DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS—NON-BASAL INSULINS

P&T Comments

A. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—Relative Clinical Effectiveness and Conclusion

Afrezza is rapid-acting inhaled human insulin indicated to improve glycemic control in adult patients with Type 1 or Type 2 diabetes mellitus. It is the only commercially available inhaled insulin. Afrezza has been compared head-to-head with insulin aspart (NovoLog) and was non-inferior in reducing hemoglobin A1c.

Common adverse effects include cough, throat pain or irritation, decreased pulmonary function, bronchitis, and urinary tract infection. Limitations to use of Afrezza include the need for concomitant subcutaneous basal insulin. Patients with dexterity issues may find manipulation of the small pieces of the device to be difficult.

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that despite the novel drug delivery system, the inhaled insulin Afrezza offers no clinically compelling advantages over the rapid acting insulin agents currently included on the UF.

B. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—Relative Cost-Effectiveness Analysis and Conclusion

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

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: insulin aspart (NovoLog), insulin lispro (Humalog), insulin glulisine (Apidra), and inhaled insulin (Afrezza).

C. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) inhaled

insulin (Afrezza) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes data, and cost disadvantage compared to the UF non-basal insulins.

D. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—Prior Authorization (PA) Criteria

Manual PA criteria for Afrezza were approved in May 2015 with an implementation date of October 21, 2015. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) maintaining the current PA criteria for Afrezza.

Full PA Criteria:

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

Coverage is approved for non-smoking patients with either:

Type 1 Diabetes Mellitus (diagnosed)

- Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting subcutaneous (SC) insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin
- Afrezza is used as adjunctive treatment to current basal insulin therapy
- Spirometry testing [baseline forced expiratory volume in the first second (FEV_1) upon initiation with repeated FEV_1 at six months after initiation and repeated annually thereafter] has been performed

Type 2 Diabetes Mellitus (diagnosed)

- Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting SC insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin
- Failure of or clinically significant adverse effect to two oral anti-diabetic agents (i.e., sulfonylurea, TZD, or DPP-4 inhibitor) if metformin is contraindicated
- Spirometry testing (baseline FEV_1 upon initiation with repeated FEV_1 at six months after initiation and repeated annually thereafter) has been performed.

Contraindications to the use of Afrezza: hypoglycemia, chronic lung disease (asthma, chronic obstructive pulmonary disease (COPD)), hypersensitivity to regular human insulin, or any Afrezza excipients

PA does not expire.

E. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—UF and PA Implementation Plan

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

III. RECENTLY APPROVED FDA AGENTS—NON-BASAL INSULINS

BAP Comments

A. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—UF Recommendation

The P&T Committee recommended Afrezza be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes data, and cost disadvantage compared to the UF non-basal insulins.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—PA Criteria

Manual PA criteria for Afrezza were approved in May 2015 with an implementation date of October 21, 2015. The P&T Committee recommended maintaining the current PA criteria for Afrezza, which allows use of Afrezza in patients who have not met target hemoglobin A1c levels or who have had an adverse event with a rapid- or short-acting insulin.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)—UF and PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

IV. RECENTLY APPROVED FDA AGENTS—NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs)

P&T Comments

A. NSAIDs: Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)—Relative Clinical Effectiveness and Conclusion

Tivorbex is a low-dose formulation of indomethacin available in 20 mg and 40 mg capsules. The formulation is intended for faster dissolution and absorption compared to other indomethacin products (indomethacin 25 mg and 50 mg; e.g., Indocin). According to the FDA, the manufacturer failed to demonstrate these theoretical advantages, as there were no significant differences in the pharmacokinetic profile when Tivorbex was compared to indomethacin. In the clinical trial used to obtain FDA approval, over 80% of patients received rescue narcotics for pain control. The Tivorbex package insert contains usual black box warnings and precautions for NSAIDs.

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that there were no clinical compelling advantages between Tivorbex and the other UF NSAIDs.

B. NSAIDs: Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)—Relative Cost-Effectiveness Analysis and Conclusion

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

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: meloxicam (Mobic, generic), ibuprofen (Motrin, generic), naproxen (Naprosyn, generic), diclofenac sodium (Voltaren, generic), indomethacin (Indocin, generic), celecoxib (Celebrex, generic), diclofenac (Zorvolex), and indomethacin (Tivorbex).

C. NSAIDs: Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) indomethacin low dose 20 mg and 40 mg capsules (Tivorbex) be designated NF, based on clinical and cost effectiveness.

D. NSAIDs: Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)—UF Implementation Plan

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

V. RECENTLY APPROVED FDA AGENTS—NSAIDs

BAP Comments

A. NSAIDs: Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)—UF Recommendation

The P&T Committee recommended low dose 20 mg and 40 mg capsules (Tivorbex) be designated NF, based on clinical and cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. NSAIDs: Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)—UF Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VI. RECENTLY APPROVED FDA AGENTS—LONG-ACTING BETA AGONISTS (LABAs)

P&T Comments

A. LABAs: Olodaterol Oral Inhaler (Striverdi Respimat)—Relative Clinical Effectiveness and Conclusion

Olodaterol (Striverdi Respimat) is the sixth marketed LABA oral inhaler approved for maintenance treatment of moderate to severe COPD. It has a long duration of action allowing for once daily dosing. There are no head-to-head trials available with olodaterol and other COPD drugs. Indirect comparisons of olodaterol with formoterol (Foradil) do not show clinically relevant differences in terms of changes in FEV_1. None of the LABAs are labeled to reduce COPD exacerbations or hospitalizations.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that other than the convenience of once daily dosing, olodaterol (Striverdi Respimat) offers no clinically compelling advantages over the existing UF LABAs. There is a high degree of therapeutic interchangeability among the LABAs.

B. LABAs: Olodaterol Oral Inhaler (Striverdi Respimat)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed, comparing olodaterol with other drugs in the Pulmonary II Drug Class. CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: olodaterol (Striverdi Respimat), salmeterol (Serevent), tiotropium (Spiriva), indacaterol (Arcapta), arformoterol inhalation solution (Brovana), and formoterol inhalation solution (Perforomist). The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that olodaterol (Striverdi Respimat) was cost effective compared with other LABA oral inhalers on the UF.

C. LABAs: Olodaterol Oral Inhaler (Striverdi Respimat)—UF Recommendation

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) olodaterol (Striverdi Respimat) be designated formulary on the UF, based on cost effectiveness.

VII. RECENTLY APPROVED FDA AGENTS—LABAs

BAP Comments

A. LABAs: Olodaterol Oral Inhaler (Striverdi Respimat)—UF Recommendation

The P&T Committee recommended Striverdi Respimat be designated formulary on the UF, based on cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VIII. RECENTLY APPROVED FDA AGENTS—OPHTHALMIC-1 CLASS

P&T Comments

A. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)—Relative Clinical Effectiveness and Conclusion

Pazeo is a dual action antihistamine/mast cell stabilizer (AH/MCS) ophthalmic agent and is the third strength of olopatadine approved for the prevention of itching associated with allergic conjunctivitis (AC). Several AH/MCS dual action agents are currently on the UF, including olopatadine 0.2% (Pataday) (once daily dosing) and olopatadine 01% (Patanol) (twice daily dosing). Generic formulations of olopatadine 0.1% (Patanol) recently entered the market.

In the placebo-controlled trials used to obtain FDA approval, Pazeo produced statistically and clinically significant results in treating ocular itching associated with AC both at the onset of action, and 24 hours after dosing. Overall, for relief of ocular itching due to AC,

there do not appear to be clinically relevant differences in efficacy or safety between olopatadine 0.7% (Pazeo) and the other dual action AH/MCS agents.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that there were no clinical compelling advantages between Pazeo and the other UF AH/MCS dual action ophthalmic agents. A once daily olopatadine product (Pataday) is currently on the UF.

B. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)—Relative Cost-Effectiveness Analysis and Conclusion

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

CMA results showed the following rankings for the AH/MCS dual action ophthalmic agents from most to least cost-effective for the UF no-step scenario: azelastine 0.1%, olopatadine 0.1% generic, olopatadine 0.2% (Pataday), olopatadine 0.7% (Pazeo), olopatadine 0.1% (Patanol), alcaftadine (Lastacaft), and bepotastine (Bepreve).

C. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) olopatadine 0.7% ophthalmic solution (Pazeo) be designated NF.

D. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)—UF Implementation Plan

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

IX. RECENTLY APPROVED FDA AGENTS—OPHTHALMIC-1 CLASS

BAP Comments

A. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)—UF Recommendation

The P&T Committee recommended Pazeo be designated NF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)—UF Implementation Plan

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

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

X. UF CLASS REVIEWS—CONTRACEPTIVE AGENTS

P&T Comments

A. Contraceptive Agents—Relative Clinical Effectiveness and Conclusion

Two of the three Contraceptive Agents subclasses were reviewed for formulary placement; the oral contraceptive products (OCPs) and the miscellaneous contraceptives (comprised of the injection, transdermal patch, and vaginal ring). The OCPs are further sub-divided into eight categories, based on the amount of estrogen and type of progesterone contained in the product. The Contraceptive Agents were previously reviewed for UF placement in August 2011.

There are over 170 products in the OCPs and miscellaneous contraceptive subclasses. There is significant generic competition, and only eight branded, proprietary products that do not have generic equivalents remain in the class. Recent entrants of note include AB-rated generic equivalents for the transdermal patch (Ortho Evra) and the multiphasic product Ortho Tri-Cyclen Lo.

The P&T Committee concluded (15 for, 0 against, 0 abstained, 0 absent) the following for the OCPs and miscellaneous contraceptive subclasses:

- There are no new substantial updates to the clinical conclusions from the August 2011 Contraceptive Agents UF class review.
- All oral and miscellaneous contraceptives are highly effective in preventing pregnancy when used as directed and have comparable efficacy benefits, as well as non-contraceptives benefits.
- New market additions since August 2011 include the replacement of former branded products with chewable formulations, introduction of a monophasic category containing 25 mcg ethinyl estradiol (EE) (e.g., Generess Fe chewable tablets), and the addition of supplements to the products, including iron (Fe) or folate. These new products do not provide clinically significant advantages or advancements in contraceptive therapy.
- Some formulations may offer better cycle control (e.g., vaginal ring), reduce adverse events associated with hormone withdrawal (e.g., extended cycle/continuous use OCPs), or provide better control of breakthrough bleeding (e.g., multiphasic OCPs).

- For the miscellaneous contraceptives, the vaginal ring and transdermal patch (NuvaRing; Xulane generic for Ortho Evra patch) offer similar contraceptive effectiveness as the OCPs. In contrast, improved contraceptive effectiveness occurs with the medroxyprogesterone injection (Depo-Provera; generic) compared to OCPs. The miscellaneous products also provide for an alternate route of administration for certain patient populations, result in sustained release of drug delivery, and offer benefits to the patient by reducing or stopping menstrual bleeding.
- Overall, all contraceptive formulations have similar safety and adverse profiles, such as breakthrough bleeding, bloating, nausea, breast tenderness, headache, migraine, weight changes, and abnormal carbohydrate/lipid metabolism. An increased risk of venous thromboembolism may be associated with OCPs containing certain progestins (desogestrel, drospirenone) and the transdermal patch users.
- Given comparable contraceptive effectiveness among the various available contraceptive formulations and methods, factors which may affect contraceptive choice include individual patients' needs and characteristics, dosing convenience, and non-contraceptive benefits.
- The UF already contains a wide variety of oral contraceptive and miscellaneous products with various types and amounts of estrogen and progestin content, and also includes products with various regimens, phasic formulations, and routes of administration.

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

CMA and budget impact analysis (BIA) were performed to evaluate the oral and miscellaneous contraceptive subclasses, mentioned above. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed there were significant overlaps in prices across each of the nine contraceptive categories of medications.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF.

C. Contraceptive Agents—UF Recommendation

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

- **Reclassify to NF (previously UF):**
  - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate chewable (Minastrin 24 Fe chewable)
  - norethindrone acetate 0.8 mg/EE 25 mcg ferrous fumarate chewable (Generess Fe chewable; generics)

- **Continue to Remain NF:**
    - drospirenone 3 mg/EE 20 mcg levomefolate (Beyaz)
    - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Lomedia 24 Fe; generics)
    - drospirenone 3 mg/EE 30 mcg levomefolate (Safyral)
    - norethindrone 0.4 mg/EE 35 mcg (Balziva; generics)
    - norethindrone 0.4 mg/EE 35 mcg ferrous fumarate chewable (Wymzya Fe chewable; generics)
    - levonorgestrel 0.09 mg/EE 20 mcg (Amethyst; generics)
    - levonorgestrel 0.15 mg/EE 30/10 mcg (Camrese; generics)
    - levonorgestrel 0.1 mg/EE 20/10 mcg (Camrese Lo; generics)
    - norethindrone acetate 1 mg/EE 10 mcg ferrous fumarate (Lo Loestrin Fe)
    - norethindrone acetate 1 mg/EE 20/30/35 mcg ferrous fumarate (Tri-Legest Fe; generics)
    - dienogest 2/3 mg and estradiol valerate 3/2/2/1 mg (Natazia)

- **Reclassify to UF (previously NF):**
    - levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen AB-rated generics to Jolessa (including Quasense, Introvale, and Setlakin [equivalent to discontinued Seasonale])

- **Remain UF**
    - levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen (Jolessa)
    - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Microgestin Fe 1/20; generics)
    - norethindrone acetate 1 mg/EE 20 mcg (Microgestin 1/20 [21-day]; generics)
    - drospirenone 3 mg/EE 20 mcg (Yaz; generics)
    - levonorgestrel 0.1 mg/EE 20 mcg (Sronyx; Lutera; generics)
    - norgestrel 0.3 mg/EE 30 mcg (Low-Ogestrel; generics [equivalent to discontinued Lo/Ovral 28])
    - norethindrone acetate 1.5 mg/EE 30 mcg ferrous fumarate (Microgestin Fe 1.5/30; generics; [equivalent to Loestrin Fe 1.5/30])
    - norethindrone acetate 1.5 mg/EE 30 mcg (Microgestin 1.5/30; generics; [equivalent to Loestrin 1.5/30])
    - desogestrel 0.15 mg/EE 30 mcg (Reclipsen; Ortho-Cept; generics)
    - levonorgestrel 0.15 mg/EE 30 mcg (Levora-28; generics)
    - drospirenone 3 mg/EE 30 mcg (Yasmin; generics)
    - ethynodiol diacetate 1 mg/EE 35 mcg (Zovia 1-35E; generics)
    - norethindrone 0.5 mg /EE 35 mcg (Notrel 0.5/35; generics)
    - norgestimate 0.25 mg/EE 35 mcg (Mononessa; generics)
    - norethindrone 1 mg/EE 35 mcg (Norinyl 1+35; generics)
    - norethindrone 1 mg + mestranol 50 mcg/EE 50 mcg (Norinyl 1+50; generics)
    - norgestrel 0.5 mg/EE 50 mcg (Ogestrel; generics)
    - ethynodiol diacetate 1 mg/EE 50 mcg (Zovia 1-50E; generics)
    - norethindrone 0.5/1 mg + EE 35 mcg (Necon 10/11; [equivalent to discontinued Ortho Novum])

- desogestrel 0.15 mg + EE 20/10 mcg (Azurette; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 25 mcg (Ortho Tri-Cyclen Lo; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 35 mcg (TriNessa; generics)
- norethindrone 0.5/0.75/1 mg + EE 35 mcg (Necon 7/7/7; generics)
- norethindrone 0.5/1/0.5 mg + EE 35 mcg (Leena; generics)
- levonorgestrel 0.05/0.075/0.125 mg + EE 30/40/30 mcg (Trivora-28; generics)
- desogestrel 0.1/0.125/0.15 mg + EE 25 mcg (Velivet; generics)
- levonorgestrel 0.15 mg + EE 20/25/30/10 mcg (Quartette)
- norethindrone 0.35 mg (Nor-Q-D; Ortho Micronor; generics)
- etonogestrel 0.12 mg + EE 15 mcg vaginal ring (per day [NuvaRing])
- norelgestromin 150 mcg + EE 35 mcg transdermal system (per day [Xulane]; equivalent to discontinued Ortho Evra patch)
- depot medroxyprogesterone acetate 150 mg/mL IM vials (Depo-Provera vials; generic)
- depot medroxyprogesterone acetate 150 mg/mL IM syringes (Depo-Provera syringes; generic)
- depot medroxyprogesterone acetate 104 mg/0.65 mL SC (Depo-SubQ Provera 104)

D. Contraceptive Agents—Manual PA Recommendation

The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) manual PA criteria for new users of Minastrin 24 Fe, Generess Fe, and Wymzya Fe chewable tablets, and their respective generics, to allow use for patients with special needs or those patients whose needs cannot be met with one of the formulary alternatives.

Full PA Criteria:

1. Norethindrone acetate 1mg/ EE 20 mcg (Minastrin 24 Fe chewable): Manual PA criteria apply to all new users of Minastrin 24 Fe chewable tablets.

   Manual PA criteria:

   Coverage is approved for Minastrin 24 Fe chewable tablets if:
   - The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty.

   PA does not expire.

2. Norethindrone acetate 0.8 mg/ EE 25 mcg (Generess Fe chewable, generics): Manual PA criteria apply to all new users of Generess Fe chewable tablets and generics.

   Manual PA criteria:

   Coverage is approved for Generess Fe chewable and generics if:
   - The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty.
     OR

- Patient's needs cannot be met with either (1) a monophasic contraceptive containing ethinyl estradiol (EE) 20 mcg or EE 30 mcg, OR (2) a multiphasic contraceptive containing EE 25 mcg.

PA does not expire.

3. Norethindrone 0.4 mg/EE 35 mcg (Wymzya Fe chewable, generics): Manual PA criteria apply to all new users of Wymzya Fe chewable tablets and generics.

   Manual PA criteria:

   Coverage is approved for Wymzya Fe chewable generics if:
   - The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty.
     OR
   - The patient's needs cannot be met with either (1) a monophasic contraceptive containing EE 35 mcg OR (2) a multiphasic with containing 35 mcg.

   PA does not expire.

E. Contraceptive Agents—UF and PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period after signing of the minutes.

XI. UF CLASS REVIEWS—CONTRACEPTIVE AGENTS

BAP Comments

A. Contraceptive Agents—UF Recommendation

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

- **Reclassify to NF (previously UF):**
  - Minastrin 24 Fe chewable
  - Generess Fe chewable; generics

- **Continue to Remain NF:**
  - Beyaz
  - Lomedia 24 Fe; generics
  - Safyral
  - Balziva; generics
  - Wymzya Fe chewable; generics
  - Amethyst; generics
  - Camrese; generics
  - Camrese Lo; generics
  - Lo Loestrin Fe
  - Tri-Legest Fe; generics
  - Natazia

- **Reclassify to UF (previously NF):**
  - levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen AB-rated generics to Jolessa (including Quasense, Introvale, and Setlakin [equivalent to discontinued Seasonale])
- **Remain UF**
  - Jolessa
  - Microgestin Fe 1/20; generics
  - Microgestin 1/20 (21-day); generics
  - Yaz; generics
  - Sronyx; Lutera; generics
  - Low-Ogestrel; generics (equivalent to discontinued Lo/Ovral 28)
  - Microgestin Fe 1.5/30; generics (equivalent to Loestrin Fe 1.5/30)
  - Microgestin 1.5/30; generics (equivalent to Loestrin 1.5/30)
  - Reclipsen; Ortho-Cept; generics
  - Levora-28; generics
  - Yasmin; generics
  - Zovia 1-35E; generics
  - Notrel 0.5/35; generics
  - Mononessa; generics
  - Norinyl 1+35; generics
  - Norinyl 1+50; generics
  - Ogestrel; generics
  - Zovia 1-50E; generics
  - Necon 10/11 (equivalent to discontinued Ortho Novum)
  - Azurette; generics
  - Ortho Tri-Cyclen Lo; generics
  - TriNessa; generics
  - Necon 7/7/7; generics
  - Leena; generics
  - Trivora-28; generics
  - Velivet; generics
  - Quartette
  - Nor-Q-D; Ortho Micronor; generics
  - NuvaRing
  - Xulane (equivalent to discontinued Ortho Evra patch)
  - Depo-Provera vials; generic
  - Depo-Provera syringes; generic
  - Depo-SubQ Provera 104

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Contraceptive Agents—Manual PA Recommendation

The P&T Committee recommended manual PA criteria for new users of Minastrin 24 Fe, Generess Fe, and Wymzya Fe chewable tablets, and their respective generics, to allow use for patients with special needs or those patients whose needs cannot be met with one of the formulary alternatives.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Contraceptive Agents—UF and PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period after signing of the minutes.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XII. UF CLASS REVIEWS—ANTIFUNGALS

P&T Comments

A. Antifungals: Topical Lacquers—Relative Clinical Effectiveness and Conclusion

The topical antifungal lacquers used for onychomycosis were reviewed for formulary placement, including ciclopirox 8% topical solution (Penlac, generic), efinaconazole 10% topical solution (Jublia), and tavaborole 5% topical solution (Kerydin). Comparisons to other treatment options used for onychomycosis (including oral terbinafine) were also reviewed by the P&T Committee but were not included in the formulary decision.

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

- The complete cure rates at one year with efinaconazole (Jublia) in the two pivotal trials were 17.8% and 15.2% for the active arms versus 3.3% and 5.5% in the vehicle arms, respectively. In comparison, complete cure rates at one year in the two pivotal trials with tavaborole (Kerydin) were 6.5% and 9.1% for the active arms versus 0.5% and 1.5% in the vehicle arms, respectively. Efficacy data with ciclopirox supports complete

cure rates ranging from 5.5% to 8.5%. The variations in the complete cure rates achieved with Jublia, Kerydin, and ciclopirox may be explained by differences in the maximum percentage of nail involvement allowed in the trials

- Oral terbinafine (Lamisil, generics) is more effective than the topical antifungal lacquers, with complete cure rates ranging from 38% to greater than 50%.

- There is only minimal follow-up data beyond one year for Jublia and Kerydin, which limits the ability to assess recurrence rates with the newer agents, compared to other onychomycosis treatments. Data with ciclopirox show a 40% relapse rate at three months while terbinafine has a five-year relapse rate of 20%.

- The safety profiles for the topical antifungal lacquers appear similar and do not differ significantly from placebo vehicle. Both Jublia and Kerydin contain a warning regarding flammability, due to high alcohol content.

Overall Relative Clinical Effectiveness Conclusion: The treatment effect of the topical antifungals is modest at best, with complete cure rate failures exceeding 80%. The topical agents ciclopirox, efinaconazole, and tavaborole are not as effective as oral terbinafine. Overall, the newer entrants Jublia and Kerydin have a benign safety profile, but their modest clinical effectiveness should limit their use to patients who are unable to tolerate oral antifungal agents and who fail topical ciclopirox.

B. Antifungals: Topical Lacquers—Relative Cost-Effectiveness Analysis and Conclusion

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

- CMA results showed that oral terbinafine was the most cost-effective antifungal agent for onychomycosis, followed by ciclopirox 8% topical solution (Penlac; generic), and lastly followed by efinaconazole 10% topical solution (Jublia) and tavaborole 5% topical solution (Kerydin).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. Designating efinaconazole (Jublia) and tavaborole (Kerydin) as NF resulted in cost avoidance for the Military Health Service (MHS).

C. Antifungals: Topical Lacquers—UF Recommendation

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

- UF:
    - Ciclopirox 8% topical solution (Penlac; generic)
- NF:
    - Efinaconazole10% topical solution (Jublia)
    - Tavaborole 5% topical solution (Kerydin)

Jublia and Kerydin were selected for NF status due to their minimal clinical advantages over ciclopirox, overall modest clinical effectiveness, and lack of cost effectiveness, particularly when compared to the clinically superior oral antifungal agent terbinafine.

D. Antifungals: Topical Lacquers—Manual PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) modifying the current PA criteria for efinaconazole (Jublia) and tavaborole (Kerydin) originally recommended at the February 2015 P&T Committee meeting (and implemented August 19, 2015). PA criteria revisions were made to ensure a trial of both a topical antifungal agent and an oral antifungal agent, prior to utilization of Jublia or Kerydin.

Full PA Criteria:

PA criteria apply to all new and current users of efinaconazole (Jublia) and tavaborole (Kerydin). (Updates are bolded.)

Manual PA criteria:

Jublia and Kerydin are approved if all of the following criteria apply:

1. The patient must have diagnostically confirmed onychomycosis by either potassium hydroxide (KOH) preparation, fungal culture, nail biopsy, or other assessment to confirm diagnosis.
2. The patient is immunocompromised, has diabetes mellitus or peripheral vascular disease and has swelling and/or redness in the surrounding nail tissue or pain in affected nail(s).
3. **The patient must have tried ciclopirox (Penlac) and had therapeutic failure AND**
4. **The patient must have tried one of the following oral agents: itraconazole (Sporonax) or terbinafine (Lamisil) and had therapeutic failure OR**
    - the patient has a contraindication [renal impairment, pre-existing liver disease, or evidence of ventricular dysfunction such as chronic heart failure (CHF)] to one of the above antifungal agents, OR
    - the patient has had an adverse event/intolerance to one of the above antifungal agents
5. Treatment is requested due to a medical condition and not for cosmetic purposes. Examples include the following:
    - patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis
    - diabetic patients with additional risk factors for cellulitis
    - patients who experience pain/discomfort associated with the infected nail
6. The patient's condition is causing debility or a disruption in their activities of daily living.

7. Have Jublia or Kerydin been used in the previous 24 months? If no, PA not approved. If yes, then proceed to next question.
8. **Have Jublia or Kerydin been used in the past 30 days? If no, PA not approved; if yes, then PA is approved.**

PA expires after 1 year.

E. Antifungals: Topical Lacquers—UF and PA Implementation Plan

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

XIII. UF CLASS REVIEWS—ANTIFUNGALS

BAP Comments

A. Antifungals: Topical Lacquers—UF Recommendation

The P&T Committee recommended the following:

- UF:
  - Penlac; generic
- NF:
  - Jublia
  - Kerydin

Jublia and Kerydin were selected for NF status due to their minimal clinical advantages over ciclopirox, overall modest clinical effectiveness, and lack of cost effectiveness, particularly when compared to the clinically superior oral antifungal agent terbinafine.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Antifungals: Topical Lacquers—Manual PA Criteria

The P&T Committee recommended modifying the current PA criteria for Jublia and Kerydin originally recommended at the February 2015 P&T Committee meeting (and implemented August 19, 2015). PA criteria revisions were made to ensure a trial of both a topical antifungal agent and an oral antifungal agent, prior to utilization of Jublia or Kerydin.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Antifungals: Topical Lacquers—UF and 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 and DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XIV. UF CLASS REVIEWS—OPHTHALMIC ANTI-INFLAMMATORY/ IMMUNOMODULATORY AGENTS

P&T Comments

A. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—Relative Clinical Effectiveness and Conclusion

The ophthalmic immunomodulatory agents have not previously been reviewed for UF placement. Restasis is the only drug currently in this subclass. There are several pipeline products in this subclass, which will be reviewed upon FDA approval. Over-the-counter (OTC) ophthalmic wetting products (artificial tears) including carboxy- and hydroxypropyl-methylcellulose (Refresh, Celluvisc); polyvinyl alcohol (Hypotears), and high viscosity formulations (Systane, glycerin, and Refresh Endura) are used for mild to moderate dry eye symptoms, but were only reviewed for cost comparisons, and are not part of the UF decision.

Restasis is FDA-approved to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with kerato-conjunctivitis sicca. In 2013, the American Academy of Ophthalmology stated that cyclosporine is appropriate for use in patients who have moderate to severe dry eye disease. In two clinical studies, Restasis 0.05% demonstrated efficacy in the treatment of moderate to severe dry eye disease, showing improvements in both objective and subjective measures. Restasis is safe in the treatment of moderate to severe dry eye diseases, with ocular burning and stinging occurring most commonly.

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that Restasis demonstrated improvements in both signs and symptoms of dry eye disease.

B. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—Relative Cost-Effectiveness Analysis and Conclusion

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

- CMA results showed that OTC ophthalmic wetting agents are the most cost effective, followed by cyclosporine 0.05% ophthalmic emulsion (Restasis).

- BIA was performed to evaluate the potential impact of designating cyclosporine 0.05% ophthalmic emulsion (Restasis) as formulary or NF on the UF. BIA results showed that designating Restasis as formulary demonstrated the largest estimated cost avoidance for the MHS.

C. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—UF Recommendation

The P&T Committee recommended (14 for, 1 opposed, 0 abstained, 0 absent) cyclosporine 0.05% ophthalmic emulsion (Restasis) be designated UF.

D. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—Manual PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) PA criteria for Restasis to ensure appropriate use.

Full PA Criteria:

PA criteria apply to all new users of Restasis.

- Current User is defined as a patient who has had Restasis dispensed during the previous 365 days at a Military Treatment Facility (MTF), a retail network pharmacy, or the mail order pharmacy.
    - If there is a Restasis prescription in the past 365 days (automated lookback with Restasis as the qualifying drug), the claim goes through and no manual PA is required.
- New User is defined as a patient who has no had Restasis dispensed in the past 365 days.
    - If there is no Restasis prescription in the past 365 days, a manual PA is required.

Manual PA Criteria:

- Coverage is approved if one of the following is fulfilled:

- Patient has diagnosis of Keratoconjunctivitis Sicca (KCS) with lack of therapeutic response to at least two OTC artificial tears agents
- Patient has ocular graft vs. host disease
- Patient has corneal transplant rejection
- Patient has experienced documented corneal surface damage while using frequent artificial tears

- Coverage is not approved for off-label uses such as, but not limited to:
  - Atopic keratoconjunctivitis (AKC)/vernal keratoconjunctivitis (VKC)
  - Pterygia
  - Blepharitis
  - Ocular rosacea
  - LASIK associated dry eye
  - Contact lens intolerance

Prior Authorization expires in one year.

- If there is a break in therapy, the patient will be subject to the PA again.

E. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XV. UF CLASS REVIEWS—OPHTHALMIC ANTI-INFLAMMATORY/ IMMUNOMODULATORY AGENTS

BAP Comments

A. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—UF Recommendation

The P&T Committee recommended Restasis be designated UF.

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

B. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—Manual PA Criteria

The P&T Committee recommended PA criteria for Restasis to ensure appropriate use.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)—UF and 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. UF CLASS REVIEWS—INNOVATOR DRUGS

P&T Comments

Section 702 of the FY15 National Defense Authorization Act (NDAA) established new authority for the P&T Committee's review process of FDA newly-approved innovator drugs. The P&T Committee is provided up to 120 days to recommend tier placement for innovator drugs on the UF. During this period, innovator drugs will be assigned a classification pending status; they will be available under terms comparable to NF drugs, unless medically necessary, in which case they would be available under terms comparable to formulary drugs. For additional information, see the August 2015 DoD P&T Committee meeting minutes at http://www.health.mil/PandT.

Drugs subject to the Innovator Rule are defined as new drugs that are approved by the FDA under a Biologic License Application (BLA) or New Drug Application (NDA). The NDA innovator drugs will be further defined by their chemical types to include, but not limited to, new molecular entities, new active ingredients, new dosage formulations, and new combinations.

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

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

B. Newly-Approved Innovator Drugs—UF Recommendation

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

- UF:
    - Metabolic Replacement Agents: Asfotase alfa injection (Strensiq)
    - Anti-retrovirals: Elvitegravir/cobicistat/emtricitabine/tenofovir/alafenamide (Genvoya)
    - Alcohol Deterrents/Narcotic Antagonists: Naloxone nasal spray (Narcan Nasal)
    - Pulmonary Arterial Hypertension Agents: Selexipag (Uptravi)
    - Binders/Chelators/Antidotes/Overdose Agents: Patiromer (Veltassa)
    - Oral Oncology Agents—Metastatic Melanoma: Cobimetinib (Cotellic)
    - Oral Oncology Agents—Multiple Myeloma: Ixazomib (Ninlaro)
    - Oral Oncology Agents—Non-Small Cell Lung Cancer (NSCLC): Osimertinib (Tagrisso)
    - Oral Oncology Agents—Lung Cancer: Alectinib (Alecensa)
    - Antihemophilic Agents: Coagulation Factor X injection (Coagadex)
    - Antihemophilic Agents: Antihemophilic factor, recombinant (rFVIII) injection (Adynovate)

- NF:
    - Anti-platelet Agents: Aspirin ER 162.5 mg (Durlaza)
    - Non-steroidal Anti-inflammatory Drugs: Meloxicam low dose 5 mg and 10 mg (Vivlodex)
    - Anti-emetics: Rolapitant (Varubi)
    - Basal Insulins: Insulin degludec (Tresiba)
    - Attention Deficit Hyperactivity Disorder (ADHD)—Stimulants: Amphetamine ER oral suspension (Dyanavel XR)
    - Pulmonary II—LABAs: Glycopyrrolate oral inhaler (Seebri Neohaler)
    - Pulmonary II—Long-Acting Beta Agonists/Long-Acting Muscarinic Agents (LABAs/LAMAs): Indacaterol/glycopyrrolate oral inhaler (Utibron Neohaler)

C. Newly-Approved Innovator Drugs—Manual PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) PA criteria for asfotase alfa injection (Strensiq). Strensiq is an orphan drug indicated for treatment of perinatal/infantile and juvenile-onset hypophosphatasia (HPP). This rare disease has a 50% mortality rate in infants who manifest within six months. No formulary alternative is available.

Full PA Criteria:

Prior Authorization applies to all new and current users of Strensiq.

Automated PA criteria

- Strensiq will be approved for patients younger than one year of age

Manual PA criteria—applies if patient is older than one year of age

- Strensiq will be approved if:
  - The patient has the FDA-approved indication of perinatal/infantile and juvenile-onset hypophosphatasia (HPP) AND
  - The diagnosis is supported by confirmatory testing
  - Off-label uses are NOT approved

Prior Authorization does not expire.

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

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

XVII. UF CLASS REVIEWS—INNOVATOR DRUGS

BAP Comments

A. Newly-Approved Innovator Drugs—UF Recommendation

The P&T Committee recommended the following:

- UF:
  - Strensiq
  - Genvoya
  - Narcan Nasal
  - Uptravi
  - Veltassa
  - Cotellic
  - Ninlaro
  - Tagrisso
  - Alecensa
  - Coagadex
  - Adynovate

- NF:
  - Durlaza
  - Vivlodex
  - Varubi
  - Tresiba
  - Dyanavel XR
  - Seebri Neohaler
  - Utibron Neohaler

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Newly-Approved Innovator Drugs—Manual PA Criteria

The P&T Committee recommended PA criteria for Strensiq, consistent with the FDA package labeling. No formulary alternative is available.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XVIII. UF CLASS REVIEWS—INNOVATOR DRUGS

P&T Comments

Two administrative function updates were proposed for the innovator drug process, as outlined below.

A. Innovator Drugs: Program Updates—Innovator Drugs with No Formulary Alternative to Adjudicate as UF

Currently, the DHA's Pharmacy Operations Division (POD) defines drug classes and assigns drugs to a UF class as part of the administrative processes required for the day-to-day operation of the UF. When a drug is assigned to a specific UF drug class, the formulary alternatives for

the drug are also identified. A formulary agent is defined as a drug from the same drug class or used for the same indication as the NF drug.

Innovator drugs are designated as NF (Tier 3 copayment) upon market entry. All NF medications, including innovator drugs, have MN criteria that establish clinical necessity based on 32 CFR Sec. 199.2. One of the criteria for MN approval is that there is no alternative pharmaceutical agent on the formulary. Some innovator drugs may have no UF alternatives, and a provider must document clinical necessity to obtain the drug when clinically necessary for each individual patient. The recommended authority below removes this requirement and the associated NF copayments when no alternative pharmaceutical agent exists on the UF.

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

1. The DHA POD, after consultation with a physician who is a DoD P&T Committee member or MHS specialist, may direct innovator products with no formulary alternative be made available under Tier 2 terms of the TRICARE pharmacy benefit, prior to a formal vote from the P&T Committee; and,
2. All innovator products, including those that the POD has determined have no formulary alternative, be reviewed by the P&T Committee at the next available meeting.

B. Innovator Drugs: Program Updates—Designation of Temporary Specific MN and PA Criteria for Innovator Drugs

General MN criteria for the Innovator program were approved at the August 2015 DoD P&T Committee meeting. While the general MN criteria are applicable to many of the innovator drugs, in certain cases more specific MN criteria are needed. Current DoD P&T processes may result in lengthy implementation periods for both MN and PA criteria for innovator drugs when they are formally reviewed by the DoD P&T Committee. The recommended authority below will allow the DHA POD to develop specific MN criteria (and PA criteria, if needed) for certain innovator drugs immediately after FDA approval and prior to market launch.

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

1. The DHA POD has authority to administratively implement temporary specific MN/PA criteria on select innovator drugs at the time of product launch, using information available from the FDA (e.g., product labeling, FDA advisory committee recommendations, FDA drug safety board), from peer-reviewed national guidelines, or from the manufacturer.
2. Physicians who are P&T Committee members or MHS specialists will be consulted prior to implementation.
3. The temporary specific MN/PA criteria will only be active until the formal P&T Committee review process is complete (i.e., P&T Committee recommendations made during the next available meeting are implemented after approval by the DHA Director).

4. Implementation of permanent criteria will become effective upon signing of the minutes. All new users who have established temporary specific MN/PA criteria will be grandfathered when the permanent criteria become effective, unless directed otherwise.

XIX. UF CLASS REVIEWS—INNOVATOR DRUGS

BAP Comments

A. Innovator Drugs: Program Updates—Innovator Drugs with No Formulary Alternative to Adjudicate as UF

The P&T Committee recommended:

1. The DHA POD, after consultation with a physician who is a DoD P&T Committee member or MHS specialist, may direct innovator products with no formulary alternative be made available under Tier 2 terms of the TRICARE pharmacy benefit, prior to a formal vote from the P&T Committee; and,
2. All innovator products, including those that the POD has determined have no formulary alternative, be reviewed by the P&T Committee at the next available meeting.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Innovator Drugs: Program Updates—Designation of Temporary Specific MN and PA Criteria for Innovator Drugs

The P&T Committee recommended:

1. The DHA POD has authority to administratively implement temporary specific MN/PA criteria on select innovator drugs at the time of product launch, using information available from the FDA (e.g., product labeling, FDA advisory committee recommendations, FDA drug safety board), from peer-reviewed national guidelines, or from the manufacturer.
2. Physicians who are P&T Committee members or MHS specialists will be consulted prior to implementation.
3. The temporary specific MN/PA criteria will only be active until the formal P&T Committee review process is complete (i.e., P&T Committee recommendations made during the next available meeting are implemented after approval by the DHA Director).
4. Implementation of permanent criteria will become effective upon signing of the minutes. All new users who have established temporary specific MN/PA criteria will be grandfathered when the permanent criteria become effective, unless directed otherwise.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XX. UTILIZATION MANAGEMENT—GASTROINTESTINAL-2 (GI-2) MISCELLANEOUS DRUGS

P&T Comments

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

The GI-2 Miscellaneous Drug Class was reviewed by the P&T Committee in November 2015. At the time of November 2015 meeting, eluxadoline (Viberzi) was approved by the FDA but not yet commercially available.

Eluxadoline is a mixed mu-opioid receptor agonist that is FDA-approved for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). Because of the mechanism of action, several contraindications and warnings exist for the product, in addition to the potential for abuse. PA criteria was recommended for Viberzi due to the safety issues. Additionally, PA criteria also apply for rifaximin for treatment of IBS-D.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Viberzi in all new patients, consistent with the new FDA-approved product labeling and safety warnings.

Full PA Criteria:

All new users of eluxadoline (Viberzi) are required to undergo manual prior authorization criteria.

Manual PA criteria: Coverage will be approved if:

- The patient is ≥ 18 years; AND
- Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink < 3 alcoholic beverages per day; AND
- Patient has no history of marijuana use or illicit drug use in the previous 6 months; AND
- Patient does not have severe hepatic impairment (Child-Pugh C); AND
- Patient has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D); AND
    - The patient has had failure, intolerance, or contraindication to at least one antispasmodic agent; e.g., dicyclomine (Bentyl), Librax, hyoscyamine (Levsin), Donnatal, loperamide (Imodium) AND

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

- Prior Authorization does not expire.

B. Gastrointestinal-2 (GI-2) Miscellaneous Drugs: Eluxadoline (Viberzi)—PA Implementation Period

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XXI. UTILIZATION MANAGEMENT—GI-2 MISCELLANEOUS DRUGS

BAP Comments

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

The P&T Committee recommended manual PA criteria for Viberzi in all new patients, consistent with the new FDA-approved product labeling and safety warnings.

The full prior authorization criteria were stated previously above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXII. UTILIZATION MANAGEMENT—ATYPICAL ANTIPSYCHOTICS (AAPs)

P&T Comments

A. AAPs: Brexpiprazole (Rexulti)—Manual PA Criteria

The AAPs, also known as the second generation antipsychotics, were reviewed by the P&T Committee in May 2011. Brexpiprazole is a new entrant to the class, and is FDA-approved for treating schizophrenia and as adjunct to antidepressant therapy for major depressive disorder. Brexpiprazole has serotonergic and dopaminergic effects similar to other AAPs.

Manual PA criteria were recommended for Rexulti due to the similar mechanism of action and FDA labeling as aripiprazole (Abilify), which recently became available in generic formulations.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for brexpiprazole (Rexulti) in all new patients.

Full PA Criteria:

All new users of brexpiprazole (Rexulti) are required to undergo manual prior authorization criteria.

Manual PA criteria: Coverage will be approved if:

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

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

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

B. AAPs: Brexpiprazole (Rexulti)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XXIII. UTILIZATION MANAGEMENT—AAPs

BAP Comments

A. AAPs: Brexpiprazole (Rexulti)—PA Criteria

Manual PA criteria were recommended for Rexulti due to the similar mechanism of action and FDA labeling as Abilify, which recently became available in generic formulations.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. AAPs: Brexpiprazole (Rexulti)—PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXIV. UTILIZATION MANAGEMENT—ANTICONVULSANTS

P&T Comments

A. Anticonvulsants: Lacosamide (Vimpat)—Manual PA Criteria

Lacosamide (Vimpat) was approved in 2008 and only has one FDA-approved indication for treating partial onset seizures. Because of the concern for off-label use, PA criteria were recommended. The Anticonvulsant Drug Class has not been previously reviewed by the P&T Committee, but will be reviewed for formulary placement at the May 2016 DoD P&T Committee meeting.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for lacosamide (Vimpat) in all new patients, consistent with the new FDA-approved product labeling.

Full PA Criteria:

All new users of lacosamide (Vimpat) are required to undergo manual prior authorization criteria.

Manual PA criteria:

- Coverage will be approved if the patient has a diagnosis of Seizure Disorder and Vimpat is used as monotherapy or adjunctive therapy in the treatment of partial-onset seizure in patients ≥ 17 years of age.

- Coverage is not approved for the following:
  - Non-FDA approved indications
  - Diabetic neuropathic pain
  - Essential tremor

- Prior Authorization does not expire.

B. Anticonvulsants: Lacosamide (Vimpat)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XXV. UTILIZATION MANAGEMENT—ANTICONVULSANTS

BAP Comments

A. Anticonvulsants: Lacosamide (Vimpat)—Manual PA Criteria

The P&T Committee recommended manual PA criteria for Vimpat in all new patients, consistent with the new FDA-approved product labeling.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Anticonvulsants: Lacosamide (Vimpat)—PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXVI. UTILIZATION MANAGEMENT—RENIN-ANGIOTENSIN-ALDOSTERONE AGENTS (RAAs)

P&T Comments

A. RAAs: Sacubitril/Valsartan (Entresto)—Automated and Manual PA Criteria

The RAAs class was previously reviewed by the P&T Committee in May 2010. Automated (step therapy) criteria apply, requiring a generic angiotensin converting enzyme (ACE) inhibitor or preferred angiotensin receptor blocker (ARB), prior to use of a non-step preferred ACE inhibitor or ARB.

Entresto is a new fixed-dose combination product containing the ARB valsartan (Diovan) and sacubitril, a neprilysin inhibitor. Sacubitril is a prodrug that inhibits neprilysin (neutral endopeptidase) through the active metabolite, leading to increased levels of peptides, including natriuretic peptides.

Entresto is FDA-approved to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (New York Heart Association [NYHA] class II-IV) and a decreased left ventricular ejection fraction (LVEF). Several ACE inhibitors and the ARBs valsartan and candesartan (Atacand, generic) are indicated for patients with heart failure due to decreased LVEF.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) automated and manual PA for Entresto in all new and current users, consistent with the current step therapy requirements for the RAAs class, and FDA labeling for Entresto.

Full PA Criteria:

Automated or manual PA criteria apply to all new and current users of Entresto.

Automated PA criteria:

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

- Step-preferred RAAs include lisinopril +/- hydrochlorothiazide (HCTZ), captopril +/- HCTZ, ramipril, losartan +/- HCTZ, valsartan +/- HCTZ, benazepril +/- HCTZ, enalapril +/- HCTZ, fosinopril +/- HCTZ, moexipril +/- HCTZ, perindopril, quinapril +/- HCTZ, telmisartan +/- HCTZ, telmisartan/amlodipine, valsartan/amlodipine, valsartan/amlodipine/HCTZ. Note that a history of candesartan +/- HCTZ also qualifies as meeting the step therapy criteria.

Manual PA criteria: If automated PA criteria are not met, Entresto is approved if:

- The patient has a documented diagnosis of chronic heart failure (New York Heart Association class II-IV heart failure) with left ventricular ejection fraction $\leq$40%. AND
- The patient is receiving concomitant treatment with a beta blocker, or the patient has a contraindication to a beta blocker. AND
- The patient is intolerant to an ACE inhibitor AND

- The patient does not have a history of angioedema to ACE inhibitors or ARBs.
- Prior Authorization does not expire.

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

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS.

XXVII. UTILIZATION MANAGEMENT—RAAs

BAP Comments

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

The P&T Committee recommended automated and manual PA for Entresto in all new and current users, consistent with the current step therapy requirements for the RAAs class, and FDA labeling for Entresto.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. RAAs: Sacubitril/Valsartan (Entresto)—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

XXVIII. UTILIZATION MANAGEMENT—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBs)

P&T Comments

A. TIBs: Secukinumab (Cosentyx)—Manual PA Criteria

The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class (implemented on December 17, 2014). Secukinumab (Cosentyx) was reviewed by the P&T Committee in February 2015; automated and manual PA criteria were recommended (and implemented on May 4, 2015). In August 2015, Cosentyx was reviewed as a newly-approved drug for treating plaque psoriasis and was recommended for formulary status on the UF, requiring a trial of adalimumab (Humira), the step-preferred TIB, first.

Secukinumab (Cosentyx) received a new FDA indication in January 2016 for treatment of psoriatic arthritis and ankylosing spondylitis in adults. The PA criteria were updated for Cosentyx to reflect the new FDA indication.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) revised manual PA criteria for Cosentyx in new patients, consistent with the new FDA-approved product labeling for psoriatic arthritis and ankylosing spondylitis.

Full PA Criteria:

Prior Authorization criteria originally approved February 2015 and implemented May 4, 2015. February 2016 changes to PA criteria in bold. Manual PA criteria for psoriatic arthritis and ankylosing spondylitis applies to new patients.

Manual PA Criteria applies to all new users of secukinumab (Cosentyx).

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

Manual PA criteria:

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

- Contraindications exist to Humira
- Inadequate response to Humira [need for different anti-tumor necrosis factor (TNF) or non-TNF]
- Adverse reactions to Humira not expected with requested non step-preferred TIB

AND

Coverage approved for patients > 18 years with:

- Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy OR
- **Psoriatic arthritis (February 2016) OR**
- **Ankylosing spondylitis (February 2016)**

Coverage is NOT provided for concomitant use with other TIBs.

Prior Authorization does not expire.

B. TIBs: Secukinumab (Cosentyx)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) implementation of the PA for Cosentyx become effective upon signing of the minutes.

XXIX. UTILIZATION MANAGEMENT—TIBs

BAP Comments

A. TIBs: Secukinumab (Cosentyx)—Manual PA Criteria

The P&T Committee recommended revised manual PA criteria for Cosentyx in new patients, consistent with the new FDA-approved product labeling for psoriatic arthritis and ankylosing spondylitis.

The full prior authorization criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. TIBs: Secukinumab (Cosentyx)—PA Implementation Plan

The P&T Committee recommended implementation of the PA for Cosentyx become effective upon signing of the minutes.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXX. OVER-THE-COUNTER (OTC) DRUG REVIEW

P&T Comments

A. OTC Drug Review: Doxylamine—Relative Clinical Effectiveness and Conclusion

Section 702 of the FY13 NDAA provides legislative authority for the OTC Drug Program. The Final Rule published in the Federal Register on July 27, 2015, establishes the process for identifying OTC products for coverage under the TRICARE pharmacy benefit and the rules for making these products available to eligible DoD beneficiaries. The Final Rule can be 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 approved OTC drugs will comply with the mandatory generic policy stated in 32 CFR 99.21(j)(2) and be available under terms similar for generic drugs, except that the need for a prescription and/or a copayment may be waived in some circumstances. No cost-sharing for OTC drugs is required at any of the three points of service for a uniformed service member on active duty.

The P&T Committee evaluated the relative clinical and cost effectiveness and patient access considerations of adding doxylamine 25 mg (Unisom, generic) to the UF via the OTC Drug Program. Doxylamine has not previously been covered as a TRICARE pharmacy benefit under the OTC Demonstration Project; it is the first OTC drug to be considered under the new legislation.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) the following

- Doxylamine 25 mg (Unisom, generics) is available OTC as a sleep aid but is frequently used for treating nausea and vomiting of pregnancy (NVP), along with pyridoxine (vitamin B6). A prescription product, Bendectin, containing doxylamine and pyridoxine was discontinued from the market in the 1980s.
- In May 2015, the P&T Committee recommended NF status for Diclegis, a prescription product containing delayed release doxylamine succinate and pyridoxine, based on clinical and cost effectiveness. Manual PA criteria were also recommended, requiring a trial of nonpharmacologic interventions and OTC pyridoxine, and consideration of alternate antiemetics.
- The May 2015 P&T Committee also found the OTC ingredients of doxylamine with or without pyridoxine were therapeutically equivalent to Diclegis.
- Input from MTF obstetrics and gynecology providers voiced concern regarding worldwide availability of OTC doxylamine at all MTFs, and the potential for confusion due to the various OTC formulations of the product available in the retail setting (other products with the name “sleep aid” contain diphenhydramine).
- A trial conducted by the manufacturer of Bendectin in 1975 showed doxylamine monotherapy to be as effective and, in some endpoints, more effective than any other combination or monotherapy agent (e.g., doxylamine/pyridoxine, pyridoxine) for treating NVP.
- The September 2015 American College of Obstetrics and Gynecology (ACOG) Practice Bulletin also supports doxylamine for first-line use in the treatment of nausea and vomiting of pregnancy.
- Advantages of OTC doxylamine include its pregnancy category A rating, and the long history of efficacy and safety in both the OTC and prescription setting for treating NVP. Disadvantages include the sedating effects and need for multiple daily dosing, which may be a significant concern for some patients in setting of NVP.
- Providing doxylamine as an OTC TRICARE pharmacy benefit allows uniform availability of the product, and would enhance obstetric care and be consistent with the recently updated ACOG guidelines.

B. OTC Drug Review: Doxylamine—Relative Cost-Effectiveness Analysis and Conclusion

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) OTC doxylamine 25 mg was less costly than the NF product Diclegis.

C. OTC Drug Review: Doxylamine—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) adding OTC doxylamine 25 mg to the UF, based on clinical and cost effectiveness. As part of this recommendation, a prescription will be required for OTC doxylamine. Additionally, an age limit of patients less than 65 years of age was also recommended, to ensure appropriate use in accordance with Beers Criteria (a list of medications considered inappropriate for use in patients older than 65 years, due to the risk of adverse effects).

D. OTC Drug Review: Doxylamine—Copayment Waiver

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) waiving the copayment requirement for OTC doxylamine 25 mg. The copayment waiver was recommended because doxylamine is considered an acute use drug, with the majority of utilization expected at the MTFs and Retail Network pharmacies. Additionally, waiving the copayment would encourage use of the most cost-effective option for NVP and potentially shift utilization from agents with concerning safety profiles.

E. OTC Drug Review: Doxylamine—UF Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period.

XXXI. OTC DRUG REVIEW

BAP Comments

A. OTC Drug Review: Doxylamine—UF Recommendation

The P&T Committee recommended adding OTC doxylamine 25 mg to the UF, based on clinical and cost effectiveness. As part of this recommendation, a prescription will be required for OTC doxylamine. Additionally, an age limit of patients less than 65 years of age was also recommended, to ensure appropriate use in accordance with Beers Criteria (a list of medications considered inappropriate for use in patients older than 65 years, due to the risk of adverse effects).

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. OTC Drug Review: Doxylamine—Copayment Waiver

The P&T Committee recommended waiving the copayment requirement for OTC doxylamine 25 mg. The copayment waiver was recommended because doxylamine is considered an acute use drug, with the majority of utilization expected at the MTFs and Retail Network pharmacies. Additionally, waiving the copayment would encourage use of the most cost-effective option for NVP and potentially shift utilization from agents with concerning safety profiles.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. OTC Drug Review: Doxylamine—UF Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

P&T Comments

A. FY08 NDAA, Section 703—Drugs Designated NF

The P&T Committee reviewed two drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with the FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will require pre-authorization prior to use in the retail point of service and medical necessity at MTFs. These NF drugs will remain available in the Mail Order point of service without pre-authorization.

- The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) maintaining the current NF status for Sebela Pharmaceuticals: calcitonin-salmon (Miacalcin), 200 International Units (3.7 mL) nasal spray. Note that Miacalcin nasal spray was designated NF when the osteoporosis drugs were reviewed at the June 2008 P&T Committee meeting. Miacalcin will now require pre-authorization at the retail point of service.

- The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) maintaining the current NF status for Vanda Pharmaceuticals: tasimelteon (Hetlioz), 20 mg capsule. Note that Hetlioz was designated NF at the February 2015 DoD P&T Committee meeting, with manual PA criteria.

B. FY08 NDAA, Section 703—Pre-Authorization Criteria for Miacalcin Nasal Spray

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) the following pre-authorization criteria for Miacalcin 200 International Units (3.7 mL) nasal spray.

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 POS other than retail network pharmacies.

C. FY08 NDAA, Section 703—Implementation Plan for Pre-Authorization Criteria for Miacalcin

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday after a 30-day implementation period in the Retail Network for Miacalcin nasal spray and DHA send letters to beneficiaries affected by this decision.

D. FY08 NDAA, Section 703—Pre-Authorization Criteria for Hetlioz

Note that tasimelteon (Hetlioz) will not be available in the Mail Order Pharmacy, as it is only available in the Retail Network via a restricted distribution process, thus pre-authorization criteria do not apply.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) to maintain the existing PA criteria for tasimelteon (Hetlioz) from the February 2015 DoD P&T Committee meeting. See the February 2015 P&T Committee meeting minutes at http://www.health.mil/PandT.

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

BAP Comments

A. FY08 NDAA, Section 703—Drugs Designated NF

- The P&T Committee recommended maintaining the current NF status for Miacalcin nasal spray.
- The P&T Committee recommended maintaining the current NF status for Hetlioz.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. FY08 NDAA, Section 703—Pre-Authorization Criteria for Miacalcin Nasal Spray

The P&T Committee recommended the following pre-authorization criteria for Miacalcin nasal spray.

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 POS other than retail network pharmacies.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. FY08 NDAA, Section 703—Implementation Plan for Pre-Authorization Criteria for Miacalcin Nasal Spray

The P&T Committee recommended an effective date of the first Wednesday after a 30-day implementation period in the Retail Network for Miacalcin nasal spray and DHA send letters to beneficiaries affected by this decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention