs should be switched to Entresto remains to be determined.

B. RAAs: Sacubitril/Valsartan (Entresto)—Relative Cost-Effectiveness Analysis and Conclusion

Cost minimization analysis (CMA) was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed the following rankings from most to least cost-effective for the UF after step therapy scenario: losartan (Cozaar, generic), enalapril (Vasotec, generic), valsartan (Diovan, generic), candesartan (Atacand, generic), valsartan/sacubitril (Entresto), ivabradine (Corlanor).

C. RAAs: Sacubitril/Valsartan (Entresto)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) sacubitril/valsartan (Entresto) be designated formulary on the UF based on the clinical results of the PARADIGM trial.

D. RAAs: Sacubitril/Valsartan (Entresto)—Prior Authorization (PA) Criteria

There is existing step therapy in the RAAs class requiring use of an ACE inhibitor or losartan, telmisartan, or valsartan prior to use of one of the non-preferred RAAs drugs. Step-therapy and manual PA criteria for Entresto were recommended in February 2016, with an implementation date of August 10, 2016.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) revising the PA criteria for Entresto since it is solely indicated for heart failure and not hypertension. The PA criteria will now require use of a step-preferred ARB for heart failure (losartan or valsartan) or a generic ACE inhibitor prior to use of Entresto in new and current users. Additionally, the Entresto PA criteria will reflect the study population from the PARADIGM trial, including patients with a left ventricular ejection fraction less than or equal to 35%, New York Heart Association Class II–IV chronic heart failure, receiving concomitant treatment with a beta blocker, and patients with no history of angioedema.

<u>Full PA Criteria</u>:

The criteria below will replace the criteria recommended at the February 2016 meeting. Updates are bolded.

Manual PA criteria apply to all new and current users of sacubitril/valsartan (Entresto).

<u>Manual PA criteria</u>: Coverage is approved for Entresto if all of the following criteria apply:

- **The initial prescription is written by a cardiologist.**
- The patient is at least 18 years of age.
- Documented diagnosis of chronic heart failure (New York Heart Association class II-IV) with a left ventricular ejection fraction < 35% with continued heart failure symptoms.

- Receiving concomitant treatment with a β-blocker that has been shown to have a survival benefit in heart failure, at maximally tolerated doses
    1. metoprolol succinate ER 200 mg QD; carvedilol 25 mg BID or 50 mg BID if > 85 kg; carvedilol ER 80 mg QD; bisoprolol 10 mg QD

  OR
- The patient has a contraindication to a β-blocker
    1. Hypersensitivity, cardiogenic shock or overt cardiac failure, 2nd or 3rd degree heart block, asthma, COPD
- **Patient has been stable on any ACE inhibitor or preferred ARB shown to have benefit in heart failure (losartan, valsartan) for at least 4 weeks at maximally tolerated doses**
- Patient does not have a history of angioedema due to ACE inhibitor or ARB

  Prior Authorization does not expire

E. RAAs: Sacubitril/Valsartan (Entresto)—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 60-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

III. RECENTLY APPROVED FDA AGENTS—RENIN-ANGIOTENSIN ANTIHYPERTENSIVES (RAAs)

BAP Comments

A. RAAs: Sacubitril/Valsartan (Entresto)—UF Recommendation

The P&T Committee recommended Entresto be designated formulary on the UF.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. RAAs: Sacubitril/Valsartan (Entresto)—PA Criteria

The P&T Committee recommended revising the PA criteria for Entresto since it is solely indicated for heart failure and not hypertension. The PA criteria will now require use of a step-preferred ARB for heart failure (losartan or valsartan) or a generic ACE inhibitor prior to use of Entresto in new and current users. Additionally, the Entresto PA criteria will reflect the study population from the PARADIGM trial.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

C. RAAs: Sacubitril/Valsartan (Entresto)—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

IV. RECENTLY APPROVED FDA AGENTS—GASTROINTESTINAL-2 (GI-2) MISCELLANEOUS DRUGS

P&T Comments

A. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—Relative Clinical Effectiveness and Conclusion

The P&T Committee previously reviewed the GI-2 Miscellaneous Drugs in November 2015. Eluxadoline is indicated to treat diarrhea-predominant irritable bowel syndrome (IBS-D) and has a novel mechanism of action compared to alosetron and rifaximin. Guidelines for IBS-D recommend that providers should consider offering antispasmodic agents along with dietary and lifestyle advice for patients.

Eluxadoline was compared to placebo in two randomized controlled trials. The results showed statistical significance in improving the composite endpoint and stool consistency, but not abdominal pain. Clinical significance is difficult to determine due to the large placebo effect.

Common adverse reactions of eluxadoline include constipation and abdominal pain. Because of the potential for abuse, eluxadoline is a Schedule IV controlled substance. Limitations to use of eluxadoline include numerous drug interactions, contraindications, and lack of long-term safety data.

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that despite a unique mechanism of action, eluxadoline offers no compelling advantages over existing formulary agents used to treat IBS-D.

B. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: rifaximin (Xifaxan), eluxadoline (Viberzi), alosetron (Lotronex).

C. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) eluxadoline (Viberzi) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term data, and cost disadvantage compared to other UF agents used for IBS-D.

D. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—PA Criteria

Prior authorization was approved for eluxadoline (Viberzi) in February 2016, with an implementation date of August 10, 2016. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updating the current PA criteria for to include the requirement that the initial prescription be written by a gastroenterologist and the patient has failed a trial of rifaximin.

Full PA Criteria:

Manual PA criteria apply to all new users of eluxadoline (Viberzi). Updates to the Manual PA criteria recommended at the February 2016 meeting are bolded.

Manual PA criteria: Coverage will be approved if:

- **Initial prescription written by gastroenterologist; AND**
- The patient is ≥ 18 years; AND
- Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink ≤ 3 alcoholic beverages per day; AND
- Patient has no history of marijuana use or illicit drug use in the previous 6 months; AND
- Patient does not have severe hepatic impairment (Child-Pugh C); AND
- Patient has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D);

AND

  - The patient has had failure, intolerance, or contraindication to at least one antispasmodic agent; e.g., dicyclomine (Bentyl), Librax, hyoscyamine (Levsin), Donnatal, loperamide (Imodium)

AND

- The patient has had failure, intolerance, or contraindication to at least one tricyclic antidepressant (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline

AND

- **The patient has failed a trial of rifaximin**

- Non-FDA approved uses are not approved.
- Prior authorization does not expire.

E. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—UF Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent)
1) an effective date of the first Wednesday after a 90-day implementation period; and,
2) DHA send a letter to beneficiaries affected by the UF decision.

V. RECENTLY APPROVED FDA AGENTS—GASTROINTESTINAL-2 (GI-2) MISCELLANEOUS DRUGS

BAP Comments

A. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—UF Recommendation

The P&T Committee recommended Viberzi be designated NF.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—PA Criteria

The P&T Committee recommended updating the current PA criteria for to include the requirement that the initial prescription be written by a gastroenterologist and the patient has failed a trial of rifaximin.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

C. GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment:	☐ Concur	☐ Non-concur
		Additional Comments and Dissention

VI. UF CLASS REVIEWS—ATYPICAL ANTIPSYCHOTIC (AAP) DRUGS

P&T Comments

A. AAP Drugs—Relative Clinical Effectiveness and Conclusion

The P&T Committee evaluated the AAP drugs. Since the last review in May 2011, generic formulations of several products are now available. The remaining branded AAP drugs include quetiapine extended release (Seroquel XR), asenapine (Saphris), iloperidone (Fanapt), and lurasidone (Latuda). Generic formulations for Seroquel XR are expected in November 2016. Brexpiprazole (Rexulti) and cariprazine (Vraylar) are two new products in the class. Vraylar is an innovator drug; however, it is included in this review.

The P&T Committee concluded (15 for, 0 against, 0 abstained, 1 absent) the following for the AAP drugs:

- Brexpiprazole (Rexulti) is FDA-approved to treat schizophrenia, and as an adjunct to antidepressant therapy for MDD. Cariprazine (Vraylar) is FDA-approved for schizophrenia and bipolar disorder. Brexpiprazole and cariprazine offer no clinically compelling advantages over the AAP drugs currently on the UF.
- There are no significant efficacy or safety updates since the May 2011 review. The safety profiles of individual AAP drugs are well known, in terms of metabolic, neurologic, and cardiovascular effects. Cariprazine has an active metabolite with a long half-life of one to three weeks that may extend adverse effects in those affected.
- According to the German Institute for Quality and Efficiency in Health Care, manufacturer claims of added benefit for fewer adverse events with lurasidone compared to risperidone, olanzapine, and quetiapine extended release (ER) could not be proven. However, lurasidone is dosed once daily and is rated as Pregnancy Category B.

- Generic formulations of AAP drugs currently on the UF are adequate to meet the needs of the majority of DoD patients with schizophrenia, bipolar disorder, or MDD requiring adjunctive therapy.
- For patients requiring an AAP drug, treatment choice should be based on efficacy, safety and tolerability of the drug, and individual patient characteristics.

B. AAP Drugs—Relative Cost-Effectiveness Analysis and Conclusion

CMA and budget impact analysis (BIA) were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed the following rankings for the AAP drugs from least costly to most costly to the MHS: risperidone, ziprasidone, quetiapine, Risperdal, olanzapine, Seroquel XR, generic aripiprazole, Saphris, Latuda, Fanapt, Rexulti, and Vraylar.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. All modeled scenarios show cost avoidance against current MHS expenditures; however, the scenario where lurasidone was added to the UF was the most cost-effective option.

C. AAP Drugs—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **UF:**
  - aripiprazole tablets, orally dissolving tablet (ODT), and oral solution (Abilify, Abilify Discmelt, generics)
  - clozapine tablets and orally dissolving tablets (Clozaril, generics; FazaClo ODT)
  - lurasidone (Latuda)
  - olanzapine tablets and ODT (Zyprexa, Zyprexa Zydis, generics)
  - olanzapine/fluoxetine (Symbyax, generics)
  - paliperidone (Invega, generics)
  - quetiapine (Seroquel, generics)
  - quetiapine ER (Seroquel XR)
  - risperidone tablets, ODT, and oral solution (Risperdal, Risperdal ODT, generics)
  - ziprasidone (Geodon, generics)
- **NF**
  - asenapine (Saphris)
  - brexpiprazole (Rexulti)
  - cariprazine (Vraylar)
  - iloperidone (Fanapt)

D. AAP Drugs—Manual PA Recommendation

Manual PA criteria for brexpiprazole (Rexulti) in all new patients were recommended at the February 2016 P&T Committee meeting, with an implementation date of August 10, 2016. The P&T Committee recommended (15 for, 0 against, 0 abstained, 1 absent) maintaining the existing PA criteria for Rexulti, which require a trial of at least two other AAPs, including aripiprazole, prior to use of Rexulti.

Full PA Criteria:

No change from February 2016.
All new users of brexpiprazole (Rexulti) are required to undergo manual prior authorization criteria.

Manual PA criteria: Coverage will be approved if:

- Diagnosis of Major Depressive Disorder
  - The patient is ≥ 18 years; AND
  - The patient has had treatment failure of at least two other antidepressant augmentation therapies (one of which must be aripiprazole); OR
  - Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti) AND
  - Patient has concurrent use of an antidepressant

- Diagnosis of schizophrenia
  - The patient is ≥ 18 years; AND
  - The patient has had treatment failure of at least two other atypical antipsychotics (one of which must be aripiprazole); OR
  - Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti)

- Non-FDA approved uses are not approved.

Prior Authorization does not expire.

E. AAP Drugs—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

VII. UF CLASS REVIEWS—ATYPICAL ANTIPSYCHOTIC (AAP) DRUGS

BAP Comments

A. AAP Drugs—UF Recommendation

The P&T Committee recommended the following:

- **UF**
  - generic Abilify, tablets, orally dissolving tablets, and oral solution
  - generic Clozril tablets and FazaClo orally dissolving tablets
  - Latuda
  - generic Zypreza tablets and orally dissolving tablets
  - generic Symbyax
  - generic Invega
  - generic Seroquel
  - Seroquel XR
  - generic Risperdal tablets, orally dissolving tablets, and oral solution
  - generic Geodon

- **NF**
  - Saphris
  - Rexulti
  - Vraylar
  - Fanapt

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. AAP Drugs—Manual PA Recommendation

The P&T Committee recommended maintaining the existing manual PA criteria for Rexulti.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

C. AAP Drugs—UF and PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment:	☐ Concur	☐ Non-concur
		Additional Comments and Dissention

VIII. UF CLASS REVIEWS—ANTICONVULSANT AND ANTI-MANIA DRUG CLASS

P&T Comments

A. Anticonvulsant and Anti-Mania Drug Class—Relative Clinical Effectiveness and Conclusion

There are over 40 anti-epileptic drugs (AEDs) available in the United States. Most are available in generic formulations, and several products now have ER versions. Five of the AEDs are unique, branded products with no generic or therapeutic equivalents: lacosamide (Vimpat), perampanel (Fycompa), clobazam (Onfi), vigabatrin (Sabril), and rufinamide (Banzel). Five other products are branded formulations with therapeutic alternatives: topiramate ER (Trokendi XR and Qudexy XR), oxcarbazepine ER (Oxtellar XR), eslicarbazepine (Aptiom), and carbamazepine (Equetro ER).

The clinical effectiveness review focused on the efficacy and safety of the branded products and the newer extended release AEDs. The older AEDs and anti-mania drugs will remain on the UF.

The P&T Committee concluded (15 for, 0 against, 0 abstained, 1 absent) that:

- Topiramate IR (Topamax, generic) is approved for several types of seizure disorders and for prophylaxis of migraine headaches. Off-label uses for topiramate IR include weight loss, bipolar disorder, alcohol dependency, obsessive compulsive disorder, and post-traumatic stress disorder. The newer topiramate ER products, Trokendi XR and Qudexy XR, do not offer clinically compelling advantages over generic topiramate IR.
- Lacosamide (Vimpat) has a unique mechanism of action at the sodium channels, is well tolerated except for dizziness and somnolence, is easy to titrate, and is approved for partial-onset seizures in patients 17 years and older. An oral solution and tablets are available.
- Perampanel (Fycompa) has a unique mechanism of action at the glutamate receptor. Its place in therapy is for refractory patients with secondary generalized seizures. Fycompa is the only AED with a black box warning for hostility, aggression, and homicidal ideation. Its long duration of action can prolong adverse effects of sedation, headache, and dizziness.
- Clobazam (Onfi) is indicated as adjunctive therapy for Lennox-Gastaut seizures in patients as young as two years old. The compound causes less sedation than

typical benzodiazepines, due to receptor selectivity. It is primarily used in pediatric patients with refractory seizures.

- Vigabatrin (Sabril) is approved for infantile spasms in patients as young as one year old. The risk of vision loss associated with Sabril requires restricted distribution and enrollment in a patient registry.
- Rufinamide (Banzel) is approved for Lennox-Gastaut seizures in children as young as one year old, but there are concerns of shortened QT interval and risk of inducing status epilepticus.
- When used for the appropriate seizure type, the AEDs are roughly equivalent in efficacy. Clinical guidelines indicate that a variety of medications are required be available to treat seizures effectively.
- AED treatment selection should be based on drug characteristics, including side effect profile, ease of administration, potential drug interactions, as well as patient characteristics, including seizure type and epilepsy syndrome.

B. Anticonvulsant and Anti-Mania Drug Class—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that generic products in the class were the most cost-effective, followed by brand carbamazepine ER (Equetro), oxcarbazepine ER (Oxtellar XR), levetiracetam ER (Keppra XR), lacosamide (Vimpat), topiramate ER (authorized generic), topiramate ER (Trokendi XR), perampanel (Fycompa), topiramate ER (Qudexy XR), clobazam (Onfi), eslicarbazepine (Aptiom), rufinamide (Banzel), and vigabatrin (Sabril).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating all agents in the Anticonvulsant and Anti-Mania Drug Class with formulary status on the UF demonstrated significant cost avoidance for the MHS.

C. Anticonvulsant and Anti-Mania Drug Class—UF Recommendation

The P&T Committee recommended (13 for, 2 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- UF:
  - Carbamazepine IR (Tegretol, generics)
  - Carbamazepine ER (Tegretol XR, Carbatrol, generics)
  - Carbamazepine ER (Equetro XR)
  - Clobazam (Onfi)
  - Divalproex IR, ER, and delayed release (Depakote, Depakote ER, Depakote Sprinkles, generics)
  - Eslicarbazepine (Aptiom)

- Ethosuximide (Zarontin, generics)
- Felbamate (Felbatol, generics)
- Lacosamide (Vimpat)
- Lamotrigine IR, ER, and chewable tablets (Lamictal, Lamictal XR, Lamictal CD, generics)
- Lamotrigine ODT (Lamictal ODT)
- Levetiracetam IR, ER (Keppra; Keppra XR, generics)
- Oxcarbazepine (Trileptal, generics)
- Oxcarbazepine ER (Oxtellar XR)
- Perampanel (Fycompa)
- Phenytoin (Dilantin, generics)
- Phenobarbital (Luminol, generics)
- Primidone (Mysoline, generics)
- Rufinamide (Banzel)
- Topiramate IR and sprinkle capsules (Topamax, Topamax Sprinkle, generics)
- Topiramate ER (Trokendi XR)
- Topiramate ER (Qudexy XR)
- Valproic Acid (Depakene, generics)
- Vigabatrin (Sabril)
- Zonisamide (Zonegran, generics)

- NF:
  - None

D. Anticonvulsant and Anti-Mania Drug Class—Topiramate ER (Trokendi XR and Qudexy XR) Manual PA Criteria

Manual PA criteria were recommended in August 2014 and implemented in December 2014 to limit use of Qudexy XR and Trokendi XR to the FDA-approved indications for seizures and appropriate age ranges. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the current PA criteria for Trokendi XR and Qudexy XR. Patients are required to try generic topiramate IR first, unless there is a contraindication or adverse reaction with the generic product.

Full PA Criteria:

No change from August 2014

Manual PA criteria apply to all new users of Trokendi XR and Qudexy XR:

- Coverage approved for
  - Partial onset seizure and 1° generalized tonic-clonic seizures in patients $\geq$ 10 years
  - Lennox-Gastaut seizures in patients $\geq$ 6 years
- Coverage not approved for

    - Non-FDA approved indications, including migraine headache and weight loss

- Patient is required to try topiramate first, unless the following has occurred:
    - Inadequate response not expected to occur with Trokendi XR or Qudexy XR
    - Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR

E. Anticonvulsant and Anti-Mania Drug Class—Lacosamide (Vimpat) Removal of PA Criteria

Manual PA criteria were recommended for new users of Vimpat at the February 2016 P&T Committee meeting, with an implementation date of August 10, 2016. A review of MHS prescribing patterns for Vimpat found a low percentage of off-label use. The P&T Committee recommended (14 for, 1 opposed, 0 abstained, 1 absent) removing the manual PA criteria for Vimpat upon signing of the minutes.

IX. UF CLASS REVIEWS—ANTICONVULSANT AND ANTI-MANIA DRUG CLASS

BAP Comments

A. Anticonvulsant and Anti-Mania Drug Class—UF Recommendation

The P&T Committee recommended the following:

- That all of the drugs in the Anticonvulsant and Anti-Mania class be designated as UF
- And that none of the drugs be designated nonformulary

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. Anticonvulsant and Anti-Mania Drug Class—Topiramate ER (Trokendi XR and Qudexy XR) Manual PA Criteria

The P&T Committee recommended maintaining the current PA criteria for Trokendi XR and Qudexy XR.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

C. Anticonvulsant and Anti-Mania Drug Class—Lacosamide (Vimpat) Removal of PA Criteria

The P&T Committee recommended removing the manual PA criteria for Vimpat upon signing of the minutes.

X. UF CLASS REVIEWS—CONTRACEPTIVE AGENTS

P&T Comments

A. Contraceptive Agents: Emergency Contraceptives—Relative Clinical Effectiveness and Conclusion

The emergency contraceptives reviewed for formulary placement included levonorgestrel 1.5 mg (Plan B One Step, generics), levonorgestrel 0.75 mg (Plan B, generics), and ulipristal acetate 30 mg (Ella). The levonorgestrel 1.5 mg single dose has largely replaced use of the 0.75 mg two-tablet regimen.

The Emergency Contraceptives were previously reviewed for UF placement in August 2011. Since then, the branded product Plan B One Step (levonorgestrel 1.5 mg) now has at least 10 AB-rated generic equivalent formulations. Plan B One Step is available over-the-counter (OTC) with no age restrictions while Ella requires a prescription.

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

- Both levonorgestrel and ulipristal acetate are effective in preventing unintended pregnancies by delaying or inhibiting ovulation. Levonorgestrel is effective when taken within 72 hours of unprotected intercourse; however, its efficacy declines over time. Ulipristal acetate is effective when taken up to 120 hours after unprotected intercourse.

- In terms of relative effectiveness, ulipristal acetate is more effective compared to levonorgestrel in preventing unintended pregnancies, based on findings from one meta-analysis and pooled data from two randomized, multicenter trials. Ulipristal acetate prevented 67% of expected pregnancies versus 52% with levonorgestrel.

- The most commonly reported adverse effects ($\geq$10%) with either levonorgestrel or ulipristal acetate are headache, nausea, and abdominal pain. Both products have a similar safety profile and contraindications.

- To ensure adequate clinical coverage for emergency contraception, both levonorgestrel and ulipristal acetate are required on the UF.

B. Contraceptive Agents: Emergency Contraceptives—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate the emergency contraceptives. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results ranked the emergency contraceptive drugs from least costly to most costly to the MHS.

- BIA was performed to evaluate the potential impact of bids offered. No significant impact was found for any scenario.

C. Contraceptive Agents: Emergency Contraceptives—UF Recommendation

The P&T Committee recommended (13 for, 0 against, 2 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **UF:**
  - levonorgestrel 0.75 mg (Plan B, generics)
  - levonorgestrel 1.5 mg (Plan B One Step, generics)
  - ulipristal acetate 30 mg (Ella)

- **NF:** None

XI. UF CLASS REVIEWS—CONTRACEPTIVE AGENTS

BAP Comments

A. Contraceptive Agents: Emergency Contraceptives—UF Recommendation

The P&T Committee recommended the following, based on clinical and cost effectiveness:

- **UF:**
  - Generic Plan B
  - Plan B One Step and generics
  - Ella

- **NF:** None

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

XII. UF CLASS REVIEWS—INNOVATOR DRUGS

P&T Comments

A. Newly-Approved Innovator Drugs—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analysis presented for the innovator drugs.

B. Newly-Approved Innovator Drugs—UF Recommendation

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

- UF:
  - antihemophilic factor (recombinant) (Kovaltry)
  - calcipotriene/betamethasone dipropionate foam (Enstilar)
  - coagulation factor IX (recombinant)/albumin fusion protein (Idelvion)
  - emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey)
  - elbasvir/grazoprevir (Zepatier)
  - tofacitinib ER tablets (Xeljanz XR)
  - uridine triacetate oral granules (Xuriden)

- NF:
  - amphetamine ER ODT (Adzenys XR ODT)
  - buprenorphine buccal film (Belbuca)
  - ixekizumab injection (Taltz)
  - methylphenidate ER chewable tablets (QuilliChew ER)

C. Newly-Approved Innovator Drugs—Manual PA Criteria

Existing step therapy and manual PA criteria currently apply to the targeted immunomodulatory biologics (TIBs), and manual PA criteria currently apply to the Hepatitis C direct acting antiviral agents (DAAs). The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) PA criteria for the TIBs tofacitinib XR (Xeljanz XR), and ixekizumab injection (Taltz); for the hepatitis C direct acting agent elbasvir/grazoprevir (Zepatier); and, for the orphan drug uridine triacetate (Xuriden).

Full PA Criteria:

1. Tofacitinib (Xeljanz), tofacitinib XR (Xeljanz XR)

Changes from previous TIB automated PA criteria are bolded.

Step therapy and Manual PA Criteria applies to all new users of tofacitinib and all new and current users of **tofacitinib ER (Xeljanz XR).**

Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Xeljanz/Xeljanz XR if:

- Contraindications exist to Humira
- Inadequate response to Humira (need for different anti-TNF or non-TNF)
- Adverse reactions to Humira not expected with requested non-step preferred TIB
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF

AND

Coverage approved for patients > 18 years with:

- Mod to severe active RA who have had an inadequate response or intolerance to methotrexate
- Not approved for use in combination with other biologics or potent immunosuppressants (azathioprine and cyclosporine)

Coverage NOT provided for concomitant use with other TIBS (abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, tocilizumab, rituximab or infliximab)

- Prior Authorization does not expire.

2. Ixekizumab injection (Taltz)

Changes from previous TIB automated PA criteria are bolded

Step therapy and Manual PA Criteria applies to all new and current users of ixekizumab (Taltz).

Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) and **secukinumab (Cosentyx)** at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days AND

Manual PA criteria:

If automated criteria are not met, coverage is approved for Taltz if:

- Contraindications exist to Humira and **Cosentyx**
- Inadequate response to Humira and **Cosentyx**
- Adverse reactions to Humira and **Cosentyx** not expected with requested non-step preferred TIB

AND

Coverage approved for patients > 18 years with:

- Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

Coverage NOT provided for concomitant use with other TIBS (abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, tocilizumab, rituximab or infliximab)

- Prior Authorization does not expire.

3. Elbasvir/Grazoprevir (Zepatier)

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

Manual PA Criteria:

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

<u>Treatment Regimens and Duration of Therapy</u>

- Treatment and duration of therapy are approved based on HCV genotype or unique population.
- Prior authorization will expire after 12 weeks or 16 weeks, based on the treatment regimen selected.

Consult the AASLD/IDSA HCV guidelines for new updates.

4. Uridine triacetate granules (Xuriden)

Prior Authorization applies to all new and current users of Xuriden

<u>Manual PA criteria</u>: Coverage is approved for Xuriden if:

- Diagnosis of hereditary orotic aciduria
- Has laboratory evidence of increased urinary orotic acid
- Off label uses are NOT approved

- Prior Authorization expires in 6 months.

- PA criteria for renewal: Re-approval requires confirmatory test. Assay of the transferase and decarboxylase enzymes in the patient's erythrocytes. Enzymes are pyrimidine phosphoribosyltransferase and orotidylate decarboxylase
- Once confirmed, PA does not expire

D. Newly-Approved Innovator Drugs—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date upon signing of the minutes in all points of service.

XIII. UF CLASS REVIEWS—INNOVATOR DRUGS

BAP Comments

A. Newly-Approved Innovator Drugs—UF Recommendation

The P&T Committee recommended the following:

- UF:
  - Kovaltry
  - Enstilar
  - Idelvion
  - Odefsey
  - Zepatier
  - Xeljanz XR
  - Xuriden
- NF:
  - Adzenys XR ODT
  - Belbuca
  - Taltz
  - QuilliChew ER

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. Newly-Approved Innovator Drugs—Manual PA Criteria

The P&T Committee recommended PA criteria Xeljanz XR, Taltz, Zepatier, and Xuriden.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur Additional Comments and Dissention

C. Newly-Approved Innovator Drugs—UF and PA Implementation Plan

The P&T Committee recommended an effective date upon signing of the minutes in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur Additional Comments and Dissention

XIV. UTILIZATION MANAGEMENT—ORAL ONCOLOGIC AGENTS

P&T Comments

A. Oral Oncologic Agents: Palbociclib (Ibrance)—Manual PA Criteria

Ibrance was approved by the FDA in February 2015 for specific types of metastatic breast cancer. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Ibrance in new patients.

Full PA Criteria:

Manual PA criteria apply to all new users of Ibrance.

Manual PA criteria—Ibrance is approved if:

A. Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND
B. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
C. The patient meets ONE of the following criteria (i, ii, or iii):
    i. The patient is a postmenopausal woman and Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR
    ii. The patient is a premenopausal or perimenopausal woman and meets the following conditions (a and b):
        a. The patient is receiving ovarian suppression/ablation with a leutinizing hormone-releasing hormone (LHRH) agonist (e.g.,

Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]), surgical bilateral oophorectomy, or ovarian irradiation; AND

b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR

iii. The patient is a man and meets the following conditions (a and b):

a. The patient is receiving a leutinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]); AND

b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole.

Prior Authorization does not expire.
Other non-FDA approved uses are not approved

B. Oral Oncologic Agents: Palbociclib (Ibrance)—PA Implementation Period

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XV. UTILIZATION MANAGEMENT—ORAL ONCOLOGIC AGENTS

BAP Comments

A. Oral Oncologic Agents: Palbociclib (Ibrance)—Manual PA Criteria

The P&T Committee recommended manual PA criteria for Ibrance in new patients.

The full prior authorization criteria were stated previously above.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. Oral Oncologic Agents: Palbociclib (Ibrance)—PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

XVI. UTILIZATION MANAGEMENT—PARKINSON'S DISEASE AGENTS

P&T Comments

A. Parkinson's Disease Agents: Carbidopa/Levodopa ER Capsules (Rytary)—Manual PA Criteria

Rytary is FDA-approved for the treatment of Parkinson's disease. Rytary is dosed three times daily and is available in the following ER capsule dosages: 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg /245 mg. Sustained-release formulations of carbidopa/levodopa (Sinemet) are dosed twice daily to three times daily.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Rytary in new patients. Rytary will be approved if the patient has tried and failed a generic ER formulation of carbidopa/levodopa.

Full PA Criteria:
Manual PA criteria apply to all new users of Rytary.

Manual PA criteria—Rytary is approved if:

- Patient has tried and failed generic extended release formulation of carbidopa/levodopa

Prior Authorization does not expire.

B. Parkinson's Disease Agents: Carbidopa/Levodopa ER Capsules (Rytary)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XVII. UTILIZATION MANAGEMENT—PARKINSON'S DISEASE AGENTS

BAP Comments

A. Parkinson's Disease Agents: Carbidopa/Levodopa ER Capsules (Rytary)—PA Criteria

The P&T Committee recommended manual PA criteria for Rytary in new patients. Rytary will be approved if the patient has tried and failed a generic ER formulation of carbidopa/levodopa.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. Parkinson's Disease Agents: Carbidopa/Levodopa ER Capsules (Rytary)—PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment:	☐ Concur	☐ Non-concur
		Additional Comments and Dissention

XVIII. UTILIZATION MANAGEMENT—GASTROINTESTINAL-2 (GI-2) OPIOID-INDUCED CONSTIPATION DRUGS

P&T Comments

A. GI-2 Opioid-Induced Constipation Drugs: Naloxegol (Movantik)—Manual PA Criteria

Movantik is FDA-approved for opioid-induced constipation and chronic non-cancer pain. It is a mu-opioid receptor antagonist given orally once daily, and has warnings regarding gastrointestinal perforation and opioid withdrawal.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Movantik in new patients. Patients are required to have a trial of two standard laxative therapies prior to use of naloxegol.

Full PA Criteria:

Manual PA criteria apply to all new users of Movantik.

Manual PA criteria—Movantik is approved if:

- The patient does not have any of the following contraindications to naloxegol
  - known or suspected gastrointestinal obstruction and at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation
  - concomitantly taking strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole)

AND

- naloxegol is being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic non-cancer pain

AND

- The patient has tried a minimum of two standard laxative therapies (e.g. Miralax, sorbitol, lactulose, Mg citrate, bisacodyl, sennosides)

Prior Authorization does not expire.
Non-FDA approved uses are not approved

B. GI-2 Opioid-Induced Constipation Drugs: Naloxegol (Movantik)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XIX. UTILIZATION MANAGEMENT—GASTROINTESTINAL-2 (GI-2) OPIOID-INDUCED CONSTIPATION DRUGS

BAP Comments

A. GI-2 Opioid-Induced Constipation Drugs: Naloxegol (Movantik)—Manual PA Criteria

The P&T Committee recommended manual PA criteria for Movantik in new patients. Patients are required to have a trial of two standard laxative therapies prior to use of naloxegol.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. GI-2 Opioid-Induced Constipation Drugs: Naloxegol (Movantik)—PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

XX. UTILIZATION MANAGEMENT—BETA-BLOCKERS

P&T Comments

A. Beta Blockers: Nebivolol (Bystolic)—Automated and Manual PA Criteria

Bystolic is an adrenergic blocking agent that is solely FDA-approved for the treatment of hypertension. It was reviewed and designated NF in June 2008. There is now widespread

cost-effective generic availability of other beta blockers, which have other indications in addition to hypertension, including heart failure, angina, and arrhythmias. There is no compelling clinical data to support use of nebivolol over the other beta blockers in the class.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users of Bystolic, requiring failure of or intolerance to two generic beta blockers. Coverage will only be approved for hypertension.

Full PA Criteria:

Manual PA criteria apply to all new users of Bystolic.

Manual PA criteria—Bystolic is approved if:

- Adult with hypertension **AND**
- Patient has tried and failed or is intolerant to two generic beta-blockers

Prior Authorization does not expire.

B. Beta Blockers: Nebivolol (Bystolic)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XXI. UTILIZATION MANAGEMENT—BETA BLOCKERS

BAP Comments

A. Beta Blockers: Nebivolol (Bystolic)—Manual PA Criteria

The P&T Committee recommended manual PA criteria for new users of Bystolic, requiring failure of or intolerance to two generic beta blockers. Coverage will only be approved for hypertension.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. Beta Blockers: Nebivolol (Bystolic)—PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment:	☐ Concur	☐ Non-concur
		Additional Comments and Dissention

XXII. UTILIZATION MANAGEMENT—NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

P&T Comments

A. NSAIDs: Esomeprazole/Naproxen (Vimovo) and Ibuprofen/Famotidine (Duexis)—Manual PA Criteria

The NSAIDs were reviewed in August 2012. Vimovo is currently designated formulary on the UF, while Duexis is NF. Manual PA criteria were recommended for Vimovo and Duexis due to the wide availability of other cost-effective generic NSAIDs, including celecoxib (Celebrex) and OTC availability of several proton pump inhibitors.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for Vimovo and Duexis in new and current patients, requiring documentation that the patient must take a fixed-dose combination product and cannot take the two drugs separately.

Full PA Criteria:

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

Manual PA criteria—Vimovo and Duexis are approved if:

- Patient requires a fixed-dose combination and cannot take the two drugs separately

Prior Authorization expires after six months.
Non-FDA approved uses are not approved.

B. NSAIDs: Esomeprazole/Naproxen (Vimovo) and Ibuprofen/Famotidine (Duexis)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XXIII. UTILIZATION MANAGEMENT—NSAIDs

BAP Comments

A. NSAIDs: Esomeprazole/Naproxen (Vimovo) and Ibuprofen/Famotidine (Duexis)—Manual PA Criteria

The P&T Committee recommended manual PA criteria for Vimovo and Duexis in new and current patients.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur Additional Comments and Dissention

B. NSAIDs: Esomeprazole/Naproxen (Vimovo) and Ibuprofen/Famotidine (Duexis)—PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur Additional Comments and Dissention

XXIV. UTILIZATION MANAGEMENT—NON-OPIOID PAIN SYNDROMES

P&T Comments

A. Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)—Manual PA Criteria

Cyclobenzaprine immediate release (IR) was reviewed in November 2011 as part of the Non-Opioid Pain Syndrome Drug Class and designated with formulary status on the UF. Cost-effective generic formulations of the IR tablets are available. Cyclobenzaprine ER capsules (Amrix) do not offer compelling advantages over cyclobenzaprine IR tablets (Flexeril, generics).

The P&T Committee recommended (14 for, 1 opposed, 0 abstained, 1 absent) manual PA criteria for Amrix in new and current patients, requiring a trial of generic immediate release cyclobenzaprine.

Full PA Criteria:

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

Manual PA criteria—Amrix is approved if:

- Patient has tried and failed generic IR cyclobenzaprine
  AND
- Patient does not have any of the following (elderly greater than age 65 years, hepatic impairment, history of urinary retention, angle-closure glaucoma, increased intraocular pressure, taking anticholinergic medications)
  AND
- Is prescribed for no more than 3 weeks

Prior Authorization expires after six months.
Non-FDA approved uses are not approved.

B. Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XXV. UTILIZATION MANAGEMENT—NON-OPIOID PAIN SYNDROMES

BAP Comments

A. Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)—Manual PA Criteria

The P&T Committee recommended manual PA criteria for Amrix in new and current patients.

The full prior authorization criteria were stated previously.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)—PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

XXVI. UTILIZATION MANAGEMENT—TOPICAL PAIN DRUGS

P&T Comments

A. Topical Pain Drugs: Lidocaine 5% Patch (Lidoderm)—Removal of Manual PA Criteria

PA criteria were recommended for Lidoderm at the February 2013 P&T Committee meeting and implemented in August 2013.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) removing the PA for Lidoderm. Cost-effective generic formulations are now available.

B. Topical Pain Drugs: Lidocaine 5% Patch (Lidoderm)—Removal of Manual PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) an effective date upon signing of the minutes.

XXVII. UTILIZATION MANAGEMENT—TOPICAL PAIN DRUGS

BAP Comments

A. Topical Pain Drugs: Lidocaine 5% Patch (Lidoderm)—Removal of Manual PA Criteria

The P&T Committee recommended removing the PA for Lidoderm.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. Topical Pain Drugs: Lidocaine 5% Patch (Lidoderm)—Removal of PA Implementation Plan

The P&T Committee recommended an effective date upon signing of the minutes.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

XXVIII. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORITY AND PA CRITERIA

P&T Comments

A. Brand Over Generic Authority

Currently in the Retail Network and Mail Order Pharmacy, there is a mandatory generic substitution policy. When AB-rated generic formulations enter the market, the generic formulation is dispensed instead of the branded product. Prior Authorization criteria do allow dispensing of the branded product in certain cases (e.g., allergy or hypersensitivity).

Currently, the DHA Pharmacy Operations Division (POD) has noticed a trend for new generic products to have a higher cost than the corresponding proprietary product for several months after market launch. The DHA POD is requesting authority to implement "brand over generic" requirements in the Retail Network and Mail Order Pharmacy when there is a cost benefit to the MHS. The recommended authority below will allow the MHS to respond quickly to instances when high cost generic formulations enter the market.

The P&T Committee recommended (14 for, 0 oppose, 1 abstain, 1 absent):

1) The DHA POD be given authority, after consulting with the Chair of the P&T Committee, to implement "brand over generic" authorization for drugs with recent generic entrants where the branded product is more cost effective than generic formulations. In these cases, the branded product will continue to be dispensed, and the generic product will only be available upon prior authorization.
2) The branded product will adjudicate at the Tier 1 co-pay in the Retail Network and Mail Order Pharmacy.
3) The "brand over generic" requirement will be removed when it is no longer cost effective to the MHS.
4) The P&T Committee will be updated during the next quarterly meeting on DHA POD administrative actions for brand over generic products.

B. Brand Over Generic Authority: PA Criteria

The P&T Committee recommended (14 for, 0 oppose, 1 abstain, 1 absent) the following PA criteria will apply to cases when the "brand over generic" authority is implemented. Patients meeting the criteria below will receive the generic formulation, rather than the specified branded product.

1) The prescriber must complete a clinical assessment and provide a patient-specific justification as to why the branded product cannot be used in the patient.

XXIX. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORITY AND PA CRITERIA

BAP Comments

A. Brand over Generic Authority

The P&T Committee recommended the brand over generic authority for the DHA POD as outlined above, for drugs with recent generic entrants where the branded product is more cost effective than generic formulations, and that the branded product will adjudicate at the Tier 1 co-pay in the Retail Network and Mail Order Pharmacy.

BAP Comment: ☐ Concur ☐ Non-concur Additional Comments and Dissention

B. Brand over Generic Authority: PA Criteria

The P&T Committee recommended patients meeting the criteria below will receive the generic formulation, rather than the specified branded product.

1) The prescriber must complete a clinical assessment and provide a patient-specific justification as to why the branded product cannot be used in the patient.

BAP Comment: ☐ Concur ☐ Non-concur Additional Comments and Dissention

XXX. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR 2008 (FY08)

P&T Comments

A. FY08 NDAA, Section 703—Tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak) Removal of Exemption from Mail Order Pharmacy Availability

Drugs from pharmaceutical manufacturers that are not included on a DoD Retail Refund Pricing Agreement are not in compliance with the FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will require pre-authorization prior to use in the retail point of service and medical necessity at military treatment facilities. These NF drugs will remain available in the Mail Order point of service without pre-authorization.

At the November 2015 P&T Committee meeting, Kitabis Pak was designated NF with pre-authorization criteria for use in the Retail Network. Because Kitabis Pak was only available in the Retail Network via a specialty distributor network of pharmacies, it was

exempt from the requirement to limit availability to the Mail Order Pharmacy. In February 2016, supply and distribution of Kitabis Pak became available through the Mail Order Pharmacy.

The P&T Committee recommended (15 for, 0 against, 0 abstained, 1 absent) removing the exemption from mail order availability for tobramycin 300 mg/5 mL inhalation solution (Kitabis Pak). Kitabis Pak will now be available through the Mail Order Pharmacy without pre-authorization. However, pre-authorization prior to use in the retail point of service and MN at MTFs is still required.

B. FY08 NDAA, Section 703—Tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak) Implementation Period

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Kitabis Pak; and, 2) DHA send letters to beneficiaries affected by this decision.

C. FY08 NDAA, Section 703—Program Updates

The P&T Committee discussed drugs that are not compliant with Section 703 and are limited in availability. The circumstances when a Section 703 non-compliant drug can be exempted from the Mail Order Pharmacy requirement include when drugs are available only via limited distribution networks or when drugs are not compliant with the Trade Agreements Act (TAA).

The P&T Committee recommended (15 for, 0 against, 0 abstained, 1 absent) administrative authority for the DHA Pharmacy Operations Division to allow availability of drugs that are non-complaint with Section 703 through the Mail Order Pharmacy when product supply or distribution issues (e.g., limited distribution or TAA non-compliance) are resolved. Drugs that are made available through the Mail Order Pharmacy will not have to undergo a formal re-review by the P&T Committee.

XXXI. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR 2008 (FY08)

BAP Comments

A. FY08 NDAA, Section 703—Tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak) Removal of Exemption from Mail Order Pharmacy Availability

The P&T Committee recommended removing the exemption from mail order availability for tobramycin 300 mg/5 mL inhalation solution (Kitabis Pak). Kitabis Pak will now be available through the Mail Order Pharmacy without pre-authorization. However, pre-authorization prior to use in the retail point of service and MN at MTFs is still required.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

B. FY08 NDAA, Section 703—Tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak) Implementation Period

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period for Kitabis Pak; and, 2) DHA send letters to beneficiaries affected by this decision.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

C. FY08 NDAA, Section 703—Program Updates

The P&T Committee recommended administrative authority for the DHA Pharmacy Operations Division to allow availability of drugs that are non-complaint with Section 703 through the Mail Order Pharmacy when product supply or distribution issues (e.g., limited distribution or TAA non-compliance) are resolved. Drugs that are made available through the Mail Order Pharmacy will not have to undergo a formal re-review by the P&T Committee.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

XXII. RE-EVALUATION OF NF AGENTS: CALCIUM CHANNEL BLOCKERS (CCBs)

P&T Comments

A. CCBs—Clinical Effectiveness and Cost-Effectiveness Conclusions

The P&T Committee re-evaluated the UF status of the six NF agents in the CCBs Drug Class, all of which are now available in generic formulations: verapamil capsule 24 hr (Verelan PM, generics); verapamil capsule 24h (Verelan, generics); diltiazem tablet ER 24h (Cardizem LA, generics); isradipine capsule (generic only); nicardipine (generic only); and, nisoldipine tablet ER 24h (Sular, generics).

Clinical Effectiveness Conclusion—The CCBs were last evaluated for UF status at the August 2005 meeting. The P&T Committee did not find new clinical evidence that would alter the overall conclusion that little to no difference in clinical effectiveness exists among the CCBs.
Cost Effectiveness Conclusion—The current costs for the CCBs was evaluated. The P&T Committee voted (15 for, 0 opposed, 0 abstained, 1 absent) that none of the NF CCBs were cost effective relative to similar UF products, when the generic prices for the NF verapamil, diltiazem, and dihydropyridine products were compared to their formulary alternatives. Given the maturity of the drug class, generic prices are not expected to decline in the future, and may increase substantially as fewer generic products remain on the market. Overall, unit costs for these six current NF products tended to be lower at mail order compared to retail.

B. CCBs—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed. 1 abstained, and 0 absent) that verapamil capsule 24hr (Verelan PM, generics); verapamil capsule 24h (Verelan, generics); diltiazem tablet ER 24h (Cardizem LA, generics); isradipine capsule (generic only); nicardipine (generic only); and nisoldipine tablet ER 24h (Sular, generics) remain NF. Additionally, all six NF CCBs will remain subject to the requirement that they be generally available only at mail order, regardless of generic status.

XXXIII. RE-EVALUATION OF NF AGENTS: CALCIUM CHANNEL BLOCKERS (CCBs)

BAP Comments

A. CCBs—UF Recommendation

The P&T Committee recommended that the following products remain nonformulary:

- generic Verelan PM
- generic Verelan
- generic Cardizem LA
- isradipine
- nicardipine
- generic Sular

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention

XXXIV. RE-EVALUATION OF NF AGENTS: PROTON PUMP INHIBITORS (PPIs)

P&T Comments

A. PPIs—Clinical Effectiveness and Cost-Effectiveness Conclusions

The P&T Committee re-evaluated the UF status of the NF PPIs in the PPIs: dexlansoprazole (Dexilant), esomeprazole strontium, lansoprazole (Prevacid, generics); omeprazole/sodium bicarbonate (Zegerid, generics), rabeprazole delayed release tablets (Aciphex, generics) and rabeprazole delayed release capsules (Aciphex Sprinkle). The PPIs were previously evaluated for UF status at the May 2007 meeting. Automated PA (step therapy) requiring a trial of omeprazole, esomeprazole (Nexium), or pantoprazole applies to new users presenting with a prescription for a nonformulary PPI.

Clinical Effectiveness Conclusion—At the May 2007 meeting, the P&T Committee reviewed evidence across a wide range of disease states and, in summary, concluded that PPIs appear very similar with regard to efficacy, safety, and tolerability. The P&T Committee did not find new clinical evidence that would alter this conclusion.

Cost-Effectiveness Conclusion—The current costs for the PPIs were evaluated. The P&T Committee voted (15 for, 0 opposed, 0 abstained, 1 absent) that, while not as cost effective as generic omeprazole or pantoprazole, generic rabeprazole delayed release (DR) tablets were more cost effective than the blended average of all UF PPIs, with additional generic price competition anticipated. The other NF PPIs were substantially less cost effective than the UF PPIs.

B. PPIs—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) that rabeprazole DR tablet (Aciphex, generics) be re-classified as formulary and step-preferred on the UF. This does not include Aciphex Sprinkle, which would therefore remain NF and non-step preferred. NF PPIs would be subject to the requirement that they generally be available only in the Mail Order Pharmacy, regardless of generic status.

XXXV. RE-EVALUATION OF NF AGENTS: PROTON PUMP INHIBITORS (PPIs)

BAP Comments

B. PPIs—UF Recommendation

The P&T Committee recommended that Aciphex tablets be reclassified as formulary and step-preferred on the UF.

BAP Comment: ☐ Concur ☐ Non-concur

Additional Comments and Dissention