EXECUTIVE SUMMARY

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

I. UF CLASS REVIEWS

A. ACNE AGENTS: TOPICAL ACNE AND ROSACEA AGENTS SUBCLASS (CAPT VONBERG)

1. Acne Agents: Topical Acne and Rosacea Agents Subclass—UF Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **UF and step-preferred**
  - adapalene 0.1% lotion, gel, cream, and 0.3% gel (Differin, generics)
  - clindamycin 1% foam (Evoclin, generics)
  - clindamycin 1% gel, cream, foam, lotion, solution, and med swab (Cleocin T, generics)
  - clindamycin/benzoyl peroxide 1%/5% gel (Benzaclin, generics)
  - clindamycin/benzoyl peroxide 1.2%/5% gel (Duac, generics)
  - clindamycin/benzoyl peroxide 1%/5% gel kit (Duac CS (Kit))
  - metronidazole 0.75% cream (MetroCream, generics)
  - metronidazole 0.75% lotion (MetroLotion, generics)
  - metronidazole 1% gel (Metrogel, generics)
  - sulfacetamide sodium/sulfur 10% lotion (Klaron, generics)
  - tretinoin 0.01% and 0.025% gel (Retin-A, generics)
  - tretinoin 0.025% gel, cream (Avita, generics)
  - tretinoin 0.025%, 0.05%, and 0.1% cream, liquid (Retin-A, generics)
  - tretinoin 0.0375%, 0.075% cream (Tretin-X, generics)
  - tretinoin 0.05% gel (Atralin, generics)
- **UF and non-step-preferred**
  - azelaic acid 20% cream (Azelex)
  - azelaic acid 15% gel, foam, kit (Finacea)
  - clindamycin/benzoyl peroxide 1.2% and 2.5% gel (Acanya)
- **NF and non-step-preferred**
  - adapalene/benzoyl peroxide 0.1% /2.5% gel (Epiduo)
  - adapalene/benzoyl peroxide 0.3% /2.5% gel (Epiduo Forte)
  - brimonidine 0.33% gel (Mirvaso)

- clindamycin 1% cleansing kits (Clindacin ETZ, Clindacin PAC)
- clindamycin 1% gel (Clindagel)
- clindamycin/benzoyl peroxide 1.2%/ 3.75% gel (Onexton)
- clindamycin/benzoyl peroxide 1.2%/5% gel/cream kit (Neuac Kit)
- clindamycin/tretinoin 1.2% /0.025% gel (Veltin; Ziana, generics)
- dapsone 5% and 7.5% gel (Aczone)
- ivermectin 1% cream (Soolantra)
- metronidazole 1% cream (Noritate)
- metronidazole 0.75% cream/cleanser kit (Rosadan Cream Kit)
- metronidazole 0.75% gel/cleanser kit (Rosadan Gel Kit)
- tretinoin microsphere 0.04%, 0.08%, and 0.1% gel (Retin-A Micro, generics; Retin-A Micro Pump, generics)
- tazarotene 0.1% foam (Fabior)

2. **Acne Agents: Topical Acne and Rosacea Agents Subclass—Automated Prior Authorization (PA) (Step Therapy) and Manual PA Recommendation**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) step therapy and manual PA criteria for the acne and rosacea drugs. Separate step therapies will be required for acne and rosacea products. Within the acne subclass, there are additional step therapies, based on mechanism of action. All branded formulations are non-step-preferred. Step therapy for the acne products generally requires use of at least three step-preferred products first, prior to use of a non-preferred product. For the rosacea products, one generic metronidazole step-preferred formulation is required prior to use of the non-step-preferred products.

Full PA Criteria:

a. Topical Antibiotics and Combinations

All new and current users of Clindacin ETZ, Clindacin PAC, Clindagel, Onexton, Neuac Kit and Acanya are required to try 3 step-preferred topical generic acne products first.

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur) at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Clindacin ETZ, Clindacin PAC, Clindagel, Onexton, Neuac Kit or Acanya will be approved if:

- The patient has a diagnosis of acne vulgaris

  AND

- Patient has tried and failed or experienced adverse effects to at least 3 step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide products.

PA expires in 6 months.

b. Topical Retinoids and Combinations

All new and current users of Epiduo, Epiduo Forte, Veltin, Ziana, Retin-A Micro, Retin-A Micro Pump, Fabior, and generics are required to try 3 step-preferred topical generic acne products, including at least 2 different strengths of tretinoin.

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic acne products including at least 2 different strengths of tretinoin, at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, the non-step-preferred product will be approved if:

- The patient has a diagnosis of acne vulgaris

AND

- Patient has tried and failed at least 3 step-preferred topical generic acne products, including at least 2 different strengths of tretinoin OR
- The patient has experienced an adverse reaction/inadequate response with formulary step-preferred topical tretinoin agents that is not expected to occur with the non-preferred product, OR
- There is no other formulary agent alternative
  - For Epiduo, Epiduo Forte: The patient requires a combination topical adapalene/benzoyl peroxide.

- For Veltin or Ziana: The patient requires this particular strength of combination topical tretinoin/clindamycin (0.025% with 1.25%, respectively).

PA expires after 6 months.

c. Topical Azelaic Acid Products

All new and current users of Azelex and Finacea are required to try 3 step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur, or metronidazole).

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic products at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Azelex or Finacea will be approved if:

- For Azelex: The patient has a diagnosis of acne vulgaris or rosacea

AND

- Patient is pregnant, OR
- Patient has tried and failed at least 3 preferred formulary topical acne agents, including combination therapy with clindamycin and benzoyl peroxide.
- For Finacea: Patient is pregnant, OR
- Patient has tried and failed, or cannot tolerate a step-preferred topical generic metronidazole product (1% gel, 0.75% lotion or 0.75% cream)

PA expires after 6 months.

d. Topical Dapsone Products

All new and current users of Aczone 5% and 7.5% are required to try 3 step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic acne products at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met Aczone will be approved if:

- The patient has a diagnosis of acne vulgaris, AND
    - Patient is an adult female with a diagnosis of inflammatory acne,

      AND
    - The patient has tried and failed at least 3 step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.

PA expires after 6 months.

e. Topical Metronidazole Products

All new and current users of Noritate and Rosadan are required to try one generic topical step-preferred metronidazole product (1% gel, 0.75% lotion or 0.75% cream).

Automated PA Criteria:

- The patient has filled a prescription for one generic topical step-preferred metronidazole product at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Noritate or Rosadan will be approved if:

- The patient has a diagnosis of rosacea, AND
- The patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream).

PA expires after 6 months.

f. Miscellaneous Topical Agents

All new and current users of Mirvaso and Soolantra are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream).

Automated PA Criteria:

- The patient has filled a prescription for one generic topical step-preferred metronidazole product at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Mirvaso or Soolantra will be approved if:

- Patient is at least 18 years of age and has the following diagnosis:
  - For Mirvaso: Patient has non-transient, persistent facial erythema of rosacea
  - For Soolantra: Patient has inflammatory lesions (papulopustular) of rosacea caused by Demodex mites

  AND

  - Patient has tried and failed one generic step-preferred formulary topical metronidazole product.

  AND

  - Patient has tried and failed topical azelaic acid.

PA expires in 365 days.

5. **Acne Agents: Topical Acne and Rosacea Agents Subclass—Manual PA Recommendation for Benzoyl Peroxide**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for legend single-ingredient benzoyl peroxide formulations (e.g., those products that are not in combination with a topical antibiotic). A trial of at least two step-preferred topical acne products will be required prior to use of a prescription benzoyl peroxide product (formulations ranging in concentration from 3% to 10%).

Full PA Criteria:

Legend Benzoyl Peroxide Products: benzoyl peroxide 4% to 10% gel, foam, cleanser, towelette, kit (Benzac, Benzac Wash, BenzEFoam, BenzEFoam Ultra, BenzePrO, Benzoyl Peroxide, BP Foam, BPO, BP Wash, Brevoxyl, Brevoxyl-4, Brevoxyl-8, Desquam E, Desquam X, Inova, NuOx, PanOxyl, Panoxyl-10, PR Benzoyl Peroxide, Riax, Sulfoxyl Regular, SE BPO, Vanoxide-HC)
PA applies to both new and current users.

Manual PA Criteria:

- Patient has a diagnosis of acne vulgaris, AND
    - Patient has failed over-the-counter benzoyl peroxide formulations (e.g., washes, gels, cleansers, lotions), OR
    - Patient has tried and failed at least 2 step-preferred topical acne agents (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur).
- PA expires in 6 months.

6. Acne Agents: Topical Acne and Rosacea Agents Subclass—UF and PA Implementation Plan

The P&T Committee recommended (16 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:

- The class was reviewed because there are numerous generic options available. Several of the new products that have been marketed contain the same active ingredient as the generic, but are just in a new strength or packaging; for example the tretinoin microshperes don't add anything clinically relevant to tretinoin, in terms of efficacy. Another example is a new strength of an existing product, including metronidazole 0.75% cream (Rosadan) packaged with a facial cleanser, when the 1% gel (Metrogel) is generic.
- The uniform formulary recommendation has several generic products or therapeutic alternatives to cover almost all of the different mechanisms of action, with the expensive branded products recommended for non-formulary placement and behind the step.
- The step therapy recommendations are also based on the different mechanisms of action; however, use of at least three generic products from the different

categories will generally satisfy the step therapy requirements. The Committee did agree that there should be "no grandfathering" of patients for the step therapy, so that all current and new patients would be affected (about 22,000 patients affected by the step therapy).

- The PA criteria for ivermectin (Soolantra) and brimonidine (Mirvaso) do take into account their potential therapeutic niches. (Mirvaso for erythema in rosacea, and Soolantra for the Demodex mites).

- We also did a provider survey, which was useful in ensuring the products required for clinical coverage would be on the formulary. Some of the providers did comment that the pricey "designer" products should be restricted, and some even recommended having pricing information more readily available for the prescriber.

Summary of Panel Questions and Comments:

Dr. Delgado questions the 180 day automated PA criteria. Was the P&T Committee able to evaluate whether that is enough time to cycle through 3 different therapies? How long are patients on each therapy before someone determines that it has failed and the patient can move onto another one? That window of time seems really short.

CAPT VonBerg stated the standard is 180 days but can opt for longer periods of time. That is something that Committee can consider.

Dr. Delgado is concerned about determining failure for 3 different medications within a 6-month time frame. Some medications take a long time to work. Before you can actually call a failure, you might not get through 6 months. It appears that it may result in a lot of manual PAs.

Dr. Kugler mentioned the frequent use of combinations

CAPT VonBerg said you can see two ingredients in one product.

Dr. Delgado acknowledges the medications aren't necessarily sequential.

Dr. Sommer asks why the length of the PA expires after 6 months. Did the P&T Committee consider a longer approval duration?

CAPT VonBerg answers that the patients may not be on the medications for very long. It takes into consideration that patients will discontinue use in short periods of time.

Dr. Anderson asks a question about 365 days PA for rosacea and asks if over-the-counter agents fit into this in any way or are there any requirements that patients try OTCs?

CAPT VonBerg replies they there was a requirement for patients to try the OTCs but there is no automated way to screen and it is not necessarily an issue.

Dr. Anderson asks will OTCs help to satisfy the step requirements.

CAPT VonBerg replies yes, for some of them.

Dr. Anderson asks a question in regards to pregnancy and azelaic acid. There is an exception is made if the patient is pregnant. Is there any consideration to women who are actively trying to become pregnant?

CAPT VonBerg replies yes. They will amend the criteria to account for women who are trying to become pregnant.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Automated PA, and Manual PA, Manual PA Recommendation for Benzoyl Peroxide and the UF and PA Implementation Plan.

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

  These comments were taken under consideration prior to my final decision

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – Automated PA (Step Therapy) and Manual PA Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

  These comments were taken under consideration prior to my final decision

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – Manual PA Recommendation for Benzoyl Peroxide**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

  These comments were taken under consideration prior to my final decision

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

B. MIGRAINE AGENTS

1. **Migraine Agents: Triptans—UF Recommendation**

   The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

   - **Oral Triptans**
     - UF and step-preferred
       - eletriptan tablets (Relpax)
       - rizatriptan tablets and orally dissolving tablets (ODT) (Maxalt, Maxalt MLT, generics)
       - sumatriptan tablets (Imitrex, generics)
       - zolmitriptan tablets and ODT (Zomig, generics; Zomig-ZMT, generics)
     - UF, non-step-preferred
       - naratriptan tablets (Amerge, generics)
     - NF, non-step-preferred
       - almotriptan (Axert, generics)
       - frovatriptan (Frova, generics)
       - sumatriptan/naproxen tablets (Treximet)
   - **Nasal Triptans**
     - UF, step-preferred
       - sumatriptan nasal spray (Imitrex, generics)
     - UF, non-step-preferred
       - zolmitriptan nasal spray (Zomig Nasal Spray)
     - NF, non-step-preferred
       - sumatriptan nasal powder (Onzetra Xsail)
   - **Injectable Triptans**
     - UF, step-preferred

- sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generics)

- NF, non-step-preferred
  - sumatriptan 4 mg and 6 mg needle-free injection (Sumavel DosePro)
  - Sumatriptan 3 mg autoinjector (Zembrace SymTouch)

- **Transdermal Triptans**

  - NF, non-step-preferred
    - sumatriptan transdermal system (Zecuity), if reintroduced to the market

2. **Migraine Agents: Triptans—Automated PA (Step Therapy) and Manual PA Criteria**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) step therapy for the triptans. There are three separate step therapies for the oral triptans, injectable triptans, and nasal triptans, respectively. A step-preferred formulation of the same dosage form must be tried first, prior to the use of the NF, non-step-preferred product.

Full PA Criteria:

a. **Oral Triptans**

All new users of naratriptan (Amerge, generics), almotriptan (Axert, generics), frovatriptan (Frova generics), and sumatriptan/naproxen (Treximet) tablets are required to try 2 different step-preferred generic oral tablets or ODT triptan formulations or Relpax tablets first (e.g., 2 products with differing active ingredients/chemical entities).

Step-preferred oral and ODT triptan formulations include sumatriptan, rizatriptan, zolmitriptan, and Relpax.

Automated PA Criteria:

- The patient has filled a prescription for at least 2 different step-preferred oral/ODT triptans with different active ingredients at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, naratriptan, almotriptan, frovatriptan, or Treximet will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to 2 step-preferred oral/ODT triptan formulations that is not expected to occur with the non- step-preferred product.

Prior Authorization does not expire.

b. **Nasal Triptans**

All new users of (Zomig Nasal Spray or Onzetra Xsail are required to try generic sumatriptan nasal spray first.

Automated PA Criteria:

- The patient has filled a prescription for generic sumatriptan nasal spray at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, Zomig Nasal Spray or Onzetra Xsail will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to generic sumatriptan nasal spray that is not expected to occur with the non step-preferred product.

Prior Authorization does not expire.

c. **Injectable Triptans**

All new users of Sumavel DosePro or Zembrace SymTouch are required to try sumatriptan injection 4 mg/6 mg (Imitrex STATdose, generics) first.

Automated PA Criteria:

- The patient has filled a prescription for sumatriptan injection 4 mg/6 mg (Imitrex STATdose, generics) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, Sumavel DosePro or Zembrace SymTouch will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to Imitrex STATdose, generics that are not expected to occur with the non-step-preferred product.

Prior Authorization does not expire.

d. **Transdermal Triptans**

All users of sumatriptan transdermal (Zecuity), if it is re-introduced to the market, are required to try 2 different step-preferred triptans with different active ingredients, regardless of dosage formulation first.

Automated PA Criteria:

- The patient has filled a prescription for at least 2 different step-preferred triptans with different active ingredients at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, Zecuity will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to 2 different step-preferred triptans with different active ingredient that is not expected to occur with Zecuity.

Prior Authorization does not expire.

5. Migraine Agents: Triptans—UF and PA Implementation Plan

The P&T Committee recommended (16 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 currently receiving Treximet.

Summary of Physician's Perspective:

- This is another class where there are several generic products available. The new approved drugs all contain sumatriptan in various devices (nasal inhaler and injection); there are no new chemical entities in the class.
- The new clinical information supported that the oral products are first-line for the majority of patients. The Committee did recognize that individual patients may respond to one product and not another, so there are several oral triptans that are step-preferred, including brand eletriptan (Relpax)
- The step therapy is based on the dosage formulation, so a patient who needs an injectable will only have to try the preferred sumatriptan injection first, and not an oral triptan. The Committee did recommend to "grandfather" existing patients, so only new users will be affected by the step therapy, (about 2,600 patients).
- One unique aspect of this step therapy is that there is a look back period of 365 days, rather than the usual 180 days. This is due to the Committee

acknowledging that migraine headaches are for acute situations, and patients may go several months without needing a triptan. The 365 day look back is more convenient to the patient.

- The new sumatriptan products, Onzetra, Zembrace and the Treximet fixed dose combination with an NSAID did not offer significant benefits over the generic sumatriptan products.

- For the Zecuity patch that is currently off the market, the Committee did want to designate it as non-formulary and non-preferred, in case it does get re-introduced.

Summary of Panel Questions and Comments:.

Dr. Anderson asks if there was any consideration given in the manual PA criteria to the products that are more commonly used for menstrual associated migraines. He recognized that it's not a FDA approved use and is not sure if the clinical practice guidelines call that out as an appropriate treatment consideration. He's not sure how compelling the evidence is for those specific products in menstrual migraines.

Lt Col Khoury replied that there is a potential for class effect. The evidence was not of a high quality and did not allow for that additional indication from the FDA.

Dr. Anderson just wanted to know if there was any compelling evidence that suggests that it's not a class effect.

Lt Col Khoury replied that data supporting use of triptans in menstrual associated migraines is not of high quality.

Dr. Anderson asked if the committee consider people who are struggling with manual PA not finding therapy that works, was there any prophylactic therapy discussed. Were agents for migraine prophylaxis considered?

Dr. Kugler replied that the manual PA was not intended to be a comprehensive clinical practice guideline for the management of migraine headache and migraine prophylaxis, while important in overall management of some patients, was not intended to be part of the manual PA.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendations, Automated PA and Manual PA, and UF and PA Implementation.

- **Migraine Agents: Triptans – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Migraine Agents: Triptains – Automated PA (Step Therapy) and Manual PA**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Migraine Agents: Triptans – UF and PA Implementation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

C. ALCOHOL DETERRENTS

1. Alcohol Deterrents: Narcotic Antagonists—UF Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **UF:** naloxone nasal spray (Narcan Nasal Spray)
- **NF:** naloxone autoinjector (Evzio)

As part of the UF recommendation, the P&T Committee also recommended that the brand (Tier 2) formulary cost share of $20.00 for Narcan Nasal Spray in the TRICARE Mail Order Pharmacy and $24 in the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share of $0 in the TRICARE Mail Order Pharmacy and $10.00 in the Retail Pharmacy Network.

The authority for the last recommendation is codified in 32 CFR 199.21(j)(3), which states that "when a blanket purchase agreement, incentive price agreement, Government contract,

or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate." Lowering the cost share for the branded product Narcan Nasal Spray will provide a greater incentive for beneficiaries to use Narcan Nasal Spray, rather than the less cost-effective naloxone auto injector (Evzio) in the purchased care setting.

2. Alcohol Deterrents: Narcotic Antagonists—UF Implementation Plan

The P&T Committee recommended (16 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 currently receiving Evzio.

Summary of Physician's Perspective:

- The P&T Committee was unanimous in their recommendation for Narcan Nasal to be the uniform formulary product, with Evzio as non-formulary, based on cost effectiveness. The P&T Committee did reach out to the Tri-Service Pain Working Group for their input.

- The Committee did recognize that a small subset of patients would be candidates for Evzio instead of Narcan Nasal. Some examples include patients with significant nasal malformations or obstructions, or in cases where there is a juvenile caregiver in the home who would be the one most likely to administer naloxone, since the autoinjector dose give a voice reminder to call 911.

- The Committee's recommendation only relates to outpatient use. The Committee did not make recommendations as to the most appropriate candidates to receive a naloxone bystander-approved product. MTFs can continue to follow local and national prescribing guidelines based on morphine equivalent daily dosage or concomitant drugs (such as benzodiazepines or Ambien). Other resources, such as the March 2016 CDC guidelines for prescribing opioids for chronic pain, are also available for consult. Additionally, further guidance is expected from the Tri-Service Pain Working Group.

Summary of Panel Questions and Comments:

Mr. Wagoner stated that this seems like a wonderful product. He asked how the product would be prescribed. Is it the facility or the individual? He stated that it's hard to say, "I would like an anti-narcotic overdose prescription." He said that it's a wonderful thing, and asked who would be the target? Is it over the counter?

CAPT VonBerg replied that it is not over-the-counter. There are multiple different ways for the patient to get the medication. The physician's office can co-prescribe with pain medications.

Dr. Kugler mentioned patients that have high morphine equivalent daily doses, or they have a little-lower morphine equivalent daily dose with a higher concomitant higher risk. Co-prescribing can happen.

CAPT VonBerg further explains that there are various efforts at the MTFs to make it even more accessible directly to the pharmacies when the MTF pharmacies notice these things. Those processes are being developed. We are trying to help facilitate those things to make it as accessible as possible. There are also various state and local health organizations, and pharmacy boards, though not available specifically as an OTC, that they are creating avenues for those different entities to prescribe under things like collaborative practice agreements. Either the public health department or local physician's office partner with local entities to allow those things to be dispensed readily to the patient and are often dispensed to patient or bystander. You want to make sure that the individual who is going to use it gets the education on how to use it. Often it's prescribed directly to the bystander. There are quite a few different laws that are being changed to lessen that risk and increasing the access to these drugs.

Dr. Wagoner thanks CAPT VonBerg for his thorough answer and states what a great product that essentially can save lives.

Dr. Anderson stated that naloxone is available outside of the auto injector. Was there any consideration given to making that injectable version available?

CAPT VonBerg replied that it is already available. Before these products existed, that's all that existed. There's evidence that its use by bystanders or emergency medical personnel is effective through various ways including kits that include nasal atomizers. You could hook the syringe to a atomizer device so the liquid could be administered easily. That is currently covered in the UF and is specifically on the self-administration list that will allow the coverage to go through easier. They can still do that. That was done prior to this P&T meeting. Should somebody write a prescription for that, it will still get covered with a co-pay.

Dr. Anderson asked if they have to use it under the nasal route to get covered by the benefit. He ultimately got at the need of the people who can't use the nasal route and recognized that it's very expensive. Asked if the injectable naloxone could be self-administered, or it that too complicated for someone to try to manage

CAPT VonBerg replied that it can be done. It's possible because needles and syringes are covered.

Dr. Kugler stated that this makes it more available for individuals at risk.

CAPT VonBerg replied that pain committees thought that one of these products had to be available.

Dr. Anderson thanked CAPT VonBerg for the clarification.

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

- **Alcohol Deterrents: Narcotic Antagonists – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA: ☒

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

- **Alcohol Deterrents: Narcotic Antagonists – UF Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA: ☒

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

D. INNOVATOR DRUGS

1. Innovator Drugs—UF Recommendation

The P&T Committee recommended the following:

- UF (16 for, 0 opposed, 0 abstained, 1 absent):
  - Antihemophilic Agents: antihemophilic (recombinant) Factor VIII injection (Afstyla)
  - Oral Oncology Agents (Renal Cell Carcinoma): cabozantinib (Cabometyx)
  - Antiretrovirals Agents: emtricitabine/tenofovir alafenamide (Descovy)
  - Miscellaneous Agents: nitisinone oral suspension (Orfadin)
  - Miscellaneous Agents: obeticholic acid (Ocaliva)
  - ***Hepatitis C Virus Direct Acting Agents:*** sofosbuvir/velpatasvir (Epclusa)
  - Oral Oncology Agents (Chronic Lymphocytic Leukemia): venetoclax (Venclexta)

- NF (16 for, 0 opposed, 0 abstained, 1 absent):
  - Topical Corticosteroids: betamethasone dipropionate 0.05% spray (Sernivo)
  - Anticonvulsant and Anti-Mania Agents: brivaracetam tablets and oral solution (Briviact)
  - Topical Antineoplastic and Premalignant Lesions Agents: fluorouracil 4% cream (Tolak)

- Topical Corticosteroids: halobetasol propionate 0.05% lotion (Ultravate)
- ***Non-Insulin Diabetes Drugs—DPP-4 Inhibitors:*** linagliptin/metformin XR tablets (Jentadueto XR), which is additionally recommended to be non step-preferred, due to existing step therapy in the class
- Atypical Antipsychotics: pimavanserin (Nuplazid)
- Narcotic Analgesics and Combinations: oxycodone extended-release capsules (Xtampza ER)

- NF (10 for, 6 opposed, 0 abstained, 1 absent):

  - Iron Chelators: deferiprone oral solution (Ferriprox) due to the lack of compelling clinical advantages over other oral iron chelator products, three times daily dosing, and the risk of agranulocytosis

2. Innovator Drugs—Manual PA Criteria

The P&T Committee also recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Applying the same step therapy and manual PA criteria for Jentadueto XR as is currently in place for linagliptin/metformin immediate release (IR) (Jentadueto) and the other non-step-preferred dipeptidyl peptidase-4 (DPP-4) inhibitor combinations with metformin. Existing step therapy currently applies to the DPP-4 inhibitors, including Jentadueto. Patients must first use metformin or a sulfonylurea, and the preferred DPP-4 inhibitor sitagliptin before using a non-step-preferred DPP-4 inhibitor.

- Applying manual PA criteria to the following: new users of the hepatitis C virus (HCV) direct acting antiviral agent (DAA) sofosbuvir/velpatasvir (Epclusa), the atypical antipsychotic pimavanserin (Nuplazid), the iron chelator deferiprone oral solution and oral tablet (Ferriprox), and the orphan drug obeticholic acid (Ocaliva).

Full PA Criteria:

a. Innovator Drugs—Non-Insulin Diabetes Mellitus DPP-4 Inhibitors: Linagliptin/Metformin XF (Jentadueto XR)

Jentadueto XR will be non-step-prefered, similar to the other non-step-preferred DPP-4 inhibitors.

All new and current users of a DPP-4 inhibitor are required to try metformin or a sulfonylurea before receiving a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR) are the preferred agents in the DPP-4 Inhibitors Subclass. New users of a DPP-4 inhibitor, including Jentadueto XR, must try a sitagliptin product first.

Automated PA Criteria

- The patient has filled a prescription for metformin or a sulfonylurea at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

- The patient has received a prescription for a preferred DPP-4 inhibitor (Januvia, Janumet, or Janumet XR) 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, Jentadueto XR is approved if:

- The patient has had an in adequate response to metformin or sulfonylurea.

- The patient has experienced any of the following adverse events while receiving a sulfonylurea: hypoglycemia requiring medical treatment.

- The patient has experienced an adverse event with sitagliptin-containing products, which is not expected to occur with linagliptin-containing products.

- The patient has had an inadequate response to a sitagliptin-containing product.

- The patient has a contraindication to sitagliptin.

PA does not expire.

b. Innovator Drugs—HCV DAAs: Sofosbuvir/Velpatasvir (Epclusa)

- New users of sofosbuvir/velpatasvir (Epclusa) are required to undergo the PA process.

- Current users are not affected by PA; they can continue therapy uninterrupted.

- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age $\geq$ 18

- Has laboratory evidence of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection
    - State the HCV genotype and HCV RNA viral load on the PA form.
- Sofosbuvir/velpatasvir (Epclusa) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Treatment Regimens and Duration of Therapy

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

c. Innovator Drugs—Atypical Antipsychotics: Pimavanserin (Nuplazid)

Manual PA criteria apply to all new users of pimavanserin.

Manual PA Criteria: Nuplazid is approved if all of the following criteria are met:

- Patient is age ≥ 18 AND
- Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's disease psychosis AND
- Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin AND
- Mini-Mental State Examination (MMSE) score ≥ 21

Prior Authorization does not expire.

Non-FDA approved uses are not approved.

d. Innovator Drugs—Iron Chelators: Deferiprone Oral Solutions and Oral Tablets (Ferriprox)

Manual PA criteria apply to new users of deferiprone oral solution and oral tablets (Ferriprox).

Manual PA Criteria: Ferriprox will be approved if the patient meets the following criteria:

- The patient has tried Exjade or Jadenu and was unable to tolerate due to adverse effects.

Prior Authorization does not expire.

e. **Innovator Drugs—Miscellaneous: Obeticholic Acid (Ocaliva) for Primary Biliary Cholangitis**

Manual PA criteria apply to all new users of obeticholic acid (Ocaliva).

Manual PA Criteria: Ocaliva is approved for 6 months for Primary Biliary Cholangitis (PBC) for initial therapy if the patient meets the following criteria:

- Patient is age ≥ 18 year old; AND
- Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND
- Patient has a diagnosis of PBC as defined by at least TWO of the following criteria (a, b, and/or c) according to the prescribing physician:
    a. alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values; AND/OR
    b. positive anti-mitochondrial antibodies (AMAs); AND/OR
    c. histologic evidence of PBC from a liver biopsy; AND
- Patient meets ONE of the following criteria (a or b):
    a. Patient has been receiving ursodiol therapy (e.g., ursodiol generics, Urso 250,Urso Forte, Actigall) for ≥ 1 year and has had an inadequate response

    OR

    b. The patient is unable to tolerate ursodiol therapy.

Renewal criteria: Ocaliva is approved indefinitely for PBC for continuation therapy if the patient meets the following criteria:

Patients Currently Receiving Therapy (renewal criteria): approve indefinitely if the patient meets the following criteria:

- Age ≥ 18 years old; AND

- Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND

- Patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC: e.g., alkaline phosphatase (ALP), bilirubin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT) levels).

Expiration date: 6 months or indefinite depending on initial or renewal criteria

Non FDA-approved uses are not approved.

3. Innovator Drugs—UF and PA Implementation Plan

The P&T Committee recommended (16 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*:**

- The authority establishing the Innovator Drugs has now been in place for a year. So far we are averaging about 10-15 innovators at each meeting. For drugs in classes that have not been previously reviewed, or for some of the orphan drugs, we do reach out to the appropriate specialists for their input.

- The recommendations for the non-formulary products are due to lack of compelling clinical advantages, or due to lack of cost effectiveness, compared to current UF drugs. The only vote that was not unanimous for the formulary recommendation was that 6 members opposed having Ferroprox as non-formulary. The reasons for the dissenting votes were concerns due to potentially limiting patient access to this iron chelator.

- The Prior Authorization recommendation for Epclusa is consistent with the PAs already in place for the hepatitis C drugs. We are actively monitoring utilization and costs for these drugs, and will consider reviewing the class again in 2017, due to the market entrance of several new products.

- The PA for Nuplazid follows the study criteria for the trial that led to FDA approval. Ocaliva is a drug for a rare disease (primary biliary cholangitis), and the PA criteria limit use to the FDA-approved indications.

Summary of Panel Questions and Comments:

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

- **Innovator Drugs – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Innovator Drugs – Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Innovator Drugs – UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

II. UTILIZATION MANAGEMENT

A. ANALGESICS AND COMBINATIONS

1. Analgesics and Combinations: Butalbital/Acetaminophen/Caffeine Oral Liquid (Vanatol LQ)—Manual PA Criteria

Vanatol LQ is an oral liquid formulation containing the same active ingredients as Fioricet and is approved for tension or muscle headaches. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for Vanatol LQ, due to cost disadvantages compared to generic Fioricet tablets and capsules.

Full PA Criteria:

Analgesics and Combinations: Vanatol LQ

All new and current users of butalbital/acetaminophen/caffeine (Vanatol LQ) are required to undergo manual prior authorization criteria.

Manual PA Criteria: Coverage will be approved if:

- Patient cannot tolerate generic Fioricet oral tablet or capsule formulations due to documented swallowing difficulties.

Prior Authorization expires in 6 months.

Non FDA-approved uses are not approved.

2. **Analgesics and Combinations: Butalbital/Acetaminophen/Caffeine Oral Liquid (Vanatol LQ)—PA Implementation Period**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

Summary of Physician's Perspective:

- This product is being marketed by compounding pharmacies and is essentially liquid fioricet. The PA requires a patient to have a clinical reason as to why they can't take generic Fioricet tablets.

Summary of Panel Questions and Comments:

Dr. Delgado asked why is there no automated PA criteria? Why is there just manual?

CAPT VonBerg replied that the committee wanted to see actual write-up every time the product was requested. We can't tell if a person has swallowing difficulties or not or whether they've used the previous products. We can only see that they've had it before. We can't see why they've requested, and that's what we want to know.

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 Criteria.

- **Analgesics and Combinations: Vanatol LQ – Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Analgesics and Combination: Vanatol LQ – PA Implementation Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

B. NEWER SEDATIVE HYPNOTICS (SED-1s)

1. SED-1s: Suvorexant (Belsomra)—Removal of Automated PA and Establishing Manual PA Criteria for New Users

Belsomra is a first-in-class orexin receptor antagonist indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or maintenance. The SED-1s Drug Class has automated PA criteria that require a trial of a step-preferred agent (zolpidem IR or zaleplon). Belsomra was designated as NF in August 2015, with step therapy implemented in October 2015. Zolpidem ER (Ambien CR) and eszopiclone (Lunesta) have the same FDA indications as Belsomra.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removing the automated PA criteria and establishing manual PA criteria for Belsomra in new users due to the lack of compelling clinical advantages and cost-disadvantages over the existing formulary SED-1s. Patients will be required to try zolpidem extended release and eszopiclone before using Belsomra.

Full PA Criteria:

Newer Sedative Hypnotics: Suvorexant (Belsomra)

The current automated PA (step therapy) will be removed.

Manual PA criteria apply to all new users of Belsomra.

Manual PA Criteria: Belsomra is approved if:

- Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance AND

- Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive therapy, sleep hygiene AND

- Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release AND eszopiclone

- Patient has no current or previous history of narcolepsy AND

- Patient has no current or previous history of drug abuse.

Prior Authorization does not expire.

Non FDA-approved uses are not approved.

2. SED-1s: Suvorexant (Belsomra)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

Summary of Physician's Perspective:

- Belsomra has the same FDA indications as Ambien CR and Lunesta, which are both on the Uniform Formulary. Although the mechanism of action is unique, Belsomra's side effect profile is similar to the other drugs in the class, and it is a controlled schedule drug (C-IV).

- There has been a step therapy in the SED-1 class for several years, which requires a trial of generic Ambien or Sonata before Belsomra. The recommendation is to remove Belsomra from the step therapy and have all new patients go through a paper PA. Patients will be required to have a trial of the other SED-1s that have the same indication as Belsomra

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel, The Chair called for a vote on the Removal of the automated PA and establishing Manual PA Criteria for new users and the PA Implementation Plan.

- **SED-1s: Suvorexant (Belsomra) – Removal of Automated PA and Establishing Manual PA Criteria for New Users**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **SED-1s: Suvorexant (Belsomra) – PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

C. GROWTH-STIMULATING AGENTS (GSAs)

1. GSAs—Manual PA Criteria

GSAs have varying indications including treatment of patients with growth hormone deficiency, Turner Syndrome, patients who are small for gestational age, and for patients with idiopathic short stature, among others. The GSAs were last reviewed in 2007, and manual PA criteria apply. Idiopathic short stature has not been a covered indication by the MHS. Since the previous review, several agents have been discontinued and new agents approved. All newly-approved GSAs will be subject to the PA criteria, which expires after one year.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updating the manual PA criteria for GSAs in new and current users to reflect the current products on the market, and to exclude idiopathic short stature as a covered indication for all products.

Full PA Criteria:

Manual PA criteria apply to all new and current users of GSAs. The following drugs will be added to the existing PA form for the GSAs: Nutropin AQ NuSpin, Nutropin AQ Pen, Genotropin, Humatrope, Omnitrope, Saizen.

Manual PA Criteria: Criteria #5 — Use for Idiopathic Short Stature is not covered for:

- Nutropin AQ NuSpin, Nutropin AQ Pen, Genotropin, Humatrope, Omnitrope, Saizen

Prescriptions for newly-approved GSAs will be subject to the PA criteria currently in place for the class.

Prior Authorization expiration: 365 days

2. GSAs—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 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 does periodically go back and review older classes for new products and FDA indications. The PA requirements for the Growth Stimulating Agents is just to ensure that we have all the products on the market covered by the PA, since it has been several years since the last class review. Any replacement product coming out on the market now will be subject to the same PA requirements as the others in the class.

Summary of Panel Questions and Comments:

Dr. Anderson stated this is more of benefit design issue. Is that the way to think about this? That it is not a covered benefit under TRICARE.

Dr. Kugler replied to be consistent.

Dr. Anderson repeated to be consistent with the other products in the class.

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

- **GSAs – Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **GSAs – PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

D. TOPICAL PAIN AGENTS

1. Topical Pain Agents: Diclofenac Sodium 2% Topical Solution (Pennsaid)—Manual PA Criteria

Diclofenac topical solution (Pennsaid) is FDA-approved for the treatment of pain from osteoarthritis of the knee. The originally approved 1.5% branded product is now available as a generic formulation, and the branded product was changed to a 2% concentration. Pennsaid 2% offers no compelling advantages over diclofenac 1.0% gel (Voltaren) or generic 1.5% topical preparations.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for new and current users of Pennsaid 2%.

Full PA Criteria:

Manual PA criteria apply to all new and current users of diclofenac sodium 2% topical solution.

Manual PA criteria: Pennsaid 2% topical solution is approved if:

- Patient has a documented diagnosis of osteoarthritis of the knee AND
  - Patient is unable to take oral NSAIDs or acetaminophen due to documented intolerance, contraindication, or adverse reaction OR
  - The patient is ≥ 75 years old

  AND

- The patient is unable to use preferred generic diclofenac 1.5% topical solution AND diclofenac 1.0% topical gel (Voltaren generics) due to documented inadequate effects.

Prior Authorization does not expire.

Non-FDA approved uses are not approved

2. **Topical Pain Agents: Diclofenac Sodium 2% Topical Solution (Pennsaid)—PA Implementation Plan**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 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 recommendation for the brand Pennsaid PA is to ensure that patients have tried the generic 1.5% formulation first, since it is much more cost effective than the 2% formulation. The PA criteria do take into account the fact that patients over 75 years may not be good candidates for oral NSAIDs.

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.

- **Topical Pain Agents: Diclofenac Sodium 2% Topical Solution (Pennsaid) – Manual Pa Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Topical Pain Agents: Diclefenac Sodium 2% Solution (Pennsaid) – PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

E. BRAND OVER GENERIC AUTHORITY AND PA CRITERIA

1. **Mandatory Generic Substitution Policy: Removal of PA Requiring Brand Over Generic for Niacin ER (Niaspan)**

TRICARE policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, when AB-rated generic formulations for niacin ER (Niaspan) were launched in September 2013, pricing for the branded product was lower than the generic formulations. The manufacturer of Niaspan offered a Voluntary Agreement for

Retail Refunds and the Tier 1 (generic) copayment was assigned to the branded product at the November 2013 P&T Committee meeting. Additionally, PA criteria allowing for a patient to receive generic niacin ER instead of branded Niaspan (i.e., the reverse of the current brand to generic policy) were recommended by the P&T Committee in May 2014.

In May 2016, the P&T Committee recommended the DHA Pharmacy Operations Division (POD) be given authority, after consulting with the Chair of the P&T Committee, to implement "brand over generic" authorization for drugs with recent generic entrants where the branded product is more cost-effective than generic formulations. In these cases, the branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. Authority was also given to the POD to remove the "brand over generic" requirement when it is no longer cost- effective to the MHS.

As of June 2016, the AB-rated generic formulations for niacin ER (Niaspan) are cost-effective compared to the branded Niaspan product.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removal of the Brand over Generic PA, and removal of the Tier 1 (generic) co-pay for branded Niaspan. Branded Niaspan will now be available at the Tier 2 (UF) co-pay in the Retail Network and Mail Order Pharmacy, and the requirement for mandatory generic substitution is re-instated.

Summary of Physician's Perspective:

- We first introduced this topic at the last BAP meeting. This authority allows the Committee to react quickly to changes in the costs of new generic products.

- The Committee found that the generic products for Niaspan ER are now cost effective, and there is no longer a benefit to the MHS to continue the "brand over generic" requirements. We will continue to bring these types of issues for review here.

Summary of Panel Questions and Comments:

Dr. Anderson asked when brand over generic is done, is it a practice that the branded version will always be offered as a Tier 1?

CAPT VonBerg replied that we don't have to, but we do.

Dr. Anderson responded that he didn't have a strong concern with it not being Tier 1, but was curious if that was practice.

There were no more questions or comments from the Panel. The Chair called for a vote on the Removal of PA requiring Brand over Generic for Niacin ER (Niaspan).

- **Mandatory Generic Substitution Policy: Removal of PA Requiring Brand Over Generic for Niacin ER (Niaspan)**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

  These comments were taken under consideration prior to my final decision

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

1. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee reviewed three drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with 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 be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail point of service and medical necessity at MTFs. These NF drugs will remain available in the mail order point of service without pre-authorization.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following products be designated NF on the UF:

- Veloxis Pharma: tacrolimus ER (Envarsus XR) 1 mg and 4 mg oral tablets
- Lachlan Pharma: benzyl alcohol (Ulesfia) 5% topical lotion
- Mist Pharma: propranolol ER (Inderal XL) 80 mg and 120 mg oral capsules

2. Section 703, NDAA FY08—Pre-Authorization Criteria

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following pre-authorization criteria for Envarsus XR, Ulesfia, and Inderal XL:

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

These pre-authorization criteria do not apply to any other point of service other than retail network pharmacies.

3. **Section 703, NDAA FY08—Implementation Plan**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Envarsus XR, Ulesfia, and Inderal XL; and, 2) DHA send letters to beneficiaries affected by this decision.

Summary of Physician's Perspective:

- For all three products recommended for NF status, cost-effective generic formulations or therapeutic alternatives are available on the UF. The Pharmacy Operations Division does follow up with the affected manufacturers, to try to ensure compliance with the Section 703 requirements.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel. The Chair called for a vote on the Drugs designated NF, Pre-Authorization Criteria, and the Implementation Plan.

- **Section 703, NDAA FY08 – Drugs Designated NF**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Section 703, NDAA FY08 – Pre-Authorization Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

- **Section 703, NDAA FY08 - Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

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

IV. OVER-THE-COUNTER (OTC) DRUG BENEFIT

1. **OTC Drug Benefit: Status of the Second Generation Antihistamines**—The Deployment Prescription Program requested that the DoD P&T Committee consider adding fexofenadine (generic Allegra) to the UF as part of the OTC pharmacy benefit, which would make it available by mail to deployed Service members in theater. The final rule implementing the legislative authority for the OTC Drug Program was published on July 27, 2015, and is found at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy. The OTC medications currently on the UF include omeprazole, loratadine, loratadine/pseudoephedrine, cetirizine, cetirizine/pseudoephedrine, levonorgestrel 1.5 mg (Plan B One-Step and its generics), and doxylamine 25 mg.

   The P&T Committee reviewed the status of the second generation antihistamines on the various Aerospace Medicine lists of medications approved for use by U.S. Air Force, U.S. Army, U.S. Navy, and U.S. Coast Guard flyers. All of the lists include loratadine and all, except for the U.S. Army list, include fexofenadine. Cetirizine is not included on any of the lists since it is more likely to cause sedation than loratadine or fexofenadine.

   Generic cetirizine OTC and generic loratadine OTC were the least costly second generation antihistamines, followed by generic fexofenadine OTC, levocetirizine (generic Xyzal), and desloratadine (generic Clarinex). The costs of combination products with pseudoephedrine ranged from 5 to 18 times higher than, and were used less frequently than, their respective single ingredient products. The P&T Committee also noted cetirizine/pseudoephedrine has not been available through the mail order point of service over the last few months due to the lack of a Trade Agreements Act (TAA) compliant generic product.

   The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, effective upon signing of the minutes:

   - adding OTC fexofenadine to the UF
   - removing OTC cetirizine/pseudoephedrine from the UF
   - removing OTC loratadine/pseudoephedrine from the UF

   Summary of Physician's Perspective:

   - The legislative authority for the P&T Committee to review OTC drugs has also been in place approximately a year. The Committee uses the same process for the OTC drugs as it does for all the legend products, in that both clinical and cost effectiveness are reviewed. For the second generation antihistamines, you can see that the Aerospace Medicine lists for the various services were also consulted.

- So far the OTC products that are on the formulary include cetirizine, loratadine, doxylamine, omeprazole and Plan B One Step, and now the recommendation is to add fexofenadine to the UF.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel. The Chair called for a vote on the status of the second generation antihistamines.

- **OTC Drug Benefit: Status of the Second Generation Antihistamines**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:

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

V. RE-EVALUATION OF GENERICALLY AVAILABLE NF AGENTS

1. Re-Evaluation of Generically Available NF Agents—Clinical Effectiveness and Cost-Effectiveness Conclusions

The P&T Committee continued the process of implementing the requirement that NF pharmaceutical agents generally be unavailable at MTFs or the Retail Network, but available in the Mail Order program. (See DoD P&T Committee meeting minutes from August 2015 and May 2016.) Implementation of the mail order requirement for generically available NF agents was temporarily deferred to allow for review of the continued necessity for NF (Tier 3) status, given price decreases typically associated with generic availability.

The P&T Committee reviewed the current utilization, formulary status, generic availability, comparative clinical effectiveness, and relative cost effectiveness, including the weighted average cost per unit, for all generically available NF agents in eight previously reviewed UF drug classes. Utilization trends by points of service found limited dispensing of the NF generic products, compared to the UF products in the respective classes.

The P&T Committee concluded that for all eight drug classes, there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusion from when the class was originally reviewed for UF placement. The P&T Committee also concluded that the costs of all the NF generic products were significantly higher than the currently available UF products, with two exceptions: generic calcitonin-salmon nasal spray and diclofenac 1.5% topical solution were comparable in price to the UF products in their respective classes. Specific comments are below:

- *Second Generation Antihistamines: Levocetirizine (Xyzal) and Desloratadine (Clarinex)*—Levocetirizine and desloratadine continue to offer no significant, therapeutically meaningful advantage over other similar agents on the UF (loratadine, cetirizine, and fexofenadine).

- *Osteoporosis/Oral Bisphosphonates and Calcitonin: Risedronate (Actonel, Atelvia), Calcitonin-Salmon Nasal Spray (Miacalcin)*

    - The oral bisphosphonates are highly therapeutically interchangeable, and there are no compelling advantages to the delayed release formulation of weekly risedronate (Atelvia). New safety data for the bisphosphonates (osteonecrosis of the jaw, esophageal cancer, atrial fibrillation, and atypical femur fractures), has led to an overall decline in use.

    - There is currently step therapy for the bisphosphonates, with alendronate (generic Fosamax) designated as step-preferred. Generic formulations of ibandronate 150 mg monthly (Boniva) are now available. The P&T Committee noted that generic ibandronate 150 mg is newly available to MTFs and through mail order at substantially decreased cost under a Joint National Contract.

    - Calcitonin nasal spray is considered a third line and/or niche agent in clinical practice guidelines. The cost per 28 days for calcitonin nasal spray was similar for recombinant calcitonin (Fortical) and for generic calcitonin-salmon (generic Miacalcin).

- *Non-Insulin Diabetes Mellitus Drugs/Biguanides: Metformin ER (Fortamet, Glumetza)*—There is no evidence to suggest that differences in the ER formulations of Glumetza and Fortamet confer clinically relevant benefits in efficacy or safety when compared to generic metformin IR or ER preparations (Glucophage, Glucophage XR, generic).

- *Selective Serotonin Reuptake Inhibitors: Fluoxetine 90 mg Delayed Release (Prozac Weekly) and Products for Premenstrual Dysphoric Disorder (PMDD) (Sarafem)*—Neither the special packaging for PMDD (Sarafem) nor a higher dosing strength for weekly administration (Prozac Weekly) offer significant clinical advantages compared to generic Prozac. Brand Sarafem is now available as tablets instead of capsules; the availability of generics for the tablets is unclear at this time, based on the FDA website.

- *Benign Prostatic Hypertrophy (BPH) Medications/5-Alpha Reductase Inhibitors (ARIs): Dutasteride (Avodart), Dutasteride/Tamsulosin (Jalyn)*—Finasteride (Proscar, generic) and dutasteride are highly therapeutically interchangeable for the treatment of BPH, and the combination product dutasteride/tamsulosin offers no additional benefit compared to the individual components. There is existing step therapy in the class.

- *Alzheimer's Medications: Donepezil 23 mg (Aricept 23 mg)*—Donepezil 23 mg shows statistical improvement in cognition but not global functioning, and tolerability is likely limited by increased adverse effects, compared to donepezil 10 mg.

- *Antilipidemics-1/Statins and Combos: Fluvastatin ER 80 mg (Lescol XR)* Lescol XR remains a moderate low-density lipoprotein (LDL) lowering statin, with LDL-lowering capacity ranging between 30% to <50%. Eight other statins fall into the moderate LDL-lowering category. Step therapy also exists in this class; a trial of a generic step-preferred statin with similar LDL-lowering capacity is required first.

- *Topical Pain Agents: Diclofenac 1.5% Topical Solution (Pennsaid 1.5% Drops)* Topical diclofenac (including the topical solution and gel) was effective for managing superficial pain (e.g., osteoarthritis, sprain, strain, contusions). Gastro-intestinal adverse events were lower with topical therapy compared to oral NSAIDs. Brand Pennsaid is now available as a diclofenac 2% topical solution, with only generic versions of the 1.5% formulation remaining on the market. Weighted average cost per day for generic diclofenac 1.5% topical solution is comparable to the weighted average cost per day for generic lidocaine 5% patch, providing another alternative in this class both overall and specifically as an alternative to Pennsaid 2% topical solution, which is far more costly.

2. **Re-Evaluation of Generically Available NF Agents—UF Recommendation, Automated PA (Step Therapy) Changes and Removal of Manual PA Criteria for Ibandronate**

   The P&T Committee recommended the following (16 for, 0 opposed, 0 abstained, 1 absent), effective upon signing of the minutes:

   - The following products will remain NF, with both brand and generics subjected to mail order requirements:

     - Second Generation Antihistamines: levocetirizine (Xyzal, generics) and desloratadine (Clarinex, generics)

     - Osteoporosis: risedronate (Atelvia, Actonel, and their generics); these products will remain as non-step-preferred

     - Antidiabetics: metformin ER (Fortamet, Glumetza, and their generics)

     - Selective Serotonin Reuptake Inhibitors: fluoxetine 90 mg (Prozac Weekly); generic Sarafem caps; Sarafem tabs

     - BPH: dutasteride (Avodart, generics); dutasteride/tamsulosin (Jalyn, generics); these products will remain as non-step-preferred

     - Alzheimer's: donepezil 23 mg (Aricept, generics)

- Antilipidemics: fluvastatin ER (Lescol XL, generics); will remain non-step-preferred

- Return to UF status
  - Osteoporosis: calcitonin-salmon nasal spray (generic Miacalcin)
  - Topical Pain Agents: diclofenac 1.5% topical solution (generic Pennsaid 1.5%)

- Automated PA (Step Therapy) Changes
  - Osteoporosis Agents/Oral Bisphosphonates
    - designate ibandronate 150 mg monthly (Boniva, generics) as step-preferred
    - Patients must now try either step-preferred alendronate or ibandronate prior to use of Actonel, Atelvia, Binosto, and Fosamax Plus D. The automated and manual PA criteria for the oral bisphosphonates will now state: "The patient has filled a prescription for alendronate or ibandronate at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days."
    - Manual PA criteria requirements (if the automated PA criteria were not met) for ibandronate will also be removed, effective upon signing of the minutes.

Full PA Criteria:

Changes are highlighted in bold and strikethrough.

Oral Bisphosphonates: ~~**ibandronate (Boniva, generics)**~~; risedronate (Actonel); risedronate delayed release (Atelvia); alendronate effervescent tablet (Binosto); alendronate with vitamin D (Fosamax Plus D)

- Ibandronate is now step-preferred

PA criteria apply to ~~**all new users of ibandronate, and**~~ all new and current users of Actonel, Atelvia, Binosto, and Fosamax Plus D.

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

AND

Manual PA criteria: ~~**ibandronate**~~, Actonel, Atelvia, Binosto, and Fosamax Plus D is approved (e.g., trial of alendronate is NOT required) if:

- Patient has experienced any of the following issues with alendronate, which is not expected to occur with the non-preferred oral bisphosphonates:
    - Intolerable adverse effects
        - ~~Patient requires once monthly ibandronate or Actonel 150 mg due to gastrointestinal adverse events from alendronate weekly dosing~~
        - Patient has experienced significant adverse effects from formulary agents
        - For Binosto: No alternative formulary agent and patient has swallowing difficulties and cannot consume 8 oz of water and has no sodium restrictions
        - For Fosamax Plus D: No alternative formulary agent and patient cannot take alendronate and vitamin D separately
    - Contraindication

Summary of Physician's Perspective:

- We are continuing to go through all the classes evaluated several years ago to assess new clinical and cost information. For the eight classes reviewed, the recommendations for which generics remains NF and which should go back to UF status was based on clinical and cost effectiveness. After the eight drug classes reviewed at the August P&T meeting, there are only about three or four classes left to evaluate, which will be reviewed at an upcoming meeting.

- Beneficiaries can refer to the TRICARE pharmacy website or the Health.mil website to find which drugs are affected by the "Mandatory Mail for maintenance drugs" and "Non-formulary goes to Mail" requirements. For all the drugs affected by these requirements, up to two prescription fills will be allowed at a Retail Network pharmacy, before having to go to the Mail Order pharmacy.

Summary of Panel Questions and Comments:

There were no questions or comments from the Panel. The Chair called for a vote on the re-evaluation of the generically available NF agents: UF Recommendation, Automated PA Changes and removal of Manual PA Criteria for Ibandronate.

- **Re-Evaluation of Generically Available NF Agents – UF Recommendation, Automated PA (Step Therapy) Changes and Removal of Manual PA Criteria for Ibandronate**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

  These comments were taken under consideration prior to my final decision

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.

- ALP – Alkaline Phosphatase
- ALT – Alanine Aminotransferases
- AASLD - American Association for the Study of Liver Disease
- AMA - Anti-mitochondral antibodies
- AST - Aspartate Aminotransferase
- BAP – Benficiary Advisory Panel
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- BP – Benzoyl Peroxide
- BPH - Benign Prostatic Hypertrophy CFR
- DAA - Direct Acting Antiviral Agent
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DoD – Department of Defense
- DPP-4 - Dipeptidyl Peptidase - 4
- ER – Extended Release
- FACA – Federal Advisory Committee Act
- FDA – Food Drug Administration
- GGT – Gamma-Glutamyl Transpeptidase
- GSA – Growth Stimulating Agents
- HCV – Hepatitis C Virus
- IDSA – Infectious Diseases Society of America
- IM - Intramuscularly
- IR – Immediate Release
- LDL – Low-Density Lipoprotein
- LQ – Oral Liquid
- MHS – Military Health System
- MMSE – Mini-Mental State Examination
- MTF – Military Treatment Facility
- NDAA – National Defense Authorization Act
- NF – Non-Formulary
- NNT – Need to Treat
- NSAID – Nonsteroidal Anti-Inflammatory Drug
- ODT – Orally Dissolving Tablet

Brief Listing of Acronyms Used in this Summary – Continued

- OTC – Over-the-Treat
- P&T – Pharmacy & Therapeutics
- PA – Prior Authorization
- PBC – Primary Biliary Cholangitis
- PMDD – Premenstrual Dysphoric Disorder
- POD – Pharmacy Operations Division
- RNA – Ribonucleic Acid
- SED-1s – Sedative Hypnotics
- SQ - Subcutaneously
- TAA – Trade Agreements Act
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- ULN – Upper Limit of Normal
- USC – United States Code
- XR – Extended Release
- ZMT – Zolmitriptan Tablets

Uniform Formulary Beneficiary Advisory Panel (BAP)

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

Present Panel Members

- Dr. Michael Anderson, United Healthcare, Chairperson
- Ms. Theresa Buchanan, National Family Association
- Dr. Kevin Sommer, U.S. Family Health Plan
- Mr. John Wagoner, Health Net Federal Services
- Dr. Sandra Delgado, Humana

Absent Panel Member

- Ms. Lisa Le Gette, Express Scripts, Inc.

The meeting was held at Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C., and Alternate DFO William Blanche called the meeting 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

  - Drug Class Reviews

    - Topical Acne and Rosacea Agents
    - Migraine Agents—Triptans
    - Narcotic Antagonists

  - Innovator Drugs

    - Antihemophilic Agents: antihemophilic factor VIII (recombinant) (Afstyla)
    - Topical Corticosteroids: betamethasone dipropionate 0.05% spray (Sernivo)
    - Anticonvulsant and Anti-Mania Agents: brivaracetam tablets and oral solution (Briviact)
    - Oral Oncology Agents (Renal Cell Carcinoma): cabozantinib (Cabometyx)
    - Iron Chelators: Deferiprone oral solution (Ferriprox)
    - Antiretrovirals Agents: emtricitabine/ tenofovir alafenamide (Descovy)
    - Topical Antineoplastic and Premalignant Lesions Agents: fluorouracil 4%cream (Tolak)

- Topical Corticosteroids: halobetasol propionate 0.05% lotion (Ultravate)
- Non-Insulin Diabetes Drugs – DPP-4 Inhibitors: linagliptin/metformin XR (Jentadueto XR)
- Miscellaneous Agents: nitisinone oral suspension (Orfadin)
- Miscellaneous Agents: obeticholic acid (Ocaliva)
- Narcotic Analgesics and Combinations: oxycodone extended-release capsules (Xtampza ER)
- Atypical Antipsychotics: pimavanserin (Nuplazid)
- Hepatitis C Virus Direct Acting Agents: sofosbuvir/velpatasvir (Epclusa)
- Oral Oncology Agents (Chronic Lymphocytic Leukemia): venetoclax (Venclexta)

➢ Utilization Management Issues

- Prior Authorization Criteria
  - Analgesics and Combinations: butalbital/acetaminophen/caffeine oral liquid (Vanatol LQ)
  - Newer Sedative Hypnotics (SED-1s): suvorexant (Belsomra)
  - Growth Stimulating Agents
  - Topical Pain Agents: diclofenac 2% topical solution (Pennsaid)

- Removal of "Brand over Generic" Prior Authorization Criteria
  - Antilipidemic-1s (LIP-1s): niacin ER (Niaspan)

➢ NDAA 2008 Section 703 Actions

➢ Over-the-Counter (OTC) Drugs: Second Generation Antihistamines UF Recommendation

➢ Re-Evaluation of Generic Non Formulary Agents

- Second Generation Antihistamines
- Osteoporosis Agents (Oral Bisphosphonates and Calcitonin)
- Non-Insulin Diabetes Drugs/Biguanides
- Selective Serotonin Receptor Inhibitors
- Benign Prostatic Hypertrophy (BPH) Medications/5-Alpha Reductase Inhibitors
- Alzheimer's Medications:
- Topical Pain Agents

➢ 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

Mr. William Blanche introduced himself as the Alternate Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP). The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on August 10th and 11th, 2016.

Mr. Blanche 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 14 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.

Mr. Blanche 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 starts the meeting.

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 Lt Col Ronald Khoury, a family medicine physician; I would also like to recognize Mr. David Hurt, Associate General Counsel for the DHA.

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

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.

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

        - Topical Acne and Rosacea Agents;
        - Migraine Agents-Triptans; and
        - Narcotic Antagonists

A summary table of the UF drug class recommendations is found on pages 41 through 43 of the background information document. It also contains the numbers of unique users affected by the recommendations.

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

c. We will also discuss Prior Authorizations (PA) for drugs in 4 classes:

- Analgesics and Combinations
- Newer Sedative Hypnotics (SED-1s)
- Growth Stimulating Agents and
- Topical Pain Agents

d. Also discussed was the removal of the "Brand over Generic" Prior Authorization and co-pay change for niacin ER (Niaspan)

4. There were three drugs under Section 703, National Defense Authorization Act (NDAA) for Fiscal Year 2008 reviewed at this meeting: tacrolimus ER (Envarsus XR) 1 mg and 4 mg oral tablets, benzyl alcohol (Ulesfia) 5% topical lotion, and propranolol ER (Inderal XL) 80 mg and 120 mg oral capsules.

5. An update to the OTC Drug benefit for the Second Generation Antihistamines will be reviewed.

6. Finally, there was a re-evaluation of Non-formulary generic drugs in the Second Generation Antihistamine, Osteoporosis, Antidiabetic, Selective Serotonin Reuptake Inhibitors, BPH, Alzheimer's, and Antilipidemic drug classes.

7. 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. UF CLASS REVIEWS

A. ACNE AGENTS: TOPICAL ACNE AND ROSACEA AGENTS SUBCLASS (CAPT VONBERG)

1. Acne Agents: Topical Acne and Rosacea Agents Subclass—Relative Clinical Effectiveness and Conclusion

The P&T Committee evaluated the Topical Acne and Rosacea Subclass, which has not been previously reviewed for UF placement. The reviewed products were further categorized based on mechanism of action, and included the topical antibiotics and combinations with benzoyl peroxide, topical retinoids, azelaic acid, dapsone, sodium sulfacetamide/sulfur products, ivermectin, and brimonidine.

There are over 35 products in the subclass, several with respective generics or therapeutic alternatives available in multiple strengths and formulations. The clinical effectiveness review focused on the new branded entrants to the market, and the place in therapy for the products. Meta-analyses and professional treatment guidelines were also reviewed. Military Health System (MHS) provider opinions were solicited and considered in the UF recommendations.

The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Benzoyl peroxide used in combination with the clindamycin 1% gel or solution is a first-line choice for treatment of mild to moderate acne. Monotherapy with clindamycin is not recommended, due to the risk of bacterial resistance.

- The topical retinoids (tretinoin, adapalene, and tazarotene) are effective when used as monotherapy in patients with comedonal or mild acne, or in combination with other products in patients with inflammatory acne lesions. Tazarotene (Fabior) has a limited role, due to its pregnancy category X rating.

- The 2015 Cochrane Review of rosacea agents reported that there is high quality evidence for use of topical azelaic acid for decreasing inflammatory lesions and erythema; for brimonidine (Mirvaso) for decreasing facial erythema; and, ivermectin (Soolantra) for decreasing inflammatory lesions. There is moderate quality evidence for topical metronidazole for decreasing inflammatory lesions and erythema, but topical metronidazole is widely used as a first line therapy.

- The available clinical data for the newer products, including dapsone 7.5% gel (Aczone) (an innovator drug), brimonidine 0.33% gel (Mirvaso), and ivermectin 1% cream (Soolantra), is limited by the lack of active controls, use of subjective rating scale, and non-rigorous study designs.

    - The acne treatment guidelines recommend topical dapsone for inflammatory acne, particularly in adult females.

- Brimonidine 0.33% gel has a clinical niche for treatment of persistent facial erythema in rosacea, but will not change the underlying course of the disease.

- A recent FDA safety alert warned of the risk of hypotension, bradycardia, and dizziness, particularly in patients with pre-existing cardiovascular disease due to its mechanism as an alpha-2 adrenergic agonist.

- Ivermectin 1% cream has a clinical niche for treating papulopustular rosacea associated with proliferation of Demodex mites.

- Safety profiles for acne and rosacea agents are primarily dermatological in nature with some unique differences, including hypopigmentation with azelaic acid, photosensitivity with retinoids, the potential to induce bacterial resistance with the topical antibiotics, and the rare potential for methemoglobinemia with dapsone 5% gel.

- A variety of agents in different dosage formulations (e.g., cream, gel, etc.) are required on the UF to meet the needs of patients. Additionally, azelaic acid is required on the formulary due to its pregnancy category rating (category B) and tolerability.

2. **Acne Agents: Topical Acne and Rosacea Agents Subclass—Relative Cost-Effectiveness Analysis and Conclusion**

   A cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

   - CMA results showed for topical acne that generic formulations in the class were the most cost-effective agents, followed by branded formulations of clindamycin/benzoyl peroxide 1.2%/2.5% gel (Acanya), clindamycin/benzoyl peroxide 1.2%/5% gel kit (Neuac), adapalene/benzoyl peroxide 0.1%/2.5% gel (Epiduo), clindamycin/tretinoin (Veltin), adapalene/benzoyl peroxide 0.3%/2.5% gel (Epiduo Forte), dapsone 5% gel and 7.5% gel (Aczone), azelaic acid 20% cream (Azelex), clindamycin cleansing kit (Clindacin ETZ), tazarotene 0.1% foam (Fabior), clindamycin/benzoyl peroxide 1.2%/3.75% gel (Onexton), clindamycin/tretinoin (Ziana), clindamycin cleansing kit (Clindacin PAC), and brand clindamycin 1% gel (Clindagel).

   - CMA results also showed that, for rosacea, generic metronidazole 1% gel, 0.75% lotion and 0.75% cream were the most cost-effective, followed by azelaic acid 15% gel and foam (Finacea), brand metronidazole 0.75% gel and cream cleanser kits (Rosadan), ivermectin 1% cream (Soolantra), brimonidine 0.33% gel (Mirvaso), and brand metronidazole 1% cream (Noritate).

   - BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating generics as UF, with selected brand agents as UF and non-step-preferred, and NF and non-step-preferred, demonstrated the largest estimated cost avoidance for the MHS.

3. **Acne Agents: Topical Acne and Rosacea Agents Subclass—UF Recommendation**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **UF and step-preferred**
  - adapalene 0.1% lotion, gel, cream, and 0.3% gel (Differin, generics)
  - clindamycin 1% foam (Evoclin, generics)
  - clindamycin 1% gel, cream, foam, lotion, solution, and med swab (Cleocin T, generics)
  - clindamycin/benzoyl peroxide 1%/5% gel (Benzaclin, generics)
  - clindamycin/benzoyl peroxide 1.2%/5% gel (Duac, generics)
  - clindamycin/benzoyl peroxide 1%/5% gel kit (Duac CS (Kit))
  - metronidazole 0.75% cream (MetroCream, generics)
  - metronidazole 0.75% lotion (MetroLotion, generics)
  - metronidazole 1% gel (Metrogel, generics)
  - sulfacetamide sodium/sulfur 10% lotion (Klaron, generics)
  - tretinoin 0.01% and 0.025% gel (Retin-A, generics)
  - tretinoin 0.025% gel, cream (Avita, generics)
  - tretinoin 0.025%, 0.05%, and 0.1% cream, liquid (Retin-A, generics)
  - tretinoin 0.0375%, 0.075% cream (Tretin-X, generics)
  - tretinoin 0.05% gel (Atralin, generics)
- **UF and non-step-preferred**
  - azelaic acid 20% cream (Azelex)
  - azelaic acid 15% gel, foam, kit (Finacea)
  - clindamycin/benzoyl peroxide 1.2% and 2.5% gel (Acanya)
- **NF and non-step-preferred**
  - adapalene/benzoyl peroxide 0.1% /2.5% gel (Epiduo)
  - adapalene/benzoyl peroxide 0.3% /2.5% gel (Epiduo Forte)
  - brimonidine 0.33% gel (Mirvaso)
  - clindamycin 1% cleansing kits (Clindacin ETZ, Clindacin PAC)
  - clindamycin 1% gel (Clindagel)
  - clindamycin/benzoyl peroxide 1.2%/ 3.75% gel (Onexton)
  - clindamycin/benzoyl peroxide 1.2%/5% gel/cream kit (Neuac Kit)
  - clindamycin/tretinoin 1.2% /0.025% gel (Veltin; Ziana, generics)
  - dapsone 5% and 7.5% gel (Aczone)
  - ivermectin 1% cream (Soolantra)
  - metronidazole 1% cream (Noritate)
  - metronidazole 0.75% cream/cleanser kit (Rosadan Cream Kit)
  - metronidazole 0.75% gel/cleanser kit (Rosadan Gel Kit)

- tretinoin microsphere 0.04%, 0.08%, and 0.1% gel (Retin-A Micro, generics; Retin-A Micro Pump, generics)
- tazarotene 0.1% foam (Fabior)

4. **Acne Agents: Topical Acne and Rosacea Agents Subclass—Automated Prior Authorization (PA) (Step Therapy) and Manual PA Recommendation**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) step therapy and manual PA criteria for the acne and rosacea drugs. Separate step therapies will be required for acne and rosacea products. Within the acne subclass, there are additional step therapies, based on mechanism of action. All branded formulations are non step-preferred. Step therapy for the acne products generally requires use of at least three step-preferred products first, prior to use of a non-preferred product. For the rosacea products, one generic metronidazole step-preferred formulation is required prior to use of the non step-preferred products.

Full PA Criteria:

1. Topical Antibiotics and Combinations

All new and current users of Clindacin ETZ, Clindacin PAC, Clindagel, Onexton, Neuac Kit and Acanya are required to try 3 step-preferred topical generic acne products first.

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur) at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Clindacin ETZ, Clindacin PAC, Clindagel, Onexton, Neuac Kit or Acanya will be approved if:

- The patient has a diagnosis of acne vulgaris

  AND

- Patient has tried and failed or experienced adverse effects to at least 3 step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide products.

PA expires in 6 months.

2. Topical Retinoids and Combinations

All new and current users of Epiduo, Epiduo Forte, Veltin, Ziana, Retin-A Micro, Retin-A Micro Pump, Fabior, and generics are required to try 3 step-preferred topical generic acne products, including at least 2 different strengths of tretinoin.

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic acne products including at least 2 different strengths of tretinoin, at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, the non-step-preferred product will be approved if:

- The patient has a diagnosis of acne vulgaris

AND

- Patient has tried and failed at least 3 step-preferred topical generic acne products, including at least 2 different strengths of tretinoin OR
- The patient has experienced an adverse reaction/inadequate response with formulary step-preferred topical tretinoin agents that is not expected to occur with the non-preferred product, OR
- There is no other formulary agent alternative
    - For Epiduo, Epiduo Forte: The patient requires a combination topical adapalene/benzoyl peroxide.
    - For Veltin or Ziana: The patient requires this particular strength of combination topical tretinoin/clindamycin (0.025% with 1.25%, respectively).

PA expires after 6 months.

3. Topical Azelaic Acid Products

All new and current users of Azelex and Finacea are required to try 3 step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur, or metronidazole).

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic products at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Azelex or Finacea will be approved if:

- For Azelex: The patient has a diagnosis of acne vulgaris or rosacea AND
- Patient is pregnant, OR
- Patient has tried and failed at least 3 preferred formulary topical acne agents, including combination therapy with clindamycin and benzoyl peroxide.
- For Finacea: Patient is pregnant, OR
- Patient has tried and failed, or cannot tolerate a step-preferred topical generic metronidazole product (1% gel, 0.75% lotion or 0.75% cream)

PA expires after 6 months.

4. Topical Dapsone Products

All new and current users of Aczone 5% and 7.5% are required to try 3 step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.

Automated PA Criteria:

- The patient has filled a prescription for at least 3 step-preferred topical generic acne products at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met Aczone will be approved if:

- The patient has a diagnosis of acne vulgaris, AND
    - Patient is an adult female with a diagnosis of inflammatory acne,

      AND

- The patient has tried and failed at least 3 step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.

PA expires after 6 months.

5. Topical Metronidazole Products

All new and current users of Noritate and Rosadan are required to try one generic topical step-preferred metronidazole product (1% gel, 0.75% lotion or 0.75% cream).

Automated PA Criteria:

- The patient has filled a prescription for one generic topical step-preferred metronidazole product at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Noritate or Rosadan will be approved if:

- The patient has a diagnosis of rosacea, AND
- The patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream).

PA expires after 6 months.

6. Miscellaneous Topical Agents

All new and current users of Mirvaso and Soolantra are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream).

Automated PA Criteria:

- The patient has filled a prescription for one generic topical step-preferred metronidazole product at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: If automated PA criteria are not met, Mirvaso or Soolantra will be approved if:

- Patient is at least 18 years of age and has the following diagnosis:

- For Mirvaso: Patient has non-transient, persistent facial erythema of rosacea

- For Soolantra: Patient has inflammatory lesions (papulopustular) of rosacea caused by Demodex mites

  AND

- Patient has tried and failed one generic step-preferred formulary topical metronidazole product.

  AND

- Patient has tried and failed topical azelaic acid.

PA expires in 365 days.

5. **Acne Agents: Topical Acne and Rosacea Agents Subclass—Manual PA Recommendation for Benzoyl Peroxide**

   The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for legend single-ingredient benzoyl peroxide formulations (e.g., those products that are not in combination with a topical antibiotic). A trial of at least two step-preferred topical acne products will be required prior to use of a prescription benzoyl peroxide product (formulations ranging in concentration from 3% to 10%).

   Full PA Criteria:

   Legend Benzoyl Peroxide Products: benzoyl peroxide 4% to 10% gel, foam, cleanser, towelette, kit (Benzac, Benzac Wash, BenzEFoam, BenzEFoam Ultra, BenzePrO, Benzoyl Peroxide, BP Foam, BPO, BP Wash, Brevoxyl, Brevoxyl-4, Brevoxyl-8, Desquam E, Desquam X, Inova, NuOx, PanOxyl, Panoxyl-10, PR Benzoyl Peroxide, Riax, Sulfoxyl Regular, SE BPO, Vanoxide-HC)
   PA applies to both new and current users.

   Manual PA Criteria:

   - Patient has a diagnosis of acne vulgaris, AND

     - Patient has failed over-the-counter benzoyl peroxide formulations (e.g., washes, gels, cleansers, lotions), OR

     - Patient has tried and failed at least 2 step-preferred topical acne agents (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur).

- PA expires in 6 months.

6. **Acne Agents: Topical Acne and Rosacea Agents Subclass—UF and PA Implementation Plan**

   The P&T Committee recommended (16 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.

7. **Physician's Perspective:**

   - The class was reviewed because there are numerous generic options available. Several of the new products that have been marketed contain the same active ingredient as the generic, but are just in a new strength or packaging; for example the tretinoin microshperes don't add anything clinically relevant to tretinoin, in terms of efficacy. Another example is a new strength of an existing product, including metronidazole 0.75% cream (Rosadan) packaged with a facial cleanser, when the 1% gel (Metrogel) is generic.

   - The uniform formulary recommendation has several generic products or therapeutic alternatives to cover almost all of the different mechanisms of action, with the expensive branded products recommended for non-formulary placement and behind the step.

   - The step therapy recommendations are also based on the different mechanisms of action; however, use of at least three generic products from the different categories will generally satisfy the step therapy requirements. The Committee did agree that there should be "no grandfathering" of patients for the step therapy, so that all current and new patients would be affected (about 22,000 patients affected by the step therapy).

   - The PA criteria for ivermectin (Soolantra) and brimonidine (Mirvaso) do take into account their potential therapeutic niches. (Mirvaso for erythema in rosacea, and Soolantra for the Demodex mites).

   - We also did a provider survey, which was useful in ensuring the products required for clinical coverage would be on the formulary. Some of the providers did comment that the pricey "designer" products should be restricted, and some even recommended having pricing information more readily available for the prescriber.

8. **Panel Questions and Comments:**

   Dr. Delgado questions the 180 day automated PA criteria. Was the P&T Committee able to evaluate whether that is enough time to cycle through 3 different therapies? How long are

patients on each therapy before someone determines that it has failed and the patient can move onto another one? That window of time seems really short.

CAPT VonBerg stated the standard is 180 days but can opt for longer periods of time. That is something that Committee can consider.

Dr. Delgado is concerned about determining failure for 3 different medications within a 6-month time frame. Some medications take a long time to work. Before you can actually call a failure, you might not get through 6 months. It appears that it may result in a lot of manual PAs.

Dr. Kugler mentioned the frequent use of combinations

CAPT VonBerg said you can see two ingredients in one product.

Dr. Delgado acknowledges the medications aren't necessarily sequential.

Dr. Sommer asks why the length of the PA expires after 6 months. Did the P&T Committee consider a longer approval duration?

CAPT VonBerg answers that the patients may not be on the medications for very long. It takes into consideration that patients will discontinue use in short periods of time.

Dr. Anderson asks a question about 365 days PA for rosacea and asks if over-the-counter agents fit into this in any way or are there any requirements that patients try OTCs?

CAPT VonBerg replies they there was a requirement for patients to try the OTCs but there is no automated way to screen and it is not necessarily an issue.

Dr. Anderson asks will OTCs help to satisfy the step requirements.

CAPT VonBerg replies yes, for some of them.

Dr. Anderson asks a question in regards to pregnancy and azelaic acid. There is an exception made if the patient is pregnant. Is there any consideration to women who are actively trying to become pregnant?
CAPT VonBerg replies yes. They will amend the criteria to account for women who are trying to become pregnant.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Automated PA, and Manual PA, Manual PA Recommendation for Benzoyl Peroxide and the UF and PA Implementation Plan.

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – Automated PA (Step Therapy) and Manual PA Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – Manual PA Recommendation for Benzoyl Peroxide**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Acne Agents: Topical Acne and Rosacea Agents Subclass – UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

B. MIGRAINE AGENTS

(LT COL KHOURY)

1. Migraine Agents: Triptans—Relative Clinical Effectiveness and Conclusion

The triptans for migraine headache were previously reviewed for formulary placement in June 2008. There are currently 12 products marketed, with many available in generic oral formulations. Eletriptan (Relpax) has patent expiration expected in December 2016. Four sumatriptan formulations are available only as branded products (Sumavel Dose Pro, Zembrace SymTouch, Onzetra Xsail, and Treximet). Sumatriptan transdermal system (Zecuity) was removed from the market in June 2016 due to safety issues, but is included in the review.

The clinical effectiveness evaluation focused on the triptans approved since the last review, and updated meta-analyses and clinical practice guidelines.

The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that:

- Clinical practice guidelines and systematic reviews found that the triptans as a class have quality evidence to support use in the treatment of moderate to severe migraine headache. The triptans as a class, compared to placebo, achieve numbers needed to treat (NNT) ranging from three to six for the preferred endpoints of two-hour pain-free and 24-hour sustained pain-free after dosing.

- Available data suggests all triptans are significantly superior to placebo for treating acute migraine. The oral agents, particularly generically available triptans, are the most convenient and easy to use, and are often preferred by patients and providers as the first choice treatment. The available data is not sufficient to clearly establish relative superiority of one oral triptan over another.

- For patients who are unable to manage their migraines with oral options, alternative delivery options are required on the formulary if the initial choice is not successful.

- While subcutaneous sumatriptan formulations provide the quickest onset of action and highest response rate, they also have the highest incidence of adverse effects and intolerability issues, along with a higher risk of recurrent migraine.

- Naratriptan (Amerge, generics) and frovatriptan (Frova, generics) have a therapeutic niche for treatment of menstrual-associated migraines, but are not specifically FDA-approved for this indication.

- Sumatriptan/naproxen (Treximet) is a fixed-dose combination of a nonsteroidal anti-inflammatory drug (NSAID) with a triptan that has shown efficacy in migraine headache versus using the individual components alone. However, using any NSAID concurrently with a triptan will likely increase efficacy.

- Overall, the class has mild to moderate adverse effects, which are usually transient. Some of the adverse effects are often unique to the delivery route. Nasal administration typically causes more pronounced nasal-related adverse effects, transdermal routes have been associated with application site reactions, and subcutaneous routes have injection-related concerns.

- The newly-approved triptans do not offer compelling clinical advantages over the older agents.

    - Sumatriptan nasal powder (Onzetra Xsail) does not have clinically or statistically significant differences in efficacy compared with oral sumatriptan and was associated with nasal discomfort.

    - The sumatriptan 3 mg autoinjector (Zembrace SymTouch) provides headache relief at two hours in 60% of patients. In contrast, the sumatriptan 4 mg and 6 mg injection (Imitrex STATdose) achieves headache relief in 57%–60% of patients.

    - The available evidence with sumatriptan transdermal system (Zecuity) suggests it may not be as effective as other triptan formulations; this product is no longer marketed.

- The triptans have a moderate to high degree of therapeutic interchangeability. Some patients will prefer one formulation over another due to their personal headache characteristics and, based on available clinical data, 40% to 50% of patients will not respond to the initial agent chosen. Overall, the majority of patients in the MHS are well served by the available formulary options.

2. **Migraine Agents: Triptans—Relative Cost-Effectiveness Analysis and Conclusion**

CMA and BIA analyses were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results found the following, ranked from most to least cost-effective: sumatriptan tablets generic, rizatriptan tablets generic, zolmitriptan orally dissolving tablet (ODT) generic, rizatriptan ODT generic, zolmitriptan tablets generic, Relpax, naratriptan tablets (Amerge and generics), Treximet, almotriptan tablets generic, sumatriptan nasal generic, frovatriptan tablets generic, Zomig Nasal Spray, Onzetra Xsail, sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generic), Sumavel DosePro, Zembrace SymTouch, and Zecuity.

- 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 most cost-effective scenario for the MHS was designating generic formulations of sumatriptan tablets, nasal spray and injection, and rizatriptan and zolmitriptan tablets and ODT, along with branded eletriptan (Relpax), as UF and step-preferred; naratriptan tablets and zolmitriptan nasal (Zomig Nasal Spray) as UF and non-step-preferred; and, all other products as NF and non-step-preferred.

3. **Migraine Agents: Triptans—UF Recommendation**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **Oral Triptans**
  - UF and step-preferred
    - eletriptan tablets (Relpax)
    - rizatriptan tablets and orally dissolving tablets (ODT) (Maxalt, Maxalt MLT, generics)
    - sumatriptan tablets (Imitrex, generics)
    - zolmitriptan tablets and ODT (Zomig, generics; Zomig-ZMT, generics)
  - UF, non-step-preferred
    - naratriptan tablets (Amerge, generics)
  - NF, non-step-preferred
    - almotriptan (Axert, generics)
    - frovatriptan (Frova, generics)
    - sumatriptan/naproxen tablets (Treximet)

- **Nasal Triptans**

  - UF, step-preferred
    - sumatriptan nasal spray (Imitrex, generics)

  - UF, non-step-preferred
    - zolmitriptan nasal spray (Zomig Nasal Spray)

  - NF, non-step-preferred
    - sumatriptan nasal powder (Onzetra Xsail)

- **Injectable Triptans**

  - UF, step-preferred
    - sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generics)

  - NF, non-step-preferred
    - sumatriptan 4 mg and 6 mg needle-free injection (Sumavel DosePro)
    - Sumatriptan 3 mg autoinjector (Zembrace SymTouch)

- **Transdermal Triptans**

  - NF, non-step-preferred
    - sumatriptan transdermal system (Zecuity), if reintroduced to the market

4. **Migraine Agents: Triptans—Automated PA (Step Therapy) and Manual PA Criteria**

   The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) step therapy for the triptans. There are three separate step therapies for the oral triptans, injectable triptans, and nasal triptans, respectively. A step-preferred formulation of the same dosage form must be tried first, prior to the use of the NF, non-step-preferred product.

   Full PA Criteria:

   - **Oral Triptans**

     All new users of naratriptan (Amerge, generics), almotriptan (Axert, generics), frovatriptan (Frova generics), and sumatriptan/naproxen (Treximet) tablets are required to try 2 different step-preferred generic oral tablets or ODT triptan formulations or Relpax tablets first (e.g., 2 products with differing active ingredients/chemical entities).

     Step-preferred oral and ODT triptan formulations include sumatriptan, rizatriptan, zolmitriptan, and Relpax.

Automated PA Criteria:

- The patient has filled a prescription for at least 2 different step-preferred oral/ODT triptans with different active ingredients at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, naratriptan, almotriptan, frovatriptan, or Treximet will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to 2 step-preferred oral/ODT triptan formulations that is not expected to occur with the non- step-preferred product.

Prior Authorization does not expire.

- **Nasal Triptans**

All new users of (Zomig Nasal Spray or Onzetra Xsail are required to try generic sumatriptan nasal spray first.

Automated PA Criteria:

- The patient has filled a prescription for generic sumatriptan nasal spray at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, Zomig Nasal Spray or Onzetra Xsail will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to generic sumatriptan nasal spray that is not expected to occur with the non-step-preferred product.

Prior Authorization does not expire.

- **Injectable Triptans**

All new users of Sumavel DosePro or Zembrace SymTouch are required to try sumatriptan injection 4 mg/6 mg (Imitrex STATdose, generics) first.

Automated PA Criteria:

- The patient has filled a prescription for sumatriptan injection 4 mg/6 mg (Imitrex STATdose, generics) at any MHS pharmacy point of service

(MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, Sumavel DosePro or Zembrace SymTouch will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to Imitrex STATdose, generics that are not expected to occur with the non-step-preferred product.

Prior Authorization does not expire.

- **Transdermal Triptans**

All users of sumatriptan transdermal (Zecuity), if it is re-introduced to the market, are required to try 2 different step-preferred triptans with different active ingredients, regardless of dosage formulation first.

Automated PA Criteria:

- The patient has filled a prescription for at least 2 different step-preferred triptans with different active ingredients at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days.

Manual PA Criteria: If automated PA criteria are not met, Zecuity will be approved if:

- The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to 2 different step-preferred triptans with different active ingredient that is not expected to occur with Zecuity.

Prior Authorization does not expire.

5. **Migraine Agents: Triptans—UF and PA Implementation Plan**

The P&T Committee recommended (16 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 currently receiving Treximet.

6. **Physician's Perspective:**

- This is another class where there are several generic products available. The new approved drugs all contain sumatriptan in various devices (nasal inhaler and injection); there are no new chemical entities in the class.

- The new clinical information supported that the oral products are first-line for the majority of patients. The Committee did recognize that individual patients may respond to one product and not another, so there are several oral triptans that are step-preferred, including brand eletriptan (Relpax)

- The step therapy is based on the dosage formulation, so a patient who needs an injectable will only have to try the preferred sumatriptan injection first, and not an oral triptan. The Committee did recommend to "grandfather" existing patients, so only new users will be affected by the step therapy, (about 2,600 patients).

- One unique aspect of this step therapy is that there is a look back period of 365 days, rather than the usual 180 days. This is due to the Committee acknowledging that migraine headaches are for acute situations, and patients may go several months without needing a triptan. The 365 day look back is more convenient to the patient.

- The new sumatriptan products, Onzetra, Zembrace and the Treximet fixed dose combination with an NSAID did not offer significant benefits over the generic sumatriptan products.

- For the Zecuity patch that is currently off the market, the Committee did want to designate it as non-formulary and non-preferred, in case it does get re-introduced.

7. Panel Questions and Comments:

Dr. Anderson asks if there was any consideration given in the manual PA criteria to the products that are more commonly used for menstrual associated migraines. He recognized that it's not a FDA approved use and is not sure if the clinical practice guidelines call that out as an appropriate treatment consideration. He's not sure how compelling the evidence is for those specific products in menstrual migraines.

Lt Col Khoury replied that there is a potential for class effect. The evidence was not of a high quality and did not allow for that additional indication from the FDA.

Dr. Anderson just wanted to know if there was any compelling evidence that suggests that it's not a class effect.

Lt Col Khoury replied that data supporting use of triptans in menstrual associated migraines is not of high quality.

Dr. Anderson asked if the committee consider people who are struggling with manual PA not finding therapy that works, was there any prophylactic therapy discussed. Were agents for migraine prophylaxis considered?

Dr. Kugler replied that the manual PA was not intended to be a comprehensive clinical practice guideline for the management of migraine headache and migraine prophylaxis,

while important in overall management of some patients, was not intended to be part of the manual PA. .

There were no more questions or comments from the Panel. The Chair called for a vote on the UF recommendations, Automated PA and Manual PA, and UF and PA Implementation.

- **Migraine Agents: Triptans – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Migraine Agents: Triptains – Automated PA (Step Therapy) and Manual PA**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Migraine Agents: Triptans – UF and PA Implementation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

C. ALCOHOL DETERRENTS

CAPT VONBERG

1. Alcohol Deterrents: Narcotic Antagonists—Relative Clinical Effectiveness and Conclusion

The narcotic antagonists were reviewed for formulary placement. The products all contain naloxone as the active ingredient; their differences lie in the route of administration and delivery device—injectable versus nasal. Two new naloxone formulations approved by the FDA specifically for bystander-administration are the Evzio autoinjector and Narcan Nasal Spray. If opioid overdose is suspected, these products must be administered by someone other than the patient including a family member or caregiver.

The formulary decision will only apply to the use of naloxone that is FDA-approved for use in the bystander setting, as part of the outpatient TRICARE pharmacy benefit. Use in the Military Treatment Facility (MTF) clinic setting or for MTF first responders is not affected by this formulary recommendation. Other formulations of naloxone, including the vials, ampules, pre-filled syringes, and luer lock syringes, are also not affected by the formulary decision.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- The Evzio autoinjector and Narcan Nasal Spray are therapeutically equivalent.

- FDA approval of Evzio and Narcan Nasal Spray was via bioequivalence studies to generic naloxone administered intramuscularly (IM) or subcutaneously (SQ). Evzio

has a published human factors validation (or ease of use) study, which concluded the autoinjector was easy to administer correctly with minimal training. Narcan Nasal Spray appears easy to use based on unpublished data submitted to the FDA by the manufacturer.

- There are no trials comparing the effectiveness of Evzio and Narcan Nasal Spray in terms of onset of action or efficacy in the opioid overdose setting.

- For the Evzio autoinjector, advantages include the ease of use, provision of audio and visual administration cues, and the retractable needle, which decreases the risk of accidental exposure. Disadvantages include the short shelf life of 24 months and that patients with needle aversion may be apprehensive about using the device.

- For the Narcan Nasal Spray, advantages include the ease of use and minimal training required, the small size and portability of the device, the fact that it is a needle-free alternative to injectable naloxone, and the low volume of liquid. Disadvantages include the lack of published usability studies, the need for placing patients in the supine position for administration and then the recovery position, and the unknown effect in patients with significant nasal malformations or blockage.

- The Evzio autoinjector and Narcan Nasal Spray provide naloxone formulations that are easy to administer by bystanders to reverse opioid overdose and respiratory depression, but neither product has data showing outcomes in the real world setting or has data in patients receiving prescriptions for opioids. However, data from studies using the intranasal or IM naloxone kits in the community setting to reverse heroin overdose has shown that these products can successfully reverse opioid-induced respiratory depression.

2. Alcohol Deterrents: Narcotic Antagonists—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate Evzio and Narcan Nasal Spray. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed Narcan Nasal Spray was the most cost-effective naloxone formulation specifically approved for bystander-administration, followed by Evzio.

- BIA was performed to evaluate the potential impact of various formulary scenarios. The scenario with Narcan Nasal Spray as formulary, with the Tier 2 copayment reduced to the Tier 1 copayment in the Retail Pharmacy Network and the TRICARE Mail Order Pharmacy, and Evzio designated as NF, was a cost-effective option for the MHS.

3. **Alcohol Deterrents: Narcotic Antagonists—UF Recommendation**

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **UF:** naloxone nasal spray (Narcan Nasal Spray)
- **NF:** naloxone autoinjector (Evzio)

As part of the UF recommendation, the P&T Committee also recommended that the brand (Tier 2) formulary cost share of $20.00 for Narcan Nasal Spray in the TRICARE Mail Order Pharmacy and $24 in the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share of $0 in the TRICARE Mail Order Pharmacy and $10.00 in the Retail Pharmacy Network.

The authority for the last recommendation is codified in 32 CFR 199.21(j)(3), which states that "when a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate." Lowering the cost share for the branded product Narcan Nasal Spray will provide a greater incentive for beneficiaries to use Narcan Nasal Spray, rather than the less cost-effective naloxone autoinjector (Evzio) in the purchased care setting.

4. **Alcohol Deterrents: Narcotic Antagonists—UF Implementation Plan**

The P&T Committee recommended (16 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 currently receiving Evzio.

5. **Physician Perspective:**

- The P&T Committee was unanimous in their recommendation for Narcan Nasal to be the uniform formulary product, with Evzio as non-formulary, based on cost effectiveness. The P&T Committee did reach out to the Tri-Service Pain Working Group for their input.

- The Committee did recognize that a small subset of patients would be candidates for Evzio instead of Narcan Nasal. Some examples include patients with significant nasal malformations or obstructions, or in cases where there is a juvenile caregiver in the home who would be the one most likely to administer naloxone, since the auto injector dose give a voice reminder to call 911.

- The Committee's recommendation only relates to outpatient use. The Committee did not make recommendations as to the most appropriate candidates to receive a naloxone bystander-approved product. MTFs can continue to follow local and national prescribing guidelines based on morphine equivalent daily dosage or concomitant

drugs (such as benzodiazepines or Ambien). Other resources, such as the March 2016 CDC guidelines for prescribing opioids for chronic pain, are also available for consult. Additionally, further guidance is expected from the Tri-Service Pain Working Group.

6. Panel Questions and Comments:

Mr. Wagoner stated that this seems like a wonderful product. He asked how the product would be prescribed. Is it the facility or the individual? He stated that it's hard to say, "I would like an anti-narcotic overdose prescription." He said that it's a wonderful thing, and asked who would be the target? Is it over the counter?

CAPT VonBerg replied that it is not over-the-counter. There are multiple different ways for the patient to get the medication. The physician's office can co-prescribe with pain medications.

Dr. Kugler mentioned patients that have high morphine equivalent daily doses, or they have a little-lower morphine equivalent daily dose with a higher concomitant higher risk. Co-prescribing can happen.

CAPT VonBerg further explains that there are various efforts at the MTFs to make it even more accessible directly to the pharmacies when the MTF pharmacies notice these things. Those processes are being developed. We are trying to help facilitate those things to make it as accessible as possible. There are also various state and local health organizations, and pharmacy boards, though not available specifically as an OTC, that they are creating avenues for those different entities to prescribe under things like collaborative practice agreements. Either the public health department or local physician's office partner with local entities to allow those things to be dispensed readily to the patient and are often dispensed to patient or bystander. You want to make sure that the individual who is going to use it gets the education on how to use it. Often it's prescribed directly to the bystander. There are quite a few different laws that are being changed to lessen that risk and increasing the access to these drugs.

Dr. Wagoner thanks CAPT VonBerg for his thorough answer and states what a great product that essentially can save lives.

Dr. Anderson stated that naloxone is available outside of the auto injector. Was there any consideration given to making that injectable version available?

CAPT VonBerg replied that it is already available. Before these products existed, that's all that existed. There's evidence that its use by bystanders or emergency medical personnel is effective through various ways including kits that include nasal atomizers. You could hook the syringe to a atomizer device so the liquid could be administered easily. That is currently covered in the UF and is specifically on the self-administration list that will allow the coverage to go through easier. They can

still do that. That was done prior to this P&T meeting. Should somebody write a prescription for that, it will still get covered with a co-pay.

Dr. Anderson asked if they have to use it under the nasal route to get covered by the benefit. He ultimately got at the need of the people who can't use the nasal route and recognized that it's very expensive. Asked if the injectable naloxone could be self-administered, or it that too complicated for someone to try to manage

CAPT VonBerg replied that it can be done. It's possible because needles and syringes are covered.

Dr. Kugler stated that this makes it more available for individuals at risk.

CAPT VonBerg replied that pain committees thought that one of these products had to be available.

Dr. Anderson thanked CAPT VonBerg for the clarification.

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

- **Alcohol Deterrents: Narcotic Antagonists – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Alcohol Deterrents: Narcotic Antagonists – UF Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

D. INNOVATOR DRUGS

(CAPT VONBERG)

1. **Innovator Drugs—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions**

   The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the innovator drugs.

2. **Innovator Drugs—UF Recommendation**

   The P&T Committee recommended the following:

   - UF (16 for, 0 opposed, 0 abstained, 1 absent):

- Antihemophilic Agents: antihemophilic (recombinant) Factor VIII injection (Afstyla)
- Oral Oncology Agents (Renal Cell Carcinoma): cabozantinib (Cabometyx)
- Antiretrovirals Agents: emtricitabine/tenofovir alafenamide (Descovy)
- Miscellaneous Agents: nitisinone oral suspension (Orfadin)
- Miscellaneous Agents: obeticholic acid (Ocaliva)
- ***Hepatitis C Virus Direct Acting Agents:*** sofosbuvir/velpatasvir (Epclusa)
- Oral Oncology Agents (Chronic Lymphocytic Leukemia): venetoclax (Venclexta)

- NF (16 for, 0 opposed, 0 abstained, 1 absent):

  - Topical Corticosteroids: betamethasone dipropionate 0.05% spray (Sernivo)
  - Anticonvulsant and Anti-Mania Agents: brivaracetam tablets and oral solution (Briviact)
  - Topical Antineoplastic and Premalignant Lesions Agents: fluorouracil 4% cream (Tolak)
  - Topical Corticosteroids: halobetasol propionate 0.05% lotion (Ultravate)
  - ***Non-Insulin Diabetes Drugs—DPP-4 Inhibitors:*** linagliptin/metformin XR tablets (Jentadueto XR), which is additionally recommended to be non step-preferred, due to existing step therapy in the class
  - Atypical Antipsychotics: pimavanserin (Nuplazid)
  - Narcotic Analgesics and Combinations: oxycodone extended-release capsules (Xtampza ER)

- NF (10 for, 6 opposed, 0 abstained, 1 absent):

  - Iron Chelators: deferiprone oral solution (Ferriprox) due to the lack of compelling clinical advantages over other oral iron chelator products, three times daily dosing, and the risk of agranulocytosis

3. Innovator Drugs—Manual PA Criteria

The P&T Committee also recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Applying the same step therapy and manual PA criteria for Jentadueto XR as is currently in place for linagliptin/metformin immediate release (IR) (Jentadueto) and the other non-step-preferred dipeptidyl peptidase-4 (DPP-4) inhibitor combinations with metformin. Existing step therapy currently applies to the DPP-4 inhibitors, including Jentadueto. Patients must first use metformin or a sulfonylurea, and the preferred DPP-4 inhibitor sitagliptin before using a non-step-preferred DPP-4 inhibitor.

- Applying manual PA criteria to the following: new users of the hepatitis C virus (HCV) direct acting antiviral agent (DAA) sofosbuvir/velpatasvir (Epclusa), the

atypical antipsychotic pimavanserin (Nuplazid), the iron chelator deferiprone oral solution and oral tablet (Ferriprox), and the orphan drug obeticholic acid (Ocaliva).

Full PA Criteria:

a. Innovator Drugs—Non-Insulin Diabetes Mellitus DPP-4 Inhibitors: Linagliptin/Metformin XF (Jentadueto XR)

Jentadueto XR will be non-step-prefered, similar to the other non-step-preferred DPP-4 inhibitors.

All new and current users of a DPP-4 inhibitor are required to try metformin or a sulfonylurea before receiving a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR) are the preferred agents in the DPP-4 Inhibitors Subclass. New users of a DPP-4 inhibitor, including Jentadueto XR, must try a sitagliptin product first.

Automated PA Criteria

- The patient has filled a prescription for metformin or a sulfonylurea at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

- The patient has received a prescription for a preferred DPP-4 inhibitor (Januvia, Janumet, or Janumet XR) 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, Jentadueto XR is approved if:

- The patient has had an in adequate response to metformin or sulfonylurea.

- The patient has experienced any of the following adverse events while receiving a sulfonylurea: hypoglycemia requiring medical treatment.

- The patient has experienced an adverse event with sitagliptin-containing products, which is not expected to occur with linagliptin-containing products.

- The patient has had an inadequate response to a sitagliptin-containing product.

- The patient has a contraindication to sitagliptin.

PA does not expire.

b. Innovator Drugs—HCV DAAs: Sofosbuvir/Velpatasvir (Epclusa)

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

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection
  - State the HCV genotype and HCV RNA viral load on the PA form.
- Sofosbuvir/velpatasvir (Epclusa) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Treatment Regimens and Duration of Therapy

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

c. Innovator Drugs—Atypical Antipsychotics: Pimavanserin (Nuplazid)

Manual PA criteria apply to all new users of pimavanserin.
Manual PA Criteria: Nuplazid is approved if all of the following criteria are met:

- Patient is age ≥ 18 AND
- Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's disease psychosis AND
- Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin AND

- Mini-Mental State Examination (MMSE) score ≥ 21

Prior Authorization does not expire.

Non-FDA approved uses are not approved.

d. **Innovator Drugs—Iron Chelators: Deferiprone Oral Solutions and Oral Tablets (Ferriprox)**

Manual PA criteria apply to new users of deferiprone oral solution and oral tablets (Ferriprox).

Manual PA Criteria: Ferriprox will be approved if the patient meets the following criteria:

- The patient has tried Exjade or Jadenu and was unable to tolerate due to adverse effects.

Prior Authorization does not expire.

e. **Innovator Drugs—Miscellaneous: Obeticholic Acid (Ocaliva) for Primary Biliary Cholangitis**

Manual PA criteria apply to all new users of obeticholic acid (Ocaliva).

Manual PA Criteria: Ocaliva is approved for 6 months for Primary Biliary Cholangitis (PBC) for initial therapy if the patient meets the following criteria:

- Patient is age ≥ 18 year old; AND
- Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND
- Patient has a diagnosis of PBC as defined by at least TWO of the following criteria (a, b, and/or c) according to the prescribing physician:
  a. alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values; AND/OR
  b. positive anti-mitochondrial antibodies (AMAs); AND/OR
  c. histologic evidence of PBC from a liver biopsy; AND
- Patient meets ONE of the following criteria (a or b):

a. Patient has been receiving ursodiol therapy (e.g., ursodiol generics, Urso 250,Urso Forte, Actigall) for ≥ 1 year and has had an inadequate response

OR

b. The patient is unable to tolerate ursodiol therapy.

Renewal criteria: Ocaliva is approved indefinitely for PBC for continuation therapy if the patient meets the following criteria:

Patients Currently Receiving Therapy (renewal criteria): approve indefinitely if the patient meets the following criteria:

- Age ≥ 18 years old; AND
- Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND
- Patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC: e.g., alkaline phosphatase (ALP), bilirubin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT) levels).

Expiration date: 6 months or indefinite depending on initial or renewal criteria

Non FDA-approved uses are not approved.

4. Innovator Drugs—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date upon signing of the minutes in all points of service.

5. Physician's Perspective:

- The authority establishing the Innovator Drugs has now been in place for a year. So far we are averaging about 10-15 innovators at each meeting. For drugs in classes that have not been previously reviewed, or for some of the orphan drugs, we do reach out to the appropriate specialists for their input.
- The recommendations for the non-formulary products are due to lack of compelling clinical advantages, or due to lack of cost effectiveness, compared to current UF drugs. The only vote that was not unanimous for the formulary recommendation was that 6 members opposed having Ferroprox as non-formulary. The reasons for the dissenting votes were concerns due to potentially limiting patient access to this iron chelator.
- The Prior Authorization recommendation for Epclusa is consistent with the PAs already in place for the hepatitis C drugs. We are actively monitoring utilization and

costs for these drugs, and will consider reviewing the class again in 2017, due to the market entrance of several new products.

- The PA for Nuplazid follows the study criteria for the trial that led to FDA approval. Ocaliva is a drug for a rare disease (primary biliary cholangitis), and the PA criteria limit use to the FDA-approved indications.

6. Panel Questions and Comments:

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

- **Innovator Drugs – UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Innovator Drugs – Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Innovator Drugs – UF and PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

II. UTILIZATION MANAGEMENT

A. ANALGESICS AND COMBINATIONS

(LT COL KHOURY)

1. Analgesics and Combinations: Butalbital/Acetaminophen/Caffeine Oral Liquid (Vanatol LQ)—Manual PA Criteria

Vanatol LQ is an oral liquid formulation containing the same active ingredients as Fioricet and is approved for tension or muscle headaches. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for Vanatol LQ, due to cost disadvantages compared to generic Fioricet tablets and capsules.
Full PA Criteria:

Analgesics and Combinations: Vanatol LQ

All new and current users of butalbital/acetaminophen/caffeine (Vanatol LQ) are required to undergo manual prior authorization criteria.

Manual PA Criteria: Coverage will be approved if:

- Patient cannot tolerate generic Fioricet oral tablet or capsule formulations due to documented swallowing difficulties.

Prior Authorization expires in 6 months.

Non FDA-approved uses are not approved.

2. **Analgesics and Combinations: Butalbital/Acetaminophen/Caffeine Oral Liquid (Vanatol LQ)—PA Implementation Period**

   The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

3. **Physician's Perspective:**

   - This product is being marketed by compounding pharmacies and is essentially liquid fioricet. The PA requires a patient to have a clinical reason as to why they can't take generic Fioricet tablets.

4. **Panel Questions and Comments:**

   Dr. Delgado asked why is there no automated PA criteria? Why is there just manual?

   CAPT VonBerg replied that the committee wanted to see actual write-up every time the product was requested. We can't tell if a person has swallowing difficulties or not or whether they've used the previous products. We can only see that they've had it before. We can't see why they've requested, and that's what we want to know.

   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 Criteria.

   - **Analgesics and Combinations: Vanatol LQ – Manual PA Criteria**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

   - **Analgesics and Combination: Vanatol LQ – PA Implementation Criteria**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

B. NEWER SEDATIVE HYPNOTICS (SED-1s)

(LT COL KHOURY)

1. SED-1s: Suvorexant (Belsomra)—Removal of Automated PA and Establishing Manual PA Criteria for New Users

Belsomra is a first-in-class orexin receptor antagonist indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or maintenance. The SED-1s Drug Class has automated PA criteria that require a trial of a step-preferred agent (zolpidem IR or zaleplon). Belsomra was designated as NF in August 2015, with step therapy implemented in October 2015. Zolpidem ER (Ambien CR) and eszopiclone (Lunesta) have the same FDA indications as Belsomra.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removing the automated PA criteria and establishing manual PA criteria for Belsomra in new users due to the lack of compelling clinical advantages and cost-disadvantages over the existing formulary SED-1s. Patients will be required to try zolpidem extended release and eszopiclone before using Belsomra.

Full PA Criteria:

Newer Sedative Hypnotics: Suvorexant (Belsomra)

The current automated PA (step therapy) will be removed.

Manual PA criteria apply to all new users of Belsomra.

Manual PA Criteria: Belsomra is approved if:

- Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance AND
- Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive therapy, sleep hygiene AND
- Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release AND eszopiclone
- Patient has no current or previous history of narcolepsy AND
- Patient has no current or previous history of drug abuse.

Prior Authorization does not expire.

Non FDA-approved uses are not approved.

2. **SED-1s: Suvorexant (Belsomra)—PA Implementation Plan**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

3. **Physician's Perspective:**

- Belsomra has the same FDA indications as Ambien CR and Lunesta, which are both on the Uniform Formulary. Although the mechanism of action is unique, Belsomra's side effect profile is similar to the other drugs in the class, and it is a controlled schedule drug (C-IV).

- There has been a step therapy in the SED-1 class for several years, which requires a trial of generic Ambien or Sonata before Belsomra. The recommendation is to remove Belsomra from the step therapy and have all new patients go through a paper PA. Patients will be required to have a trial of the other SED-1s that have the same indication as Belsomra.

4. **Panel Questions and Comments:**

There were no questions or comments from the Panel, The Chair called for a vote on the Removal of the automated PA and establishing Manual PA Criteria for new users and the PA Implementation Plan.

- **SED-1s: Suvorexant (Belsomra) – Removal of Automated PA and Establishing Manual PA Criteria for New Users**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **SED-1s: Suvorexant (Belsomra) – PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

C. GROWTH-STIMULATING AGENTS (GSAs)

(LT COL KHOURY)

1. **GSAs—Manual PA Criteria**

GSAs have varying indications including treatment of patients with growth hormone deficiency, Turner Syndrome, patients who are small for gestational age, and for patients with idiopathic short stature, among others. The GSAs were last reviewed in 2007, and manual PA criteria apply. Idiopathic short stature has not been a covered indication by the

MHS. Since the previous review, several agents have been discontinued and new agents approved. All newly-approved GSAs will be subject to the PA criteria, which expires after one year.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updating the manual PA criteria for GSAs in new and current users to reflect the current products on the market, and to exclude idiopathic short stature as a covered indication for all products.

Full PA Criteria:

Manual PA criteria apply to all new and current users of GSAs. The following drugs will be added to the existing PA form for the GSAs: Nutropin AQ NuSpin, Nutropin AQ Pen, Genotropin, Humatrope, Omnitrope, Saizen.

Manual PA Criteria: Criteria #5 — Use for Idiopathic Short Stature is not covered for:

- Nutropin AQ NuSpin, Nutropin AQ Pen, Genotropin, Humatrope, Omnitrope, Saizen

Prescriptions for newly-approved GSAs will be subject to the PA criteria currently in place for the class.

Prior Authorization expiration: 365 days

2. **GSAs—PA Implementation Plan**

   The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 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 does periodically go back and review older classes for new products and FDA indications. The PA requirements for the Growth Stimulating Agents is just to ensure that we have all the products on the market covered by the PA, since it has been several years since the last class review. Any replacement product coming out on the market now will be subject to the same PA requirements as the others in the class.

4. **Panel Questions and Comments:**

   Dr. Anderson stated this is more of benefit design issue. Is that the way to think about this? That it is not a covered benefit under TRICARE.

   Dr. Kugler replied to be consistent.

   Dr. Anderson repeated to be consistent with the other products in the class.

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

- **GSAs – Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **GSAs – PA Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

D. TOPICAL PAIN AGENTS

(LT COL KHOURY)

1. Topical Pain Agents: Diclofenac Sodium 2% Topical Solution (Pennsaid)—Manual PA Criteria

Diclofenac topical solution (Pennsaid) is FDA-approved for the treatment of pain from osteoarthritis of the knee. The originally approved 1.5% branded product is now available as a generic formulation, and the branded product was changed to a 2% concentration. Pennsaid 2% offers no compelling advantages over diclofenac 1.0% gel (Voltaren) or generic 1.5% topical preparations.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for new and current users of Pennsaid 2%.

Full PA Criteria:

Manual PA criteria apply to all new and current users of diclofenac sodium 2% topical solution.

Manual PA criteria: Pennsaid 2% topical solution is approved if:

- Patient has a documented diagnosis of osteoarthritis of the knee AND
  - Patient is unable to take oral NSAIDs or acetaminophen due to documented intolerance, contraindication, or adverse reaction OR
  - The patient is ≥ 75 years old

  AND
- The patient is unable to use preferred generic diclofenac 1.5% topical solution AND diclofenac 1.0% topical gel (Voltaren generics) due to documented inadequate effects.

Prior Authorization does not expire.

Non-FDA approved uses are not approved

2. **Topical Pain Agents: Diclofenac Sodium 2% Topical Solution (Pennsaid)—PA Implementation Plan**

   The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

3. **Physician's Perspective:**

   The recommendation for the brand Pennsaid PA is to ensure that patients have tried the generic 1.5% formulation first, since it is much more cost effective than the 2% formulation. The PA criteria do take into account the fact that patients over 75 years may not be good candidates for oral NSAIDs.

4. **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.

   - **Topical Pain Agents: Diclofenac Sodium 2% Topical Solution (Pennsaid) – Manual Pa Criteria**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

   - **Topical Pain Agents: Diclefenac Sodium 2% Solution (Pennsaid) – PA Implementation Plan**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

E. BRAND OVER GENERIC AUTHORITY AND PA CRITERIA

(LT COL KHOURY)

1. **Mandatory Generic Substitution Policy: Removal of PA Requiring Brand Over Generic for Niacin ER (Niaspan)**

   TRICARE policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, when AB-rated generic formulations for niacin ER (Niaspan) were launched in September 2013, pricing for the branded product was lower than the generic formulations. The manufacturer of Niaspan offered a Voluntary Agreement for Retail Refunds and the Tier 1 (generic) copayment was assigned to the branded product at the November 2013 P&T Committee meeting. Additionally, PA criteria allowing for a

patient to receive generic niacin ER instead of branded Niaspan (i.e., the reverse of the current brand to generic policy) were recommended by the P&T Committee in May 2014.

In May 2016, the P&T Committee recommended the DHA Pharmacy Operations Division (POD) be given authority, after consulting with the Chair of the P&T Committee, to implement "brand over generic" authorization for drugs with recent generic entrants where the branded product is more cost-effective than generic formulations. In these cases, the branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. Authority was also given to the POD to remove the "brand over generic" requirement when it is no longer cost- effective to the MHS.

As of June 2016, the AB-rated generic formulations for niacin ER (Niaspan) are cost-effective compared to the branded Niaspan product.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removal of the Brand over Generic PA, and removal of the Tier 1 (generic) co-pay for branded Niaspan. Branded Niaspan will now be available at the Tier 2 (UF) co-pay in the Retail Network and Mail Order Pharmacy, and the requirement for mandatory generic substitution is re-instated.

2. **Physician's Perspective:**

   - We first introduced this topic at the last BAP meeting. This authority allows the Committee to react quickly to changes in the costs of new generic products.

   - The Committee found that the generic products for Niaspan ER are now cost effective, and there is no longer a benefit to the MHS to continue the "brand over generic" requirements. We will continue to bring these types of issues for review here.

3. **Panel Questions and Comments:**

   Dr. Anderson asked when brand over generic is done, is it a practice that the branded version will always be offered as a Tier 1?

   CAPT VonBerg replied that we don't have to, but we do.

   Dr. Anderson responded that he didn't have a strong concern with it not being Tier 1, but was curious if that was practice.

There were no more questions or comments from the Panel. The Chair called for a vote on the Removal of PA requiring Brand over Generic for Niacin ER (Niaspan).

- **Mandatory Generic Substitution Policy: Removal of PA Requiring Brand Over Generic for Niacin ER (Niaspan)**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

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

(LT COL KHOURY)

1. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee reviewed three drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with 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 be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail point of service and medical necessity at MTFs. These NF drugs will remain available in the mail order point of service without pre-authorization.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following products be designated NF on the UF:

- Veloxis Pharma: tacrolimus ER (Envarsus XR) 1 mg and 4 mg oral tablets
- Lachlan Pharma: benzyl alcohol (Ulesfia) 5% topical lotion
- Mist Pharma: propranolol ER (Inderal XL) 80 mg and 120 mg oral capsules

2. Section 703, NDAA FY08—Pre-Authorization Criteria

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following pre-authorization criteria for Envarsus XR, Ulesfia, and Inderal XL:

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

These pre-authorization criteria do not apply to any other point of service other than retail network pharmacies.

3. **Section 703, NDAA FY08—Implementation Plan**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Envarsus XR, Ulesfia, and Inderal XL; and, 2) DHA send letters to beneficiaries affected by this decision.

4. **Physician's Perspective:**

- For all three products recommended for NF status, cost-effective generic formulations or therapeutic alternatives are available on the UF. The Pharmacy Operations Division does follow up with the affected manufacturers, to try to ensure compliance with the Section 703 requirements.

5. **Panel Questions and Comments:**

There were no questions or comments from the Panel. The Chair called for a vote on the Drugs designated NF, Pre-Authorization Criteria, and the Implementation Plan.

- **Section 703, NDAA FY08 – Drugs Designated NF**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Section 703, NDAA FY08 – Pre-Authorization Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Section 703, NDAA FY08 - Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

IV. OVER-THE-COUNTER (OTC) DRUG BENEFIT

(LT COL KHOURY)

1. **OTC Drug Benefit: Status of the Second Generation Antihistamines**—The Deployment Prescription Program requested that the DoD P&T Committee consider adding fexofenadine (generic Allegra) to the UF as part of the OTC pharmacy benefit, which would make it available by mail to deployed Service members in theater. The final rule implementing the legislative authority for the OTC Drug Program was published on July 27, 2015, and is found at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy. The OTC medications currently on the UF include omeprazole, loratadine, loratadine/pseudoephedrine, cetirizine, cetirizine/pseudoephedrine, levonorgestrel 1.5 mg (Plan B One-Step and its generics), and doxylamine 25 mg.

The P&T Committee reviewed the status of the second generation antihistamines on the various Aerospace Medicine lists of medications approved for use by U.S. Air Force, U.S. Army, U.S. Navy, and U.S. Coast Guard flyers. All of the lists include loratadine and all, except for the U.S. Army list, include fexofenadine. Cetirizine is not included on any of the lists since it is more likely to cause sedation than loratadine or fexofenadine.

Generic cetirizine OTC and generic loratadine OTC were the least costly second generation antihistamines, followed by generic fexofenadine OTC, levocetirizine (generic Xyzal), and desloratadine (generic Clarinex). The costs of combination products with pseudoephedrine ranged from 5 to 18 times higher than, and were used less frequently than, their respective single ingredient products. The P&T Committee also noted cetirizine/pseudoephedrine has not been available through the mail order point of service over the last few months due to the lack of a Trade Agreements Act (TAA) compliant generic product.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, effective upon signing of the minutes:

- adding OTC fexofenadine to the UF
- removing OTC cetirizine/pseudoephedrine from the UF
- removing OTC loratadine/pseudoephedrine from the UF

2. **Physician's Perspective:**

   - The legislative authority for the P&T Committee to review OTC drugs has also been in place approximately a year. The Committee uses the same process for the OTC drugs as it does for all the legend products, in that both clinical and cost effectiveness are reviewed. For the second generation antihistamines, you can see that the Aerospace Medicine lists for the various services were also consulted.
   - So far the OTC products that are on the formulary include cetirizine, loratadine, doxylamine, omeprazole and Plan B One Step, and now the recommendation is to add fexofenadine to the UF.

3. **Panel Questions and Comments:**

   There were no questions or comments from the Panel. The Chair called for a vote on the status of the second generation antihistamines.

   - **OTC Drug Benefit: Status of the Second Generation Antihistamines**

     Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

V. RE-EVALUATION OF GENERICALLY AVAILABLE NF AGENTS (LT COL KHOURY)

1. Re-Evaluation of Generically Available NF Agents—Clinical Effectiveness and Cost-Effectiveness Conclusions

The P&T Committee continued the process of implementing the requirement that NF pharmaceutical agents generally be unavailable at MTFs or the Retail Network, but available in the Mail Order program. (See DoD P&T Committee meeting minutes from August 2015 and May 2016.) Implementation of the mail order requirement for generically available NF agents was temporarily deferred to allow for review of the continued necessity for NF (Tier 3) status, given price decreases typically associated with generic availability.

The P&T Committee reviewed the current utilization, formulary status, generic availability, comparative clinical effectiveness, and relative cost effectiveness, including the weighted average cost per unit, for all generically available NF agents in eight previously reviewed UF drug classes. Utilization trends by points of service found limited dispensing of the NF generic products, compared to the UF products in the respective classes.

The P&T Committee concluded that for all eight drug classes, there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusion from when the class was originally reviewed for UF placement. The P&T Committee also concluded that the costs of all the NF generic products were significantly higher than the currently available UF products, with two exceptions: generic calcitonin-salmon nasal spray and diclofenac 1.5% topical solution were comparable in price to the UF products in their respective classes. Specific comments are below:

- *Second Generation Antihistamines: Levocetirizine (Xyzal) and Desloratadine (Clarinex)*—Levocetirizine and desloratadine continue to offer no significant, therapeutically meaningful advantage over other similar agents on the UF (loratadine, cetirizine, and fexofenadine).

- *Osteoporosis/Oral Bisphosphonates and Calcitonin: Risedronate (Actonel, Atelvia), Calcitonin-Salmon Nasal Spray (Miacalcin)*

    - The oral bisphosphonates are highly therapeutically interchangeable, and there are no compelling advantages to the delayed release formulation of weekly risedronate (Atelvia). New safety data for the bisphosphonates (osteonecrosis of the jaw, esophageal cancer, atrial fibrillation, and atypical femur fractures), has led to an overall decline in use.

    - There is currently step therapy for the bisphosphonates, with alendronate (generic Fosamax) designated as step-preferred. Generic formulations of ibandronate 150 mg monthly (Boniva) are now available. The P&T Committee noted that generic

ibandronate 150 mg is newly available to MTFs and through mail order at substantially decreased cost under a Joint National Contract.

- Calcitonin nasal spray is considered a third line and/or niche agent in clinical practice guidelines. The cost per 28 days for calcitonin nasal spray was similar for recombinant calcitonin (Fortical) and for generic calcitonin-salmon (generic Miacalcin).

- *Non-Insulin Diabetes Mellitus Drugs/Biguanides: Metformin ER (Fortamet, Glumetza)*—There is no evidence to suggest that differences in the ER formulations of Glumetza and Fortamet confer clinically relevant benefits in efficacy or safety when compared to generic metformin IR or ER preparations (Glucophage, Glucophage XR, generic).

- *Selective Serotonin Reuptake Inhibitors: Fluoxetine 90 mg Delayed Release (Prozac Weekly) and Products for Premenstrual Dysphoric Disorder (PMDD) (Sarafem)*—Neither the special packaging for PMDD (Sarafem) nor a higher dosing strength for weekly administration (Prozac Weekly) offer significant clinical advantages compared to generic Prozac. Brand Sarafem is now available as tablets instead of capsules; the availability of generics for the tablets is unclear at this time, based on the FDA website.

- *Benign Prostatic Hypertrophy (BPH) Medications/5-Alpha Reductase Inhibitors (ARIs): Dutasteride (Avodart), Dutasteride/Tamsulosin (Jalyn)*—Finasteride (Proscar, generic) and dutasteride are highly therapeutically interchangeable for the treatment of BPH, and the combination product dutasteride/tamsulosin offers no additional benefit compared to the individual components. There is existing step therapy in the class.

- *Alzheimer's Medications: Donepezil 23 mg (Aricept 23 mg)*—Donepezil 23 mg shows statistical improvement in cognition but not global functioning, and tolerability is likely limited by increased adverse effects, compared to donepezil 10 mg.

- *Antilipidemics-1/Statins and Combos: Fluvastatin ER 80 mg (Lescol XR)*
  Lescol XR remains a moderate low-density lipoprotein (LDL) lowering statin, with LDL-lowering capacity ranging between 30% to <50%. Eight other statins fall into the moderate LDL-lowering category. Step therapy also exists in this class; a trial of a generic step-preferred statin with similar LDL-lowering capacity is required first.

- *Topical Pain Agents: Diclofenac 1.5% Topical Solution (Pennsaid 1.5% Drops)*
  Topical diclofenac (including the topical solution and gel) was effective for managing superficial pain (e.g., osteoarthritis, sprain, strain, contusions). Gastro-intestinal adverse events were lower with topical therapy compared to oral NSAIDs. Brand Pennsaid is now available as a diclofenac 2% topical solution, with only generic versions of the 1.5% formulation remaining on the market. Weighted average cost per day for generic diclofenac 1.5% topical solution is comparable to the weighted

average cost per day for generic lidocaine 5% patch, providing another alternative in this class both overall and specifically as an alternative to Pennsaid 2% topical solution, which is far more costly.

2. **Re-Evaluation of Generically Available NF Agents—UF Recommendation, Automated PA (Step Therapy) Changes and Removal of Manual PA Criteria for Ibandronate**

The P&T Committee recommended the following (16 for, 0 opposed, 0 abstained, 1 absent), effective upon signing of the minutes:

- The following products will remain NF, with both brand and generics subjected to mail order requirements:
    - Second Generation Antihistamines: levocetirizine (Xyzal, generics) and desloratadine (Clarinex, generics)
    - Osteoporosis: risedronate (Atelvia, Actonel, and their generics); these products will remain as non-step-preferred
    - Antidiabetics: metformin ER (Fortamet, Glumetza, and their generics)
    - Selective Serotonin Reuptake Inhibitors: fluoxetine 90 mg (Prozac Weekly); generic Sarafem caps; Sarafem tabs
    - BPH: dutasteride (Avodart, generics); dutasteride/tamsulosin (Jalyn, generics); these products will remain as non-step-preferred
    - Alzheimer's: donepezil 23 mg (Aricept, generics)
    - Antilipidemics: fluvastatin ER (Lescol XL, generics); will remain non-step-preferred
- Return to UF status
    - Osteoporosis: calcitonin-salmon nasal spray (generic Miacalcin)
    - Topical Pain Agents: diclofenac 1.5% topical solution (generic Pennsaid 1.5%)
- Automated PA (Step Therapy) Changes
    - Osteoporosis Agents/Oral Bisphosphonates
        - designate ibandronate 150 mg monthly (Boniva, generics) as step-preferred
        - Patients must now try either step-preferred alendronate or ibandronate prior to use of Actonel, Atelvia, Binosto, and Fosamax Plus D. The automated and

manual PA criteria for the oral bisphosphonates will now state: "The patient has filled a prescription for alendronate or ibandronate at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days."

- Manual PA criteria requirements (if the automated PA criteria were not met) for ibandronate will also be removed, effective upon signing of the minutes.

Full PA Criteria:

Changes are highlighted in bold and strikethrough.

Oral Bisphosphonates: ~~**ibandronate (Boniva, generics)**~~; risedronate (Actonel); risedronate delayed release (Atelvia); alendronate effervescent tablet (Binosto); alendronate with vitamin D (Fosamax Plus D)

- Ibandronate is now step-preferred

PA criteria apply to ~~**all new users of ibandronate, and**~~ all new and current users of Actonel, Atelvia, Binosto, and Fosamax Plus D.

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

AND

Manual PA criteria: ~~**ibandronate**~~, Actonel, Atelvia, Binosto, and Fosamax Plus D is approved (e.g., trial of alendronate is NOT required) if:

- Patient has experienced any of the following issues with alendronate, which is not expected to occur with the non-preferred oral bisphosphonates:
    - Intolerable adverse effects
        - ~~**Patient requires once monthly ibandronate or Actonel 150 mg due to gastrointestinal adverse events from alendronate weekly dosing**~~
        - Patient has experienced significant adverse effects from formulary agents
        - For Binosto: No alternative formulary agent and patient has swallowing difficulties and cannot consume 8 oz of water and has no sodium restrictions

        - For Fosamax Plus D: No alternative formulary agent and patient cannot take alendronate and vitamin D separately

    - Contraindication

3. **Physician's Perspective:**

- We are continuing to go through all the classes evaluated several years ago to assess new clinical and cost information. For the eight classes reviewed, the recommendations for which generics remains NF and which should go back to UF status was based on clinical and cost effectiveness. After the eight drug classes reviewed at the August P&T meeting, there are only about three or four classes left to evaluate, which will be reviewed at an upcoming meeting.

- Beneficiaries can refer to the TRICARE pharmacy website or the Health.mil website to find which drugs are affected by the "Mandatory Mail for maintenance drugs" and "Non-formulary goes to Mail" requirements. For all the drugs affected by these requirements, up to two prescription fills will be allowed at a Retail Network pharmacy, before having to go to the Mail Order pharmacy.

4. **Panel Questions and Comments:**

There were no questions or comments from the Panel. The Chair called for a vote on the re-evaluation of the generically available NF agents: UF Recommendation, Automated PA Changes and removal of Manual PA Criteria for Ibandronate.

- **Re-Evaluation of Generically Available NF Agents – UF Recommendation, Automated PA (Step Therapy) Changes and Removal of Manual PA Criteria for Ibandronate**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

Dr. Anderson thanked the DHA Staff for their preparation, for fielding the Panel's questions, and for their helpfulness.

The Alternate DFO Mr. William Blanche thanks the Panel members for their participation, thanks the audience for attending, and adjourns 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.

- ALP – Alkaline Phosphatase
- ALT – Alanine Aminotransferases
- AASLD - American Association for the Study of Liver Disease
- AMA - Anti-mitochondral antibodies
- AST - Aspartate Aminotransferase
- BAP – Benficiary Advisory Panel
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- BP – Benzoyl Peroxide
- BPH - Benign Prostatic Hypertrophy CFR
- DAA - Direct Acting Antiviral Agent
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DoD – Department of Defense
- DPP-4 - Dipeptidyl Peptidase - 4
- ER – Extended Release
- FACA – Federal Advisory Committee Act
- FDA – Food Drug Administration
- GGT – Gamma-Glutamyl Transpeptidase
- GSA – Growth Stimulating Agents
- HCV – Hepatitis C Virus
- IDSA – Infectious Diseases Society of America
- IM - Intramuscularly
- IR – Immediate Release
- LDL – Low-Density Lipoprotein
- LQ – Oral Liquid
- MHS – Military Health System
- MMSE – Mini-Mental State Examination
- MTF – Military Treatment Facility
- NDAA – National Defense Authorization Act
- NF – Non-Formulary
- NNT – Need to Treat
- NSAID – Nonsteroidal Anti-Inflammatory Drug
- ODT – Orally Dissolving Tablet

Brief Listing of Acronyms Used in this Summary – Continued

- OTC – Over-the-Treat
- P&T – Pharmacy & Therapeutics
- PA – Prior Authorization
- PBC – Primary Biliary Cholangitis
- PMDD – Premenstrual Dysphoric Disorder
- POD – Pharmacy Operations Division
- RNA – Ribonucleic Acid
- SED-1s – Sedative Hypnotics
- SQ - Subcutaneously
- TAA – Trade Agreements Act
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- ULN – Upper Limit of Normal
- USC – United States Code
- XR – Extended Release
- ZMT – Zolmitriptan Tablets