DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. UF CLASS REVIEWS—ACNE AGENTS: TOPICAL ACNE AND ROSACEA AGENTS SUBCLASS

P&T Comments

A. 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.

B. 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.

C. 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)

D. 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 1.2%, 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.

E. 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.

F. 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.

III. UF CLASS REVIEWS—ACNE AGENTS

BAP Comments

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

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

- **UF and step-preferred**
    - Differin, generics

- Evoclin, generics
- Cleocin T, generics
- Benzaclin, generics
- Duac, generics
- Duac CS (Kit)
- MetroCream, generics
- MetroLotion, generics
- Metrogel, generics
- Klaron, generics
- Retin-A, generics
- Avita, generics
- Tretin-X, generics
- Atralin, generic)

- **UF and non step-preferred**
  - Azelex
  - Finacea
  - Acanya

- **NF and non step-preferred**
  - Epiduo
  - Epiduo Forte
  - Mirvaso
  - Clindacin ETZ, Clindacin PAC
  - Clindagel
  - Onexton
  - Neuac Kit
  - Veltin; Ziana, generics
  - Aczone 5% and 7.5%
  - Soolantra
  - Noritate
  - Rosadan Cream Kit
  - Rosadan Gel Kit
  - Retin-A Micro, generics; Retin-A Micro Pump, generics
  - Fabior

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Acne Agents: Topical Acne and Rosacea Agents Subclass—Automated PA (Step Therapy) and Manual PA Recommendation

The P&T Committee recommended 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.

The full automated and manual PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee recommended 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%).

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

IV. UF CLASS REVIEWS—MIGRAINE AGENTS

P&T Comments

A. 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.

B. 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.

C. 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

D. 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.

1. **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.

2. 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 is not expected to occur with the non step-preferred product.

Prior Authorization does not expire.

3. 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 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.

E. 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.

V. UF CLASS REVIEWS—MIGRAINE AGENTS

BAP Comments

A. Migraine Agents: Triptans—UF Recommendation

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

- Oral Triptans
  - UF and step-preferred
    - Relpax
    - Maxalt, Maxalt MLT, generics
    - Imitrex, generics
    - Zomig, Zomig-ZMT, generics
  - UF, non step-preferred
    - Amerge, generics
  - NF, non step-preferred
    - Axert, generics
    - Frova, generics
    - Treximet

- Nasal Triptans
  - UF, step-preferred
    - Imitrex, generics
  - UF, non step-preferred
    - Zomig Nasal Spray
  - NF, non step-preferred
    - Onzetra Xsail

- Injectable Triptans
  - UF, step-preferred
    - Imitrex STATdose, generics
  - NF, non step-preferred
    - Sumavel DosePro
    - Zembrace SymTouch

- Transdermal Triptans
  - NF, non step-preferred
    - Zecuity, if reintroduced to the market

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee recommended 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.

For the oral and ODT triptans, a trial of at least two different step-preferred products (e.g., two products with differing active ingredients) is required before use of a non step-preferred product. For the nasal and injectable triptans, a trial of one generic formulation is required first. For the withdrawn transdermal system, if the product is reintroduced into the market, it will also be subject to step therapy, requiring use of at least two UF triptans, regardless of formulation, first.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Migraine Agents: Triptans—UF and PA Implementation

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VI. UF CLASS REVIEWS—ALCOHOL DETERRENTS

P&T Comments

A. 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.

B. 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.

C. 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.

D. 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.

VII. UF CLASS REVIEWS—ALCOHOL DETERRENTS

BAP Comments

A. Alcohol Deterrents: Narcotic Antagonists—UF Recommendation

The P&T Committee recommended 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 for Narcan Nasal Spray be lowered to the generic (Tier 1) formulary cost share in the TRICARE Mail Order Pharmacy in the Retail Pharmacy Network.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Alcohol Deterrents: Narcotic Antagonists—UF Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period, and DHA send a letter to beneficiaries currently receiving Evzio.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VIII. UF CLASS REVIEWS—INNOVATOR DRUGS

P&T Comments

A. 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.

B. 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

C. 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:

1. **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.

2. 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.

3. 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:

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

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

4. 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.

5. 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 (i, ii, iii, and iv):

i. Patient is age ≥ 18 year old; AND
ii. Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND
iii. 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
iv. 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 (i, ii, iii, and iv):

Patients Currently Receiving Therapy (renewal criteria): approve indefinitely if the patient meets the following criteria (i, ii, and iii):

i. Age ≥ 18 years old; AND
ii. Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND
iii. 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.

D. 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.

IX. UF CLASS REVIEWS—INNOVATOR DRUGS

BAP Comments

A. Innovator Drugs—UF Recommendation

The P&T Committee recommended the following:

- UF:
  - Afstyla
  - Cabometyx
  - Descovy
  - Orfadin
  - Ocaliva
  - Epclusa
  - Venclexta

- NF:
  - Sernivo
  - Briviact
  - Tolak
  - Ultravate
  - Jentadueto XR, which is additionally recommended to be non step-preferred, due to existing step therapy in the class
  - Nuplazid
  - Xtampza ER
  - Ferriprox

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Innovator Drugs—Manual PA Criteria

The P&T Committee also recommended the following:

- Applying the same step therapy and manual PA criteria for Jentadueto XR as is currently in place for Jentadueto and the other non step-preferred DPP-4 inhibitors combinations with metformin.
- 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).

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Innovator Drugs—UF and PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

X. UTILIZATION MANAGEMENT—ANALGESICS AND COMBINATIONS

P&T Comments

A. 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.

B. 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.

XI. UTILIZATION MANAGEMENT—ANALGESICS AND COMBINATIONS

BAP Comments

A. Analgesics and Combinations: Vanatol LQ—Manual PA Criteria

The P&T Committee recommended manual PA criteria for Vanatol.

The full prior authorization criteria were stated previously above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Analgesics and Combinations: Vanatol LQ—PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XII. UTILIZATION MANAGEMENT—NEWER SEDATIVE HYPNOTICS (SED-1s)

P&T Comments

A. 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.

B. 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.

XIII. UTILIZATION MANAGEMENT—SED-1s

BAP Comments

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

The P&T Committee recommended removing the automated PA criteria and establishing manual PA criteria for Belsomra in new users.

The full prior authorization criteria were stated previously.

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

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

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

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

XIV. UTILIZATION MANAGEMENT—GROWTH-STIMULATING AGENTS (GSAs)

P&T Comments

A. 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

B. 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.

XV. UTILIZATION MANAGEMENT—GSAs

BAP Comments

A. GSAs—Manual PA Criteria

The P&T Committee recommended 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.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. GSAs—PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XVI. UTILIZATION MANAGEMENT—TOPICAL PAIN AGENTS

P&T Comments

A. 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

B. 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.

XVII. UTILIZATION MANAGEMENT—TOPICAL PAIN AGENTS

BAP Comments

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

The P&T Committee recommended manual PA criteria for new and current users of Pennsaid 2%.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

P&T Comments

A. 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.

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

BAP Comments

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

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

P&T Comments

A. 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

B. 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:

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

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

C. 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.

XXI. SECTION 703, NDAA FY08

BAP Comments

A. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee recommended the following products be designated NF on the UF:

- Envarsus XR 1 mg and 4 mg oral tablets
- Ulesfia 5% topical lotion
- Inderal XL 80 mg and 120 mg oral capsules

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee recommended the pre-authorization criteria for Envarsus XR, Ulesfia, and Inderal XL as previously stated.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Section 703, NDAA FY08—Implementation Plan

The P&T Committee recommended 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.

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

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

P&T Comments

A. 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

XXIII. OTC DRUG BENEFIT

BAP Comments

A. OTC Drug Benefit: Status of the Second Generation Antihistamines—The P&T Committee recommended 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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXIV. RE-EVALUATION OF GENERICALLY AVAILABLE NF AGENTS

P&T Comments

A. 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 Receptor 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.

B. 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

o Contraindication

XXV. RE-EVALUATION OF GENERICALLY AVAILABLE NF AGENTS

BAP Comments

A. 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, effective upon signing of the minutes:

- The following products will remain NF, with both brand and generics subjected to mail order requirements:
  - Xyzal, generics and Clarinex, generics
  - Atelvia, Actonel, and their generics; these products will remain as non step-preferred
  - Fortamet, Glumetza, and their generics
  - Prozac Weekly; generic Sarafem caps; Sarafem tabs
  - Avodart, generics; Jalyn, generics; these products will remain as non step-preferred
  - Aricept 23 mg, generics
  - Lescol XL, generics; will remain non step-preferred

- The following products will return to UF status:
  - generic Miacalcin nasal spray
  - generic Pennsaid 1.5%

- Automated PA (Step Therapy) Changes:
  - Osteoporosis Agents/Oral Bisphosphonate: Boniva will be designated as step-preferred, and the PA revised as previously stated.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implementation	Notes & Unique Utilizers Affected
Aug 2016	**Topical Acne & Rosacea Agents**	Subclass not previously reviewed	**UF step-preferred** ▪ adapalene 0.1% lotion, gel, cream; 0.3% gel (Differin, generics) ▪ clindamycin 1% gel, cream, lotion and solution (Cleocin, generics) ▪ clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics) ▪ clindamycin 1% foam (Evoclin, generics) ▪ clindamycin 1% gel, cream, foam, lotion, solution, med swab (Cleocin T, generics) ▪ clindamycin/benzoyl peroxide 1% - 5% gel (Benzaclin, generics) ▪ clindamycin/ benzoyl peroxide 1% - 5% gel kit (Duac CS (Kit)) ▪ metronidazole 0.75% cream & 0.75% lotion (MetroCream, MetroLotion generics) ▪ metronidazole 1% gel (MetroGel, generics) ▪ sulfacetamide sodium/sulfur 10% lotion (Klaron, generics) ▪ tretinoin 0.01%, 0.025% gel (Retin-A, generics) ▪ tretinoin 0.025% and 0.05% cream (Retin-A, generics) ▪ tretinoin 0.025% gel, cream (Avita, generics) ▪ tretinoin 0.1% cream, liquid (Retin-A, generics) ▪ tretinoin 0.0375%, 0.075% cream (Tretin-X, generics) ▪ tretinoin 0.05% gel (Atralin, generics) **UF non step-preferred** ▪ azelaic acid 20% cream (Azelex) ▪ azelaic acid 15% gel, foam, kit (Finacea) ▪ clindamycin/benzoyl peroxide 1.2% - 2.5% gel (Acanya)	**NF non step-preferred** ▪ adapalene/ benzoyl peroxide 0.1% - 2.5% gel (Epiduo) ▪ adapalene/ benzoyl peroxide 0.3% - 2.5% gel (Epiduo Forte) ▪ brimonidine tartrate 0.33% gel (Mirvaso) ▪ clindamycin 1% kits (Clindacin TZ/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, Retin-A Micro Pump, and generics) ▪ tazarotene 0.1% foam (Fabior)	Pending signing of the minutes / 90 days	▪ Step therapy applies to the class <u>Adapalene Products</u> ▪ Retail: 4,681 ▪ Mail: 907 ▪ MTF: 467 **Total**: 6,055 <u>Clindamycin & Combos Products</u> ▪ Retail: 1,946 ▪ Mail: 342 ▪ MTF: 168 **Total**: 2,456 <u>Dapsone 5% (Aczone)</u> ▪ Retail: 2,574 ▪ Mail: 479 ▪ MTF: 387 **Total**: 3,440 <u>Tazarotene (Fabior)</u> ▪ Retail: 32 ▪ Mail: 5 ▪ MTF: 1 **Total**: 38 <u>Tretinoin Microsphere Products</u> ▪ Retail: 1.440 ▪ Mail: 496 ▪ MTF: 3,450 **Total**: 5,386

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implementation	Notes & Unique Utilizers Affected
						<u>Metronidazole and Combos</u> ▪ Retail: 132 ▪ Mail: 171 ▪ MTF: 76 **Total**: 379 <u>Mirvaso</u> ▪ Retail: 702 ▪ Mail: 337 ▪ MTF: 89 **Total**: 1,128 <u>Soolantra</u> ▪ Retail: 1,421 ▪ Mail: 547 ▪ MTF: 126 **Total**: 2,094
Aug 2016	**Migraine Agents: Triptans**	UF class previously reviewed Jun 2008	**UF step-preferred** ▪ rizatriptan tablets and ODT (Maxalt, Maxalt MLT, generics) ▪ sumatriptan tablets (Imitrex, generics) ▪ sumatriptan nasal spray (Imitrex, generics) ▪ sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generics) ▪ eletriptan (Relpax) ▪ zolmitriptan tablets and ODT (Zomig, Zomig ZMT, generics) **UF non step-preferred** ▪ naratriptan (Amerge) ▪ zolmitriptan nasal (Zomig Nasal Spray)	**NF and non step-preferred** ▪ sumatriptan/naproxen (Treximet) ▪ almotriptan (Axert, generics) ▪ frovatriptan (Frova, generics) ▪ sumatriptan nasal powder (Onzetra Xsail) ▪ sumatriptan 4 mg and 6 mg needle-free injection (Sumavel DosePro) ▪ sumatriptan 3 mg autoinjector (Zembrace SymTouch) ▪ sumatriptan transdermal system (Zecuity)	Pending singing of the minutes / 90 days	▪ Step therapy applies to new users of non-preferred oral, nasal, injectable, and transdermal formulations <u>Treximet UUs Affected</u> ▪ Retail: 1,283 ▪ Mail Order: 741 ▪ MTF: 606 **Total**: 2,630 ▪ Onzetra Xsail and Zembrace SymTouch are Innovator products and remain NF

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implementation	Notes & Unique Utilizers Affected
Aug 2016	**Narcotic Antagonists**	UF class review	▪ naloxone nasal spray (Narcan Nasal Spray)	▪ naloxone autoinjector (Evzio)	Pending signing of the minutes / 60 days	Evzio Approximate UUs Affected ▪ Retail: 1,182 ▪ Mail Order: 41 ▪ MTF: 338 **Total**: 1,561

TRICARE Formulary Search tool: http://www.express-scripts.com/tricareformulary

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

August 2016 Drugs with Prior Authorization Criteria
Unique Utilizers Affected Per Drug

	MTF	Mail Order	Retail	Total
Vanatol LQ	0	0	48	48
Belsomra	181	678	1,646	2,505
Growth Stimulating Agents	414	1,213	248	1,875
Pennsaid 2% Topical Soln	48	561	1,092	1,701