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 (PA), 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—BASAL INSULIN ANALOGS

P&T Comments

A. Basal Insulin Analogs—Relative Clinical Effectiveness and Conclusion

Background—The Basal Insulin Analogs were previously reviewed for UF status in February 2010. There are several new entrants to the class; however, there are no generic or biosimilar products available. The class is comprised of insulin glargine vials and pens (Lantus), insulin glargine 100 U/mL (Basaglar), insulin detemir vials and pen (Levemir), insulin degludec (Tresiba), and insulin glargine 300 U/mL (Toujeo). Manual PAs are currently in place for Toujeo and Tresiba.

Note that the combination products degludec/liraglutide (Xultophy) and degludec/lixisenatide (Soliqua) are part of the glucagon-like peptide-1 receptor agonists (GLP1RA) subclass, and were not included in the review. The formulary recommendations do not apply to neutral protamine Hagedorn (NPH) or 70/30 insulin preparations.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- Basal insulin analogs are dosed subcutaneously (SQ) once daily, and have similar initial dosing.
    - Insulin glargine (Lantus) was marketed in 2000, and was designated with formulary status in 2010.
    - Insulin detemir (Levemir) may be dosed once or twice daily and has been marketed since 2005.
    - Insulin degludec (Tresiba) has a long duration of action of up to 42 hours, versus 24 hours for the other products. It also has flexibility with regard

to time of administration, and is available in two concentrations (100 U/mL, 200 U/mL).
    - Basaglar is another insulin glargine identical to Lantus in terms of amino acid sequence and pH. It was approved using the FDA 505(b)(2) pathway, since it is a similar biologic version of Lantus.
    - Toujeo is a more concentrated version of Lantus containing 300 U/mL, and has an onset of action developing over 6 hours, compared to Lantus at 3 to 4 hours.

- Although the basal insulin analogs differ in their pharmacokinetic profiles, this variance does not translate into differences in glycemic control or hemoglobin A1c improvements when comparing one product to one another.
- When compared in head-to-head trials, there were no clinically relevant differences reported between the basal insulin analogs and their effect on glycemic control. Lantus was the active comparator in the majority of the non-inferiority trials.
- A 2016 meta-analysis from the Institute of Clinical and Economic Review evaluated eight trials comparing insulin degludec (Tresiba) with insulin glargine (Lantus) or insulin detemir (Levemir). For all eight trials, insulin degludec was non-inferior to the other insulins based on A1c results.
- Regarding hypoglycemia, it is difficult to conclude emphatically that one basal insulin analog is less likely to cause clinically relevant severe or nocturnal hypoglycemia events. This is due to the differences in the definitions of hypoglycemia used in the individual clinical trials, the open label study designs, and the different primary endpoints.
- For special populations, Lantus, Levemir, and Tresiba are approved for use in pediatrics. The basal insulin analogs are rated as pregnancy category C, with the exception of Levemir, which is rated as pregnancy category B.
- A survey of Military Health System (MHS) providers found that the majority of respondents (90%) stated a preference for Lantus in their clinical setting and that it should remain on the UF, due to their familiarity with the product. Additionally, most clinicians responded that two basal insulins were required on the formulary. After Lantus, most providers stated a preference for Levemir, followed by Tresiba as a second available agent.
- The majority of MHS patients can be treated with Lantus, based on the lack of compelling advantages of the newer basal insulin analogs, existing MHS utilization patterns, and MHS provider opinion.

B. Basal Insulin Analogs—Relative Cost-Effectiveness Analysis and Conclusion

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

- CMA results showed that glargine pens and vials (Lantus) were the most cost-effective basal insulin analogs followed by glargine 300 U/mL (Toujeo), detemir vial (Levemir), glargine 100 U/mL (Basaglar), detemir pen (Levemir), and degludec (Tresiba).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating glargine pens and vials (Lantus) as UF and step-preferred, and designating detemir vials (Levemir) and glargine 300 U/mL (Toujeo) as UF and non step-preferred, with glargine 100 U/mL (Basaglar), detemir pen (Levemir), and degludec (Tresiba) as NF and non step-preferred, demonstrated a significant estimated cost avoidance for the MHS.

C. Basal Insulin Analogs—UF Recommendation

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

- **UF and Step-Preferred:**
  - insulin glargine pen and vial (Lantus)
- **UF and Non Step-Preferred**
  - insulin detemir vial (Levemir)
  - insulin glargine 300 U/mL (Toujeo)
- **NF and Non Step-Preferred:**
  - insulin detemir pen (Levemir)
  - insulin degludec (Tresiba)
  - insulin glargine 100 U/mL (Basaglar)

Note that as part of this recommendation, all new users of a basal insulin analog are required to try Lantus first.

D. Basal Insulin Analogs—Manual Prior Authorization (PA) Criteria

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) step therapy for the basal insulin analogs, requiring a trial of Lantus in all new users, prior to use of the non step-preferred products (Basaglar, Levemir, Tresiba, and Toujeo). The step therapy requirement will be included in the manual PAs.

The existing PAs for Tresiba and Toujeo currently include the requirement for a trial of Lantus first. The Tresiba PA criteria were updated to include use in pediatrics. New PA criteria for Levemir pens and vials, and Basaglar were recommended to incorporate the step therapy. In general, the non step-preferred product will only be allowed if the patient has tried and failed or is intolerant to Lantus, or in the pregnant population, if the patient cannot be treated with Lantus.

PA Criteria:

- Tresiba**—changes from the August 2017 meeting are in BOLD**

  Patients is age ≥ 1

- Levemir

  Manual PA criteria apply to all new users of Levemir pens and vials.

  Manual PA criteria—Levemir pen or vial is approved if all criteria are met:
  1. Patient must have tried and failed insulin glargine (Lantus)
     Or
  2. Patient is pregnant and cannot use insulin glargine (Lantus)

  PA does not expire.
  Non-FDA approved uses are not approved.

- Basaglar

  Manual PA criteria apply to all new users of Basaglar.

  Manual PA criteria—Basaglar is approved if the following criteria is met:

  1. Patient must have tried and failed insulin glargine (Lantus).

  PA does not expire.
  Non-FDA approved uses are not approved.

- Toujeo

  Note – No changes from the previous PA from November 2015 were recommended at the August 2017 meeting.

  Manual PA criteria apply to all new users of Toujeo.

  Manual PA criteria—Toujeo is approved if:
  - The patient is at least 18 years of age

  AND
  - The patient has diabetes and is using a minimum of 100 units of Lantus per day

  AND
  - The patient requires a dosage increase with Lantus and has experienced a clinically significant, severe hypoglycemia episode, despite splitting the Lantus dose

  AND
  - The patient has been counseled regarding the risk of dosing errors.

- Note that the following are not acceptable reasons for Toujeo:
  - Non-adherence to previous insulin treatment
  - Patient or prescriber preference for the use of Toujeo
  - Patient or prescriber preference for a smaller injection volume

PA does not expire.

E. Basal Insulin Analogs—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 30-day implementation.

III. UF CLASS REVIEWS—BASAL INSULIN ANALOGS

BAP Comments

A. Basal Insulin Analogs—UF Recommendation

The P&T Committee recommended the following:

- **UF and Step-Preferred:**
  - Lantus
- **UF and Non Step-Preferred**
  - Levemir
  - Toujeo
- **NF and Non Step-Preferred:**
  - Levemir
  - Tresiba
  - Basaglar

Note that as part of this recommendation, all new users of a basal insulin analog are required to try Lantus first.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Basal Insulin Analogs—Manual PA Criteria

The P&T Committee recommended step therapy for the basal insulin analogs, requiring a trial of Lantus in all new users, prior to use of the non step-preferred products (Basaglar,

Levemir, Tresiba, and Toujeo). The step therapy requirement will be included in the manual PAs.

The existing PAs for Tresiba and Toujeo currently include the requirement for a trial of Lantus first. The Tresiba PA criteria were updated to include use in pediatrics. New PA criteria for Levemir pens and vials, and Basaglar were recommended to incorporate the step therapy. In general, the non step-preferred product will only be allowed if the patient has tried and failed or is intolerant to Lantus, or in the pregnant population, if the patient cannot be treated with Lantus.

Updated and full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Basal Insulin Analogs—UF and PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 30-day implementation.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

IV. UF CLASS REVIEWS—CORTICOSTEROIDS – IMMUNE MODULATORS DRUG CLASS: HEREDITARY ANGIOEDEMA (HAE) AGENTS SUBCLASS

P&T Comments

A. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass

Background—HAE is a rare disease characterized by lack of or dysfunction of C1 esterase inhibitor. The disease presents as frequent edema episodes affecting the gastrointestinal (GI) tract, extremities, face, and airway. HAE is mediated by bradykinin, and is unresponsive to typical therapy of steroids, epinephrine, and antihistamines.

The drugs in the HAE subclass include the C1 esterase inhibitors and the bradykinin B2 receptor antagonist icatibant (Firazyr). The C1 esterase inhibitors all contain the same active ingredient, but differ in manufacturing and source (plasma derived versus recombinant), FDA indications (treatment versus prophylaxis), and dosing (weight-based versus fixed dosing).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 1 abstained, 1 absent) the following for the HAE drugs:

- Treatment
    - Berinert, Ruconest, and icatibant (Firazyr) are indicated for treatment of acute angioedema episodes, based on placebo-controlled trials. The C1 esterase inhibitors are self-administered via intravenous (IV) infusion, while Firazyr is administered by SQ injection. Berinert and icatibant (Firazyr) have FDA approval for treatment of laryngeal attacks, but clinical trial data is available with Ruconest.
    - The individual trials for Berinert, Ruconest, and Firazyr had different primary endpoints and study designs. Berinert and Ruconest showed a reduction in the time to onset of symptom relief compared to placebo, while Firazyr showed improvement in the time to reach a 50% decrease in symptoms over placebo.
    - There are no direct comparative studies between the products for treatment of HAE. However, indirect comparison shows that Berinert, Ruconest, and Firazyr start relieving symptoms within 30 to 90 minutes following administration.
    - Guidelines for treatment of HAE recommend the C1 esterase inhibitors or Firazyr, and do not place preference of one treatment over another.
- Prophylaxis
    - For long-term prophylaxis of HAE, guidelines recommend Cinryze and the attenuated androgen Danazol. Factors to consider for initiation of prophylaxis include attack frequency and severity, comorbid conditions, access to emergent treatment, patient experience and preference, and risk factors for adverse effects.
    - Evidence for efficacy of Danazol from a retrospective study showed a 94% response rate, with a decrease from 33.3 attacks per year pre-treatment to 5.4 attacks following Danazol administration.
    - Cinryze approval was based on one trial showing a 51% reduction in the mean number of attacks per 12 weeks with Cinryze (6.3 attacks) versus placebo (12.7 attacks). Head-to-head trials with Danazol are lacking.
- Safety
    - The C1 esterase inhibitors all contain warnings for thrombosis. The plasma-derived products (Berinert, Cinryze) carry a risk of blood-borne pathogens, while the recombinant product (Ruconest) has a risk for hypersensitivity reactions in patients allergic to rabbits. Differences between the products regarding the long-term risks of viral transmission and thrombosis remain to be determined.
    - For the bradykinin product icatibant (Firazyr), over 97% of patients experience injection site reactions.

- Attenuated androgens are rated Pregnancy Category X. Well-known risks of using androgens include virilization in females, stroke, myocardial infarction (MI), and venous thromboembolism.

- Other Factors
  - A new SQ-administered product, Haegarda, was recently approved for HAE prophylaxis and will be reviewed at an upcoming meeting.
  - A survey of Military Treatment Facility (MTF) providers who treat HAE patients commented that Danazol is recommended for prophylaxis but should be avoided in patients with contraindications and women of child-bearing age.

B. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (13 for, 0 opposed, 1 abstained, 1 absent) the following:

- CMA results showed that Berinert, Cinryze, Ruconest, and icatibant (Firazyr) were cost-effective agents.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating all four HAE agents (Berinert, Cinryze, Ruconest, and icatibant [Firazyr]) as formulary on the UF demonstrated the largest estimated cost avoidance for the MHS.

C. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass—UF Recommendation

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

- **UF:**
  - plasma-derived human C1 esterase inhibitor IV (Cinryze)
  - plasma-derived human C1 esterase inhibitor IV (Berinert)
  - recombinant C1 esterase inhibitor IV (Ruconest)
  - icatibant SQ (Firazyr)

- **NF:** None
- Plasma-derived human C1 esterase inhibitor SQ (Haegarda) will remain in pending NF status until the November DoD P&T Committee review.

D. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass—Manual PA Criteria

The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for the HAE prophylaxis product Cinryze, requiring a trial of Danazol in new users. The PA will also apply to Haegarda upon market launch.

Full PA Criteria

Manual PA criteria apply to all new users of Cinryze and Haegarda.

Manual PA criteria—Cinryze or Haegarda is approved if:

- The patient is ≥13 years old (Cinryze) or ≥12 years old (Haegarda) AND
- The patient must be diagnosed with hereditary angioedema Type I, II, or III (HAE with normal C1-esterase inhibitor) AND
- The drug is prescribed by an allergist, immunologist, or rheumatologist, or in consultation with an HAE specialist AND
- The patient must experience ≥2 HAE attacks per month AND
- The patient has tried and failed an attenuated androgen (danazol) OR
  - Patient has experienced or is expected to experience serious adverse effects from the use of an androgen (e.g., virilization of women, stroke, or myocardial infarction, venous thromboembolism) OR
  - Patient is female of childbearing age
- Cinryze or Haegarda is not approved for any indication other than HAE.
- PA does not expire.

E. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass—UF and PA Implementation Plan

The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 30-day implementation period.

V. UF CLASS REVIEWS—CORTICOSTEROIDS – IMMUNE MODULATORS DRUG CLASS: HAE AGENTS SUBCLASS

BAP Comments

A. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass—UF Recommendation

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

- **UF:**
  - Cinryze
  - Berinert
  - Ruconest
  - Firazyr

- **NF:** None

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

B. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass—Manual PA Criteria

The P&T Committee recommended manual PA criteria for the HAE prophylaxis product Cinryze, requiring a trial of Danazol in new users. The PA will also apply to Haegarda upon market launch.

The full manual PA criteria were stated previously.

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

C. Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass—UF and PA Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday after a 30-day implementation period.

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

VI. UF CLASS REVIEWS—HUMAN IMMUNODEFICIENCY VIRUS (HIV)

P&T Comments

A. HIV—Relative Clinical Effectiveness and Conclusion

The antiretroviral agents for HIV include 27 unique chemical entities that are combined into over 42 medications. The class was further categorized based on mechanism of action of the individual active ingredients into the integrase strand transfer inhibitors (INSTIs), non-nucleoside reverse transcriptase inhibitor (NNRTIs), nucleoside/nucleotide reverse transcriptase inhibitor (NRTIs), and combination products.

Only a few of the older HIV agents are available in generic formulations. Therefore, the clinical effectiveness review focused on the place in therapy of the new branded entrants to the market.

Relative Clinical Effectiveness Analysis and Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- The newer antiretroviral regimens are associated with fewer serious and intolerable adverse effects than regimens used in the past. First-line (recommended) antiretroviral agents are generally safe and well tolerated in comparison to the other products.
- In treatment-naïve patients, the optimal therapy for HIV should include at least three different drugs, from two or more different drug classes, ideally administered once daily. Current guidelines recommend a regimen containing two NRTIs plus one protease inhibitor or one INSTI.
- First line single-tablet regimens include Triumeq, Stribild, and Genvoya.
- Emtricitabine/tenofovir disoproxil fumarate (Truvada) is the only product FDA approved for HIV pre-exposure prophylaxis (PrEP) based on the iPrEX and PartnersPrEP studies enrolling a population of men who have sex with men, high-risk individuals, or serodiscordant couples
- A systematic review from 11 placebo-controlled trials enrolling 9,000 patients comparing Truvada versus placebo reported that treatment resulted in a 51% reduction in the risk of HIV infection (risk ratio = 0.49, 95% CI: 0.28–0.85, P = 0.001). In terms of safety, Truvada is comparable to placebo.
- Effectiveness of Truvada for PreEP is dependent on adherence. PrEP therapy with Truvada is more effective in patients with high rates of medication adherence, and is essentially not effective in patients who have low adherence rates.
- The HIV antiretroviral agents have a low degree of therapeutic interchangeability; treatment choice must be tailored to the individual patient by considering drug characteristics and risk of resistance.

B. HIV—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 of the top three most cost-effective treatment regimens, Triumeq was the most cost effective, followed by Genvoya, and Stribild.
- BIA results showed that designating all the HIV antiretroviral agents as formulary on the UF had a lower budget impact on MHS costs than the current baseline.

C. HIV—UF Recommendation

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following, listed alphabetically by trade name, with first-line or recommended products bolded:

- **UF**:
  - Aptivus (tipranavir)
  - Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
  - Combivir (lamivudine/zidovudine)
  - **Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)**
  - Crixivan (indinavir)
  - **Descovy (emtricitabine/tenofovir alafenamide)**
  - Edurant (rilpivirine)
  - Emtriva (emtricitabine)
  - Epivir (lamivudine)
  - Epzicom (abacavir/lamivudine)
  - Evotaz (atazanavir/cobicistat)
  - Fuzeon (enfuviritide)
  - **Genvoya (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide)**
  - Intelence (etravirine)
  - Invirase (saquinavir)
  - Isentress (raltegravir)
  - **Isentress HD (raltegravir extended-release)**
  - Lexiva (fosamprenavir)
  - Kaletra (lopinavir/ritonavir)
  - **Norvir (ritonavir)**
  - **Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)**
  - Prezcobix (darunavir/cobicistat)
  - **Prezista (darunavir)**
  - Rescriptor (delavirdine)
  - Retrovir (zidovudine)
  - Reyataz (atazanavir)
  - **Selzentry (maraviroc injection and oral solution)**
  - **Stribild (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)**
  - Sustiva (efavirenz)
  - **Tivicay (dolutegravir)**
  - **Triumeq (abacavir/dolutegravir/lamivudine)**
  - Trizivir (abacavir/lamivudine/zidovudine)
  - **Truvada (emtricitabine/tenofovir disoproxil fumarate)**
  - Tybost (cobicistat)

- Videx EC (didanosine delayed-release)
- Videx Pediatric (didanosine)
- Viracept (nelfinavir)
- Viramune (nevirapine)
- Viramune XR (nevirapine ER)
- Viread (tenofovir disoproxil fumarate)
- Zerit (stavudine)
- Ziagen (abacavir)

- **NF**: None

D. HIV—UF and PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date upon signing of the minutes in all points of service.

VII. UF CLASS REVIEWS—HIV

BAP Comments

A. HIV—UF Recommendation

The P&T Committee recommended the following, listed alphabetically by trade name, with first-line or recommended products bolded:

- **UF**:
  - Aptivus
  - Atripla
  - Combivir
  - **Complera**
  - Crixivan
  - **Descovy**
  - Edurant
  - Emtriva
  - Epivir
  - Epzicom
  - Evotaz
  - Fuzeon
  - **Genvoya**
  - Intelence
  - Invirase
  - Isentress
  - **Isentress HD**
  - Lexiva
  - Kaletra
  - **Norvir**
  - **Odefsey**
  - Prezcobix
  - **Prezista**

- Rescriptor
- Retrovir
- Reyataz
- **Selzentry**
- **Stribild**
- Sustiva
- **Tivicay**
- **Triumeq**
- Trizivir
- **Truvada**
- Tybost
- Videx EC
- Videx Pediatric
- Viracept
- Viramune (nevirapine)
- Viramune XR
- Viread
- Zerit
- Ziagen

- **NF**: None

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

B. HIV—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 Dissension

VIII. NEWLY-APPROVED DRUGS PER CFR 199.21(g)(5)

P&T Comments

A. Newly-Approved Drugs per CFR 199.21(g)(5)—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed (Day 1: 15 for, 0 opposed, 0 abstained, 0 absent; Day 2: 13 for, 0 opposed, 1 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5).

B. Newly-Approved Drugs per CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended (Day 1: 14 for, 0 opposed, 1 abstained, 0 absent; Day 2: 13 for, 0 opposed, 1 abstained, 1 absent) the following:

- **UF**:
  - brigatinib (Alunbrig) – Oral Oncology Agents for Lung Cancer
  - methotrexate (Xatmep) oral solution – Antirheumatic Drugs
  - midostaurin (Rydapt) – Oral Oncology Agents for Acute Myeloid Leukemia (AML)
  - niraparib (Zejula) – Oral Oncology Agents for Ovarian Cancer
  - prasterone (Intrarosa) vaginal insert – Vaginal Lubricants
  - ribociclib/letrozole (Kisqali Femara Co-Pack) – Oral Oncologic Agents for Breast Cancer
- **NF:**
  - abaloparatide (Tymlos) injection – Osteoporosis Agents
  - brodalumab (Siliq) injection – Targeted Immunomodulatory Biologics (TIBs)
  - dronabinol (Syndros) oral solution – Antiemetic and Antivertigo Agents
  - fluticasone/salmeterol (AirDuo RespiClick) oral inhaler – Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)
  - mixed amphetamine salts ER (Mydayis) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
  - morphine sulfate ER (Morphabond XR) – Narcotic Analgesics
  - safinamide (Xadago) – Parkinson's Disease Drugs
  - sarilumab (Kevzara) injection – TIBs
  - valbenazine (Ingrezza) – Neuromuscular Miscellaneous Agents

C. Newly-Approved Drugs per CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (Day 1: 14 for, 0 opposed, 1 abstained, 0 absent; Day 2: 13 for, 0 opposed, 1 abstained, 1 absent) the following:

- Applying the same manual PA criteria for sarilumab (Kevzara) and brodalumab (Siliq) in new and current users, as is currently in place for the other non step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for brodalumab, a trial of secukinumab (Cosentyx) is required if the patient cannot be treated with Humira.

- Applying PA criteria to new users of midostaurin (Rydapt), ribociclib/letrozole (Kisqali Femara Co-Pack), prasterone vaginal insert (Intrarosa), safinamide (Xadago), and valbenazine (Ingrezza).

- Applying PA criteria to new and current users of dronabinol oral solution (Syndros), fluticasone/salmeterol (AirDuo RespiClick), methotrexate (Xatmep) oral solution, and mixed amphetamine salts ER (Mydayis).

Full PA Criteria for the Newly-Approved Drugs per CFR 199.21(g)(5)

1. brodalumab (Siliq) – TIBs

Step Therapy and Manual PA Criteria apply to all new and current users of brodalumab (Siliq).

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

Manual PA criteria:
If automated criteria are not met, coverage is approved for Siliq if:

- Contraindications exist to Humira and Cosentyx
- Inadequate response to Humira and Cosentyx
- Adverse reactions to Humira and Cosentyx not expected with Siliq.

AND

Coverage approved for patients > 18 years with:

- Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy AND
- The patient does NOT have suicidal ideation and behavior

Coverage NOT provided for concomitant use with other TIBs including but not limited to, Humira, Kineret, Cimzia, Enbrel, Simponi, Remicade, Orencia, Actemra, Xeljanz, Stelara, Otezla, or Rituxan, Cosentyx, and Taltz.

Off-label uses are NOT approved.

Prior Authorization expires in 6 months

Renewal PA Criteria: After 6 months, PA must be resubmitted. Continued use of Siliq will be allowed if the patient has responded to therapy and has not exhibited suicidal ideation and behavior.

2. sarilumab (Kevzara) – TIBs

Step therapy and Manual PA Criteria apply to all new and current users of Kevzara.

Automated PA criteria: The patient has filled a prescription for 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 Kevzara 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
- There is no formulary alternative: patient requires a non-TNF TIB for symptomatic congestive heart failure

AND

Coverage approved for patients > 18 years with:

- Moderate to severe active rheumatoid arthritis who have had an inadequate response to > 1 disease modifying anti-rheumatic drugs (DMARDs)

Coverage is NOT provided for concomitant use with other TIBs.

Off-label uses are not approved, including uveitis, polyarticular and systemic juvenile idiopathic arthritis (JIA) or ankylosing spondylitis

PA does not expire.

3. midostaurin (Rydapt) – Oral Oncologic Agents

Manual PA criteria apply to all new users of Rydapt.

Manual PA criteria—Rydapt is approved if:

- Patient is ≥ 18 AND
- Rydapt is being prescribed by or in consultation with a hematologist/ oncologist

AND

- Patient uses Rydapt in combination with standard chemotherapy protocols AND

- Patient has a diagnosis of Acute Myelogenous Leukemia (AML) and FLT3 mutation as determined by FDA-approved test OR
- Patient has a diagnosis of advanced systemic mastocytosis (aggressive systemic mastocytosis; systemic mastocytosis associated with hematologic neoplasm) or mast cell leukemia

Off-label uses are not approved.

PA expires in 1 year.

Renewal Manual PA criteria: Rydapt is approved indefinitely for continuation of therapy if patient has documented clinical and/or symptom improvement.

4. ribociclib/letrozole (Kisqali Femara Co-Pack) – Oral Oncologic Agents

Manual PA criteria apply to all new users of Kisqali-Femara.

Manual PA criteria—Kisqali-Femara is approved if:

- Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND
- Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer

Off-label uses are not approved.

PA does not expire.

5. prasterone (Intrarosa) – Vaginal Lubricants

Manual PA criteria apply to all new users of Intrarosa.

Manual PA criteria—Intrarosa coverage approved for one year if all criteria are met:

(1) Patient is a post-menopausal woman with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy.
(2) Patient has tried and failed a low dose vaginal estrogen preparation (e.g., Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem).
(3) Patient does not have any of the following:
    a. Undiagnosed abnormal genital bleeding
    b. Pregnant or breastfeeding
    c. History of breast cancer or currently have breast cancer
(4) Use of Intrarosa will be for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be reevaluated periodically as clinically appropriate to determine if treatment is still necessary.

Off-label uses are not approved.

PA expires in 1 year.

PA Renewal criteria: PA is approved indefinitely if the patient has had improvement in the severity of dyspareunia symptoms.

6. safinamide (Xadago) – Parkinson's Disease Drugs

Manual PA criteria apply to all new users of Xadago.

Manual PA Criteria: Coverage approved if all criteria are met:

(1) Patient is ≥ 18 years old AND
(2) Patient has a diagnosis of Parkinson's disease AND
(3) Patient has tried and failed rasagiline or selegiline AND
(4) Xadago is used as an adjunct to levodopa/carbidopa or a dopamine agonist.

Off-label uses are NOT approved.

PA does not expire.

7. valbenazine (Ingrezza) – Neuromuscular Miscellaneous Agents

Manual PA criteria apply to all new users of Ingrezza.

Manual PA Criteria: Coverage approved if all criteria are met:

(1) Age > 18 years
(2) Prescribed by or in consultation with a neurologist or psychiatrist
(3) Patient has moderate to severe tardive dyskinesia along with schizophrenia, schizoaffective disorder, or a mood disorder
(4) Patient does not have congenital long QT syndrome or arrhythmias associated with QT prolongation
(5) Patient has had an adequate trial of or has a contraindication to tetrabenazine or deutetrabenazine
(6) Provider has considered use of clonazepam and ginkgo biloba
(7) Patient is not taking any of the following:
    - MAOI inhibitor
    - Another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine)
    - CYP3A4 inducers

Off-label uses are NOT approved.
PA does not expire.

8. dronabinol (Syndros) – Antiemetic and Antivertigo Agents

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

Manual PA criteria—Syndros is approved if all criteria are met:

- Patient is ≥ 18 years old AND
- Patient cannot take dronabinol capsule due to swallowing difficulties AND
- Patient has chemotherapy-induced nausea and vomiting that has not responded to therapy with other antiemetics, including 5HT3 antagonists (ondansetron, granisetron), substance P/neurokinin (NK1) receptor antagonists (aprepitant), benzodiazepine, metoclopramide, phenothiazines (promethazine or prochlorperazine), or dexamethasone OR

- Patient has weight loss due to acquired immune deficiency syndrome (AIDS) and has not responded to steroids or megestrol

Off-label uses are NOT approved, including use as an opioid-sparing agent for patient receiving opioids

PA does not expire.

9. fluticasone/salmeterol (AirDuo RespiClick) – ICS/LABAs

PA criteria apply to all new and current users of AirDuo RespiClick who are 12 years of age or older.

Note that AirDuo will not be part of the current automated step therapy for the ICS/LABA oral inhalers; separate manual PA will be required.

Manual PA criteria—AirDuo RespiClick is approved if:

- Patient has a diagnosis of asthma AND
- Patient is older than 12 years of age AND
- Patient requires salmeterol as the LABA component and requires the lower dose found in AirDuo versus Advair Diskus or HFA OR
- Patient requires fluticasone/salmeterol and cannot manipulate the Advair Diskus or Advair HFA metered dose inhaler

Off-label uses are NOT approved.

PA does not expire.

10. methotrexate (Xatmep) oral solution – Antirheumatic Drugs

PA criteria apply to all new and current users of Xatmep.

Automated PA criteria

- Xatmep will be approved for patients 12 years of age and younger.

Manual PA criteria—Manual PA criteria apply if the patient is older than 12 years of age. Xatmep is approved if:

- The patient must have a diagnosis of acute lymphoblastic leukemia (ALL) or active polyarticular juvenile idiopathic arthritis (pJIA); AND
- The patient has a history of difficulty swallowing tablets or has a medical condition that is characterized by difficulty swallowing or inability to swallow

Off-label uses are not approved.

PA does not expire.

11. mixed amphetamine salts ER (Mydayis) – ADHD Drugs

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

Manual PA criteria—Mydayis is approved if all criteria are met:

- Patient is 13 years of age or older AND
- Patient has a diagnosis of ADHD AND
- Patient has tried and failed generic Adderall XR AND
- Patient has tried and failed generic Concerta

Off-label uses are NOT approved.
PA does not expire.

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

The P&T Committee recommended (Day 1: 14 for, 0 opposed, 1 abstained, 0 absent; Day 2: 13 for, 0 opposed, 1 abstained, 1 absent) an effective date upon the first Wednesday after the signing of the minutes in all points of service.

IX. NEWLY-APPROVED DRUGS PER CFR 199.21(g)(5)

BAP Comments

A. Newly-Approved Drugs per CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended the following:

- **UF**:
  - Alunbrig
  - Xatmep
  - Rydapt
  - Zejula
  - Intrarosa
  - Kisqali Femara Co-Pack
- **NF:**
  - Tymlos
  - Siliq
  - Syndros
  - AirDuo RespiClick
  - Mydayis
  - Morphabond XR
  - Xadago
  - Kevzara
  - Ingrezza

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Newly-Approved Drugs per CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended the following:

- Applying the same manual PA criteria for Kevzara and Siliq in new and current users, as is currently in place for the other non step-preferred TIBs. Patients must first try Humira. Additionally, for Siliq a trial of Cosentyx is required if the patient cannot be treated with Humira.

- Applying PA criteria to new users of Rydapt, Kisqali Femara Co-Pack, Intrarosa, Xadago, and Ingrezza.

- Applying PA criteria to new and current users of Syndros, AirDuo RespiClick, Xatmep, and Mydayis.

The full PA criteria for these newly-approved agents were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Newly-Approved Drugs per CFR 199.21(g)(5)—UF and PA Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

X. UTILIZATION MANAGEMENT—TIBs

P&T Comments

A. TIBs: Guselkumab (Tremfya)—New 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. Adalimumab (Humira) was selected as the UF step-preferred agent. Guselkumab (Tremfya) is the fifth TIB approved for treating moderate to severe psoriasis; it will be reviewed for formulary status as a newly-approved drug at an upcoming meeting.

The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) and manual PA criteria for Tremfya, in new and current users, to require a trial of adalimumab (Humira) first, consistent with the existing step therapy criteria for the TIBs Drug Class.

Full PA Criteria:

Step therapy and Manual PA Criteria apply to all new and current users of guselkumab (Tremfya).

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 Tremfya if:

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

AND

Coverage approved for patients ≥ 18 years with:

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

Prior Authorization does not expire.

Non-FDA approved uses are not approved.

Coverage is NOT provided for concomitant use with other TIBs.

B. TIBs: Guselkumab (Tremfya)—Manual PA Implementation Plan

The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) that the new step therapy and manual PA for Tremfya become effective on the first Wednesday after a 90-day implementation period in all points of service.

XI. UTILIZATION MANAGEMENT—TIBs

BAP Comments

A. TIBs: Tremfya—New Manual PA Criteria

The P&T Committee recommended automated (step therapy) and manual PA criteria for Tremfya, in new and current users, to require a trial of Humira first, consistent with the existing step therapy criteria for the TIBs Drug Class.

The full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. TIBs: Tremfya—Manual PA Implementation Plan

The P&T Committee recommended that the new step therapy and manual PA for Tremfya become effective on the first Wednesday after a 90-day implementation period in all points of service.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XII. UTILIZATION MANAGEMENT—GI-2 AGENTS FOR OPIOID-INDUCED CONSTIPATION (OIC)

P&T Comments

A. GI-2 Agents for OIC: Naloxegol (Movantik) and Methylnaltrexone (Relistor)—Manual PA Criteria

The GI-2 drugs were previously reviewed for UF status in November 2015, and the chloride channel activator lubiprostone (Amitiza) was selected for UF status. Naloxegol (Movantik) and methylnaltrexone (Relistor) are peripherally-acting mu opioid receptor antagonists (PAMORAs) approved for OIC. OIC treatment guidelines list lifestyle modifications and

laxatives as first line treatment, with PAMORAs and chloride channel activators are recommended as second-line agents.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Movantik and Relistor in all new and current users, requiring a trial of Amitiza first.

Full PA Criteria:

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

Manual PA criteria: Coverage will be approved if:

- The patient is ≥ 18 years with a diagnosis of OIC;
  AND
- The patient is concurrently taking an opioid agonist and is not receiving other opioid antagonists; AND
- The patient has failed or is unable to tolerate two or more of the following:
  - At least one stimulant laxative (e.g., sennosides or bisacodyl)
  - At least one osmotic laxative (e.g., MiraLAX, lactulose, or magnesium citrate); AND
- The patient has failed therapy with lubiprostone (Amitiza); AND
- The patient does not have a known or suspected GI obstruction or is not at increased risk of recurrent obstruction); AND
- The patient is not currently on strong CYP3A4 inducers

Non-FDA approved uses are not approved.

Prior authorization does not expire.

B. GI-2 Agents for OIC: Naloxegol (Movantik) and Methylnaltrexone (Relistor)—PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) that the new manual PAs for Movantik and Relistor become effective on the first Wednesday after a 90-day implementation period in all points of service.

XIII. UTILIZATION MANAGEMENT—GI-2 AGENTS FOR OIC

BAP Comments

A. GI-2 Agents for OIC: Movantik and Relistor— Manual PA Criteria

The P&T Committee recommended manual PA criteria for Movantik and Relistor in all new and current users, requiring a trial of Amitiza first. The full PA criteria were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. GI-2 Agents for OIC: Movantik and Relistor—PA Implementation Plan

The P&T Committee recommended that the new manual PAs for Movantik and Relistor become effective on the first Wednesday after a 90-day implementation period in all points of service.

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

XIV. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA AND STEP THERAPY

P&T Comments

A. Updated Manual PA Criteria

Updates to the step therapy and manual PA criteria for several drugs were recommended by the Committee due to a variety of reasons, including expanded FDA indications. Updated manual PA will apply to new users.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for Aczone, Actemra, Xiidra, Eucrisa, Nexium delayed release packets for suspension, and the step therapy and manual PA changes for the SGLT2 inhibitors.

1. Acne Agents—Topical Acne and Rosacea Agents: Dapsone Gel 5% and 7.5% (Aczone)

Aczone was reviewed in August 2016 with step therapy and manual PA criteria recommended. Current clinical practice guidelines for acne specify women over the age of 18 as the group who gain the most benefit from Aczone. However, the Aczone package insert states the drug is approved for patients 13 years of age and older. The manual PA criteria were updated to reflect the labeled indication. Note that there are no changes recommended for the existing step therapy criteria.

Updated PA Criteria

Changes from August 2017 meeting are in bold and strikethrough. See the August 2016 meeting minutes for the complete automated PA criteria implemented on February 8, 2017.

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

- Patient is ~~**an adult female**~~ **≥ 13 years** with a diagnosis of inflammatory acne

2. **TIBs: Tocilizumab (Actemra)**—PA criteria were updated for tocilizumab (Actemra) to allow for the new indication for giant cell arteritis.

   Updated PA Criteria

   Changes from August 2017 meeting are in bold. See the August 2014 meeting minutes for the full automated PA criteria implemented on February 18, 2014.

   Manual PA criteria:

   Coverage approved for patients ≥ 18 years with:

   - **Adult patients with giant cell arteritis**

3. **Ophthalmic Immunomodulatory Agents: Lifitegrast (Xiidra)**—Xiidra was reviewed as a new drug in November 2016 with manual PA criteria recommended. Criteria were updated to have an expiration date of one year, similar to what is in place for cyclosporine (Restasis).

   Updated PA Criteria

   Changes from August 2017 meeting are in bold.

   ~~PA does not expire~~ PA expires in one year.

   Renewal PA Criteria: After one year, PA must be resubmitted. Coverage approved indefinitely if:

   - **Patient must have documented improvement in signs of dry eye disease as measured by at least one of the following:**
     - **decrease in corneal fluorescein staining score OR**
     - **increase in number of mm per 5 minutes using Schirmer's tear test in comparison to original scores AND**
   - **Patient has documented improvement in ocular discomfort AND**
   - **Patient is not using Xiidra and Restasis as combination therapy.**

4. **Corticosteroids – Immune Modulators: Crisaborole (Eucrisa)**—Eucrisa was reviewed for formulary status in May 2017. The manual PA criteria were updated to allow for prescribing by allergists or immunologists, in addition to dermatologists.

   Updated PA Criteria

   Changes from August 2017 meeting are in bold.

   Manual PA Criteria: coverage will be approved if:

   - Prescribed by a dermatologist, **allergist or immunologist**

5. **Proton Pump Inhibitors (PPIs): Esomeprazole Delayed Release Packets for Suspension (Nexium Packets)** Esomeprazole (Nexium) was designated NF and non step-preferred at an interim meeting in March 2017; a trial of at least three formulary step-preferred products is required prior to use of Nexium. Nexium delayed release packets for suspension are approved for patients as young as one month of age, and are also approved for use in patients with percutaneous endoscopic gastrostomy (PEG) tubes. The Nexium PA criteria were revised to allow use of the delayed release packets for suspension in patients younger than five years and in patients with PEG tubes.

   Updated PA Criteria

   Changes from August 2017 meeting are in bold. See the February 2017 Interim Meeting minutes for complete automated PA criteria implemented on June 28, 2017.

   Manual PA criteria: A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole (Aciphex, generics) is NOT required if:

   - **For esomeprazole delayed release packets for suspension only:**
     - **The patient is younger than 5 years of age.**

   OR

     - **The patient requires a PEG tube.**

6. **Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors Step Therapy and Manual PA Criteria**—Existing PA criteria for the SGLT2 inhibitors requires a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses. The P&T Committee recommended simplifying the step therapy and manual PA requirements for the SGLT2 inhibitors. All new users of SGLT2 inhibitors are required to try only metformin unless contraindications exist. Empagliflozin remains the preferred agent within the SGLT2 inhibitor class.

   The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for Aczone, Actemra, Xiidra, Eucrisa, Nexium delayed release packets for suspension, and the step therapy and manual PA changes to the SGLT2 inhibitors.

   Updated PA Criteria

   Changes from August 2017 meeting are in strikethrough.

   All new users of an SGLT2 inhibitor are required to try metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin ~~or a sulfonylurea (SU) and a DPP-4 inhibitor~~ first.

Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first.

Automated PA criteria

- The patient has filled a prescription for metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days.

  OR

- The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days.

  AND

Manual PA criteria—If automated PA criteria are not met, Jardiance or Glyxambi is approved (e.g., a trial of metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ ~~are~~ is NOT required) if:

- The patient has had an inadequate response to metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~; or
- The patient has experienced a significant adverse effect from metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~;

  or
- The patient has a contraindication to metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~.

B. Updated Manual PA Criteria and Step Therapy—Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) updates to the current PAs for Aczone, Actemra, Xiidra, Eucrisa, Nexium Packets and the step therapy and manual PA for the SGLT2 inhibitors become effective upon signing of the minutes in all points of service.

XV. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA AND STEP THERAPY

BAP Comments

A. Updated Manual PA Criteria

The P&T Committee recommended updates to the manual PA criteria for Aczone, Actemra, Xiidra, Eucrisa, Nexium delayed release packets for suspension, and the step therapy and manual PA changes for the SGLT2 inhibitors. The updates were stated previously.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Updated Manual PA Criteria and Step Therapy—Implementation Plan

The P&T Committee recommended updates to the current PAs for Aczone, Actemra, Xiidra, Eucrisa, Nexium Packets and the step therapy and manual PA for the SGLT2 inhibitors become effective upon signing of the minutes in all points of service.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XVI. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

P&T Comments

A. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee reviewed one drug from a pharmaceutical manufacturer that was not included on a DoD Retail Refund Pricing Agreement; this drug was 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 (15 for, 0 opposed, 0 abstained, 0 absent) the following product be designated NF on the UF:

- Canton Labs: naproxen sodium (Naprosyn) 500 tablet

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

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following pre-authorization criteria for Naprosyn:

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 points of service other than retail network pharmacies.

C. Section 703, NDAA FY08—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 for Naprosyn and DHA send letters to beneficiaries affected by this decision.

XVII. SECTION 703, NDAA FY08

BAP Comments

A. Section 703, NDAA FY08—Drugs Designated NF

The P&T Committee recommended Naprosyn be designated NF on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

B. Section 703 NDAA FY08—Pre Authorization Criteria

The P&T Committee recommended the pre authorization criteria for Naprosyn as previously presented.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

C. Section 703, NDAA FY08—Implementation Plan

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XVIII. PRENATAL VITAMINS AND OTHER PRODUCTS LOSING PRESCRIPTION STATUS IN FIRST DATABANK

P&T Comments

A. Prenatal Vitamins and Other Products—UF Recommendation and Implementation Plan

The P&T Committee discussed a list containing 694 National Drug Codes (NDCs) that the First Databank drug database will transition from designation as prescription drugs to non–prescription items in January 2018. The affected agents are primarily prenatal vitamins containing folic acid but also include various urinary pH modifiers and prescription fluoride or zinc products. The action resulted from an FDA guidance regarding medical foods in September 2016.

The P&T Committee recommended temporarily continuing coverage for the affected drugs under the TRICARE pharmacy benefit, to allow adequate time for a full evaluation and to dovetail with current efforts to standardize non-prescription items supplied by MTFs (both across MTFs and across MHS points of service).

The issue of prenatal vitamins was specifically considered by the Committee. Prenatal vitamins are a low-cost intervention known to improve outcomes by preventing neural tube defects and providing adequate iron stores to prevent anemia and decrease nausea and vomiting during pregnancy. U.S. Preventive Services Task Force guidelines recommend that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg of folic acid (Grade A recommendation). Therefore, continued coverage of prenatal vitamins is highly desirable in order to ensure uninterrupted access to essential care. The P&T Committee further noted that provision of prenatal vitamins as part of the TRICARE pharmacy benefit is more important for the MHS than civilian health plans, given worldwide assignment of female service members and beneficiaries to countries with variable availability of food products fortified with folic acid.

The P&T Committee also recommended standardizing the availability of prenatal vitamins across the MHS points of service (retail, mail order, and MTFs). The highest volume, most cost effective options that would provide a variety of formulations to meet the clinical needs of beneficiaries were identified, with the selected products comprising 91% of the dispensed prescriptions.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following, effective upon signing of the minutes:

1. **Classes other than the Prenatal Vitamins**: Temporarily continuing coverage for products on the list of 694 NDCs losing prescription status in classes other than prenatal vitamins, to allow time for full evaluation and review for standardization.

2. **Prenatal Vitamins:** Adding the following 8 products (by brand name) to the over-the-counter (OTC) program: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi + DHA, Prenatal Vitamin +

Low Iron, and Prenatal Plus DHA to standardize availability across the MHS. (Note: Some of these brand names may be used by multiple manufacturers; the intent is to select the lowest cost, highest value products that provide the same formulations.)

3. Evaluating statutory and/or regulatory authorities to address continued coverage of selected vitamins and other products when considered to be clinically and cost effective.

XIX. PRENATAL VITAMINS AND OTHER PRODUCTS LOSING PRESCRIPTION STATUS IN FIRST DATABANK

BAP Comments

A. Prenatal Vitamins and Other Products—UF Recommendation and Implementation Plan

The P&T Committee recommended the following, effective upon signing of the minutes:

1. **Classes other than the Prenatal Vitamins**: Temporarily continuing coverage for those products losing prescription status in classes other than prenatal vitamins.

2. **Prenatal Vitamins:** Adding the following products to the over-the-counter) program: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi + DHA, Prenatal Vitamin + Low Iron, and Prenatal Plus DHA.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

XX. NDAA 2017 PILOT PROGRAM: INCORPORATION OF VALUE-BASED HEALTH CARE IN PURCHASED CARE COMPONENT OF TRICARE AND MEDICATION ADHERENCE

P&T Comments

A. NDAA 2017 Pilot Program—Committee Recommendation and Implementation Plan

A pilot program outlined in the NDAA 2017 requires identification of high-value medications where copayments or cost shares would be reduced for targeted populations of covered beneficiaries. The Committee identified rosuvastatin (Crestor generics) and insulin glargine (Lantus) as candidates for inclusion in the pilot, which is intended to assess the effects of copayment reduction or elimination on medication adherence rates. Implementation was recommended for January 1, 2018, to align with currently recommended regulatory language.

The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) the following:

- Rosuvastatin: Eliminating the cost share for rosuvastatin at the Mail Order and Retail point of service; the resulting cost share will be $0.
- Insulin Glargine (Lantus): Lowering the normal brand formulary cost share of $20 at the Mail Order and $24 at the Retail Network to the Tier 1 (generic) formulary cost share that is currently $0 and $10, respectively.

XXI. NDAA 2017 PILOT PROGRAM: INCORPORATION OF VALUE-BASED HEALTH CARE IN PURCHASED CARE COMPONENT OF TRICARE AND MEDICATION ADHERENCE

BAP Comments

NDAA 2017 Pilot Program—Committee Recommendation and Implementation Plan

The P&T Committee recommended the following:

- Rosuvastatin: Eliminating the cost share for rosuvastatin at the Mail Order and Retail point of service; the resulting cost share will be $0.
- Insulin Glargine (Lantus): Lowering the normal brand formulary cost share of $20 at the Mail Order and $24 at the Retail Network to the Tier 1 (generic) formulary cost share that is currently $0 and $10, respectively.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissension

Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implement Date	Notes and Unique Users Affected
Aug 2017	**Basal Insulin Analogs**	UF Class Review Previously reviewed Feb 2010	**UF Step-Preferred** ▪ glargine pen and vial (Lantus) **UF Non Step-Preferred** ▪ detemir vial (Levemir) ▪ glargine 300 U/mL (Toujeo)	**NF Non Step-Preferred** ▪ degludec (Tresiba) ▪ detemir pen (Levemir) ▪ glargine 100 U/mL (Basaglar)	30 days	▪ Manual PA required. Must try Lantus first in all new users of Toujeo, Tresiba, Basaglar, and Levemir Unique Users Affected Not applicable since only new users affected by PA, and current NF drugs remain NF
Aug 2017	**Corticosteroids - Immune Modulators Drug Class - Hereditary Angioedema (HAE) Subclass**	UF Class review Class not previously reviewed	▪ plasma-derived human C1 esterase inhibitor IV (Cinryze) ▪ plasma-derived human C1 esterase inhibitor IV (Berinert) ▪ recombinant C1 esterase inhibitor IV (Ruconest) ▪ icatibant SQ (Firazyr)	None	30 days	▪ Manual PA required. New patients must try attenuated androgen (Danazol) prior to use of Cinryze or Haegarda Unique Users Affected Not applicable - PA applies only to new users
Aug 2017	**Antiretroviral Agents for HIV**	UF Class Review	All HIV drugs marketed in the U.S. as of August 2017 were recommended for UF status, as listed on pages 12–13 of this document.	▪ None	Upon signing	

August 2017 Drugs with New Prior Authorization Criteria—Unique Utilizers Affected Per Drug

Drug	MTF	Mail Order	Retail	Total
Targeted Immunomodulatory Biologics (TIBs) — Guselkumab (Tremfya)	0	0	0	0
GI-2 Agents for Opioid Induced Constipation (OIC) — Naloxegol (Movantik)	356	1,752	1,912	4,020
GI-2 Agents for Opioid Induced Constipation (OIC) — Methylnaltrexone (Relistor)	38	154	249	441