EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP)
June 22, 2016

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

1. RENIN-ANGIOTENSIN ANTIHYPERTENSIVES (RAAs)

A. 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.

B. 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.

Full PA Criteria:

The new criteria will replace the criteria recommended at the February 2016 meeting.

Manual PA criteria apply to all new and current users of sacubitril/valsartan (Entresto). Coverage is approved for Entresto if all of the following criteria apply:

- **(new update) The initial prescription is written by or in consultation with 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

- **(new update) 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

C. **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.

Summary of Physician's Perspective

The primary discussion revolved around the Prior Authorization criteria. We requested feedback from the cardiology consultants, and they all felt that Entresto should initially be written with cardiologist input, and that the use of Entresto should be limited to the patients who meet the inclusion criteria from the the PARADIGM trial. The revisions to the PA criteria originally recommended at the February P&T meeting included these recommendations.

One member was concerned that having everyone go through the PA process would be burdensome to patients with trying to get an appointment. However, currently the overall numbers of patients on Entresto is about 1,000 and the cardiology consultants said there haven't been a large number of patients who are candidates. Additionally, other professional groups, including the Institute for Clinical and Economic Research, do recommend ensuring use of Entresto for those patients most likely to benefit from the drug.

New joint guidelines from the American Heart Association, American College of Cardiology and the Heart Failure Society of America came out the week after the P&T meeting, and the European Society of Cardiology also updated their heart failure

guidelines. The new guidelines place Entresto as a class I-B recommendation for heart failure, but the level of evidence was below that of the ACE inhibitors and ARBs, which remain a Class I-A recommendation. The guidelines do mention that there are safety issues when initiating therapy with Entresto, and that if patients are not candidates for Entresto, an ACE inhibitor should be continued for all classes of heart failure.

Summary of Panel Questions and Comments

Dr. Sommer asked if the initial prescription for Entresto must be written by a cardiologist. Does that include physician's assistants and nurse practitioners that are overseen by cardiologists or does it have to have a cardiologist stamp on it.

Dr. Allerman responded that it is actually "written by or in consultation with" so the PA would mean a cardiology office.

Dr. Anderson states that I think you addressed the question I have regarding the guidelines. Just to be clear, there are no guidelines today that are formally recommending Entresto as first line therapy definitively. Is that accurate?

Dr. Allerman responded that that statement was correct.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, PA Criteria, and UF and PA Implementation Plan for the RAAs: Sacubitril/Valsartan (Entresto)

- **RAAs: Sacubitril/Valsartan (Entresto)—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

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

- **RAAs: Sacubitril/Valsartan (Entresto)—Prior Authorization (PA) Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

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

- **RAAs: Sacubitril/Valsartan (Entresto)—UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

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

2. **GASTROINTESTINAL-2 (GI-2) MISCELLANEOUS DRUGS**

   A. **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.

   B. **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:

   - **(new update) Initial prescription written by OR in consultation with a 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

- **(new update) The patient has failed a trial of rifaximin**

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

C. **GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—UF 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 90-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

Summary of Physician's Perspective

Viberzi had not been launched when the GI-2 drugs were reviewed by the Committee back in November, so it was reviewed as a new drug.

There was no controversy over the recommendation for the non-formulary designation, due to safety concerns and cost effectiveness. Viberzi will require long term therapy, compared to a 14 day courses of therapy with rifaximin. There was a GI specialist at the meeting.

Prior Authorization criteria were originally placed on Viberzi at the February 2016 P&T Committee meeting, with an implementation date of Aug 10, 2016. Based on the safety issues and cost effectiveness, the PA criteria were revised to require a trial of rifaximin first.

Summary of Panel Questions and Comments

Dr. Anderson asked for clarification regarding the new update. Should it state "in consultation with or prescribed by gastroenterologists"?

Dr. Allerman responded that it is in consultation with but the language was inadvertently left off.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, PA Criteria, and UF Implementation Plan for the GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  These comments were taken under consideration prior to my final decision

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  These comments were taken under consideration prior to my final decision

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  These comments were taken under consideration prior to my final decision

UF CLASS REVIEWS

1. ATYPICAL ANTIPSYCHOTIC (AAP) DRUGS

A. 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)

B. **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 requires a trial of at least two other AAPs, including aripiprazole, prior to use of Rexulti.

Full PA Criteria:

All new users of 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 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 Rexulti.

- Non-FDA approved uses are not approved.

Prior Authorization does not expire.

C. **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.

Summary of Physician's Perspective

The clinical review focused on the branded products, and the indications for schizophrenia, bipolar disorder, and as adjunctive therapy to antidepressants for major depressive disorder.

We did ask Military Health System providers for their input and over 75% of the respondents were psychiatrists. Their opinions were considered when making the Uniform Formulary recommendations. Additionally, a child/adolescent psychiatrist attended the meeting.

There were no significant safety updates from the August 2011 review. In May 2016, the FDA did release new safety warnings for aripiprazole (for impulse control problems) and olanzapine (for hypersensitivity reactions); however, these are rare adverse events. The psychiatrist at the meeting did note that these new warnings would not prevent prescribing of these two drugs if not contraindicated and required for management.

The formulary recommendation was unanimous. The main decision to move Latuda from NF to UF status was based on cost effectiveness, and also based on the feedback from providers, along with the pregnancy category B rating. The recommendations for the non-formulary products (Saphris, Fanapt, Rexulti, and Vraylar) were that they did not offer clinical advantages over the current formulary drugs.

Summary of Panel Questions and Comments

Dr. Anderson asked whether the PA for Rexulti was just for new patients because it mentions somewhere else that it might be for current patients.

Dr. Allerman responded that it should be just new patients.

Dr. Anderson asked for clarification regarding the beneficiary population, impacted by the change that will be receiving a communication about the change in benefit.

Dr. Allerman responded that it would be the patients who will now have the non-formulary status. Their co-pay will change.

Dr. Anderson responded, given the sensitivity of this class, for people who pursue a PA on Rexulti, if they are denied because they haven't tried other alternatives, is there any additional outreach for these patients. He is concerned that patients will fall through the cracks and not receive any therapy. I think Express Scripts, with some of your programs; have outreach for people who don't meet the criteria. Would that apply to a class like this?

Ms. Le Gette stated the ESI is required to send letters based on the DHA Director decision regarding the PA criteria. Letters are sent to the physicians and beneficiaries announcing that a PA is going into place.

Ms. Le Gette asked if the PA for Rexulti was still going into place on August 10. She clarified that the change is just for the 90 days implementation period and the formulary status.

Dr. Allerman responded that is for the formulary status and the co-pay change.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, PA Criteria, and UF and PA Implementation Plan for the AAP Drugs.

- **AAP Drugs—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

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

- **AAP Drugs—Manual PA Recommendation**

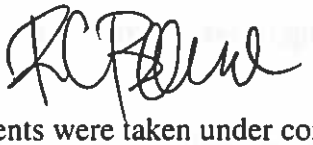
  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

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

- **AAP Drugs—UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

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

2. ANTICONVULSANT AND ANTI-MANIA DRUG CLASS

A. 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

B. 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

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

- Coverage approved for
  - Partial onset seizure and primary generalized tonic-clonic seizures in patients ≥ 10 years
  - Lennox-Gastaut seizures in patients ≥ 6 years for Trokendi XR and age ≥2 years and older for Qudexy XR
  - Adjunctive therapy of partial onset seizure or primary generalized tonic-clonic seizure in patients 2 years of age and older (Qudexy XR) or 6 years and older (Trokendi XR)
- 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

C. **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.

Summary of Physician's Perspective

These drugs have widely varying indications and mechanisms of action. Some drugs (mainly topiramate) have significant off-label use. Many of the branded products have very low utilization due to the safety profile and specific FDA-indications.
For several of the drugs, new extended release formulations have been approved, but there are either generic equivalents or therapeutic substitutes for some of these products. For example Trokendi and Qudexy have the same active ingredient as topiramate, but are extended release formulations.

The decision to have all the products in the class be designated as uniform formulary is due to acknowledgment of the difficulty with treating seizures, and also the fact that several products are available in low cost generic formulations. We did reach out to several pediatric neurologists for their opinion on what is needed for children and adolescents.

There was some discussion on whether Trokendi and Qudexy should be non-formulary or uniform formulary, due to the higher cost compared to generic topiramate. The members who opposed the formulary recommendation were because they felt that only the generic topiramate products should be UF. However, the Committee recommended overall that the existing prior authorization criteria, which limit use of the two new products to patients with seizures, would be sufficient to ensure appropriate use of these higher cost extended release formulations.

For Vimpat, the PA authorization requirements were recommended to be removed.. The PA recommendation from the February meeting is due to be implemented on August 10; but we will notify to ESI not to implement the PA at all.

Summary of Panel Questions and Comments

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation and Manual PA Criteria for the Anticonvulsant and Anti-Mania Drug Class.

- **Anticonvulsant and Anti-Mania Drug Class—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

  These comments were taken under consideration prior to my final decision

- **Anticonvulsant and Anti-Mania Drug Class—Topiramate ER (Trokendi XR and Qudexy XR) Manual PA Criteria and Removal of the PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

  These comments were taken under consideration prior to my final decision

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

  These comments were taken under consideration prior to my final decision

3. CONTRACEPTIVE AGENTS

A. 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

Summary of Physician's Perspective

The other contraceptive subclasses (oral contraceptives and the miscellaneous products) were evaluated in February, so we were completing the review. The entire class has been reviewed before, most recently in August 2011.

There was no controversy here for the formulary recommendation. There is now widespread over-the-counter availability of the Plan B One Step products, and there were no significant efficacy or safety updates from the previous formulary decision.

Summary of Panel Questions and Comments

Dr. Anderson asked if a TRICARE beneficiary needs a prescription to get the Plan B One Step or Ella.

Dr. Allerman responded a prescription is not required for the Plan B One Step product. Only the Ella requires a prescription but we have very little prescription utilization for Ella.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation Contraceptive Agents.

- **Contraceptive Agents: Emergency Contraceptives—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: RCRaud

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

4. INNOVATOR DRUGS

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) – for hemophilia
  - calcipotriene/betamethasone dipropionate foam (Enstilar) – for psoriasis
  - coagulation factor IX (recombinant)/albumin fusion protein (Idelvion) – for hemophilia
  - emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey) – for HIV infection
  - elbasvir/grazoprevir (Zepatier) – for hepatitis C virus infection
  - tofacitinib ER tablets (Xeljanz XR) – a targeted immunologic biologic (TIB) for rheumatoid arthritis which is an extended release formulation of Xeljanz
  - uridine triacetate oral granules (Xuriden) – hereditary orotic aciduria
- NF:
  - amphetamine ER ODT (Adzenys XR ODT) – for ADHD
  - buprenorphine buccal film (Belbuca) – for severe pain
  - ixekizumab injection (Taltz) – a TIB for severe plaque psoraisis
  - methylphenidate ER chewable tablets (QuilliChew ER) – for ADHD

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 Xeljanz XR, and Taltz; for the hepatitis C direct acting agent Zepatier; and, for the orphan drug Xuriden.

The PA criteria for these drugs is as follows:

1) **Xeljanz XR and Xeljanz will have the same PA criteria.**

   Step therapy and Manual PA Criteria applies to all new users of Xeljanz and all new and current users of Xeljanz XR. Xeljanz XR and Xeljanz will have the same PA criteria.

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-Tumor Necrosis Factor or non-TNF drug)
- 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 chronic heart failure

  AND

Coverage approved for patients > 18 years with:

- Moderate to severely active Rheumatoid Arthritis 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.

- Prior Authorization does not expire.

2) **Ixekizumab injection (Taltz)**

Step therapy and Manual PA Criteria applies to all new and current users of ixekizumab (Taltz). The criteria will include a trial of both Humira and Cosentyx.

Automated PA criteria: The patient has filled a prescription for 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**
- There has been an inadequate response to Humira and **Cosentyx**
- Adverse reactions to Humira and **Cosentyx** that are 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

- 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 American Association for the Study of Liver Disease / Infectious Disease Society of America 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
    - The HCV genotype and HCV RNA viral load must be stated on the PA form
- Zepatier is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved based on HCV genotype or unique population.

- Prior authorization will expire after 12 weeks or 16 weeks, based on the treatment regimen selected.

4) **Uridine triacetate granules (Xuriden)**

Prior Authorization applies to all new and current users of Xuriden

Manual PA criteria: 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.

Summary of Physician's Perspective

For the innovator drugs, the clinical data and whether there are therapeutic alternatives for the drugs are taken into consideration, along with the cost. Additionally, we do consult with the appropriate specialists for some of the products that are in classes that have not been previously reviewed, or for some of the orphan drugs.

There was no controversy over the Uniform Formulary and Non-Formulary recommendations. The drugs recommended for NF status are in classes that have been previously reviewed by the Committee.

The Prior Authorization recommendations for Xeljanz and Zepatier reflect the existing criteria for the respective classes. The PA for Taltz does have a recommendation for

patients to require a trial of Humira and Cosentyx first, as Taltz is only indicated for plaque psoriasis. For Xuriden, which is an orphan drug, the PA criteria limit use to the FDA-approved indications

Summary of Panel Questions and Comments

Dr. Anderson asked about the economic analysis for HEP C and Zepatier. Will adding it to the formulary affect the overall cost of care within the class or is it holding steady? He further states that he knows that Zepatier may be a lower cost option. A response with specific information is not required but he is thinking more in terms of sustaining the benefit. More specifically, does the addition of Zepatier to the formulary increase or decrease HEP C treatment costs under the TRICARE benefits?

CAPT VonBerg that there was no significant change in the cost of care.

Dr. Anderson asked for clarification regarding the drugs designated NF for the innovator products. What is the process for periodic review? Does this occur when new clinical evidence becomes available or new contracting opportunities become available? Is there a review process?

CAPT VonBerg responded that we will be conducting follow-up on all of the innovator products. It will vary depending on the change in clinical and economic data. We have not had a follow-up, to date, because most the drugs are brand new and there are defined periods of when things happen; how long it takes the clinical data to mature; or how long it takes for prices to stabilize. However, we do have an actual, organized process to go back and look at the drugs to see if there are changes to the information. We just haven't gotten to that point yet.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Newly-Approved Innovator Drugs.

- **Newly-Approved Innovator Drugs—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: RC Reed

  These comments were taken under consideration prior to my final decision

- **Newly-Approved Innovator Drugs—Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: RC Reed

  These comments were taken under consideration prior to my final decision

- **Newly-Approved Innovator Drugs—UF and PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA: 

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

UTILIZATION MANAGEMENT

1. ORAL ONCOLOGIC AGENTS

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—Ibrance is approved if:

1) Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND

2) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND

3) 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 (Arimidex), exemestane (Aromasin), or letrozole (Femara); 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 Arimidex, Aromasin, or Femara; OR

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

      a. The patient is receiving a LHRH agonist AND

b. Ibrance will be used as first-line endocrine therapy in combination with Arimidex, Aromasin, or Femara

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.

Summary of Physician's Perspective

The Prior Authorization recommended for Ibrance takes into account the FDA approved indications and the off-label uses with good supporting evidence. The PA will only apply to new patients, and we currently have about 560 patients on Ibrance. As new indications get added to the package insert, we will update the PA criteria.

Summary of Panel Questions and Comments

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the ORAL Oncologic Agents - Palbociclib (Ibrance).

- **Oral Oncologic Agents: Palbociclib (Ibrance)—Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  These comments were taken under consideration prior to my final decision

- **Oral Oncologic Agents: Palbociclib (Ibrance)—PA Implementation Period**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

  These comments were taken under consideration prior to my final decision

2. PARKINSON'S DISEASE AGENTS

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 all new patients.

Full PA Criteria: Rytary will be approved if the patient has tried and failed a 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.

Summary of Physician's Perspective

The Parkinson's disease drugs have not previously been reviewed by the Committee, and currently all of the products are designated as formulary. The active ingredients of Rytary are found in other products, (generic Sinemet), and Rytary does require three times a day dosing.

The Committee felt that a trial of a generic product was reasonable. Currently there are about 700 patients, and the PA will apply only to new patients.

Summary of Panel Questions and Comments

Dr. Anderson asked if it was ever an option to exclude certain drugs from the TRICARE Benefit. He is not picking on this drug specifically but if there are therapeutically equivalent products already on the market, with same active ingredients, is there an option to not only place the drug in a non-formulary status but to vote that it not be a covered benefit.

CAPT VonBerg responded that there are drugs or products that TRICARE policies list as not covered. Specifically, cosmetic products are not covered the TRICARE benefit but not individual therapeutic products.

CAPT Norton stated the under the TRICARE benefit structure there is no class of products that are not covered because there are other drugs that are similar or more cost effective.

Dr. Anderson asks, in other words, there are always exceptions to the process.

CAPT Norton states, that they can be placed in a non-formulary status or we can utilize the PA and step therapy to monitor access to the product.

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

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

3. GASTROINTESTINAL-2 (GI-2) OPIOID-INDUCED CONSTIPATION DRUGS

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:

Movantik is approved if:

- The patient does not have any of the following contraindications:
  - 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

- Movantik 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.

Summary of Physician's Perspective

There was no controversy over the recommendations for the PA criteria here. The standard therapies for opioid-induced constipation should be tried before Movantik.

There are over 3,000 patients currently on Movantik, and the existing patients will be grandfathered.

Summary of Panel Questions and Comments

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the GI-2 Opioid-Induced Constipation Drugs.

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA: RC Reed

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

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

  These comments were taken under consideration prior to my final decision

4. BETA-BLOCKERS

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

Bystolic is a beta blocker that is solely FDA-approved for the treatment of hypertension.

It was reviewed by the DoD P&T Committee in June 2008, and designated NF. 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 Bystolic 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.

Summary of Physician's Perspective

The Committee did not find any new clinical data to support preferred use of Bystolic over the generic beta blockers. Due to the large numbers of patient currently on Bystolic (over 30,000 patients) the existing Bystolic users will be grandfathered.

Summary of Panel Questions and Comments

Ms. Le Gette asks why now? Was there an increase in usage or cost? It was 2008 when Bystolic was originally reviewed.

Dr. Allerman responded that it was a combination of the cost and clinical effectiveness because every other beta blocker except 1 is generic now and there is nothing clinically to say that this is better than the others.

Ms. Le Gette asks when the drug will go generic.

Dr. Allerman stated that it will go generic in 2024. We plan to recommend grandfathering with this product.

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Beta Blockers: Nebivolol (Bystolic).

- **Beta Blockers: Nebivolol (Bystolic)— Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

- **Beta Blockers: Nebivolol (Bystolic)—PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

5. NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

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

The NSAIDs were reviewed in August 2012. Vimovo is currently designated as 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 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.

Manual PA criteria—Vimovo and Duexis are approved if:

- The 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.

Summary of Physician's Perspective

The individual ingredients of Vimovo and Duexis are available as single formulations. The Committee did recommend "no grandfathering" here, which will affect approximately 3,400 patients.

Summary of Panel Questions and Comments

Dr. Anderson referred to the question he had previously, regarding the benefit exclusion. In cases like this, would a benefit change require a Congressional change where they would have to redefine the TRICARE benefit?

CAPT Norton stated that to have an additional class of drugs not covered or moved to a 4th tier that would require a change in the statute.

Dr. Anderson asks if a statutory change would be required if a drug had OTC equivalent.

CAPT Norton stated that he was not sure about the OTC.

Dr. Anderson stated that he is thinking about a situation like with Vimovo where you could achieve the same combination with OTC alternatives. He is just curious and he agrees with the recommendation presented. He was just wondering if there is a process available to prevent utilization of these drugs.

CAPT VonBerg stated that it would require a statute change.

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the NSAIDs: Esomeprazole/Naproxen (Vimovo) and Ibuprofen/Famotidine (Duexis)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: RCT

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

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: RCT

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

6. NON-OPIOID PAIN SYNDROMES

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. Amrix does not offer compelling advantages over cyclobenzaprine IR tablets (generic Flexeril).

The P&T Committee recommended (**14 for, 1 opposed, 0 abstained, 1 absent**) manual PA criteria for Amrix in new and current patients.

Manual PA criteria—Amrix is approved if:

- Patient has tried and failed generic Flexeril

AND

- Patient does not have any of the following (patient older than age 65 years, hepatic impairment, history of urinary retention, angle-closure glaucoma, increased intraocular pressure, or 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.

Summary of Physician's Perspective

Amrix is a sustained release preparation which contains the same active ingredient as Flexeril. The current patients will not be grandfathering, and there are about 1,400 patients on the drugs. The package insert recommends Amrix should only be used for short periods (up to 2 or 3 weeks), so a new PA will be required after six months.

Summary of Panel Questions and Comments

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA: 

These comments were taken under consideration prior to my final decision

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

7. TOPICAL PAIN DRUGS

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.

Summary of Physician's Perspective

The Committee does periodically re-assess whether the drugs with existing PA criteria still require them, based on either clinical or economic factors. The cost of generic Lidoderm patches has fallen, so the benefit of removing the PA criteria was apparent here.

Other cases where it is no longer necessary to have PA criteria will be brought here before the Panel.

Summary of Panel Questions and Comments

Dr. Anderson asks if there are quantity limits on the patches.

Dr. Allerman stated that that was not sure if there was a quantity limit the patches or not.

Ms. Le Gette stated that the ointments have quantity limits.

Dr. Anderson stated that that would be my only comment to look and see if there was any type of egregious use.

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent:

  Director, DHA: 

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

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: 

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

8. BRAND OVER GENERIC AUTHORITY AND PA CRITERIA

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 will 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.

Summary of Physician's Perspective

The reasoning behind this request is to ensure that the most cost-effective products are available when a new generic formulation enters the market. If there is a cost-benefit to the MHS, the patient will continue to receive the branded product; no paperwork is necessary unless the generic formulation is required for some clinical reason, for example a drug allergy to an excipients.

We expect that cases where there is a need to fill out the "Brand over Generic" PA to receive the generic product would occur rarely.

Summary of Panel Questions and Comments

Ms. Le Gette asks if the change gives the P&T Committee the administrative authority to approve a brand over a generic formulation if there is a cost benefit to the MHS.

CAPT VonBerg replies yes.

Ms. Le Gette asked if this policy the same as the one currently in place for Nexium. We are changing the Niaspan, as of this week actually, where the brand is preferred and the generic requires a PA. It is the same thing but this is giving the committee the authority to approve a brand over a generic formulation.

CAPT VonBerg responded that is the perfect example.

Dr. Anderson stated that he applauds these changes and he thinks it makes a lot of sense financially. Hopefully, it puts more pressure on generic manufactures to be price competitive at launch. The one question that he would have is what type of communication is being sent

to the pharmacy network or affected beneficiaries as these changes are happening. Do you communicate, to the pharmacy network, the expectations about brand and generic dispensing? Also, when the benefit changes do you communicate anything to affected parties that the generic should now be dispensed?

Ms. Le Gette stated that secondary massaging does go out to the pharmacy network.

Dr. Anderson asks if it is clear what you want them to do.

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)

- **Brand Over Generic Authority**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: RCBell

  These comments were taken under consideration prior to my final decision

- **Brand Over Generic Authority: PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA: RCBell

  These comments were taken under consideration prior to my final decision

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

1. FY08 NDAA, Section 703

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 POD 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.

Summary of Physician's Perspective

The request here for the administrative authority is another example of creating a process to allow for faster implementation of Section 703 requirements. Cases where the Section 703 products can be limited to the Mail Order do provide a cost savings to the MHS.

Summary of Panel Questions and Comments

Ms. Le Gette asks if there are any changes on the Kitabis Paks because it is already on the 703-B list, non-formulary at the mail and retail POS and then requires a PA at retail. That is how the 703-B rule works. Are there any changes regarding 90 implementation period and sending letters to the beneficiaries?

CAPT VonBerg stated that the product was formally available at retail because of limited distribution. This change allows the committee to formally follow the normal path of the 703-Bs. So essentially we are just catching up to what you talked about with a formal vote.

Ms. Le Gette states as of May 4th it was put on that rule.

Dr. Allerman stated that with this particular product the patient is on for 28 days and then they were off for 28 days. Dr. Moore ran data that indicated patients have not yet filled their prescriptions. We wanted to notify these patients that the drug will now be available at mail. We wanted to make sure that they know that they have to go to mail now instead of retail.

Ms. Le Gette states that this particular rule the 703-B is not enforced in the mail. That is the enhanced EMM Program. There is a PA requirement at retail but it does not exclude home delivery.

Dr. Allerman stated that they would have to have the PA and that is the information that we are trying to communicate.

Ms. Le Gette, so it is just basically communication and ESI is not loading anything.

There were no more questions or comments from the Panel. The Chair called for a vote on the removal of exemption from Mail Order Pharmacy availability, the Implementation Period and the Program Updates on the FY08 NDAA, Section 703—Tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

- **FY08 NDAA, Section 703—Program Updates**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

RE-EVALUATION OF NF AGENTS:

1. CALCIUM CHANNEL BLOCKERS (CCBs)

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); verapamil capsule 24h (Verelan); diltiazem tablet ER 24h (Cardizem LA,); isradipine capsule (generic only); nicardipine (generic only); and, nisoldipine tablet ER 24h (Sular).

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 non-formulary 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 non-formulary products tended to be lower at mail order compared to retail.

B. CCBs—UF Recommendation

The P&T Committee recommended (**15 for, 0 opposed, 0 abstained, and 1 absent**) that Verelan PM, generics; Verelan, generics; Cardizem LA, generics; isradipine capsules; nicardipine; and Sular, generics) remain NF. Additionally, all six non-formulary CCBs will remain subject to the requirement that they be generally available only at mail order, regardless of generic status.

Summary of Physician's Perspective

This is an example of re-evaluating decisions from several years ago in classes where there are non-formulary products that are now available in generic formulations. For the calcium channel blockers, the recommendation was that no change in the formulary status was needed.

Summary of Panel Questions and Comments

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation for the CCBs.

- **CCBs—UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

Director, DHA:

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

2. PROTON PUMP INHIBITORS (PPIs)

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 non-formulary 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 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 delayed release tablets (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.

Summary of Physician's Perspective

Once again, another example of re-assessing a class where there are now generic products from the original non-formulary recommendations. The Panel will be seeing additional types of these analyses in the future.

Summary of Panel Questions and Comments

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation for the PPIs.

- **PPIs—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent:

  Director, DHA:

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

Dr. Anderson thanked everyone for organizing the meeting. In closing, he stated that in his opinion, a lot of the drugs on the agenda don't add significant value to the healthcare system. Anything the committee or the Panel can do in the form of advocacy or policy changes that we have statutory authority to implement in an effort to curtail the use of products that just drive up the costs to the system and don't add any incremental value is a move in the right direction. He would encourage us to continue to do that to preserve the dollars, the benefit and direct the dollars where they do the most good for the beneficiary.

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 "Panel" in this summary refers to the "Uniform Formulary Beneficiary Panel," the group who's meeting in the subject of this report.

- AAP - Atypical Antipsychotics
- ACE - Angiotensin Converting Enzyme
- ADHD - Attention Deficit Hyperactivity Disorder
- AED – Anti-epileptic drugs
- ARB - Angiotensin Receptor Blocker
- BAP - Beneficiary Advisory Panel
- BCF - Basic Core Formula
- BIA - Budget Impact Analysis
- CCB – Calcium Channel Blockers
- CFR – Code of Federal Regulations
- CMA - Cost Minimization Analysis
- COPD - Chronic Obstructive Pulmonary Disease
- DAA – Direct Acting Antiviral Agents
- DFO - Designated Federal Officer
- DHA - Defense Health Agency
- DoD -Department of Defense
- ER - Extended Release
- FACA - Federal Advisory Committee Act
- FDA - Food Drug Administration
- IR – Immediate Release
- LHRH – Leutinizing hormone-releasing hormone
- MDD – Major Depressive Disorder
- MN - Medical Necessity
- MTF - Military Treatment Facility
- NDAA - National Defense Authorization Act
- NF – Non-Formulary
- NSAID - Non-steroid Anti-Inflammatory Drug
- OTC - Over the Counter
- P&T – Pharmacy & Therapeutic
- PA- Prior Authorization
- POD - Pharmacy Operations Division
- PPI – Proton Pump Inhibitors
- RAAs - Renin-Angiotensin Antihypertensive Agents
- TAA – Trade Agreements Act
- TRICARE - Military Health Care System
- UF - Uniform Formulary
- XR - Extended Release

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
June 22, 2016
Washington, D.C.

Present Panel Members

- Michael Anderson, United Healthcare, Chairperson
- Theresa Buchanan, the National Family Association
- Sandra Delgado, Humana
- Lisa Le Gette, Express Scripts, Inc.
- Kevin Sommer, U.S. Family Health Plan
- John Wagoner, HealthNet Federal Services

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C., and CAPT Edward Norton called the proceedings to order at 9:00 A.M.

Agenda

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

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

  - Designated Newly-Approved Drugs
    - Renin-Angiotensin Antihypertensives: sacubitril/valsartan (Entresto)
    - Gastrointestinal-2 (GI-2) Miscellaneous Drugs: eluxadoline (Viberzi)

  - Drug Class Reviews
    - Atypical Antipsychotics
    - Anticonvulsant and Anti-Mania Agents
    - Contraceptive Agents—Emergency Contraceptives

  - Innovator Drugs
    - Antihemophilic Agents: antihemophilic factor (recombinant) (Kovaltry)
    - Attention Deficit Hyperactivity Disorder (ADHD)—Stimulants: amphetamine ER orally dissolving tablets (Adzenys XR ODT)
    - Narcotic Analgesics and Combinations: buprenorphine buccal film (Belbuca)
    - Psoriasis Agents: calcipotriene/betamethasone dipropionate foam (Enstilar)
    - Antihemophilic Agents: coagulation factor IX (recombinant)/albumin fusion protein (Idelvion)
    - Antiretrovirals Agents: emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey)

- Hepatitis C Virus—Direct Acting Antiviral Agents: grazoprevir/elbasvir (Zepatier)
- Targeted Immunomodulatory Biologics (TIBs): ixekizumab injection (Taltz)
- ADHD—Stimulants: methylphenidate ER chewable tablets (QuilliChew ER)
- TIBs: tofacitinib ER tablets (Xeljanz XR)
- Binders, Chelators, Antidotes, Overdose Agents: uridine triacetate oral granules (Xuriden)

- Utilization Management Issues
  - Prior Authorization Criteria
    - Oral Oncologic Agents: palbociclib (Ibrance)
    - Parkinson's Disease Agents: carbidopa/levodopa ER capsules (Rytary)
    - Gastrointestinal-2 (GI-2) Opioid-Induced Constipation: naloxegol (Movantik)
    - Beta-Blockers: nebivolol (Bystolic)
    - Non-Steroidal Anti-Inflammatory Agents (NSAIDs): esomeprazole/naproxen (Vimovo) and ibuprofen/famotidine (Duexis)
    - Non-Opioid Pain Syndrome Drugs: cyclobenzaprine ER capsules (Amrix)
  - Removal of Prior Authorization Criteria
    - Topical Pain Drugs: lidocaine 5% patch (Lidoderm)
  - "Brand over Generic" Authority and Prior Authorization Criteria

- NDAA 2008 Section 703 Actions

- Re-evaluation of Non-formulary Agents
  - Calcium Channel Blockers
  - Proton Pump Inhibitors

- Panel Discussions

The Uniform Formulary Beneficiary Advisory Panel 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 recommendation and vote to accept or reject the recommendations. The Panel will provide comments on their vote as directed by the Panel Chairman.

Opening Remarks

CAPT Edward Norton introduced himself as the Designated Federal Officer (DFO) for the Uniform Formulary Beneficiary Advisory Panel. The panel has convened to comment on the recommendations of the DoD P&T Committee meeting, which occurred May 11-12, 2016.

CAPT Norton 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, CAPT Norton 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 maybe interested in the drug class the 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 12 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:

- All discussions take place in an open public forum. There is to be no committee discussion outside the room, during breaks, or at lunch.

- Audience participation is limited to private citizens who signed up to address the Panel.

- 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.

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

There were no individuals signed up this morning to provide comments to the BAP.

Chairman's Opening Remarks

Dr. Anderson welcomes everyone, states he has no comments and turns the meeting over to the presenters.

DRUG CLASS REVIEW PRESENTATION

(PEC Script - CAPT VONBERG)

GOOD MORNING. I am CAPT Edward VonBerg, Chief of the Formulary Management Branch. Joining me is doctor and retired Army Colonel John Kugler, the Chairman of the Pharmacy & Therapeutics Committee, who will provide the physician perspective and comments on the recommendations made by the P&T Committee. Also joining us from the Formulary Management Branch today is Dr. Angela Allerman, a clinical pharmacist and Deputy Chief P&T Section.

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 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.

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 non-formulary 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 its collective professional judgment when considering the analyses from both the relative clinical- and relative cost-effectiveness evaluations. The Committee reviewed the following:

    a. Two newly approved drugs. They are

        - *Sacubitril/valsartan (Entresto)* for chronic heart failure; and

        - *Eluxadoline (Viberzi)* for diarrhea predominate irritable bowel syndrome (IBS-D);

b. The P&T Committee also reviewed three Uniform Formulary Drug Classes:

- Atypical Antipsychotics;
- Anticonvulsants and Anti-Mania Drugs; and
- Contraceptive Agents – the Emergency Contraceptives drug class

c. The P&T Committee also evaluated eleven Innovator Drugs, which are currently in pending status and available under terms comparable to non-formulary drugs.

d. We will also discuss Prior Authorizations (PA) for drugs in 6 classes:

- Oral Oncologic Agents
- Parkinson's Disease Agents
- Gastrointestinal-2 (GI-2); Opioid-Induced Constipation
- Beta-Blockers;
- Non-Steroidal Anti-Inflammatory Agents (NSAIDs); and
- Non-Opioid Pain Syndrome Drugs.

e. Also discussed was the removal of the PA for Lidoderm patch, and a program update for the "Brand over Generic" authority and PA criteria.

4. There was one drug under Section 703, National Defense Authorization Act (NDAA) for Fiscal Year 2008 reviewed at this meeting: tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak). A program update will also be reviewed.

5. Finally, there was a re-evaluation of Non-formulary generic drugs in the Calcium Channel Blockers and Proton Pump Inhibitors drug classes.

6. The DoD P & T Committee will make a recommendation as to the effective date of the agents being changed from the Uniform Formulary tier to Non-formulary 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.

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

(ANGELA ALLERMAN)

A. RENIN-ANGIOTENSIN ANTIHYPERTENSIVES (RAAs)

1. **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.

2. **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).

3. **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.

4. **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.

Full PA Criteria:

The new criteria will replace the criteria recommended at the February 2016 meeting.

Manual PA criteria apply to all new and current users of sacubitril/valsartan (Entresto). Coverage is approved for Entresto if all of the following criteria apply:

- **(new update) The initial prescription is written by or in consultation with 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

- **(new update) 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

5. **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.

6. **Physician's Perspective**

The primary discussion revolved around the Prior Authorization criteria. We requested feedback from the cardiology consultants, and they all felt that Entresto should initially be written with cardiologist input, and that the use of Entresto should be limited to the patients who meet the inclusion criteria from the the PARADIGM trial. The revisions to the PA criteria originally recommended at the February P&T meeting included these recommendations.

One member was concerned that having everyone go through the PA process would be burdensome to patients with trying to get an appointment. However, currently the overall numbers of patients on Entresto is about 1,000 and the cardiology consultants said there haven't been a large number of patients who are candidates. Additionally, other professional groups, including the Institute for Clinical and Economic Research, do recommend ensuring use of Entresto for those patients most likely to benefit from the drug.

New joint guidelines from the American Heart Association, American College of Cardiology and the Heart Failure Society of America came out the week after the P&T meeting, and the European Society of Cardiology also updated their heart failure guidelines. The new guidelines place Entresto as a class I-B recommendation for heart failure, but the level of evidence was below that of the ACE inhibitors and ARBs, which remain a Class I-A recommendation. The guidelines do mention that there are safety issues when initiating therapy with Entresto, and that if patients are not candidates for Entresto, an ACE inhibitor should be continued for all classes of heart failure.

7. **BAP Comments**

Dr. Sommer asked if the initial prescription for Entresto must be written by a cardiologist. Does that include physician's assistants and nurse practitioners that are overseen by cardiologists or does it have to have a cardiologist stamp on it.

Dr. Allerman responded that it is actually "written by or in consultation with" so the PA would mean a cardiology office.

Dr. Anderson states that I think you addressed the question I have regarding the guidelines. Just to be clear, there are no guidelines today that are formally recommending Entresto as first line therapy definitively. Is that accurate?

Dr. Allerman responded that that statement was correct.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, PA Criteria, and UF and PA Implementation Plan for the RAAs: Sacubitril/Valsartan (Entresto)

- **RAAs: Sacubitril/Valsartan (Entresto)—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **RAAs: Sacubitril/Valsartan (Entresto)—Prior Authorization (PA) Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **RAAs: Sacubitril/Valsartan (Entresto)—UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

B. GASTROINTESTINAL-2 (GI-2) MISCELLANEOUS DRUGS

(ANGELA ALLERMAN)

1. **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.

2. **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).

3. **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.

4. **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:

   - **(new update) Initial prescription written by OR in consultation with a 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

  - **(new update) The patient has failed a trial of rifaximin**

- Non-FDA approved uses are not approved.

- Prior authorization does not expire.

5. **GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)—UF 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 90-day implementation period; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

6. **Physician's Perspective**

   Viberzi had not been launched when the GI-2 drugs were reviewed by the Committee back in November, so it was reviewed as a new drug.
   There was no controversy over the recommendation for the non-formulary designation, due to safety concerns and cost effectiveness. Viberzi will require

long term therapy, compared to a 14 day courses of therapy with rifaximin. There was a GI specialist at the meeting.

Prior Authorization criteria were originally placed on Viberzi at the February 2016 P&T Committee meeting, with an implementation date of Aug 10, 2016. Based on the safety issues and cost effectiveness, the PA criteria were revised to require a trial of rifaximin first.

7. **BAP Comments**

Dr. Anderson asked for clarification regarding the new update. Should it state "in consultation with or prescribed by gastroenterologists"?

Dr. Allerman responded that it is in consultation with but the language was inadvertently left off.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, PA Criteria, and UF Implementation Plan for the GI-2 Miscellaneous Drugs: Eluxadoline (Viberzi)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

II. UF CLASS REVIEWS

A. ATYPICAL ANTIPSYCHOTIC (AAP) DRUGS

(CAPT VONBERG)

1. **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 major depressive disorder (MDD). Cariprazine (Vraylar) is FDA-approved for schizophrenia and bipolar disorder. Rexulti and Vraylar 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. Vraylar 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 Latuda compared to risperidone, olanzapine, and quetiapine extended release could not be proven. However, Latuda 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.

2. **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: generic formulations of risperidone, ziprasidone, and quetiapine; Risperdal brand, generic 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 Latuda was added to the UF was the most cost-effective option.

3. **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)

4. **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 requires a trial of at least two other AAPs, including aripiprazole, prior to use of Rexulti.

Full PA Criteria:

All new users of 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 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 Rexulti.

- Non-FDA approved uses are not approved.

Prior Authorization does not expire.

5. **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.

6. **Physician's Perspective**

   The clinical review focused on the branded products, and the indications for schizophrenia, bipolar disorder, and as adjunctive therapy to antidepressants for major depressive disorder.

   We did ask Military Health System providers for their input and over 75% of the respondents were psychiatrists. Their opinions were considered when making the Uniform Formulary recommendations. Additionally, a child/adolescent psychiatrist attended the meeting.

   There were no significant safety updates from the August 2011 review. In May 2016, the FDA did release new safety warnings for aripiprazole (for impulse control problems) and olanzapine (for hypersensitivity reactions); however, these are rare adverse events. The psychiatrist at the meeting did note that these new warnings would not prevent prescribing of these two drugs if not contraindicated and required for management.

The formulary recommendation was unanimous. The main decision to move Latuda from NF to UF status was based on cost effectiveness, and also based on the feedback from providers, along with the pregnancy category B rating. The recommendations for the non-formulary products (Saphris, Fanapt, Rexulti, and Vraylar) were that they did not offer clinical advantages over the current formulary drugs.

7. **BAP Comments**

Dr. Anderson asked whether the PA for Rexulti was just for new patients because it mentions somewhere else that it might be for current patients.

Dr. Allerman responded that it should be just new patients.

Dr. Anderson asked for clarification regarding the beneficiary population, impacted by the change that will be receiving a communication about the change in benefit.

Dr. Allerman responded that it would be the patients who will now have the non-formulary status. Their co-pay will change.

Dr. Anderson responded, given the sensitivity of this class, for people who pursue a PA on Rexulti, if they are denied because they haven't tried other alternatives, is there any additional outreach for these patients. He is concerned that patients will fall through the cracks and not receive any therapy. I think Express Scripts, with some of your programs; have outreach for people who don't meet the criteria. Would that apply to a class like this?

Ms. Le Gette stated the ESI is required to send letters based on the DHA Director decision regarding the PA criteria. Letters are sent to the physicians and beneficiaries announcing that a PA is going into place.

Ms. Le Gette asked if the PA for Rexulti was still going into place on August 10. She clarified that the change is just for the 90 days implementation period and the formulary status.

Dr. Allerman responded that is for the formulary status and the co-pay change.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, PA Criteria, and UF and PA Implementation Plan for the AAP Drugs.

- **AAP Drugs—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **AAP Drugs—Manual PA Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **AAP Drugs—UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

B. ANTICONVULSANT AND ANTI-MANIA DRUG CLASS

(CAPT VONBERG)

1. **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 to 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.

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

   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 Equetro, Oxtellar XR, Keppra XR, Vimpat, topiramate ER (authorized generic), Trokendi XR, Fycompa, Qudexy XR, Onfi, Aptiom, Banzel, and 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.

3. **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

4. **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

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

- Coverage approved for
    - Partial onset seizure and primary generalized tonic-clonic seizures in patients ≥ 10 years
    - Lennox-Gastaut seizures in patients ≥ 6 years for Trokendi XR and age ≥2 years and older for Qudexy XR
    - Adjunctive therapy of partial onset seizure or primary generalized tonic-clonic seizure in patients 2 years of age and older (Qudexy XR) or 6 years and older (Trokendi XR)
- 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

5. **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.

6. **Physician's Perspective**

These drugs have widely varying indications and mechanisms of action. Some drugs (mainly topiramate) have significant off-label use. Many of the branded products have very low utilization due to the safety profile and specific FDA-indications.

For several of the drugs, new extended release formulations have been approved, but there are either generic equivalents or therapeutic substitutes for some of these

products. For example Trokendi and Qudexy have the same active ingredient as topiramate, but are extended release formulations.

The decision to have all the products in the class be designated as uniform formulary is due to acknowledgment of the difficulty with treating seizures, and also the fact that several products are available in low cost generic formulations. We did reach out to several pediatric neurologists for their opinion on what is needed for children and adolescents.

There was some discussion on whether Trokendi and Qudexy should be non-formulary or uniform formulary, due to the higher cost compared to generic topiramate. The members who opposed the formulary recommendation were because they felt that only the generic topiramate products should be UF. However, the Committee recommended overall that the existing prior authorization criteria, which limit use of the two new products to patients with seizures, would be sufficient to ensure appropriate use of these higher cost extended release formulations.

For Vimpat, the PA authorization requirements were recommended to be removed.. The PA recommendation from the February meeting is due to be implemented on August 10; but we will notify to ESI not to implement the PA at all.

7. **BAP Comments**

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation and Manual PA Criteria for the Anticonvulsant and Anti-Mania Drug Class.

- **Anticonvulsant and Anti-Mania Drug Class—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **Anticonvulsant and Anti-Mania Drug Class—Topiramate ER (Trokendi XR and Qudexy XR) Manual PA Criteria and Removal of the PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

C. CONTRACEPTIVE AGENTS

(ANGELA ALLERMAN)

1. **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 regimen (Plan B One Step) has largely replaced use of the 0.75 mg two-tablet regimen (or Plan B).

   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 the prescription product Ella 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. Ella is effective when taken up to 120 hours after unprotected intercourse.

   - In terms of relative effectiveness, Ella 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. Ella acetate prevented 67% of expected pregnancies versus 52% with levonorgestrel.

   - The most commonly reported adverse effects ($\geq$10%) with either levonorgestrel or Ella 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 Ella are required on the UF.

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

   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.

3. **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

4. **Physician's Perspective**

   The other contraceptive subclasses (oral contraceptives and the miscellaneous products) were evaluated in February, so we were completing the review. The entire class has been reviewed before, most recently in August 2011.

   There was no controversy here for the formulary recommendation. There is now widespread over-the-counter availability of the Plan B One Step products, and there were no significant efficacy or safety updates from the previous formulary decision.

5. **BAP Comments**

   Dr. Anderson asked if a TRICARE beneficiary needs a prescription to get the Plan B One Step or Ella.

   Dr. Allerman responded a prescription is not required for the Plan B One Step product. Only the Ella requires a prescription but we have very little prescription utilization for Ella.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation Contraceptive Agents.

- **Contraceptive Agents: Emergency Contraceptives—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

D. INNOVATOR DRUGS

(CAPT VONBERG)

1. **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.

2. **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) – for hemophilia
     - calcipotriene/betamethasone dipropionate foam (Enstilar) – for psoriasis
     - coagulation factor IX (recombinant)/albumin fusion protein (Idelvion) – for hemophilia
     - emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey) – for HIV infection
     - elbasvir/grazoprevir (Zepatier) – for hepatitis C virus infection
     - tofacitinib ER tablets (Xeljanz XR) – a targeted immunologic biologic (TIB) for rheumatoid arthritis which is an extended release formulation of Xeljanz
     - uridine triacetate oral granules (Xuriden) – hereditary orotic aciduria
   - NF:
     - amphetamine ER ODT (Adzenys XR ODT) – for ADHD
     - buprenorphine buccal film (Belbuca) – for severe pain
     - ixekizumab injection (Taltz) – a TIB for severe plaque psoraisis
     - methylphenidate ER chewable tablets (QuilliChew ER) – for ADHD

3. **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 Xeljanz XR, and Taltz; for the hepatitis C direct acting agent Zepatier; and, for the orphan drug Xuriden.

The PA criteria for these drugs is as follows:

1) Xeljanz XR and Xeljanz will have the same PA criteria.

Step therapy and Manual PA Criteria applies to all new users of Xeljanz and all new and current users of Xeljanz XR**.** Xeljanz XR and Xeljanz will have the same PA criteria.

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-Tumor Necrosis Factor or non-TNF drug)
- 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 chronic heart failure

AND

Coverage approved for patients > 18 years with:

- Moderate to severely active Rheumatoid Arthritis 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.

- Prior Authorization does not expire.

2) Ixekizumab injection (Taltz)

Step therapy and Manual PA Criteria applies to all new and current users of ixekizumab (Taltz). The criteria will include a trial of both Humira and Cosentyx.

Automated PA criteria: The patient has filled a prescription for 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**
- There has been an inadequate response to Humira and **Cosentyx**

- Adverse reactions to Humira and **Cosentyx** that are 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

- 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 American Association for the Study of Liver Disease / Infectious Disease Society of America 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
    - The HCV genotype and HCV RNA viral load must be stated on the PA form
- Zepatier is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician

Treatment Regimens and Duration of Therapy

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

4) Uridine triacetate granules (Xuriden)

Prior Authorization applies to all new and current users of Xuriden

Manual PA criteria: 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

4. **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.

5. **Physician's Perspective**

For the innovator drugs, the clinical data and whether there are therapeutic alternatives for the drugs are taken into consideration, along with the cost. Additionally, we do consult with the appropriate specialists for some of the products that are in classes that have not been previously reviewed, or for some of the orphan drugs.

There was no controversy over the Uniform Formulary and Non-Formulary recommendations. The drugs recommended for NF status are in classes that have been previously reviewed by the Committee.

The Prior Authorization recommendations for Xeljanz and Zepatier reflect the existing criteria for the respective classes. The PA for Taltz does have a recommendation for patients to require a trial of Humira and Cosentyx first, as Taltz is only indicated for plaque psoriasis. For Xuriden, which is an orphan drug, the PA criteria limit use to the FDA-approved indications

6. **BAP Comments**

Dr. Anderson asked about the economic analysis for HEP C and Zepatier. Will adding it to the formulary affect the overall cost of care within the class or is it holding steady? He further states that he knows that Zepatier may be a lower cost option. A response with specific information is not required but he is thinking more in terms of sustaining the benefit. More specifically, does the addition of Zepatier to the formulary increase or decrease HEP C treatment costs under the TRICARE benefits?

CAPT VonBerg that there was no significant change in the cost of care.

Dr. Anderson asked for clarification regarding the drugs designated NF for the innovator products. What is the process for periodic review? Does this occur when new clinical evidence becomes available or new contracting opportunities become available? Is there a review process?

CAPT VonBerg responded that we will be conducting follow-up on all of the innovator products. It will vary depending on the change in clinical and economic data. We have not had a follow-up, to date, because most the drugs are brand new and there are defined periods of when things happen; how long it takes the clinical data to mature; or how long it takes for prices to stabilize. However, we do have an actual, organized process to go back and look at the drugs to see if there are changes to the information. We just haven't gotten to that point yet.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Newly-Approved Innovator Drugs.

- **Newly-Approved Innovator Drugs—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **Newly-Approved Innovator Drugs—Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **Newly-Approved Innovator Drugs—UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

III. UTILIZATION MANAGEMENT

A. ORAL ONCOLOGIC AGENTS

(ANGELA ALLERMAN)

1. **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—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 (Arimidex), exemestane (Aromasin), or letrozole (Femara); 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 Arimidex, Aromasin, or Femara; OR

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

a. The patient is receiving a LHRH agonist AND

b. Ibrance will be used as first-line endocrine therapy in combination with Arimidex, Aromasin, or Femara

Prior Authorization does not expire.

Other non-FDA approved uses are not approved

2. **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.

3. **Physician's Perspective**

The Prior Authorization recommended for Ibrance takes into account the FDA approved indications and the off-label uses with good supporting evidence. The PA will only apply to new patients, and we currently have about 560 patients on Ibrance. As new indications get added to the package insert, we will update the PA criteria.

4. **BAP Comments**

   There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the ORAL Oncologic Agents - Palbociclib (Ibrance).

   - **Oral Oncologic Agents: Palbociclib (Ibrance)—Manual PA Criteria**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

   - **Oral Oncologic Agents: Palbociclib (Ibrance)—PA Implementation Period**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

B. PARKINSON'S DISEASE AGENTS

(ANGELA ALLERMAN)

1. **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 all new patients.

   Full PA Criteria: Rytary will be approved if the patient has tried and failed a generic extended release formulation of carbidopa/levodopa.

   Prior Authorization does not expire.

2. **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.

3. **Physician's Perspective**

The Parkinson's disease drugs have not previously been reviewed by the Committee, and currently all of the products are designated as formulary. The active ingredients of Rytary are found in other products, (generic Sinemet), and Rytary does require three times a day dosing.

The Committee felt that a trial of a generic product was reasonable. Currently there are about 700 patients, and the PA will apply only to new patients.

4. **BAP Comments**

Dr. Anderson asked if it was ever an option to exclude certain drugs from the TRICARE Benefit. He is not picking on this drug specifically but if there are therapeutically equivalent products already on the market, with same active ingredients, is there an option to not only place the drug in a non-formulary status but to vote that it not be a covered benefit.

CAPT VonBerg responded that there are drugs or products that TRICARE policies list as not covered. Specifically, cosmetic products are not covered the TRICARE benefit but not individual therapeutic products.

CAPT Norton stated the under the TRICARE benefit structure there is no class of products that are not covered because there are other drugs that are similar or more cost effective.

Dr. Anderson asks, in other words, there are always exceptions to the process.

CAPT Norton states, that they can be placed in a non-formulary status or we can utilize the PA and step therapy to monitor access to the product.

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

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

C. GASTROINTESTINAL-2 (GI-2) OPIOID-INDUCED CONSTIPATION DRUGS

1. 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:

Movantik is approved if:

- The patient does not have any of the following contraindications:
    - 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

- Movantik 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

2. 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.

3. **Physician's Perspective**

   There was no controversy over the recommendations for the PA criteria here. The standard therapies for opioid-induced constipation should be tried before Movantik.

   There are over 3,000 patients currently on Movantik, and the existing patients will be grandfathered.

4. **BAP Comments**

   There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the GI-2 Opioid-Induced Constipation Drugs.

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

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

D. BETA-BLOCKERS

(ANGELA ALLERMAN)

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

   Bystolic is a beta blocker that is solely FDA-approved for the treatment of hypertension.

   It was reviewed by the DoD P&T Committee in June 2008, and designated NF. 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 Bystolic 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.

2. **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.

3. **Physician's Perspective**

   The Committee did not find any new clinical data to support preferred use of Bystolic over the generic beta blockers. Due to the large numbers of patient currently on Bystolic (over 30,000 patients) the existing Bystolic users will be grandfathered.

4. **BAP Comments**

   Ms. Le Gette asks why now? Was there an increase in usage or cost? It was 2008 when Bystolic was originally reviewed.

   Dr. Allerman responded that it was a combination of the cost and clinical effectiveness because every other beta blocker except 1 is generic now and there is nothing clinically to say that this is better than the others.

   Ms. Le Gette asks when the drug will go generic.

   Dr. Allerman stated that it will go generic in 2024. We plan to recommend grandfathering with this product.

   There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Beta Blockers: Nebivolol (Bystolic).

   - **Beta Blockers: Nebivolol (Bystolic)— Manual PA Criteria**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **Beta Blockers: Nebivolol (Bystolic)—PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

E. NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

(ANGELA ALLERMAN)

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

   The NSAIDs were reviewed in August 2012. Vimovo is currently designated as 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 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.

   Manual PA criteria—Vimovo and Duexis are approved if:

   - The 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.

2. **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.

3. **Physician's Perspective**

   The individual ingredients of Vimovo and Duexis are available as single formulations. The Committee did recommend "no grandfathering" here, which will affect approximately 3,400 patients.

4. **BAP Comment**

   Dr. Anderson referred to the question he had previously, regarding the benefit exclusion. In cases like this, would a benefit change require a Congressional change where they would have to redefine the TRICARE benefit?

CAPT Norton stated that to have an additional class of drugs not covered or moved to a 4th tier that would require a change in the statute.

Dr. Anderson asks if a statutory change would be required if a drug had OTC equivalent.

CAPT Norton stated that he was not sure about the OTC.

Dr. Anderson stated that he is thinking about a situation like with Vimovo where you could achieve the same combination with OTC alternatives. He is just curious and he agrees with the recommendation presented. He was just wondering if there is a process available to prevent utilization of these drugs.

CAPT VonBerg stated that it would require a statute change.

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the NSAIDs: Esomeprazole/Naproxen (Vimovo) and Ibuprofen/Famotidine (Duexis)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

F. NON-OPIOID PAIN SYNDROMES

1. **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. Amrix does not offer compelling advantages over cyclobenzaprine IR tablets (generic Flexeril).

   The P&T Committee recommended (**14 for, 1 opposed, 0 abstained, 1 absent**) manual PA criteria for Amrix in new and current patients.

Manual PA criteria—Amrix is approved if:

- Patient has tried and failed generic Flexeril

AND

- Patient does not have any of the following (patient older than age 65 years, hepatic impairment, history of urinary retention, angle-closure glaucoma, increased intraocular pressure, or 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.

2. **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.

3. **Physician's Perspective**

   Amrix is a sustained release preparation which contains the same active ingredient as Flexeril. The current patients will not be grandfathering, and there are about 1,400 patients on the drugs. The package insert recommends Amrix should only be used for short periods (up to 2 or 3 weeks), so a new PA will be required after six months.

4. **BAP Comments**

   There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)

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

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

G. TOPICAL PAIN DRUGS

(ANGELA ALLLERMAN)

1. **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.

2. **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.

3. **Physician's Perspective**

   The Committee does periodically re-assess whether the drugs with existing PA criteria still require them, based on either clinical or economic factors. The cost of generic Lidoderm patches has fallen, so the benefit of removing the PA criteria was apparent here.

   Other cases where it is no longer necessary to have PA criteria will be brought here before the Panel.

4. **BAP Comment**

Dr. Anderson asks if there are quantity limits on the patches.

Dr. Allerman stated that that was not sure if there was a quantity limit the patches or not.

Ms. Le Gette stated that the ointments have quantity limits.

Dr. Anderson stated that that would be my only comment to look and see if there was any type of egregious use.

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

H. BRAND OVER GENERIC AUTHORITY AND PA CRITERIA

(CAPT VONBERG)

1. **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 will 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.

2. **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.

3. **Physician's Perspective**

The reasoning behind this request is to ensure that the most cost-effective products are available when a new generic formulation enters the market. If there is a cost-benefit to the MHS, the patient will continue to receive the branded product; no paperwork is necessary unless the generic formulation is required for some clinical reason, for example a drug allergy to an excipients.

We expect that cases where there is a need to fill out the "Brand over Generic" PA to receive the generic product would occur rarely.

4. **BAP Comments**

Ms. Le Gette asks if the change gives the P&T Committee the administrative authority to approve a brand over a generic formulation if there is a cost benefit to the MHS.

CAPT VonBerg replies yes.

Ms. Le Gette asked if this policy the same as the one currently in place for Nexium. We are changing the Niaspan, as of this week actually, where the brand is preferred and the generic requires a PA. It is the same thing but this is giving the committee the authority to approve a brand over a generic formulation.

CAPT VonBerg responded that is the perfect example.

Dr. Anderson stated that he applauds these changes and he thinks it makes a lot of sense financially. Hopefully, it puts more pressure on generic manufactures to be price competitive at launch. The one question that he would have is what type of communication is being sent to the pharmacy network or affected beneficiaries as these changes are happening. Do you communicate, to the pharmacy network, the expectations about brand and generic dispensing? Also, when the benefit changes do you communicate anything to affected parties that the generic should now be dispensed?

Ms. Le Gette stated that secondary massaging does go out to the pharmacy network.

Dr. Anderson asks if it is clear what you want them to do.

There were no more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and the PA Implementation Plan for the Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix)

- **Brand Over Generic Authority**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **Brand Over Generic Authority: PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

(CAPT VONBERG)

A. FY08 NDAA, Section 703

1. **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.

2. **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.

3. **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 POD 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.

4. **Physician's Perspective**

The request here for the administrative authority is another example of creating a process to allow for faster implementation of Section 703 requirements. Cases where the Section 703 products can be limited to the Mail Order do provide a cost savings to the MHS.

5. **BAP Comments**

Ms. Le Gette asks if there are any changes on the Kitabis Paks because it is already on the 703-B list, non-formulary at the mail and retail POS and then requires a PA at retail. That is how the 703-B rule works. Are there any changes regarding 90 implementation period and sending letters to the beneficiaries?

CAPT VonBerg stated that the product was formally available at retail because of limited distribution. This change allows the committee to formally follow the normal path of the 703-Bs. So essentially we are just catching up to what you talked about with a formal vote.

Ms. Le Gette states as of May 4th it was put on that rule.

Dr. Allerman stated that with this particular product the patient is on for 28 days and then they were off for 28 days. Dr. Moore ran data that indicated patients have not yet filled their prescriptions. We wanted to notify these patients that the drug will now be available at mail. We wanted to make sure that they know that they have to go to mail now instead of retail.

Ms. Le Gette states that this particular rule the 703-B is not enforced in the mail. That is the enhanced EMM Program. There is a PA requirement at retail but it does not exclude home delivery.

Dr. Allerman stated that they would have to have the PA and that is the information that we are trying to communicate.

Ms. Le Gette, so it is just basically communication and ESI is not loading anything.

There were no more questions or comments from the Panel. The Chair called for a vote on the removal of exemption from Mail Order Pharmacy availability, the Implementation Period and the Program Updates on the FY08 NDAA, Section 703—Tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak)

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

- **FY08 NDAA, Section 703—Program Updates**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

V. RE-EVALUATION OF NF AGENTS:

(CAPT VONBERG)

A. CALCIUM CHANNEL BLOCKERS (CCBs)

1. **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); verapamil capsule 24h (Verelan); diltiazem tablet ER 24h (Cardizem LA,); isradipine capsule (generic only); nicardipine (generic only); and, nisoldipine tablet ER 24h (Sular).

   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 non-formulary 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 non-formulary products tended to be lower at mail order compared to retail.

2. **CCBs—UF Recommendation**

The P&T Committee recommended (**15 for, 0 opposed, 0 abstained, and 1 absent**) that Verelan PM, generics; Verelan, generics; Cardizem LA, generics; isradipine capsules; nicardipine; and Sular, generics) remain NF. Additionally, all six non-formulary CCBs will remain subject to the requirement that they be generally available only at mail order, regardless of generic status.

3. **Physician's Perspective**

This is an example of re-evaluating decisions from several years ago in classes where there are non-formulary products that are now available in generic formulations. For the calcium channel blockers, the recommendation was that no change in the formulary status was needed.

4. **BAP Comments**

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation for the CCBs.

- **CCBs—UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 0

B. PROTON PUMP INHIBITORS (PPIs)

1. **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 non-formulary 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 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.

2. **PPIs—UF Recommendation**

   The P&T Committee recommended (**15 for, 0 opposed, 0 abstained, 1 absent**) that rabeprazole delayed release tablets (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.

3. **Physician's Perspective**

   Once again, another example of re-assessing a class where there are now generic products from the original non-formulary recommendations. The Panel will be seeing additional types of these analyses in the future.

4. **BAP Comments**

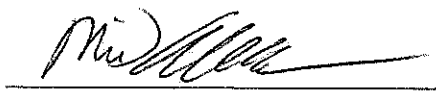
   There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation for the PPIs.

   - **PPIs—UF Recommendation**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent:

Dr. Anderson thanked everyone for organizing the meeting. In closing, he stated that in his opinion, a lot of the drugs on the agenda don't add significant value to the healthcare system. Anything the committee or the Panel can do in the form of advocacy or policy changes that we have statutory authority to implement in an effort to curtail the use of products that just drive up the costs to the system and don't add any incremental value is a move in the right direction. He would encourage us to continue to do that to preserve the dollars, the benefit and direct the dollars where they do the most good for the beneficiary.

CAPT Norton thanked the Chairperson and stated that we would include his comments in the minutes. As we stated, the changes discussed to require statutory changes. CAPT Norton adjourned the meeting.



Dr. Michael J. Anderson

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 "Panel" in this summary refers to the "Uniform Formulary Beneficiary Panel," the group who's meeting in the subject of this report.

- AAP - Atypical Antipsychotics
- ACE - Angiotensin Converting Enzyme
- ADHD - Attention Deficit Hyperactivity Disorder
- AED – Anti-epileptic drugs
- ARB - Angiotensin Receptor Blocker
- BAP - Beneficiary Advisory Panel
- BCF - Basic Core Formula
- BIA - Budget Impact Analysis
- CCB – Calcium Channel Blockers
- CFR – Code of Federal Regulations
- CMA - Cost Minimization Analysis
- COPD - Chronic Obstructive Pulmonary Disease
- DAA – Direct Acting Antiviral Agents
- DFO - Designated Federal Officer
- DHA - Defense Health Agency
- DoD -Department of Defense
- ER - Extended Release
- FACA - Federal Advisory Committee Act
- FDA - Food Drug Administration
- IR – Immediate Release
- LHRH – Leutinizing hormone-releasing hormone
- MDD – Major Depressive Disorder
- MN - Medical Necessity
- MTF - Military Treatment Facility
- NDAA - National Defense Authorization Act
- NF – Non-Formulary
- NSAID - Non-steroid Anti-Inflammatory Drug
- OTC - Over the Counter
- P&T – Pharmacy & Therapeutic
- PA- Prior Authorization
- POD - Pharmacy Operations Division
- PPI – Proton Pump Inhibitors
- RAAs - Renin-Angiotensin Antihypertensive Agents
- TAA – Trade Agreements Act
- TRICARE - Military Health Care System
- UF - Uniform Formulary
- XR - Extended Release