

EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP) September 21, 2017

I. UNIFORM FORMULARY DRUG CLASS REVIEWS

A. BASAL INSULIN ANALOGS

1. Basal Insulin Analogs – UF Recommendation

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

- **UF and Step-Preferred:**
 - a) insulin glargine pen and vial (Lantus)

- **UF and Non Step-Preferred**
 - a) insulin detemir vial (Levemir)
 - b) insulin glargine 300 U/mL (Toujeo)

- **NF and Non Step-Preferred:**
 - a) insulin detemir pen (Levemir)
 - b) insulin degludec (Tresiba)
 - c) 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.

2. 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 . The PA previously limited use to patients 18 years and older.

- **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.

PA does not expire.

3. 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.

Summary of Physician's Perspective:

The major recommendation here is that now Lantus will be the preferred basal insulin. There is no change in the drugs recommended for non-formulary status. Tresiba, Levemir pens, and Basaglar are currently NF, and we have about 14,500 patients receiving them. What is changing is that the step therapy will require all new patients to try Lantus first. The patients currently receiving a drug other than Lantus will be grandfathered, and won't be required to have a trial of Lantus.

For special populations, a pediatric endocrinologist at the meeting mentioned that for children, Lantus is preferred since it is a once daily injection and parents don't have to worry about variability in daily routines. However, the Prior Authorization criteria for Tresiba does allow use for children down to the age of one year, which is in the package insert.

For pregnant patients, the PA for the Levemir pens does allow use in this situation, since Levemir has a pregnancy category B rating. However the Ob-Gyn on the Committee commented that most pregnant patient requiring insulin are treated with NPH insulin.

Overall, the formulary recommendation is consistent with the utilization patterns we already have in the MHS, since Lantus accounts for 80% of the basal insulin prescriptions. Having Lantus as the preferred basal insulin also meets the requests from the provider survey.

Summary of Panel Questions and Comments:

Mr. Du Tiel stated he doesn't see anything wrong with the recommendation from the P&T. He asked if there was a reason for the abstention vote.

Dr. Kugler responded that the committee members are allowed to abstain from voting on a particular class of drugs. Members are not asked to make a statement about why they abstain. It is usually an individual on the committee who chooses not to participate in a final formulary recommendation on a specific drug class.


Dr. Anderson states in his experience this is common to see management like this in this drug class. I've seen private insurers go with one product or another. Some go with Basaglar. Some go with Lantus. It is very reasonable. For utilization purposes, many prefer Lantus.

There were not more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation for the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Basal Insulin Analogs.

- **Basal Insulin Analogs - UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

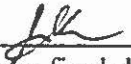
Director, DHA:

 These comments were taken under consideration prior to my final decision

- **Basal Insulin Analogs - Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3


Director, DHA:

 These comments were taken under consideration prior to my final decision

- **Basal Insulin Analogs - UF and PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision

**B. CORTICOSTEROIDS – IMMUNE MODULATORS DRUG CLASS:
HEREDITARY ANGIOEDEMA (HAE) AGENTS SUBCLASS**

**1. Corticosteroid – 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:**
 - a) plasma-derived human C1 esterase inhibitor IV (Cinryze)
 - b) plasma-derived human C1 esterase inhibitor IV (Berinert)
 - c) recombinant C1 esterase inhibitor IV (Ruconest)
 - d) 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.

2. Corticosteroid – 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
 - a) 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
 - b) Patient is female of childbearing age
- Cinryze or Haegarda is not approved for any indication other than HAE.
- PA does not expire.

3. 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.

Summary of Physician's Perspective:

There are an increasing number of drugs for rare conditions receiving FDA approval, and this was our first attempt at reviewing a drug class in this specialty market.

For HAE determining a typical treatment course is difficult, due to the variation in the numbers of edema episodes per person, and the differences in the dosing between products. The recommendation was unanimous to have all the agents be designated as Uniform Formulary.

A PA was recommended for the drugs used for prophylaxis of edema episodes (Cinryze and Haegarda). Due to the adverse effect profile, women and patients with a history of cardiovascular events will not be required to try Danazol first. The PA does follow the recommendations from the allergy/immunology consultants, and also is consistent with professional guidelines.

Summary of Panel Questions and Comments:

Mr. Hostettler asked how many patients have HAE.

Lt Col Khoury responded that the number is very low. It is under 100. I am not mistaken the number is approximately 70.

Mr. Hostettler asked with the number so low, is the manual PA necessary.

Lt Col Khoury responded that based on the 70 identified and assessed; there were significant and wide distributions in patterns of use and not always within available guidelines.

Mr. Hostettler asked if they are being treated by specialists.

Lt Col Khoury stated that specialty designation is not currently identified for those prescribers/prescriptions.


Mr. Hostettler said being treated by a specialist would be his suggestion to be the only criteria.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass.

- **Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass – UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

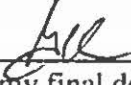
Director, DHA:

 These comments were taken under consideration prior to my final decision

- **Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass – Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

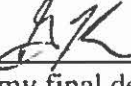
Director, DHA:

 These comments were taken under consideration prior to my final decision

- **Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass – UF and PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision

Additional Panel Questions and Comments:

Lt Col Khoury provided a clarification regarding HAE. He said 71, but it's actually 91. Since 2016, there were 91 unique utilizers. Since 2010, there have been 151 unique utilizers prescribed these agents.

Mr. Hostettler thanked him.

C. HUMAN IMMUNODEFICIENCY VIRUS (HIV)

1. 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:**
 - a) Aptivus (tipranavir)
 - b) Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
 - c) Combivir (lamivudine/zidovudine)
 - d) Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)**
 - e) Crixivan (indinavir)
 - f) Descovy (emtricitabine/tenofovir alafenamide)**
 - g) Edurant (rilpivirine)
 - h) Emtriva (emtricitabine)
 - i) Epivir (lamivudine)
 - j) Epzicom (abacavir/lamivudine)
 - k) Evotaz (atazanavir/cobicistat)
 - l) Fuzeon (enfuvirtide)
 - m) Genvoya (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide)**
 - n) Intelence (etravirine)
 - o) Invirase (saquinavir)
 - p) Isentress (raltegravir)
 - q) Isentress HD (raltegravir extended-release)**
 - r) Lexiva (fosamprenavir)
 - s) Kaletra (lopinavir/ritonavir)
 - t) Norvir (ritonavir)**
 - u) Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)**
 - v) Prezcobix (darunavir/cobicistat)
 - w) Prezista (darunavir)**
 - x) Rescriptor (delavirdine)
 - y) Retrovir (zidovudine)
 - z) Reyataz (atazanavir)
 - aa) Selzentry (maraviroc injection and oral solution)**
 - bb) Stribild (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)**
 - cc) Sustiva (efavirenz)
 - dd) Tivicay (dolutegravir)**
 - ee) Triumeq (abacavir/dolutegravir/lamivudine)**
 - ff) Trizivir (abacavir/lamivudine/zidovudine)
 - gg) Truvada (emtricitabine/tenofovir disoproxil fumarate)**
 - hh) Tybost (cobicistat)

- ii) Videx EC (didanosine delayed-release)
- jj) Videx Pediatric (didanosine)
- kk) Viracept (nelfinavir)
- ll) Viramune (nevirapine)
- mm) Viramune XR (nevirapine ER)
- nn) Viread (tenofovir disoproxil fumarate)
- oo) Zerit (stavudine)
- pp) Ziagen (abacavir)

- NF: None

2. 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.

Summary of Physician's Perspective:

The HIV drugs had not previously been reviewed for formulary status. The recommendation was to have all the drugs as UF. Many older agents are not the current clinical choice of therapy however, for patients already stabilized on these medications or experiencing resistance to first-line agents, an increase in co-pay is not justifiable.

The Committee recognized that selecting the most appropriate HIV agent for a patient depends on several factors, including resistance patterns, rapidly changing treatment guidelines, patient co-morbidities, and individual drug-drug interaction profiles.

Summary of Panel Questions and Comments:

Mr. Hostettler asked if there are any specific programs to monitor adherence for the patient population affected by this drug class.


CAPT VonBerg stated that we have providers centered in locations for HIV. These centers keep the patients and providers informed at the MTFs. The network care systems have indirect programs that can help with refills.

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

- **HIV – UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3


Director, DHA:

 These comments were taken under consideration prior to my final decision

- **HIV – UF and PA Implementation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision

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

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

1. Newly-Approved Drugs per CFR 199.21 – 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:**
 - a) brigatinib (Alunbrig) – Oral Oncologic Agents for Lung Cancer
 - b) methotrexate (Xatmep) oral solution – Antirheumatic Drugs
 - c) midostaurin (Rydapt) – Oral Oncologic Agents for Acute Myeloid Leukemia (AML)
 - d) niraparib (Zejula) – Oral Oncologic Agents for Ovarian Cancer
 - e) prasterone (Intrarosa) vaginal insert – Vaginal Lubricants
 - f) ribociclib/letrozole (Kisqali Femara Co-Pack) – Oral Oncologic Agents for Breast Cancer

- **NF:**
 - a) abaloparatide (Tymlos) injection – Osteoporosis Agents
 - b) brodalumab (Siliq) injection – Targeted Immunomodulatory Biologics (TIBs)
 - c) dronabinol (Syndros) oral solution – Antiemetic and Antivertigo Agents
 - d) fluticasone/salmeterol (AirDuo RespiClick) oral inhaler – Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)
 - e) mixed amphetamine salts ER (Mydayis) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
 - f) morphine sulfate ER (Morphabond XR) – Narcotic Analgesics
 - g) safinamide (Xadago) – Parkinson’s Disease Drugs
 - h) sarilumab (Kevzara) injection – TIBs
 - i) valbenazine (Ingrezza) – Neuromuscular Miscellaneous Agents

2. 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)

a. 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:

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

AND

Coverage approved for patients > 18 years with:

- a) Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy AND
- b) 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.

b. 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:

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

AND

Coverage approved for patients > 18 years with:

- a) 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.

c. midostaurin (Rydapt) – Oral Oncologic Agents

Manual PA criteria apply to all new users of Rydapt.

Manual PA criteria—Rydapt is approved if:

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

AND

- a) Patient uses Rydapt in combination with standard chemotherapy protocols AND
- b) Patient has a diagnosis of Acute Myelogenous Leukemia (AML) and FLT3 mutation as determined by FDA-approved test OR
- c) 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.

d. 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:

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

Off-label uses are not approved.

PA does not expire.

e. 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.

f. 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:

- Patient is \geq 18 years old AND
- Patient has a diagnosis of Parkinson’s disease AND
- Patient has tried and failed rasagiline or selegiline AND
- Xadago is used as an adjunct to levodopa/carbidopa or a dopamine agonist.

Off-label uses are NOT approved.

PA does not expire.

g. 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:

- a) Age > 18 years
- b) Prescribed by or in consultation with a neurologist or psychiatrist
- c) Patient has moderate to severe tardive dyskinesia along with schizophrenia, schizoaffective disorder, or a mood disorder
- d) Patient does not have congenital long QT syndrome or arrhythmias associated with QT prolongation
- e) Patient has had an adequate trial or has failed or has a contraindication to tetrabenazine or deutetrabenazine
- f) Provider has considered use of clonazepam and ginkgo biloba
- g) 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.

h. 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 \geq 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.

i. 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.

j. 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.

k. 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.

3. 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.

Summary of Physician’s Perspective:

There were 15 newly approved drugs. For drugs in disease states that have not been previously reviewed for formulary status, we do consult with the specialists to get their input, especially if PA criteria are recommended. If non-formulary status is recommended for a new drug, there are alternative therapies available that are clinically effective or cost effective.

There was one drug where Uniform Formulary status was recommended prior to the August meeting. Rydapt is the first oral drug approved for

AML. We have administrative authority to grant Tier 2 status to new drugs where there are no formulary alternatives or clinical comparators. The Committee then saw the full clinical and cost review at the meeting.

PA criteria was recommended for 11 new drugs.

- a) The PAs for the two TIBs drugs (Siliq for psoriasis and Kevzara for arthritis) were recommended since there is already step therapy in the class. The PA for Siliq took the suicidal ideation concern into consideration. The oral inhalers for asthma and COPD also have step therapy requirements, so the Air Duo inhaler was placed behind the step.
- b) The PAs for two of the oncology drugs (Kisqali co-pack and Rydapt) reflect their FDA approved indications.
- c) PAs were also recommended for the antiemetic (Syndros) and the ADHD drug (Mydayis), due to the risk for off-label use, and since there are cost effective drugs already available that have been reviewed by the P&T committee. For Syndros, the PA and non-formulary status were recommended due to the availability of alternative antiemetics, the fact that Syndros is a schedule II drug, and the high alcohol content.

Summary of Panel Questions and Comments:

Dr. Bertin stated he's a new member of this group and asked a procedural question. In terms of the PAs that are seen here, what actually happens when a patient is newly diagnosed with one of these conditions; gets a prescription from the physician; goes to retail networks?

CAPT VonBerg responded that the prescription is sent to the pharmacy and the pharmacy receives a notification that prior authorization is required. Either the patient or the pharmacy contacts the doctor for that request. That PA information is transmitted to the contracted pharmacy benefits manager who then lets the MTF or network pharmacy know of the approval.

Lt Col Khoury stated that typically on the commercial side, most of the medications, especially the oncological ones, the providers do not involve themselves in the PA process. There are very structured formats for acknowledging the insurance that covers the patients and identifying the requirements for that insurance to complete that paperwork as part of the prescriptions that they submit. Often times, in oncology drugs, the patients won't go down to the pharmacy because of distribution issues. A beneficiary can't just go to a corner store like CVS and pick up an agent

that costs \$15,000. There has to be a procedure in place to ensure they can obtain the drugs. They do have the procedure built into the process on how they prescribe.

Dr. Bertin stated that he understands that for the 'onc' drugs. Maybe these are more mundane as drugs that may be prescribed in general practice for a patient. How does the information about this specific PA requirement get back to the physician?

CAPT VonBerg responded there are several ways that can happen. Providers can communicate with the contracted benefits manager or contact the pharmacy at the MTFs. They have telephone and fax methods along with websites with newer technology that allows a physician to pick the patient, pick the drug, and pick the health plan. That can be filled out and that information can be turned into the insurance agencies electronically. These are new efficiencies and processes that can be followed. Prior authorizations can be submitted electronically. Electronic along with paper PAs can be done by the prescriber before the patient goes to the pharmacy too to reduce processing time, and we continue to work on making that more efficient.

Dr. Bertin stated from his point of view, efficiency is the goal. When patients are presumably needing the drug, there has to be a way to get this process resolved.

CAPT VonBerg responded with absolutely.

Mr. Hostettler asked about the TIB that doesn't expire.

CAPT VonBerg responded that there is one with suicidal ideation. There are concerns with mental health issues.

Mr. Hostettler thanks him for that then follows up on Bertin's comments. Regarding retail pharmacy, the process can take days to weeks then can die on the vine. That is something we need to pay attention to, and it's a hard to manage. It's difficult. Thank you.

Dr. Anderson asked if the Parkinson's drug Xadago has been incorporated into any national treatment guidelines.

CAPT VonBerg said he didn't check this week, but the Parkinson's Guidelines are fairly old. The guidelines were checked worldwide before the P&T meeting and the drug had not been incorporated into guidelines in Canada, Australia, or the UK either. We will continue to monitor.

Dr. Anderson said that since all the questions have been about prior authorizations, might be good for the Panel to better understand what kind of monitoring you all do. When prior authorizations are put into place, I assume there is ongoing monitoring for the ongoing need. Or is the prior authorization, I assume...

Dr. VonBerg interjected that they are continuing monitoring individually.

Dr. Anderson continued I assume you are monitoring the approvals and denials. In addition to why things are being approved; when they are being denied, why these things are occurring.

VonBerg replied yes.

CAPT Norton responded that they will provide the panel with background at a future meeting in an executive session where we help the panel process.

Dr. Anderson said he thinks that would be really helpful especially with the newer people on the Panel to help them understand a little bit better.

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

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:



These comments were taken under consideration prior to my final decision

- **Newly-Approved Drugs per CFR 199.21(g)(5) – PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

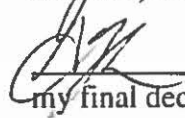


These comments were taken under consideration prior to my final decision

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF and PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:



These comments were taken under consideration prior to my final decision

Additional Panel Questions and Comments:

Lt Col Khoury stated going back to a question regarding monitoring the PA our stakeholders or industry giving us feedback in regards to PA in place.

III. UTILIZATION MANAGEMENT

A. TIBs

1. 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 plaque 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 \geq 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.

2. TIBs: Guselkumad (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.

Summary of Physician's Perspective:

We will not review this new drug until the November meeting; however, since we have step therapy in the TIB class, we wanted to ensure that Tremfya will follow the requirements for the other TIBs. This is similar to how we handle any new TIB, as we discussed earlier with the two other new drugs (Siliq and Kevzara).


Summary of Panel Questions and Comments:

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

• **TIBs: Tremfya – New Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3


Director, DHA:

 These comments were taken under consideration prior to my final decision

• **TIBs: Tremfya – Manual PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision

Additional Panel Questions and Comments:

Mr. Hostettler asks there are zero users today?

Lt Col Khoury replied with as of the meeting, zero users, correct.

Mr. Hostettler questioned the 90 day implementation period. I don't usually go with the shorter implementation period.

Dr. Anderson stated he agreed if this is operationally possible. Our goal is to manage the drug right away so people won't get caught up in it later. That seems consistent with our goal.

Mr. Hostettler asked that there are no utilizers ...

Lt Col Khoury responded the 90 day implementation period was based on the need to allow time to operationalize the prior authorization.

PANEL RECOMMENDATION:

Implementation begins upon the signing of the minutes, if operationally feasible.

Director, DHA:



These comments were taken under consideration prior to my final decision

B. GI-2 Agents for Opioid- Induced Constipation (OIC)

1. 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 \geq 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:
 - a) At least one stimulant laxative (e.g., sennosides or bisacodyl)
 - b) 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 taking a drug metabolized by CYP3A4 (for Movantik)

Non-FDA approved uses are not approved.

Prior authorization does not expire.

2. GI-2 Agents for OIC: Naloxegol (Movantik) and Methylnaltexone (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.

Summary of Physician's Perspective:

We are recommending new manual PA criteria. We have not yet reviewed the OIC drugs by themselves for formulary status. However, back in November 2015 we reviewed what we call the GI-2 drugs, which primarily included the drugs used for irritable bowel syndrome. Amitiza was part of the GI-2 class, and also has an indication for OIC. Since Amitiza is cost effective, we would like patients with OIC to have a trial of Amitiza, prior to use of Relistor or Movantik. The PA criteria also reflect some of the safety issues with Relistor and Movantik that are not seen with Amitiza. The P&T Committee may consider reviewing the OIC drugs as a subclass in the future.

Summary of Panel Questions and Comments:

Mr. Hostettler asked why new and current users. The impact in retail is about 2000 patients. Again, the PA process is not the smoothest and will interrupt therapy. I am curious to hear what you think.

Lt Col Khoury responded that there are a couple of factors for having the prior authorization ensure the appropriate agent is selected for patients. Providers did not necessarily believe it was harmful to patients to have considered alternative interventions and to try Amitiza before they had moved on to Movantik or Relistor

Mr. Hostettler stated it is most likely a break in therapy and will end up in another doctor visit. Seems to be a burden on the system overall. Not to mention there are 2000 patients are affected. It doesn't take into consideration how fast that process works.

Dr. Anderson asked for any other concerns.

Dr. Bertin stated he concurs that is a valid concern.

Dr Anderson stated there are a couple of concerns voiced regarding the Manual PA criteria. Do other panelists support the other criteria as proposed? 3 Concur. He asked if the remainder is non-concur.

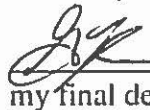
Hostettler will concur with a recommendation.

There were not more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and PA Implementation Plan.

- **GI-2 Agents for OIC: Movantik and Relistor – Manual PA Criteria**

Concur: 3 Non-Concur: 3 Abstain: 0 Absent: 3

Director, DHA:

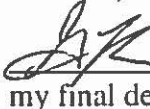


These comments were taken under consideration prior to my final decision

- **GI-2 Agents for OIC: Movantik and Relistor – PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:



These comments were taken under consideration prior to my final decision

Additional Panel Questions and Comments

The panel agreed with proposed manual PA criteria, and was split regarding recommendation to grandfather current users

Mr. Hostettler asked if letters will be mailed to the beneficiaries.

Lt Col Khoury replied yes, if needed.

C. Updated Manual PA Criteria and Step Therapy

1. 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.

a. 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

b. 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**

c. 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.**

d. 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**

e. **Proton Pump Inhibitors (PPIs): Esomeprazole Delayed and 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.

f. **Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (DGLT2) Inhibitors Step Therapy and Manual PA Criteria**

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.**

- g. **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.

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~~.

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

2. 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

Summary of Physician's Perspective:

We do continually monitor drugs with existing PA criteria to ensure that they are up to date. The updates include such things as new FDA approved indications – which were done for the TIB Actemra. We also do respond to feedback from providers – this is the case with Aczone where

we expanded the PA criteria to include adolescents and males, or for Eucrisa, to recognize that allergists or immunologists would also be likely to prescribe this drug for atopic dermatitis. For Xiidra, the PA was updated to include renewal criteria, which is similar to what is in place for Restasis. For the SGLT-2 step therapy, we are simplifying the step therapy to make it consistent to what is in place for the other non-insulin diabetes drugs (like the DPP4 inhibitors and the GLP1 drugs.)

The PPI class was changed back in February to have Nexium become non-formulary and non-preferred. The vast majority of patients are on the Nexium capsules, however we did receive questions on the status of the Nexium packets. Although the Nexium packets only represent 1% of the overall Nexium utilization, we do acknowledge that Nexium has the lowest age indication of all the PPIs (down to age one month). Young children or those with PEG tubes will now be allowed to receive the Nexium Packet formulation.

Summary of Panel Questions and Comments:

Mr. Hostettler asked how many current users will be affected in the SLGT2 class.

Lt Col Khoury responded they are removing the requirement for an additional agent beyond metformin. The answer is Zero.

Dr. Anderson asked if they are relaxing the requirement.

Lt Col Khoury replied they are only requiring the use of metformin and removing the additional requirement for 1 of 2 additional classes.

Mr. Hostettler stated that patients currently taking an SGLT2 inhibitor must have had a trial of metformin. The background information goes on the state new and current users. He asked if current users were required to meet the criteria a second time.

CAPT VonBerg said that was part of the original criteria. Anybody who's passed through the criteria is not required to do it again. When it was originally implemented, that was the original language.

Dr. Anderson said clinically he agrees with what they are doing. In my experience, some private insurance plans require the steps through metformin. I know some of our competitors, private, and pretty much everyone is trying metformin. I'm assuming it'll be a high pass on the step therapy criteria. I don't recall the look back data that is used.

Lt Col Khoury replied yes.

CAPT VonBerg stated there are still some that will need modification. We have been watching the literature. There have been safety reports for the SGLT2 drugs, not necessarily all of them that we are watching.

Dr. Anderson said it is due diligence to ensure metformin is used. CAPT VonBerg said that is why we left the PA and didn't get rid of it. There are still some concerns.

Dr. Anderson stated that he thinks that is fair commentary. He requests on-going monitoring of the program to ensure that the approval rate does not reach 100%. A 100% approval rate would be a reason to revisit the criteria.

Lt Col Khoury replied there is literature that suggests not everybody follows the guidelines.


Dr. Anderson said that you may find that not everyone follows the guidelines but it wasn't our experience.

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

- **Updated Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

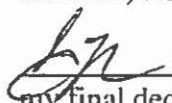
Director, DHA:

 These comments were taken under consideration prior to my final decision

- **Updated Manual Criteria and Step Therapy – Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision

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

A. Section 703, NDAA FY08

1. 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

2. 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 brand by Canton labs.

- a) Obtaining the product by home delivery would be detrimental to the patient; and,
- b) 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.

3. 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.

Summary of Physician's Perspective:

For the product recommended for NF status, several cost-effective generic formulations and therapeutic alternatives are available on the UF. The Pharmacy Operations Division does follow up with the affected

manufacturers, to try to ensure compliance with the Section 703 requirements.

Summary of Panel Questions and Comments:

Mr. Hostettler asked why not the MTFs as well? It's not cost effective for them either.

CAPT VonBerg replied that it's how the statute is written. The MTFs weren't likely to buy it. They have a little more direct control and they are more efficient and cost conscient^{ous} as they are actually buying it whereas pharmacies are essentially a pass through for payment. How many MTF pharmacies have the brand name naproxen on the shelf? The answer is zero.

Mr. Hostettler said he will go back many years in his career. They have found pharmacies buying things they shouldn't be buying at much higher cost. It does occur.

CAPT VonBerg replied it does, but we have drastically improved our monitoring of purchasing.

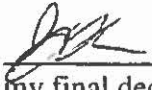
Hostettler said yes, but he is a dinosaur.

There were no more questions or comments from the Panel. The Chair called for a vote on the Drugs Designated NF, Pre-Authorization Criteria, and the Implementation Plan for the Section 703, NDAA FY08.

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

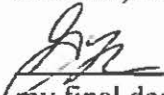
Director, DHA:

 These comments were taken under consideration prior to my final decision

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3


Director, DHA:

 These comments were taken under consideration prior to my final decision

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision

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

A. Prenatal Vitamins and Other Products

1. 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:

- a. **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.
- b. **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.)
- c. Evaluating statutory and/or regulatory authorities to address continued coverage of selected vitamins and other products when considered to be clinically and cost effective.

Note that following the August P&T Committee meeting, the POD was notified of First DataBank's plans to delay the January 1, 2018 implementation. As a result, implementation of the above recommendations to add 8 products to the OTC program is delayed pending further clarification. They will be continued to be covered as prescription products.

Summary of Physician's Perspective:

We became aware of a change in regulatory status for several drugs that currently require prescriptions that would be moving to OTC status. Since we now can add OTC drugs to the formulary, the Committee recommended adding the 8 most commonly prescribed cost-effective prenatal vitamins to the UF, given the reasons noted previously. The Committee is also in the process of identifying OTC drugs that are currently dispensed at the MTFs in order to align availability across the MTFs, as part of the changeover to an electronic health record system (MHS Genesis).

Following the P&T meeting, we were notified that First DataBank is planning to delay the original January 1, 2018 implementation of the Rx to OTC change. As a result, implementation of the above recommendations to add 8 products to the OTC program will be delayed pending further clarification. The affected products will continue to be covered as prescription products.

Summary of Panel Questions and Comments:

Mr. Hostettler asked of the 694 products, have you had a chance to look and see how many patients are on the 694 drugs.

CAPT VonBerg replied yes. Off the top of his head, out of the 694 agents, 131 of them are prenatal vitamins. Of the prenatal vitamins that we selected as covered already, 91% of the prescriptions are covered with the 8 selected products had been dispensed. At least 91% of those patients will be unaffected by any need to change because coverage will continue with those items. Any other patients that were on a different item can switch to the covered items.

Mr. Hostettler asked if 191 of the 694 are prenatal vitamins.

CAPT VonBerg corrected 131 are PNV products. 694 were different types of vitamins. It doesn't specify the number of unique utilizers.

Mr. Hostettler said forget prenatal vitamins. There are approximately one third of the other products. How many patients are impacted?

CAPT VonBerg states that the number is in our minutes. I don't know the number off the top of my head. No one is affected right now.

Mr. Hostettler stated he understands. It is not his intent to fight with you on this issue and applauds on the effort. He would like to know the impact to the patients on the other products. Due to the delay notice from First Databank, you now have more time to address those patient needs. Is the delay in implementation indefinite, 6 months, or less?

CAPT VonBerg states that they haven't said. Even if they did change it, our recommendation is to continue covering the drugs. The prescription benefit was moving to OTC which would automatically cause it to not be covered. The P&T minutes say to cover them under the OTC authority that we have until we have time to evaluate all the products.

Mr. Hostettler said the word "temporary" got my attention.

CAPT VonBerg replied P&T will conduct a review just like they did with prenatal vitamins. They will reach out to the providers and ask what these patients need. What can we give them? P&T will do an analysis on the products and their availability. There is not a lot a variation on what is in the prenatal vitamin products but there are a lot of different products with variation in value.

Mr. Hostettler stated again he applauds the effort on prenatal vitamins, but take that same approach with the other products.

CAPT VonBerg replied with absolutely. As mentioned, we are not only going to that with the 694, but will do that with all the other products offered throughout the benefit. We want to ensure the things that are needed are consistently available. Things that don't have any evidence, we may remove those.

Dr. Anderson stated that's good work.

Mr. Du Teil stated he's not as smart as all the other folks. He's interested in what those other items were and also the impact of the studies. For instance, someone with chronic acid reflux, would you provide them with Prilosec or another prescription drug that does the same thing. Is that kind of analysis being done to make sure we're not wasting money and providing service to those patients?

CAPT VonBerg replied with absolutely. Omeprazole is already on the official list for the OTC program. We have completed several analyses on PPIs, antihistamines, nausea medications, pregnancy, and emergency contraceptives agents. We already have a program that requires analysis. We are going to continue to do further analysis. We always strive to ensure the efficacy, safety and evidence is there and also the financial piece.

CAPT Norton added there was also a pilot done in approximately 2011. It looked at some of the OTC products proven to provide high value for treating these conditions as an alternative measure. An example, as CAPT VonBerg mentioned, is Omeprazole. The NDAA 2014 or 16 changed the statutes to allow a pilot program giving the Committee the authority to look at OTCs that provide high value relative to prescription alternatives and to make those part of the pharmacy benefits for retail and MTFs although they were OTC.


CAPT VonBerg said our directive was cost-effectiveness and access to OTC.

There were not more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation and Implementation Plan for the Prenatal Vitamins and Other products.

- **Prenatal Vitamins and Other Products – UF Recommendation and Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision

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

A. NDAA 2017 Pilot Program

1. 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 pens (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 pens (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.

Summary of Physician's Perspective:

In order to comply with the requirements of the NDAA pilot program, Defense Health Agency had already identified several chronic conditions

as constituting a high value component of clinical services, for example diabetes. We then identified two drugs where a reduction or elimination in the cost share would encourage beneficiaries to use the medication. The statins and basal insulin were good choices, since they represent chronic disease states (hyperlipidemia and diabetes, respectively) that impact a large number of DoD beneficiaries, and have proven benefits on mortality (statins) or surrogate endpoints (Hemoglobin A1C) that are of interest to patients and improve health outcomes. Rosuvastatin and Lantus pens were the specific drugs selected for the pilot.

Currently, TRICARE already has an advanced medication benefit, since generics are encouraged, and most organizations view generics as high-value medications. Additionally, the current formulary copays range from \$10/month to \$24/month, and are not viewed as a barrier to access in the Mail Order and Retail points of service. These co-pays likely don't have a huge impact on patient behaviors.

A review of MHS utilization and cost found that implementing the pilot program will positively impact 96,000 unique utilizers currently receiving rosuvastatin, and 40,000 patients receiving the Lantus Pens. Note that this recommendation for the Lantus pens is not tied to the previous UF recommendation from this meeting, but will align with the recommendation for Lantus to be step-preferred.

There is follow up reporting requirements that will be due to the Senate Armed Services Committee, so the results of this pilot will be monitored and assessed as to the true effect on adherence.

Summary of Panel Questions and Comments:

Dr. Anderson asked is there a timeline on how long the pilot runs.

CAPT VonBerg replied with 5 years.

Mr. Hostettler stated the MTFs have zero copays today. Do they have an adherence problem? Have you looked to see what the adherence issues are in the MTF.

CAPT VonBerg replied that they have done various analyses on different products. They will be watching all of those. When they draft the reports, they will include monitoring at all three points of service. They will also be monitoring comparators. We are monitoring both to get focused view on the selected agents and points of service and broad enough views to understand the larger market.

Mr. Hostettler asked if the MTFs are part of the pilot.

CAPT VonBerg replied that they are not part of the pilot, but they will separately be watching the MTFs.

Mr. Hostettler stated he is not against the Pilot and doesn't want to sound negative. He is interesting in ensuring analysis conducted on the MTF as well since the copay is zero for everything. He's sure they probably have some adherence issues. It'd be nice to look at that and validate that.

CAPT VonBerg responded they are a baseline right now. That is what they use them for.

Lt Khoury said the intent of the pilot is to assess the effect of reducing or eliminating copay on adherence.

Dr. Anderson said they are just complying. In his opinion, the general cost is over-emphasized under the current and agreed with Dr. Kugler. I'd be curious to watch the findings evolve. I'll also be a little bit surprised if there is a huge impact.

CAPT VonBerg said that most of the studies that look at this show changes with plans with much higher copays.

Dr. Anderson said the copays are higher and what I typically see in literature is cost gets talked about a lot. If there is a high deductible, the insurance plan cost is definitely a variance for adherence. I think with this benefit design, I'll be curious/interested to see the results.

Mr. Hostettler said he hopes it's positive.

Dr. Anderson replied it's good for the members around these drugs. My concern regarding these programs is impact to the beneficiaries whose drugs was not chosen. There's no perfect way to pick which drugs go into this. There are a lot of drugs that you could stay away for the copay. That would be great for everyone. It's hard to choose. Good job on the ones you've chosen.

CAPT Norton said the background with NDAA 2017 was described as reformed TRICARE. There were a lot of provisions that started at 701 and went as high as 746 provisions. There were 46 provisions that has some tweaks. I think the pilot has shown the copay as a positive to adherence and ultimately help outcomes and will be expanded to other drugs. The pilot I described with the OTC has purged medications and changed status to make it broader.

Mr. Hostettler asked how you are measuring. I only ask that question because in mail order the prescription drugs mailed out are significant.

Lt Col Khoury replied that each has different measure since they are used differently, with one being a pill and the other an injectable. For insulin, it will be the intensity of fill rate. For the statins, it will be the proportion of days covered.

Mr. Du Teil said he is not trying to get out of the purview of what the Panel is designed to do. In the larger sense, as a representative of patients in general on a lot of issues, this information is going to be useful because you can't really look at the cost of prescription drugs in a vacuum. Again, way outside the purview, but we're looking at perhaps getting rid of the grandfathering clause for existing retirees for copays and other stressors that increase costs of the nation. From that standpoint, I look forward to the results of the study so we don't have a retired population, with all these things factoring together, has to choose between eating and taking medicine. I applaud your efforts as well.

Ms. Buchanan asked if he said 96,000 for the statins.

Dr. Kugler replied that the program could impact 96,000 unique utilizers currently receiving the statin rosuvastatin and 40,000 patients receiving the Lantus Pens.

Mr. Hostettler asked why there were 2 votes on Day 1, Day 2.


CAPT VonBerg replied the meeting was going so long, they had to separate. Each drug was presented with deliberations. As deliberations go, they look for recommendations. In previous meetings, we've had one day. This one was two.

There were no more questions or comments from the Panel. The Chair called for a vote on the Committee Recommendation and Implementation for the NDAA 2017 Pilot Program.

- **NDAA 2017 Pilot Program – Committee Recommendation and Implementation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

Director, DHA:

 These comments were taken under consideration prior to my final decision



Guy T. Kiyokawa, SES
Deputy Director, DHA

Date: 18 Oct 17

Appendix A: Brief Listing of Acronyms Used in the Summary

Brief Listing of Acronyms Used in this Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in the Panel discussions are listed below for easy reference. The term “Pan” in this summary refers to the “Uniform Formulary Beneficiary Panel,” the group who’s meeting in the subject of this report.

- ADHD – Attention Deficit Hyperactivity Disorder
- AIDS – Acquired Immune Deficiency Syndrome
- ALL – Acute Lymphoblastic Leukemia
- AML – Acute Myeloid Leukemia
- BIA – Budget Impact Analysis
- CFR – Code of Federal Regulations
- CMA – Cost Minimization Analysis
- DHA – Defense Health Agency
- DMARDs – Disease Modifying Anti-Rheumatic Drugs
- DoD- Department of Defense
- ER – Extended Release
- FDA – Food & Drug Administration
- G – Grams
- GI-2 – Gastrointestinal-2
- GLP1RA – Glucagon-Like Peptide-1 Agonists
- HAE – Hereditary Angiodema
- HD – Extended Release
- HER2 – Human Epidermal Growth Factor Receptor
- HFA – Hydrofluoroalkane
- HIV – Human Immunodeficiency Virus
- ICS/LABAs – Inhaled Corticosteroids/Long-Acting Beta Agonists
- INSTI – Integrase Strand Transfer Inhibitors
- JIA – Juvenile Idiopathic Arthritis
- MAOI – Monamine Oxidase Inhibitors
- MHS – Military Health Systems
- mL- milliliter
- MTF – Military Treatment Facility
- NDAA – National Defense Authorization Act
- NDC – National Drug Codes
- NF – Non-Formulary
- NKI – Neurokinin
- NNRTI – Nucleoside/Nucleotide Reverse Transcriptase Inhibitor
- NPH – Neutral Protamine Hagedorn
- OIC – Opioid-Induced Constipation

- PA- Prior Authorization
- PAMORAs – Peripherally-Acting MU Opioid Receptor Agonists
- PEG – Percutaneous Endoscopic Gastronomy
- P&T – Pharmacy & Therapeutics
- pJLA – Polyarticular Juvenile Idiopathic Arthritis
- PPIs – Proton Pump Inhibitors
- PrEP – Pre-Exposure Prophylaxis
- SGLT2 – Sodium Glucose Co-Transporter
- SQ – Subcutaneously
- SU – Sulfonylurea
- TIBs – Targeted Immunomodulatory Biologics
- TNF – Anti-Tumor Necrosis Factor
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- VMAT2 – Vesicular Monoamine Transporter 2
- XR – Extended Release

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
September 21, 2017
Washington, D.C.

Present Panel Members

- Dr. Michael Anderson, United Healthcare, Chairperson
- Ms. Theresa Buchanan, National Military Family Association
- Mr. John Du Teil, US Army Warrant Officers Association
- Mr. Charles Hostettler, AMSUS, The Society of Federal Health Professionals
- Mr. Richard Bertin, Commissioned Officers Association of the USPHS
- Ms. Suzanne Walker, Military Officers Association of America

Absent Panel Members

- Dr. Sandra Delgado, Humana
- Mr. John Ostrowski, Non Commissioned Officers Association
- Dr. Sarika Joshi, HealthNet Federal Services

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

Agenda

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

- Welcome and Opening Remarks
- Public Citizen Comments
- Therapeutic Class Reviews
 1. Drug Class Reviews
 - a) Basal Insulin Analogs
 - b) Corticosteroids - Immune Modulators Drug Class—Hereditary Angioedema Agents (HAE) Subclass
 - c) Antiretroviral Agents: Human Immunodeficiency Virus (HIV)
 2. Newly-Approved Drugs per CFR 199.21(g)(5)
 - a) abaloparatide (Tymlos) injection – Osteoporosis Agents
 - b) brigatinib (Alunbrig) – Oral Oncology Agents for Lung Cancer
 - c) brodalumab (Siliq) injection – Targeted Immunomodulatory Biologics (TIBs)
 - d) dronabinol (Syndros) oral solution – Antiemetic and Antivertigo Agents

- e) fluticasone/salmeterol (AirDuo RespiClick) oral inhaler – Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)
- f) methotrexate (Xatmep) oral solution – Antirheumatic Drugs
- g) mixed amphetamine salts ER (Mydayis) – Attention Deficit
- h) Hyperactivity Disorder (ADHD) Drugs
- i) midostaurin (Rydapt) – Oral Oncology Agents for Acute Myeloid
- j) Leukemia (AML)
- k) morphine sulfate ER (Morphabond XR) – Narcotic Analgesics
- l) niraparib (Zejula) – Oral Oncology Agents for Ovarian Cancer
- m) prasterone (Intrarosa) vaginal insert – Vaginal Lubricants
- n) ribociclib/letrozole (Kisqali Femara Co-Pack)—Oral Oncologic Agents for Breast Cancer
- o) safinamide (Xadago) – Parkinson’s Disease Drugs
- p) sarilumab (Kevzara) injection – TIBs
- q) valbenazine (Ingrezza) – Neuromuscular Miscellaneous Agents

3. Utilization Management Issues

a) Prior Authorization Criteria—New Criteria

- TIBs: guselkumab (Tremfya)
- Gastrointestinal-2 Agents for Opioid-Induced Constipation (OIC): naloxegol (Movantik) and methylnaltrexone (Relistor)

b) Prior Authorization Criteria—Updated Criteria

- Acne Agents—Topical Acne and Rosacea Agents: dapsone gel 5% and 7.5% (Aczone)
- TIBs: tocilizumab (Actemra)
- Ophthalmic Immunomodulatory Agents: lifitegrast (Xiidra)
- Corticosteroids – Immune Modulators: crisaborole (Eucrisa)
- Proton Pump Inhibitors (PPIs): esomeprazole delayed release packets for suspension (Nexium Packets)
- Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors

4. National Defense Authorization Act (NDAA) 2008, Section 703 Actions

5. Prenatal Vitamins and other Products Losing Prescription Status in First DataBank

6. NDAA 2017 Pilot Program: Incorporation of Value-Based Health Care in Purchased Care Component of TRICARE and Medication Adherence (addendum to the August P&T Committee Meeting)

7. Panel Discussion

The Uniform Formulary Beneficiary Advisory Panel will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will discuss the recommendation and vote to accept or reject the recommendations. The Panel will provide comments on their vote as directed by the Panel Chairman.

Opening Remarks

CAPT Edward Norton introduced himself as the Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP). The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on August 9 – 10, 2017.

CAPT Norton indicated Title 10, United States, (U.S.C.) section 1074g, subsection b requires the Secretary of Defense to establish a DoD Uniform Formulary (UF) of the pharmaceutical agent and established the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

In addition, 10 U.S.C. Section 1074g, subsection c, also requires the Secretary to establish a UF Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. The Panel's comments must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF.

The Panel's meetings are conducted in accordance of the Federal Advisory Committee Act (FACA).

The duties of the Uniform Formulary Beneficiary Advisory Panel include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and subsequently recommending changes. Comments to the Director of the DHA regarding recommended formulary status, pre-authorizations and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.
- To hold quarterly meetings in an open forum. The panel may not hold meetings except at the call or with the advance approval of the DFO and in consultation with the chairperson of the Panel.
- To prepare minutes of the proceedings and prepared comments of the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website, and comments will be prepared for the Director of

DHA. As guidance to the Panel regarding this meeting, CAPT Norton said the role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the department appreciates that the BAP maybe interested in the drug class they selected for review, drugs recommended for the basic core formula (BCF) or specific pricing data, these items do not fall under the purview of the BAP.

- The P&T Committee met for approximately 15 hours conducting this review of the drug class recommendation presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information as presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website. Detailed minutes of this meeting are being prepared. The BAP minutes, the DoD P&T Committee minutes, and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO provided ground rules for conducting the meeting:

- All discussions take place in an open public forum. There is to be no committee discussion outside the room, during breaks, or at lunch.
- Audience participation is limited to private citizens who signed up to address the Panel.
- Members of the Formulary Management Branch and P&T Committee are available to answer questions related to the BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure the minutes accurately reflect relevant facts, regulations, or policy.

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

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

Chairman's Opening Remarks

Dr. Anderson welcomes everyone, states he has no opening remarks and starts the meeting.

DRUG CLASS REVIEW PRESENTATION

(POD Script – CAPT VONBERG)

GOOD MORNING. I am CAPT Edward VonBerg, Chief of the Formulary Management Branch. Joining me is doctor and retired Army Colonel John Kugler, the Chairman of the Pharmacy & Therapeutics Committee, who will provide the physician perspective and comments on the recommendations made by the P&T Committee. Also joining us from the Formulary Management Branch today is Lt Col Ron Khoury, a family medicine physician and Chief P&T Section. I would also like to recognize Randy Stone, Assistant General Counsel.

The DoD Formulary Management Branch supports the DoD P&T Committee by conducting the relative clinical-effectiveness analyses and relative cost-effectiveness analyses of the drug classes under review and consideration by the DoD P&T Committee for the Uniform Formulary (relative meaning in comparison to the other agents defined in the same class).

We are here to present an overview of the analyses presented to the P&T Committee. 32 Code of Federal Regulations (CFR) establishes procedures for inclusion of pharmaceutical agents on the Uniform Formulary based upon both relative clinical effectiveness and relative cost effectiveness.

The goal of this presentation is not to provide you with the same in-depth analyses presented to the DoD P&T Committee but a summary of the processes and analyses presented to the DoD P&T Committee. These include:

- A brief overview of the relative clinical effectiveness analyses considered by the DoD P & T Committee. All reviews include but are not limited to the sources of information listed in 32 CFR 199.21 (e)(1) and (g)(5). Also note that nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.
- A brief general overview of the relative cost effectiveness analyses. This overview will be general in nature since we are unable to disclose the actual costs used in the economic models. This overview will include the factors used to evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes.
- The DoD P&T Committee's Uniform Formulary recommendation is based upon its collective professional judgment when considering the analyses from both the relative clinical- and relative cost-effectiveness evaluations.

The Committee reviewed the following:

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

- a) the Basal Insulin Analogs;
- b) the Corticosteroids – Immune Modulators Drug Class: Hereditary Angioedema (HAE) Agents Subclass; and
- c) the Antiretroviral Agents: Human Immunodeficiency Virus (HIV)

A summary table of the UF drug class recommendations is found in the background document. It also contains the numbers of the unique utilizers affected by the recommendations.

2. The P&T Committee also evaluated 15 Newly Approved Drug per CFR 199.21 (g)(5), which are currently in pending status and available under terms comparable to non-formulary drugs.
3. We will also discuss Prior Authorizations (PAs) for 8 drugs in 6 drug classes, plus one drug class with a step therapy modification.
 - a) Targeted Immunomodulatory Biologics
 - b) Gastrointestinal-2 Agents for opioid induced constipation
 - c) Topical Acne and Rosacea Agents
 - d) Ophthalmic Immunomodulatory Agents
 - e) Corticosteroids – Immune Modulators
 - f) Proton Pump Inhibitors
 - g) Non-Insulin Diabetes Drugs – sodium glucose Co-transporter 2 inhibitors
4. There was one drug under Section 703, National Defense Authorization Act (NDAA) for Fiscal Year 2008 reviewed at this meeting.
5. We will also discuss a planned legend Prescription-to-OTC status change for the prenatal vitamins and some other products; and
6. A discussion of a program that requires identification of high-value medications where copayments or cost shares would be reduced for targeted populations of covered beneficiaries.

The DoD P & T Committee will make a recommendation as to the effective date of the agents being changed from the Uniform Formulary tier to Non-formulary tier. Based on 32 CFR 199.21 such change will not be longer than 180 days from the final decision date but may be less.

UNIFORM FORMULARY DRUG CLASS REVIEWS

I. UF CLASS REVIEWS

A. BASAL INSULIN ANALOGS

(LT COL KHOURY)

1. 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.
 - a) Insulin glargine (Lantus) was marketed in 2000, and was designated with formulary status in 2010.
 - b) Insulin detemir (Levemir) may be dosed once or twice daily and has been marketed since 2005.
 - c) 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).
 - d) 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.
 - e) 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) network 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 network provider opinion.

2. Basal Insulin Analogs – Relative Cost Effectiveness Analysis

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.

3. Basal Insulin Analogs – UF Recommendation

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

- **UF and Step-Preferred:**
 - a) insulin glargine pen and vial (Lantus)

- **UF and Non Step-Preferred**
 - a) insulin detemir vial (Levemir)
 - b) insulin glargine 300 U/mL (Toujeo)

- **NF and Non Step-Preferred:**
 - a) insulin detemir pen (Levemir)
 - b) insulin degludec (Tresiba)
 - c) 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.

4. 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 . The PA previously limited use to patients 18 years and older.

- 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.

PA does not expire.

5. 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.

6. Physician’s Perspective

The major recommendation here is that now Lantus will be the preferred basal insulin. There is no change in the drugs recommended for non-formulary status. Tresiba, Levemir pens, and Basaglar are currently NF, and we have about 14,500 patients receiving them. What is changing is that the step therapy will require all new patients to try Lantus first. The patients currently receiving a drug other than Lantus will be grandfathered, and won’t be required to have a trial of Lantus.

For special populations, a pediatric endocrinologist at the meeting mentioned that for children, Lantus is preferred since it is a once daily injection and parents don’t have to worry about variability in daily routines. However, the Prior Authorization criteria for Tresiba does allow use for children down to the age of one year, which is in the package insert.

For pregnant patients, the PA for the Levemir pens does allow use in this situation, since Levemir has a pregnancy category B rating. However the Ob-Gyn on the Committee commented that most pregnant patient requiring insulin are treated with NPH insulin.

Overall, the formulary recommendation is consistent with the utilization patterns we already have in the MHS, since Lantus accounts for 80% of the basal insulin prescriptions. Having Lantus as the preferred basal insulin also meets the requests from the provider survey.

7. Panel Questions and Comments

Mr. Du Tiel stated he doesn’t see anything wrong with the recommendation from the P&T. He asked if there was a reason for the abstention vote.

Dr. Kugler responded that the committee members are allowed to abstain from voting on a particular class of drugs. Members are not asked to make a statement about why they abstain. It is usually an individual on the committee who chooses not to participate in a final formulary recommendation on a specific drug class.

Dr. Anderson states in his experience this is common to see management like this in this drug class. I've seen private insurers go with one product or another. Some go with Basaglar. Some go with Lantus. It is very reasonable. For utilization purposes, many prefer Lantus.

There were not more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation for the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Basal Insulin Analogs.

- **Basal Insulin Analogs - UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **Basal Insulin Analogs - Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **Basal Insulin Analogs - UF and PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

**B. CORTICOSTEROIDS – IMMUNE MODULATORS DRUG CLASS:
HEREDITARY ANGIOEDEMA (HAE) AGENTS SUBCLASS
(LT COL KHOURY)**

1. 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
 - a) 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.
 - b) 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.
 - c) 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.
 - d) Guidelines for treatment of HAE recommend the C1 esterase inhibitors or Firazyr, and do not place preference of one treatment over another.

- Prophylaxis
 - a) 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.
 - b) 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.
 - c) 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
 - a) 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.

- b) For the bradykinin product icatibant (Firazyr), over 97% of patients experience injection site reactions.
 - c) 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) A new SQ-administered product, Haegarda, was recently approved for HAE prophylaxis and will be reviewed at an upcoming meeting.
 - b) A survey of Military Treatment Facility (MTF) and network 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.

2. 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.

3. Corticosteroid – 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:
 - a) plasma-derived human C1 esterase inhibitor IV (Cinryze)
 - b) plasma-derived human C1 esterase inhibitor IV (Berinert)
 - c) recombinant C1 esterase inhibitor IV (Ruconest)
 - d) 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.

4. Corticosteroid – 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
 - a) 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
 - b) Patient is female of childbearing age
- Cinryze or Haegarda is not approved for any indication other than HAE.
- PA does not expire.

5. 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.

6. Physician's Perspective

There are an increasing number of drugs for rare conditions receiving FDA approval, and this was our first attempt at reviewing a drug class in this specialty market.

For HAE determining a typical treatment course is difficult, due to the variation in the numbers of edema episodes per person, and the differences in the dosing between products. The recommendation was unanimous to have all the agents be designated as Uniform Formulary.

A PA was recommended for the drugs used for prophylaxis of edema episodes (Cinryze and Haegarda). Due to the adverse effect profile, women and patients with a history of cardiovascular events will not be required to try Danazol first. The PA does follow the recommendations from the allergy/immunology consultants, and also is consistent with professional guidelines.

7. Panel's Questions and Comments

Mr. Hostettler asked how many patients have HAE.

Lt Col Khoury responded that the number is very low. It is under 100. I am not mistaken the number is approximately 70.

Mr. Hostettler asked with the number so low, is the manual PA necessary.

Lt Col Khoury responded that based on the 70 identified and assessed; there were significant and wide distributions in patterns of use and not always within available guidelines.

Mr. Hostettler asked if they are being treated by specialists.

Lt Col Khoury stated that specialty designation is not currently identified for those prescribers/prescriptions.

Mr. Hostettler said being treated by a specialist would be his suggestion to be the only criteria.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria, and UF and PA Implementation Plan for the Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass.

- **Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass – UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass – Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **Corticosteroids – Immune Modulators Drug Class: HAE Agents Subclass – UF and PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

8. Additional Panel Comments and Questions.

Lt Col Khoury provided a clarification regarding HAE. He said 71, but it's actually 91. Since 2016, there were 91 unique utilizers. Since 2010, there have been 151 unique utilizers prescribed these agents.

Mr. Hostettler thanked him.

C. HUMAN IMMUNODEFICIENCY VIRUS (HIV)

(CAPT VONBERG)

1. 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 Trumeq, 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 PrEP 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.

2. 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, Trumeq 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.

3. 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:**
 - a) Aptivus (tipranavir)
 - b) Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
 - c) Combivir (lamivudine/zidovudine)
 - d) Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)**
 - e) Crixivan (indinavir)
 - f) Descovy (emtricitabine/tenofovir alafenamide)**
 - g) Edurant (rilpivirine)
 - h) Emtriva (emtricitabine)
 - i) Epivir (lamivudine)
 - j) Epzicom (abacavir/lamivudine)
 - k) Evotaz (atazanavir/cobicistat)
 - l) Fuzeon (enfuvirtide)
 - m) Genvoya (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide)**
 - n) Intelence (etravirine)
 - o) Invirase (saquinavir)
 - p) Isentress (raltegravir)
 - q) Isentress HD (raltegravir extended-release)**
 - r) Lexiva (fosamprenavir)
 - s) Kaletra (lopinavir/ritonavir)
 - t) Norvir (ritonavir)**
 - u) Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)**
 - v) Prezcofix (darunavir/cobicistat)
 - w) Prezista (darunavir)**
 - x) Rescriptor (delavirdine)
 - y) Retrovir (zidovudine)
 - z) Reyataz (atazanavir)
 - aa) Selzentry (maraviroc injection and oral solution)**
 - bb) Stribild (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)**
 - cc) Sustiva (efavirenz)
 - dd) Tivicay (dolutegravir)**
 - ee) Triumeq (abacavir/dolutegravir/lamivudine)**
 - ff) Trizivir (abacavir/lamivudine/zidovudine)

gg) Truvada (emtricitabine/tenofovir disoproxil fumarate)

hh) Tybost (cobicistat)

ii) Videx EC (didanosine delayed-release)

jj) Videx Pediatric (didanosine)

kk) Viracept (nelfinavir)

ll) Viramune (nevirapine)

mm) Viramune XR (nevirapine ER)

nn) Viread (tenofovir disoproxil fumarate)

oo) Zerit (stavudine)

pp) Ziagen (abacavir)

- **NF:** None

4. 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.

5. Physician’s Perspective

The HIV drugs had not previously been reviewed for formulary status. The recommendation was to have all the drugs as UF. Many older agents are not the current clinical choice of therapy however, for patients already stabilized on these medications or experiencing resistance to first-line agents, an increase in co-pay is not justifiable.

The Committee recognized that selecting the most appropriate HIV agent for a patient depends on several factors, including resistance patterns, rapidly changing treatment guidelines, patient co-morbidities, and individual drug-drug interaction profiles.

6. Panel Questions and Comments

Mr. Hostettler asked if there are any specific programs to monitor adherence for the patient population affected by this drug class.

CAPT VonBerg stated that we have providers centered in locations for HIV. These centers keep the patients and providers informed at the MTFs. The network care systems have indirect programs that can help with refills.

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

- **HIV – UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **HIV – UF and PA Implementation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

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

(CAPT VONBERG)

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

1. 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).

2. Newly-Approved Drugs per CFR 199.21 – 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:**
 - a) brigatinib (Alunbrig) – Oral Oncologic Agents for Lung Cancer
 - b) methotrexate (Xatmep) oral solution – Antirheumatic Drugs
 - c) midostaurin (Rydapt) – Oral Oncologic Agents for Acute Myeloid Leukemia (AML)
 - d) niraparib (Zejula) – Oral Oncologic Agents for Ovarian Cancer
 - e) prasterone (Intrarosa) vaginal insert – Vaginal Lubricants
 - f) ribociclib/letrozole (Kisqali Femara Co-Pack) – Oral Oncologic Agents for Breast Cancer

- **NF:**
 - a) abaloparatide (Tymlos) injection – Osteoporosis Agents
 - b) brodalumab (Siliq) injection – Targeted Immunomodulatory Biologics (TIBs)
 - c) dronabinol (Syndros) oral solution – Antiemetic and Antivertigo Agents
 - d) fluticasone/salmeterol (AirDuo RespiClick) oral inhaler – Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)
 - e) mixed amphetamine salts ER (Mydayis) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
 - f) morphine sulfate ER (Morphabond XR) – Narcotic Analgesics
 - g) safinamide (Xadago) – Parkinson’s Disease Drugs
 - h) sarilumab (Kevzara) injection – TIBs
 - i) valbenazine (Ingrezza) – Neuromuscular Miscellaneous Agents

3. 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)

a. 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:

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

AND

Coverage approved for patients > 18 years with:

- a) Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy AND
- b) 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.

b. 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:

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

AND

Coverage approved for patients > 18 years with:

- a) 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.

c. midostaurin (Rydapt) – Oral Oncologic Agents

Manual PA criteria apply to all new users of Rydapt.

Manual PA criteria—Rydapt is approved if:

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

AND

- a) Patient uses Rydapt in combination with standard chemotherapy protocols AND
- b) Patient has a diagnosis of Acute Myelogenous Leukemia (AML) and FLT3 mutation as determined by FDA-approved test OR
- c) 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.

d. 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:

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

Off-label uses are not approved.

PA does not expire.

e. 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.

f. 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:

- Patient is ≥ 18 years old AND
- Patient has a diagnosis of Parkinson’s disease AND
- Patient has tried and failed rasagiline or selegiline AND
- Xadago is used as an adjunct to levodopa/carbidopa or a dopamine agonist.

Off-label uses are NOT approved.

PA does not expire.

g. 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:

- a) Age > 18 years
- b) Prescribed by or in consultation with a neurologist or psychiatrist
- c) Patient has moderate to severe tardive dyskinesia along with schizophrenia, schizoaffective disorder, or a mood disorder
- d) Patient does not have congenital long QT syndrome or arrhythmias associated with QT prolongation
- e) Patient has had an adequate trial or has failed or has a contraindication to tetrabenazine or deutetrabenazine
- f) Provider has considered use of clonazepam and ginkgo biloba
- g) 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.

h. 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.

i. 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.

j. 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.

k. 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.

4. 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.

5. Physician’s Perspective

There were 15 newly approved drugs. For drugs in disease states that have not been previously reviewed for formulary status, we do consult with the specialists to get their input, especially if PA criteria are recommended. If non-formulary status is recommended for a new drug, there are alternative therapies available that are clinically effective or cost effective.

There was one drug where Uniform Formulary status was recommended prior to the August meeting. Rydapt is the first oral drug approved for AML. We have administrative authority to grant Tier 2 status to new drugs where there are no formulary alternatives or clinical comparators. The Committee then saw the full clinical and cost review at the meeting.

PA criteria was recommended for 11 new drugs.

- a) The PAs for the two TIBs drugs (Siliq for psoriasis and Kevzara for arthritis) were recommended since there is already step therapy in the class. The PA for Siliq took the suicidal ideation concern into consideration. The oral inhalers for asthma and COPD also have step therapy requirements, so the Air Duo inhaler was placed behind the step.
- b) The PAs for two of the oncology drugs (Kisqali co-pack and Rydapt) reflect their FDA approved indications.
- c) PAs were also recommended for the antiemetic (Syndros) and the ADHD drug (Mydayis), due to the risk for off-label use, and since there are cost effective drugs already available that have been reviewed by the P&T committee. For Syndros, the PA and non-formulary status were recommended due to the availability of alternative antiemetics, the fact that Syndros is a schedule II drug, and the high alcohol content.

6. Panel Questions and Comments

Dr. Bertin stated he's a new member of this group and asked a procedural question. In terms of the PAs that are seen here, what actually happens when a patient is newly diagnosed with one of these conditions; gets a prescription from the physician; goes to retail networks?

CAPT VonBerg responded that the prescription is sent to the pharmacy and the pharmacy receives a notification that prior authorization is required. Either the patient or the pharmacy contacts the doctor for that request. That PA information is transmitted to the contracted pharmacy benefits manager who then lets the MTF or network pharmacy know of the approval.

Lt Col Khoury stated that typically on the commercial side, most of the medications, especially the oncological ones, the providers do not involve themselves in the PA process. There are very structured formats for acknowledging the insurance that covers the patients and identifying the requirements for that insurance to complete that paperwork as part of the prescriptions that they submit. Often times, in oncology drugs, the patients won't go down to the pharmacy because of distribution issues. A beneficiary can't just go to a corner store like CVS and pick up an agent that costs \$15,000. There has to be a procedure in place to ensure they can obtain the drugs. They do have the procedure built into the process on how they prescribe.

Dr. Bertin stated that he understands that for the ‘onc’ drugs. Maybe these are more mundane as drugs that may be prescribed in general practice for a patient. How does the information about this specific PA requirement get back to the physician?

CAPT VonBerg responded there are several ways that can happen. Providers can communicate with the contracted benefits manager or contact the pharmacy at the MTFs. They have telephone and fax methods along with websites with newer technology that allows a physician to pick the patient, pick the drug, and pick the health plan. That can be filled out and that information can be turned into the insurance agencies electronically. These are new efficiencies and processes that can be followed. Prior authorizations can be submitted electronically. Electronic along with paper PAs can be done by the prescriber before the patient goes to the pharmacy too to reduce processing time, and we continue to work on making that more efficient.

Dr. Bertin stated from his point of view, efficiency is the goal. When patients are presumably needing the drug, there has to be a way to get this process resolved.

CAPT VonBerg responded with absolutely.

Mr. Hostettler asked about the TIB that doesn’t expire.

CAPT VonBerg responded that there is one with suicidal ideation. There are concerns with mental health issues.

Mr. Hostettler thanks him for that then follows up on Bertin’s comments. Regarding retail pharmacy, the process can take days to weeks then can die on the vine. That is something we need to pay attention to, and it’s a hard to manage. It’s difficult. Thank you.

Dr. Anderson asked if the Parkinson’s drug Xadago has been incorporated into any national treatment guidelines.

CAPT VonBerg said he didn’t check this week, but the Parkinson’s Guidelines are fairly old. The guidelines were checked worldwide before the P&T meeting and the drug had not been incorporated into guidelines in Canada, Australia, or the UK either. We will continue to monitor.

Dr. Anderson said that since all the questions have been about prior authorizations, might be good for the Panel to better understand what kind of monitoring you all do. When prior authorizations are put into place, I assume there is ongoing monitoring for the ongoing need. Or is the prior authorization, I assume...

Dr. VonBerg interjected that they are continuing monitoring individually.

Dr. Anderson continued I assume you are monitoring the approvals and denials. In addition to why things are being approved; when they are being denied, why these things are occurring.

VonBerg replied yes.

CAPT Norton responded that they will provide the panel with background at a future meeting in an executive session where we help the panel process.

Dr. Anderson said he thinks that would be really helpful especially with the newer people on the Panel to help them understand a little bit better.

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

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **Newly-Approved Drugs per CFR 199.21(g)(5) – PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **Newly-Approved Drugs per CFR 199.21(g)(5) – UF and PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

7. Additional Panel Questions and Comments

Lt Col Khoury stated going back to a question regarding monitoring the PA our stakeholders or industry giving us feedback in regards to PA in place.

III. UTILIZATION MANAGEMENT

A. TIBs

(LT COL KHOURY)

1. 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 plaque 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.

2. TIBs: Guselkumad (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.

3. Physician’s Perspective

We will not review this new drug until the November meeting; however, since we have step therapy in the TIB class, we wanted to ensure that Tremfya will follow the requirements for the other TIBs. This is similar to how we handle any new TIB, as we discussed earlier with the two other new drugs (Siliq and Kevzara).

4. Panel Questions and Comments

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

• TIBs: Tremfya – New Manual PA Criteria

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

• TIBs: Tremfya – Manual PA Implementation Plan

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

5. Additional Panel Questions and Comments.

Mr. Hostettler asks there are zero users today?

Lt Col Khoury replied with as of the meeting, zero users, correct.

Mr. Hostettler questioned the 90 day implementation period. I don’t usually go with the shorter implementation period.

Dr. Anderson stated he agreed if this is operationally possible. Our goal is to manage the drug right away so people won’t get caught up in it later. That seems consistent with our goal.

Mr. Hostettler asked that there are no utilizers ...

Lt Col Khoury responded the 90 day implementation period was based on the need to allow time to operationalize the prior authorization.

6. Panel Recommendation

Implementation begins upon the signing of the minutes, if operationally feasible.

Mr. Du Teil stated it is a good point.

B. GI-2 Agents for Opioid- Induced Constipation (OIC)

(LT COL KHOURY)

1. 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:
 - a) At least one stimulant laxative (e.g., sennosides or bisacodyl)

b) 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 taking a drug metabolized by CYP3A4 (for Movantik)

Non-FDA approved uses are not approved.

Prior authorization does not expire.

2. GI-2 Agents for OIC: Naloxegol (Movantik) and Methylnaltexone (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.

3. Physician’s Perspective

We are recommending new manual PA criteria. We have not yet reviewed the OIC drugs by themselves for formulary status. However, back in November 2015 we reviewed what we call the GI-2 drugs, which primarily included the drugs used for irritable bowel syndrome. Amitiza was part of the GI-2 class, and also has an indication for OIC. Since Amitiza is cost effective, we would like patients with OIC to have a trial of Amitiza, prior to use of Relistor or Movantik. The PA criteria also reflect some of the safety issues with Relistor and Movantik that are not seen with Amitiza. The P&T Committee may consider reviewing the OIC drugs as a subclass in the future.

4. Panel Questions and Comments

Mr. Hostettler asked why new and current users. The impact in retail is about 2000 patients. Again, the PA process is not the smoothest and will interrupt therapy. I am curious to hear what you think.

Lt Col Khoury responded that there are a couple of factors for having the prior authorization ensure the appropriate agent is selected for patients. Providers did not necessarily believe it was harmful to patients to have considered alternative interventions and to try Amitiza before they had moved on to Movantik or Relistor

Mr. Hostettler stated it is most likely a break in therapy and will end up in another doctor visit. Seems to be a burden on the system overall. Not to mention there are 2000 patients are affected. It doesn't take into consideration how fast that process works.

Dr. Anderson asked for any other concerns.

Dr. Bertin stated he concurs that is a valid concern.

Dr Anderson stated there are a couple of concerns voiced regarding the Manual PA criteria. Do other panelists support the other criteria as proposed? 3 Concur. He asked if the remainder is non-concur.

Hostettler will concur with a recommendation.

There were not more questions or comments from the Panel. The Chair called for a vote on the Manual PA Criteria and PA Implementation Plan.

- **GI-2 Agents for OIC: Movantik and Relistor – Manual PA Criteria**

Concur: 3 Non-Concur: 3 Abstain: 0 Absent: 3

(3 will concur with recommendation of grandfathering)

- **GI-2 Agents for OIC: Movantik and Relistor – PA Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

5. Additional Panel Questions and Comments.

The panel agreed with proposed manual PA criteria, and was split regarding recommendation to grandfather current users

Mr. Hostettler asked if letters will be mailed to the beneficiaries.

Lt Col Khoury replied yes if needed.

C. Updated Manual PA Criteria and Step Therapy

1. Updated Manual PA Criteria

(LT COL KHOURY)

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.

a. 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

b. 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 \geq 18 years with:

- **Adult patients with giant cell arteritis**

c. 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.**

d. 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**

e. Proton Pump Inhibitors (PPIs): Esomeprazole Delayed and 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.**

f. Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (DGLT2) Inhibitors Step Therapy and Manual PA Criteria

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.**

- g. 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.

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~~.

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

2. 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

3. Physician’s Perspective

We do continually monitor drugs with existing PA criteria to ensure that they are up to date. The updates include such things as new FDA approved indications – which were done for the TIB Actemra. We also do respond to feedback from providers – this is the case with Aczone where we expanded the PA criteria to include adolescents and males, or for Eucrisa, to recognize that allergists or immunologists would also be likely to prescribe this drug for atopic dermatitis. For Xiidra, the PA was updated to include renewal criteria, which is similar to what is in place for Restasis. For the SGLT-2 step therapy, we are simplifying the step

therapy to make it consistent to what is in place for the other non-insulin diabetes drugs (like the DPP4 inhibitors and the GLP1 drugs.)

The PPI class was changed back in February to have Nexium become non-formulary and non-preferred. The vast majority of patients are on the Nexium capsules, however we did receive questions on the status of the Nexium packets. Although the Nexium packets only represent 1% of the overall Nexium utilization, we do acknowledge that Nexium has the lowest age indication of all the PPIs (down to age one month). Young children or those with PEG tubes will now be allowed to receive the Nexium Packet formulation.

4. Panel Questions and Comments

Mr. Hostettler asked how many current users will be affected in the SGLT2 class.

Lt Col Khoury responded they are removing the requirement for an additional agent beyond metformin. The answer is Zero.

Dr. Anderson asked if they are relaxing the requirement.

Lt Col Khoury replied they are only requiring the use of metformin and removing the additional requirement for 1 of 2 additional classes.

Mr. Hostettler stated that patients currently taking an SGLT2 inhibitor must have had a trial of metformin. The background information goes on the state new and current users. He asked if current users were required to meet the criteria a second time.

CAPT VonBerg said that was part of the original criteria. Anybody who's passed through the criteria is not required to do it again. When it was originally implemented, that was the original language.

Dr. Anderson said clinically he agrees with what they are doing. In my experience, some private insurance plans require the steps through metformin. I know some of our competitors, private, and pretty much everyone is trying metformin. I'm assuming it'll be a high pass on the step therapy criteria. I don't recall the look back data that is used.

Lt Col Khoury replied yes.

CAPT VonBerg stated there are still some that will need modification. We have been watching the literature. There have been safety reports for the SGLT2 drugs, not necessarily all of them that we are watching.

Dr. Anderson said it is due diligence to ensure metformin is used.

CAPT VonBerg said that is why we left the PA and didn't get rid of it. There are still some concerns.

Dr. Anderson stated that he thinks that is fair commentary. He requests on-going monitoring of the program to ensure that the approval rate does not reach 100%. A 100% approval rate would be a reason to revisit the criteria.

Lt Col Khoury replied there is literature that suggests not everybody follows the guidelines.

Dr. Anderson said that you may find that not everyone follows the guidelines but it wasn't our experience.

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

- **Updated Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

- **Updated Manual Criteria and Step Therapy – Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

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

A. Section 703, NDAA FY08

(LT COL KHOURY)

1. 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

2. 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 brand by Canton labs.

- a) Obtaining the product by home delivery would be detrimental to the patient; and,
- b) 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.

3. 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.

4. Physician’s Perspective

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

5. Panel Questions and Comments

Mr. Hostettler asked why not the MTFs as well? It’s not cost effective for them either.

CAPT VonBerg replied that it’s how the statute is written. The MTFs weren’t likely to buy it. They have a little more direct control and they are more efficient and cost conscience as they are actually buying it whereas pharmacies are essentially a pass through for payment. How many MTF pharmacies have the brand name naproxen on the shelf? The answer is zero.

Mr. Hostettler said he will go back many years in his career. They have found pharmacies buying things they shouldn't be buying a much higher cost. It does occur.

CAPT VonBerg replied it does, but we have drastically improved our monitoring of purchasing.

Hostettler said yes, but he is a dinosaur.

There were no more questions or comments from the Panel. The Chair called for a vote on the Drugs Designated NF, Pre-Authorization Criteria, and the Implementation Plan for the Section 703, NDAA FY08.

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

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

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

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

A. Prenatal Vitamins and Other Products

(CAPT VONBERG)

1. 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:

- a. **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.
- b. **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.)
- c. Evaluating statutory and/or regulatory authorities to address continued coverage of selected vitamins and other products when considered to be clinically and cost effective.

Note that following the August P&T Committee meeting, the POD was notified of First DataBank's plans to delay the January 1, 2018 implementation. As a result, implementation of the above recommendations to add 8 products to the OTC program is delayed pending further clarification. They will be continued to be covered as prescription products.

2. Physician's Perspective

We became aware of a change in regulatory status for several drugs that currently require prescriptions that would be moving to OTC status. Since we now can add OTC drugs to the formulary, the Committee recommended adding the 8 most commonly prescribed cost-effective prenatal vitamins to the UF, given the reasons noted previously. The Committee is also in the process of identifying OTC drugs that are currently dispensed at the MTFs in order to align availability across the MTFs, as part of the changeover to an electronic health record system (MHS Genesis).

Following the P&T meeting, we were notified that First DataBank is planning to delay the original January 1, 2018 implementation of the Rx to OTC change. As a result, implementation of the above recommendations to add 8 products to the OTC program will be delayed pending further clarification. The affected products will continue to be covered as prescription products.

3. Panel Questions and Comments

Mr. Hostettler asked of the 694 products, have you had a chance to look and see how many patients are on the 694 drugs.

CAPT VonBerg replied yes. Off the top of his head, out of the 694 agents, 131 of them are prenatal vitamins. Of the prenatal vitamins that we selected as covered already, 91% of the prescriptions are covered with the 8 selected products had been dispensed. At least 91% of those patients will be unaffected by any need to change because coverage will continue with those items. Any other patients that were on a different item can switch to the covered items.

Mr. Hostettler asked if 191 of the 694 are prenatal vitamins.

CAPT VonBerg corrected 131 are PNV products. 694 were different types of vitamins. It doesn't specify the number of unique utilizers.

Mr. Hostettler said forget prenatal vitamins. There are approximately one third of the other products. How many patients are impacted?

CAPT VonBerg states that the number is in our minutes. I don't know the number off the top of my head. No one is affected right now.

Mr. Hostettler stated he understands. It is not his intent to fight with you on this issue and applauds on the effort. He would like to know the impact to the patients on the other products. Due to the delay notice from First Databank, you now have more time to address those patient needs. Is the delay in implementation indefinite, 6 months, or less?

CAPT VonBerg states that they haven't said. Even if they did change it, our recommendation is to continue covering the drugs. The prescription benefit was moving to OTC which would automatically cause it to not be covered. The P&T minutes say to cover them under the OTC authority that we have until we have time to evaluate all the products.

Mr. Hostettler said the word "temporary" got my attention.

CAPT VonBerg replied P&T will conduct a review just like they did with prenatal vitamins. They will reach out to the providers and ask what these patients need. What can we give them? P&T will do an analysis on the products and their availability. There is not a lot a variation on what is in the prenatal vitamin products but there are a lot of different products with variation in value.

Mr. Hostettler stated again he applauds the effort on prenatal vitamins, but take that same approach with the other products.

CAPT VonBerg replied with absolutely. As mentioned, we are not only going to that with the 694, but will do that with all the other products offered throughout the benefit. We want to ensure the things that are needed are consistently available. Things that don't have any evidence, we may remove those.

Dr. Anderson stated that's good work.

Mr. Du Teil stated he's not as smart as all the other folks. He's interested in what those other items were and also the impact of the studies. For instance, someone with chronic acid reflux, would you provide them with Prilosec or another prescription drug that does the same thing. Is that kind of analysis being done to make sure we're not wasting money and providing service to those patients?

CAPT VonBerg replied with absolutely. Omeprazole is already on the official list for the OTC program. We have completed several analyses on PPIs, antihistamines, nausea medications, pregnancy, and emergency

contraceptives agents. We already have a program that requires analysis. We are going to continue to do further analysis. We always strive to ensure the efficacy, safety and evidence is there and also the financial piece.

CAPT Norton added there was also a pilot done in approximately 2011. It looked at some of the OTC products proven to provide high value for treating these conditions as an alternative measure. An example, as CAPT VonBerg mentioned, is Omeprazole. The NDAA 2014 or 16 changed the statutes to allow a pilot program giving the Committee the authority to look at OTCs that provide high value relative to prescription alternatives and to make those part of the pharmacy benefits for retail and MTFs although they were OTC.

CAPT VonBerg said our directive was cost-effectiveness and access to OTC.

There were not more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation and Implementation Plan for the Prenatal Vitamins and Other products.

- **Prenatal Vitamins and Other Products – UF Recommendation and Implementation Plan**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

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

A. NDAA 2017 Pilot Program

(CAPT VONBERG)

1. 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 pens (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 pens (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.

2. Physician's Perspective

In order to comply with the requirements of the NDAA pilot program, Defense Health Agency had already identified several chronic conditions as constituting a high value component of clinical services, for example diabetes. We then identified two drugs where a reduction or elimination in the cost share would encourage beneficiaries to use the medication. The statins and basal insulin were good choices, since they represent chronic disease states (hyperlipidemia and diabetes, respectively) that impact a large number of DoD beneficiaries, and have proven benefits on mortality (statins) or surrogate endpoints (Hemoglobin A1C) that are of interest to patients and improve health outcomes. Rosuvastatin and Lantus pens were the specific drugs selected for the pilot.

Currently, TRICARE already has an advanced medication benefit, since generics are encouraged, and most organizations view generics as high-value medications. Additionally, the current formulary copays range from \$10/month to \$24/month, and are not viewed as a barrier to access in the Mail Order and Retail points of service. These co-pays likely don't have a huge impact on patient behaviors.

A review of MHS utilization and cost found that implementing the pilot program will positively impact 96,000 unique utilizers currently receiving rosuvastatin, and 40,000 patients receiving the Lantus Pens. Note that this recommendation for the Lantus pens is not tied to the previous UF recommendation from this meeting, but will align with the recommendation for Lantus to be step-preferred.

There is follow up reporting requirements that will be due to the Senate Armed Services Committee, so the results of this pilot will be monitored and assessed as to the true effect on adherence.

3. Panel Questions and Comments

Dr. Anderson asked is there a timeline on how long the pilot runs.

CAPT VonBerg replied with 5 years.

Mr. Hostettler stated the MTFs have zero copays today. Do they have an adherence problem? Have you looked to see what the adherence issues are in the MTF.

CAPT VonBerg replied that they have done various analyses on different products. They will be watching all of those. When they draft the reports, they will include monitoring at all three points of service. They will also be monitoring comparators. We are monitoring both to get focused view on the selected agents and points of service and broad enough views to understand the larger market.

Mr. Hostettler asked if the MTFs are part of the pilot.

CAPT VonBerg replied that they are not part of the pilot, but they will separately be watching the MTFs.

Mr. Hostettler stated he is not against the Pilot and doesn't want to sound negative. He is interesting in ensuring analysis conducted on the MTF as well since the copay is zero for everything. His sure they probably have some adherence issues. It'd be nice to look at that and validate that.

CAPT VonBerg responded they are a baseline right now. That is what they use them for.

Lt Khoury said the intent of the pilot is to assess the effect of reducing or eliminating copay on adherence.

Dr. Anderson said they are just complying. In his opinion, the general cost is over-emphasized under the current and agreed with Dr. Kugler. I'd be curious to watch the findings evolve. I'll also be a little bit surprised if there is a huge impact.

CAPT VonBerg said that most of the studies that look at this show changes with plans with much higher copays.

Dr. Anderson said the copays are higher and what I typically see in literature is cost gets talked about a lot. If there is a high deductible, the insurance plan cost is definitely a variance for adherence. I think with this benefit design, I'll be curious/interested to see the results.

Mr. Hostettler said he hopes it's positive.

Dr. Anderson replied it's good for the members around these drugs. My concern regarding these programs is impact to the beneficiaries whose drugs was not chosen. There's no perfect way to pick which drugs go into this. There are a lot of drugs that you could stay away for the copay. That would be great for everyone. It's hard to choose. Good job on the ones you've chosen.

CAPT Norton said the background with NDAA 2017 was described as reformed TRICARE. There were a lot of provisions that started at 701 and went as high as 746 provisions. There were 46 provisions that has some tweaks. I think the pilot has shown the copay as a positive to adherence and ultimately help outcomes and will be expanded to other drugs. The pilot I described with the OTC has purged medications and changed status to make it broader.

Mr. Hostettler asked how you are measuring. I only ask that question because in mail order the prescription drugs mailed out are significant.

Lt Col Khoury replied that each has different measure since they are used differently, with one being a pill and the other an injectable. For insulin, it will be the intensity of fill rate. For the statins, it will be the proportion of days covered.

Mr. Du Teil said he is not trying to get out of the purview of what the Panel is designed to do. In the larger sense, as a representative of patients in general on a lot of issues, this information is going to be useful because you can't really look at the cost of prescription drugs in a vacuum. Again, way outside the purview, but we're looking at perhaps getting rid of the grandfathering clause for existing retirees for copays and other stressors that increase costs of the nation. From that standpoint, I look forward to the results of the study so we don't have a retired population, with all these things factoring together, has to choose between eating and taking medicine. I applaud your efforts as well.

Ms. Buchanan asked if he said 96,000 for the statins.

Dr. Kugler replied that the program could impact 96,000 unique utilizers currently receiving the statin rosuvastatin and 40,000 patients receiving the Lantus Pens.

Mr. Hostettler asked why there were 2 votes on Day 1, Day 2.

CAPT VonBerg replied the meeting was going so long, they had to separate. Each drug was presented with deliberations. As deliberations

go, they look for recommendations. In previous meetings, we've had one day. This one was two.

There were no more questions or comments from the Panel. The Chair called for a vote on the Committee Recommendation and Implementation for the NDAA 2017 Pilot Program.

- **NDAA 2017 Pilot Program – Committee Recommendation and Implementation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 3

CAPT Norton thanked the panel and the audience for their attendance.

Meeting Concludes



Dr. Michael J. Anderson
Chair, Uniform Formulary Beneficiary
Advisory Panel

Brief Listing of Acronyms Used in this Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in the Panel discussions are listed below for easy reference. The term “Pan” in this summary refers to the “Uniform Formulary Beneficiary Panel,” the group who’s meeting in the subject of this report.

- ADHD – Attention Deficit Hyperactivity Disorder
- AIDS – Acquired Immune Deficiency Syndrome
- ALL – Acute Lymphoblastic Leukemia
- AML – Acute Myeloid Leukemia
- BIA – Budget Impact Analysis
- CFR – Code of Federal Regulations
- CMA – Cost Minimization Analysis
- DHA – Defense Health Agency
- DMARDs – Disease Modifying Anti-Rheumatic Drugs
- DoD- Department of Defense
- ER – Extended Release
- FDA – Food & Drug Administration
- G – Grams
- GI-2 – Gastrointestinal-2
- GLP1RA – Glucagon-Like Peptide-1 Agonists
- HAE – Hereditary Angiodema
- HD – Extended Release
- HER2 – Human Epidermal Growth Factor Receptor
- HFA – Hydrofluoroalkane
- HIV – Human Immunodeficiency Virus
- ICS/LABAs – Inhaled Corticosteroids/Long-Acting Beta Agonists
- INSTI – Integrase Strand Transfer Inhibitors
- JIA – Juvenile Idiopathic Arthritis
- MAOI – Monamine Oxidase Inhibitors
- MHS – Military Health Systems
- mL- milliliter
- MTF – Military Treatment Facility
- NDAA – National Defense Authorization Act
- NDC – National Drug Codes
- NF – Non-Formulary
- NKI – Neurokinin
- NNRT1 – Nucleoside/Nucleotide Reverse Transcriptase Inhibitor
- NPH – Neutral Protamine Hagedorn
- OIC – Opioid-Induced Constipation

- PA- Prior Authorization
- PAMORAs – Peripherally-Acting MU Opioid Receptor Agonists
- PEG – Percutaneous Endoscopic Gastronomy
- P&T – Pharmacy & Therapeutics
- pJLA – Polyarticular Juvenile Idiopathic Arthritis
- PPIs – Proton Pump Inhibitors
- PrEP – Pre-Exposure Prophylaxis
- SGLT2 – Sodium Glucose Co-Transporter
- SQ – Subcutaneously
- SU – Sulfonylurea
- TIBs – Targeted Immunomodulatory Biologics
- TNF – Anti-Tumor Necrosis Factor
- TRICARE – Healthcare Network
- UF – Uniform Formulary
- VMAT2 – Vesicular Monoamine Transporter 2
- XR – Extended Release