EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel (BAP)

September 30, 2015

RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENT

1. LONG-ACTING MUSCARINIC ANTAGONIST

A. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)—Uniform Formulary Recommendation:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** umeclidinium (Incruse Ellipta) be designated formulary on the Uniform Formulary, based on clinical and cost effectiveness.

B. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** implementation upon signing of the minutes.

***Summary of Physician's Perspective*:**

There is a high degree of therapeutic interchangeability between the three LAMAs – Incruse Ellipta, Spiriva, and Tudorza. Although there are no head-to head trials between the LAMAs, the effect on FEV1 appears similar when the results of placebo-controlled trials are compared.

The Ellipta device is a new device that is very easy for the patient to use, and it only requires one inhalation once daily.

Several COPD drugs have been recently approved by the FDA, including fixed dose combinations of two drugs in once inhaler, containing a LAMA and a long-acting beta agonist. The P&T Committee is considering whether to review the LAMAs and the fixed dose combination LAMA/LABA drugs sometime in 2016.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta).

- **LAMA: Umeclidinium (Incruse Ellipta) – UF Recommendation:**

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

  Director, DHA:

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

- **LAMA: Umeclidinium (Incruse Ellipta) – Implementation Plan:**

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

  Director, DHA:

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

2. TARGETED IMMUNOMODULATORY BIOLOGICS

A. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)—Uniform Formulary Recommendation:

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

- Secukinumab (Cosentyx) be designated formulary and non-preferred based on cost effectiveness and the previously accepted solicitation condition sets from the August 2014 P&T Committee TIBs Drug Class review. A trial of adalimumab (Humira) is required prior to use of Cosentyx.
- The current prior authorization criteria for Cosentyx, previously approved at the February 2015 P&T Committee meeting will be continued.

B. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** the Uniform Formulary implementation plan become effective upon signing of the minutes. .

***Summary of Physician's Perspective*:**

The Committee recommended UF status for Cosentyx, but it will be behind the step and require a trial of Humira first. Humira has the largest number of FDA-approved indications for the TIBs.

Cosentyx does have a unique mechanism of action, but there are several other TIBs approved for treating psoriasis.

For Cosentyx, the FDA approved dose has to be administered as two injections once daily, as the volume is too large to be given in one injection. There is the potential that a patient could be under-dosed, if only one syringe is used inadvertently.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx).

- **(TIBs): Secukinumab (Cosentyx) – UF Recommendation:**

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

  Director, DHA:

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

- **(TIBs): Secukinumab (Cosentyx) – Implementation Plan:**

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

  Director, DHA:

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

UNIFORM FORMULARY CLASS REVIEWS

1. NON-INSULIN DIABETES DRUGS: SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS:

A. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Uniform Formulary Recommendation:

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

- Uniform Formulary and step-preferred:

  a. Empagliflozin (Jardiance)
  b. Empagliflozin/linagliptin (Glyxambi)

- Non-formulary and non-step-preferred:

  a. Canagliflozin (Invokana)
  b. Canagliflozin/metformin (Invokamet)
  c. Dapagliflozin (Farxiga)
  d. Dapagliflozin/metformin extended release (Xigduo XR)

This recommendation includes step therapy (automated prior authorization), which requires a trial of empagliflozin or empagliflozin/metformin prior to use of the non-formulary, non-step-preferred SGLT2 inhibitors in all new and current users. Prior authorization criteria currently apply to the entire SGLT2 inhibitors subclass.

B. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Automated Prior Authorization (Step Therapy) and Manual Prior Authorization Criteria:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** to modify the existing prior authorization criteria to require a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses prior to use of an SGLT2 inhibitor in new users. The P&T Committee also recommended step therapy criteria for Invokana, Invokamet, Farxiga, and Xigduo XR.

The full prior authorization (PA) criteria are as follows:

All new users of an SGLT2 inhibitor are required to try metformin and at least one drug from two 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 two additional different oral non-insulin diabetes drug classes at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days.

  OR

- The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 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 two additional different oral non-insulin diabetes drug classes are NOT required) if:

- The patient has had an inadequate response to metformin and at least one drug from two 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 two additional different oral non-insulin diabetes drug classes; or
- The patient has a contraindication to metformin and at least one drug from two additional different oral non-insulin diabetes drug classes.

  AND

In addition to the above criteria regarding metformin and at least one drug from two additional different oral non-insulin diabetes drug classes, the following prior authorization criteria would apply specifically to all new and current users of canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/metformin ER (Xigduo XR):

- The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance or Glyxambi) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.

C. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Uniform Formulary and Prior Authorization Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 90-day implementation period in all points of service and DHA send a letter to beneficiaries affected by the Uniform Formulary decision.

***Summary of Physician's Perspective*:**

This is the first time the Committee has reviewed the SGLT2 inhibitors for formulary status. The three "parent" drugs (Invokana, Farxiga, and Jardiance) had previously been reviewed individually as newly approved drugs.

Fixed dose combinations of an SGLT2 inhibitor with other drugs, including metformin and the DPP-4 inhibitors, are starting to enter the market. However, the utilization of the fixed dose combination products only represent about 3% of the total market share for the subclass. Last month the fixed dose combination of empagliflozin with metformin was approved by the FDA, and will be reviewed at an upcoming meeting.

The SGLT2 inhibitors do have a unique mechanism of action –they primarily work in the kidneys to prevent reabsorption of glucose back into the bloodstream, and increase the excretion of glucose into the urine. However, this mechanism may be associated with adverse effects of female genital fungal infections and urinary tract infections.

The drugs do have some positive effects, including a slight reduction in blood pressure and about a four pound weight loss.

The major Diabetes guidelines, including the American Diabetes Association and the American Association of Clinical Endocrinologists, all mention the SGLT2 inhibitors can be used as second or third line. However there is agreement in the guidelines that metformin should still be used first.

We conducted a survey of DoD providers for the SGLT2 inhibitors. Over 400 providers responded to the survey. There was no clear agreement on whether an SGLT2 inhibitor needed to be on the formulary, with 26% of responders undecided, 41% wanting a formulary agent, and 33% not wanting a formulary agent. Most providers felt that patients should try other drugs or drug classes before using a SGLT2 including metformin, a sulfonylurea, a DPP-4 inhibitor,

a GLP1, or insulin. Additionally, the responders did mention the risk of adverse effects.

The Committee did feel that there was a high degree of therapeutic interchangeability between the products, and that is why a preferred product was chosen for the subclass (Jardiance and Glyxambi).

The Committee also suggested some changes to the existing step therapy criteria, and now recommends that a trial of metformin and two additional diabetes drug classes be tried before using an SGLT2 inhibitor. The step therapy recommendation was based on the major Diabetes Guidelines and because of the efficacy and safety data available with the other oral diabetes classes.

Last week, the Jardiance cardiovascular outcome study was published in the New England Journal of Medicine so we will review this study and determine if any changes to the Prior Authorization criteria are needed.

***Summary of Panel Questions and Comments*:**

Dr. Anderson asked if the data, referenced by Dr. Allerman, would align with the recommendation of the Committee because there was some outcomes data.

Dr. Allerman responded, we were not expecting the cardiovascular outcomes study for any of these drugs but all of them have studies underway. Jardiance products did have their study published in the New England Journal. It did show a beneficial effect on a composite employee group re: cardiovascular death. As always we will go back and review the study in detail. Unfortunately that there was not study completed on the drugs the P&T Committee preferred.

There were no more questions from the Panel. The Chair called for the vote on UF recommendation, Automated Prior Authorization (Step Therapy) and Manual Prior Authorization, UF and PA Implementation Plan for Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 Inhibitors.

- **(SGLT2) Inhibitors – Uniform Formulary Recommendation:**

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

Director, DHA:

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

- **SGLT2 Inhibitors – Automated PA (Step Therapy) and Manual PA Criteria:**

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

  Director, DHA:

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

- **SGLT2 Inhibitors – UF and PA Implementation Plan:**

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

  Director, DHA:

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

2. GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs)

A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Uniform Formulary Recommendation:

The P&T Committee recommended **(13 for, 2 opposed, 2 abstained, 0 absent)**

- Uniform Formulary and step-preferred:

  a. Exenatide once weekly (Bydureon)
  b. Albiglutide (Tanzeum)

- Non-formulary and non-step-preferred

  a. Exenatide twice daily (Byetta)
  b. Dulaglutide (Trulicity)
  c. Liraglutide (Victoza)

This recommendation includes step therapy (automated prior authorization), which requires a trial of exenatide once weekly (Bydureon) and albiglutide (Tanzeum) prior to use of the nonformulary, non-preferred GLP1RA drugs, in all new and current users. Additionally, prior authorization criteria currently apply to the entire GLP1RAs subclass.

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Automated Prior Authorization (Step Therapy) and Manual Prior Authorization Criteria Recommendation:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** maintaining the existing PA criteria, requiring a trial of metformin or sulfonylurea prior to use of a GLP1RA in all current and new users. The P&T Committee also recommended step therapy criteria for Byetta, Trulicity, and Victoza.

The full prior authorization (PA) criteria are as follows:

- All new and current users of a Bydureon, Tanzeum, Byetta, Trulicity, and Victoza are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA.

- Additionally, all new and current users of Victoza, Byetta, and Trulicity are required to try Bydureon or Tanzeum first.

Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days,

AND

Manual PA criteria: If automated prior authorization criteria are not met, Bydureon, Tanzeum, Byetta, Trulicity, or Victoza is approved (e.g., trial of metformin or SU is NOT required) if:

- The patient has a confirmed diagnosis of type 2 diabetes mellitus
- The patient has experienced any of the following issues on metformin:

  a. impaired renal function precluding treatment with metformin
  b. history of lactic acidosis

- The patient has experienced any of the following issues on a SU:

  a. hypoglycemia requiring medical treatment

- The patient has had inadequate response to metformin or a SU
- The patient has a contraindication to metformin or a SU

AND

In addition to the above criteria regarding metformin and SU, the following prior authorization criteria would apply specifically to new and current users of Byetta, Trulicity, and Victoza:

- The patient has had an inadequate response to Bydureon and Tanzeum.

C. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Uniform Formulary and Prior Authorization Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 90-day implementation period in all points of service and DHA send a letter to beneficiaries affected by the Uniform Formulary decision.

***Summary of Physician's Perspective*:**

The P&T Committee has previously reviewed the GLP-1RAs in 2010 and 2012, and we wanted to review the class again, due to the market entry of new products.

When we surveyed the providers for the SGLT2 inhibitors, we also asked the about the GLP-1RAs. Overall, 42% of providers felt that 2 agents were needed on the uniform formulary. Most providers chose Victoza as the drug they wanted on formulary, followed by Byetta, then Bydureon; but the reasons for these preferences were due to having the most experience with Victoza and Byetta.

The Committee did realize that the majority of the market share currently in DoD is with Victoza. Victoza is dosed once daily, and was the easiest product to use for several years, since Byetta required twice a day dosing and Bydureon was previously only available in a cartridge that was difficult to activate.

The Committee did recognize the advantages of the once weekly dosing with Bydureon and Tanzeum. Bydureon is now available in a prefilled syringe, and Tanzeum has a small needle size. Additionally, choosing Bydureon and Tanzeum allows for having products with two different chemical entities, instead of having Bydureon and Byetta, which have the same active ingredient of exenatide.

The overall goal of the step therapy is to continue to promote the use of metformin or sulfonylurea prior to the GLP1RAs, which is consistent with the guidelines, and to promote use of the preferred GLP1RAs – Bydureon and Tanzeum.

The formulary recommendation is for "no grandfathering" so the patients currently receiving Victoza will need to try Bydureon or Tanzeum. However, now patients have the opportunity for a once weekly injection instead of a once daily product.

Several products are in the pipeline, including formulations with long durations of action that could potentially be dosed once monthly. So it is likely that we will be reviewing the class again in a couple of years.

***Summary of Panel Questions and Comments*:**

Dr. Anderson asked for the beneficiary count of Victoza users that are affected by the Committee recommendation.

Dr. Allerman responded approximately 21, 000 patients and the beneficiary count was taken into consideration by the P&T committee. The Committee believed that since these products were self-injected it would provide an opportunity for the patients switch to a product that is injected once a week would be beneficial to the patients. For several years there has been an attending endocrinologists that sits on the Committee and he believes that the once a week dosing would be beneficial to the patients.

Dr. Kugler interjected that the endocrinologists did agree with the step therapy.

Dr. Allerman stated that she forgot to mention that there were two (2) opposing votes who wanted Byetta and Bydureon but they both have the same active ingredients. The committee members wanted two different active ingredients.

Dr. Anderson asked Dr. Allerman to clarify the statement regarding the reformulation of Bydureon.

Dr Allerman responded that the original Bydureon formulation was very complicated to put together. The patient had to wait several minutes but now it is in a prefilled syringe. The patient has to wait approximately10 minutes for it to mix but it is much more user friendly. It the drug had been available in the older formulation the committee would not have recommended it.

There were no more questions or comments from the Panel. The Chair called for the vote on UF recommendation, Automated Prior Authorization (Step Therapy) and Manual Prior Authorization, UF and PA Implementation Plan for Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs).

- **GLPR1RAs – Uniform Formulary Recommendation:**

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

  Director, DHA:

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

- **GLPR1RAs – Automated PA (Step Therapy) and Manual PA Criteria:**

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

  Director, DHA:

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

- **GLPR1RAs – UF and PA Implementation Plan:**

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

  Director, DHA:

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

3. ORAL ONCOLOGY DRUGS: CHRONIC MYELOGENOUS LEUKEMIA

A. Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)—Uniform Formulary Recommendation:

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

- Uniform Formulary (no-step scenario):

  a. Imatinib (Gleevec)
  b. Dasatinib (Sprycel)
  c. Nilotinib (Tasigna)
  d. Bosutinib (Bosulif)
  e. Ponatinib (Iclusig)

- Non-formulary: None

B. Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** the Uniform Formulary implementation plan become effective upon signing of the minutes.

***Summary of Physician's Perspective*:**

This was the second oral oncology drug class that has been reviewed. There are differences in the safety profiles between the drugs, and based on individual patient factors, one product can be preferred over another.

Overall, this was a win-win situation for the DoD – all the products resulted in a cost avoidance, and were recommended to be added to the formulary.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Oral Oncology Drugs: Chronic Myelogenous Leukemia.

- **Chronic Myelogenous Leukemia – Uniform Formulary Recommendation:**

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

  Director, DHA:

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

- **Chronic Myelogenous Leukemia – Implementation Plan:**

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

  Director, DHA:

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

4. NARCOTIC ANALGESIC DRUGS: LONG ACTING HIGH POTENCY NARCOTIC ANALGESICS

A. Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics—Uniform Formulary Recommendation:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** the following:

- Uniform Formulary (no step scenario):

  a. Fentanyl transdermal system (Duragesic, generics)
  b. Hydrocodone ER (Hysingla ER, Zohydro ER)
  c. Hydromorphone ER (Exalgo, generics)
  d. Morphine sulfate sustained release (MS Contin, generics)
  e. Morphine ER (Avinza, Kadian, generics)
  f. Morphine ER/naltrexone (Embeda)
  g. Oxycodone controlled release (Oxycontin)
  h. Oxymorphone ER (Opana ER, generics)
  i. Tapentadol ER (Nucynta ER)

- Non-formulary: None

B. Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** the Uniform Formulary implementation plan become effective upon signing of the minutes.

***Summary of Physician's Perspective*:**

There has been a lot of publicity given to the new "abuse deterrent' formulations of narcotics. Ideally these new formulations prevent the drugs from being inhaled or injected, but they do not prevent all cases of inappropriate use – patients can always ingest multiple tablets. The data does not yet show that these abuse deterrent formulations result in measurable decreases in abuse.

There are several DoD resources for providers to help ensure safe opioid prescribing. Some of the programs include the Sole Provider Program, the Prescription Monitoring Program, "Do no harm" mandatory training, Project ECHO (Extension for Community Healthcare Outcomes), and the VA/DoD Clinical Practice Guidelines "Management of Opioid Therapy for Chronic Pain" Toolkit.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics.

- **Long Acting High Potency Narcotic Analgesics – Uniform Formulary Recommendation:**

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

Director, DHA:

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

- **Long Acting High Potency Narcotic Analgesics – Implementation Plan:**

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

Director, DHA:

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

UTILIZATION MANAGEMENT

1. PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE INHIBITORS:

A. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Alirocumab (Praluent) – Prior Authorization Criteria:

The PCSK9 inhibitors are a new class of biologic drugs that lower low-density lipoprotein (LDL) cholesterol. Alirocumab (Praluent) was approved on July 24, 2015, and is administered as biweekly subcutaneous injections. At the time of the August P&T Committee meeting, the second drugs in the class, evolocumab (Repatha) was anticipated to obtain FDA approval on August 27, 2015. Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional LDL lowering. The product labeling states that the effect of Praluent on cardiovascular morbidity and mortality has not been determined. Prior authorization criteria were recommended for the PCSK9 inhibitors due to the lack of data on cardiovascular morbidity and mortality, unknown long-term safety profile, and anticipated high cost.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual prior authorization criteria for alirocumab (Praluent) in all new and current users. Prior authorization will be approved for patients with heterozygous familial hypercholesterolemia or patients with atherosclerotic cardiovascular disease with LDL levels greater than 100 mg/dL despite maximally tolerated statins doses (atorvastatin 40 mg to 80 mg and rosuvastatin 20 mg to 40 mg, or any statin at maximally tolerated doses in combination with ezetimibe).

The full prior authorization (PA) criteria are as follows:

Manual PA criteria apply to all new and current users of alirocumab (Praluent).

Manual PA criteria—Alirocumab is approved if:

- A cardiologist, lipidologist, or endocrinologist prescribes the drug.
- The patient is at least 18 years of age.
- The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.
- The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below:

    a. The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR

b. The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR
c. If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND
d. The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy.

- For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:

  a. Intolerance

- The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND
- The patient has undergone at least two trials of statin re-challenges with reappearance of muscle symptoms, OR
- The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.

  a. Contraindication to statin

- The contraindication must be defined.
- Praluent is not approved for any indication other than heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease.
- Praluent is not approved for patients who are pregnant or lactating.
- The dosage must be documented on the Prior Authorization Form as either:

  a. 75 mg every 2 weeks, or
  b. 150 mg every 2 weeks.

- PA expires in one year.
- PA criteria for renewal: After one year, prior authorization must be resubmitted. Continued use of Praluent will be approved for the following:

  a. The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
  b. The patient has documented adherence.

B. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Evolocumab (Repatha)—Prior Authorization Criteria:

Due to the impending FDA approval of evolocumab, the P&T Committee also recommended **(16 for, 0 opposed, 1 abstained, 0 absent),** contingent upon FDA approval, manual prior authorization criteria for evolocumab (Repatha) in

all new and current users. The product labeling for Repatha is similar to Praluent, with the exception that in addition to patients with heterozygous familial hypercholesterolemia and clinical atherosclerotic heart disease, Repatha is also approved for treating patients with homozygous familial hypercholesterolemia, including pediatric patients from the ages of 13 to 17 years.

The full prior authorization (PA) criteria are as follows: Manual prior authorization criteria apply to all new and current users of evolocumab (Repatha).

Manual PA criteria—Evolocumab is approved if:

- A cardiologist, lipidologist, or endocrinologist prescribes the drug.
- The patient is at least 18 years of age for heterozygous familial hypercholesterolemia (HeFH) and clinical atherosclerotic cardiovascular disease (ASCVD). For homozygous familial hypercholesterolemia (HoFH), patients as young as 13 years of age can receive the drug.
- The patient has HoFH and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol.
- The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.
- The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below:

    a. The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR
    b. The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR
    c. If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND
    d. The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy.

- For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:

    a. Intolerance

- The patient has experienced intolerable and persistent (for longer than two weeks) muscle symptoms (muscle pain, weakness, cramps), AND

- The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR
- The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.

a. Contraindication to statin

- The contraindication must be defined.
- Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD.
- Repatha is not approved for patients who are pregnant or lactating.
- The dosage must be documented on the PA Form as either:

a. 140 mg every 2 weeks, or
b. 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose.

- PA expires in one year.
- PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Repatha will be approved for the following:

a. The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
b. The patient has documented adherence.

C. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Alirocumab (Praluent) and Evolocumab (Repatha)—Implementation Plans:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** the PA implementation plans for alirocumab (Praluent) and evolocumab (Repatha) become effective upon signing of the minutes in all points of service.

***Summary of Physician's Perspective*:**

Although this new therapy is a promising treatment for patients with elevated LDL levels, it has yet to be established whether these drugs will cause a reduction in heart attacks or stroke.

Prior Authorization criteria were recommended, since there is limited data on outcomes with these products, and also because the statins have a large body of evidence of their benefits. Additionally, several civilian health plans and the VA are recommending Prior Authorization criteria.

The PA criteria are consistent with the FDA-approved indications in the package inserts. The P&T Committee did want to ensure that statin therapy had been maximized, and they also did define what constituted a statin failure.

Since these drugs do require injections by the patient, and are very expensive, we want to be sure that patients will be compliant and achieve the most beneficial effects possible. This was the reasoning as to why the PA will expire in one year – we want to be sure that the patient's response to therapy is assessed.

***Summary of Panel Questions and Comments*:**

Dr. Anderson asked if the committee discussed the controversial criteria for this drug class and the LDL threshold of 100. Can you speak to has that was established?

Dr. Allerman responded in November 2013 the American College of Cardiology and the American Heart Association stated or published that is was not necessary to treat to a target LDL anymore. However when the drugs put on the market, there was a recommendation for LDL monitoring on the label. The committee did reach out to the cardiology consultants but there with the dilemma the there is no recommended monitoring for LDL and asked for guidance. The threshold of the 100 LDL was recommended by the cardiology consultants and agreed on by the committee. The traditional treatment for patients who have already had a cardiovascular event is that their LDL remains less than 100. After the patient has had treatment the LDL should to be below 70.

Dr. Kugler and Dr. Allerman provided comments regarding patient adherence.

Dr. Anderson asked if the adherence documented or achieved by looking a claims data.

Dr. Allerman responded that a lot of health plans will be evaluating and the Committee will conduct another drug class review for these products. She further states that there are a lot of things the committee would like to do from a research perspective to make sure patients are responding appropriately. Unfortunately, the committee does not have easy access on client data and would be relying on the Specialist to say that the patients LDL has dropped and they are compliant. She asks Dr. Anderson is he had any recommendations on how to assess adherence the committee would be happy to discuss.

There were no more questions or comments from the Panel. The Chair called for the vote on Prior Authorization Criteria and Implementation Plan for Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors: Alirocumab (Praluent) and Evolocumab (Repatha).

- **PCSK9 - Alirocumab (Praluent) – Prior Authorization Criteria:**

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

  Director, DHA:

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

- **PCSK9 – Evolocumab (Repatha) – Prior Authorization Criteria:**

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

  Director, DHA:

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

- **PCSK9 – Alirocumab (Praluent) – Implementation Plan:**

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

  Director, DHA:

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

- **PCSK9 – Evolocumab (Repatha) – Implementation Plan:**

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

  Director, DHA:

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

2. INHALED CORTICOSTEROIDS

A. Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Prior Authorization Criteria:

The FDA approved Arnuity Ellipta and Asmanex HFA in August and April 2014, respectively. The ICS products were reviewed by the P&T Committee in May 2014 and automated prior authorization (step therapy) and manual prior authorization criteria were approved. Fluticasone propionate (Flovent Diskus

and Flovent HFA) are the step-preferred ICS products; the remaining ICS products are non-step-preferred.

Arnuity Ellipta and Asmanex HFA are approved for treating asthma in patients 12 years of age and older; Flovent Diskus is approved in patients as young as four years of age. Arnuity Ellipta and Asmanex HFA were recommended to follow the same prior authorization criteria as the other non-step-preferred ICS products.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** step therapy and manual prior authorization criteria for all new users of Arnuity Ellipta and Asmanex HFA, consistent with the current prior authorization for the other non-step-preferred inhaled corticosteroids products.
The full prior authorization (PA) criteria are as follows:

PA criteria apply to all new users of **Arnuity Ellipta** and **Asmanex HFA** who are older than 12 years of age.

Automated PA criteria: The patient has filled a prescription for Flovent Diskus or Flovent HFA at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria: Arnuity Ellipta and Asmanex HFA are approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if:

- Patient has experienced any of the following issues with Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred inhaled corticosteroids:

  a. inadequate response to the step preferred drugs
  b. contraindication
  c. patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk

B. Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Implementation Plan

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA) become effective on the first Wednesday after a 90-day implementation period in all points of service.

***Summary of Physician's Perspective*:**

These updates to the prior authorization criteria for the inhalers are consistent with the FDA-approved indications and age ranges listed in the package inserts.

These are examples of the Committee keeping up to date with new data that becomes available with the drug classes that already have step therapy in place.

***Summary of Panel Questions and Comment*s:**

There were no questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization for Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA).

- **ICS Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Prior Authorization Criteria – Prior Authorization Criteria:**

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

  Director, DHA:

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

- **ICS Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Prior Authorization Criteria – Implementation Plan:**

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

  Director, DHA:

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

3. INHALED CORTICOSTEROIDS (ICS) AND LONG-ACTING BETA2-ADRENERGIC AGONIST (LABA) COMBINATIONS: FLUTICASONE FUROATE/VILANTEROL (BREO ELLIPTA)

A. Inhaled Corticosteroids (ICS) and Long-Acting Beta2-Adrenergic Agonist (LABA) Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)—Manual Prior Authorization Criteria:

Fluticasone furoate/vilanterol (Breo Ellipta) is indicated for the long-term treatment of chronic obstructive pulmonary disease (COPD). In April 2015, the FDA-approved indication was further expanded to include the daily treatment of asthma in patients aged 18 years and older. The ICS/LABA products were reviewed by the P&T Committee in February 2014, where automated prior authorization (step therapy) and manual prior authorization criteria were approved for patients older than 12 years. Fluticasone propionate/salmeterol

(Advair Diskus and Advair HFA) are the step-preferred ICS/LABA products; the remaining ICS/LABA products are non-step-preferred.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** updating the manual PA criteria for Breo Ellipta to include the expanded FDA-approved indication.

The full prior authorization (PA) criteria are as follows:

Existing step therapy criteria apply to all new and current users of Breo Ellipta who are older than 12 years of age.

New PA criteria for Breo Ellipta will apply to patients who are at least 18 years of age for treating asthma.

Automated PA criteria: The patient has filled a prescription for Advair or Advair HFA at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

- Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) if:
    a. Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with the non-preferred ICS/LABA combination drug:
        - inadequate response to Advair Diskus or Advair HFA
        - intolerable adverse effects
        - contraindication
        - patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk

- **Additionally, Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) in patients who are 18 years of age and older for treating asthma if:**

  a. Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with Breo Ellipta:

     - inadequate response to Advair Diskus or Advair HFA
     - intolerable adverse effects

B. Inhaled Corticosteroids (ICS) and Long-Acting Beta2-Adrenergic Agonist (LABA) Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Fluticasone Furoate/Vilanterol (Breo Ellipta) become effective on the first Wednesday after a 90-day implementation period in all points of service.

***Summary Physician's Perspective*:**

These updates to the prior authorization criteria for the inhalers are consistent with the FDA-approved indications and age ranges listed in the package inserts.These are examples of the Committee keeping up to date with new data that becomes available with the drug classes that already have step therapy in place.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization and the Implementation Plan for Inhaled Corticosteroids (ICS): Fluticasone Furoate/Vilanterol (Breo Ellipta)—Manual Prior Authorization Criteria:

- **ICS and LABA Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)—Manual Prior Authorization Criteria**:

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

  Director, DHA:

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

- **ICS and LABA Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)—Implementation Plan:**

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

  Director, DHA:

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

4. PULMONARY FIBROSIS DRUGS

A. Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Prior Authorization:

Ofev and Esbriet are two oral drugs that were FDA-approved in October 2014 for treatment of idiopathic pulmonary fibrosis (IPF). Ofev and Esbriet improve symptoms in IPF, as measured by a reduction in the decline in forced vital capacity, but have not been shown to decrease mortality. Manual PA criteria were recommended to ensure appropriate use of the drug for IPF diagnoses. The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual prior authorization criteria for Ofev and Esbriet, consistent with the FDA-approved product labeling for use in idiopathic pulmonary fibrosis. Prior authorization will expire after one year.

The full prior authorization (PA) criteria are as follows:

Manual prior authorization criteria will apply to all new and current users of nintedanib (Ofev) and pirfenidone (Esbriet).

Manual PA criteria:

Ofev or Esbriet is approved if:

- The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND
- The patient is being actively managed by a pulmonologist, AND
- The patient is only receiving one therapy—either Ofev or Esbriet. The patient cannot receive both drugs concomitantly (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa).

PA will expire after one year. Subsequent PA approval (Renewal PA) will require clinical documentation of efficacy, and will be limited to one year.

B. Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Nintedanib (Ofev) and Pirfenidone (Esbriet) become effective on the first Wednesday after a 90-day implementation period in all points of service.

***Summary of Physician's Perspective*:**

Ofev and Esbriet are new therapies for pulmonary fibrosis, however, they don't cure the condition, and have only been found to have an effect on pulmonary function testing and improve symptoms.

The Committee recommended Prior Authorization criteria, to ensure that the patient has been correctly diagnosed.

Currently there are about 750 patients in the DoD with idiopathic pulmonary fibrosis.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Manual Prior Criteria Authorization and Implementation Plan for Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Prior Authorization

- **Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Prior Authorization:**

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

  Director, DHA:

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

- **Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Implementation Plan:**

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

  Director, DHA:

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

5. ALZHEIMER'S DISEASE DRUGS

A. Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric)—Manual Prior Authorization Criteria:

Namenda XR and Namzaric are both approved for treatment of patients with moderate to severe dementia of Alzheimer's disease. Namenda XR is an ER formulation of memantine that is dosed once daily, in contrast to memantine IR, which is dosed twice daily. There are no studies addressing whether once daily therapy improves efficacy of memantine.

Namzaric contains a fixed-dose combination of memantine ER and donepezil (Aricept, generics). Memantine IR and donepezil are both available in low-cost generic formulations. FDA approval of Namzaric was based on bioequivalence studies and not clinical trial data. These two products will be reviewed as new drugs in November 2015. PA criteria were recommended to ensure appropriate use.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual PA criteria for Namenda XR and Namzaric in new users, consistent with the FDA-approved product labeling for Alzheimer's disease.

The full prior authorization (PA) criteria for Namenda XR are as follows: Manual prior authorization criteria apply to all new users of Namenda XR.

Manual PA criteria: Namenda XR is approved:

- The patient is being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia), AND
- Taking Namenda IR (memantine) twice daily causes undue burden to the patient or care provider, AND
- The patient's functional status has not declined while receiving Namenda IR.

The full prior authorization (PA) criteria for Namzaric are as follows: Manual PA criteria apply to all new users of Namzaric.

Manual PA criteria: Namzaric is approved if:

1. The patient is being treated for moderate to severe dementia of the Alzheimer's type, AND
2. The patient is stabilized on one of the following regimens:

    a. memantine IR 10 mg twice daily or memantine ER 28 mg once daily and donepezil hydrochloride 10 mg, OR
    b. memantine IR 5 mg twice daily or ER 14 mg once daily and donepezil hydrochloride 10 mg, AND

3. The patient is unable to take Namenda (memantine) and Aricept (donepezil) separately, OR
4. The patient has progressive swallowing difficulties.

B. Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric) become effective on the first Wednesday after a 90-day implementation period in all points of service.

***Summary of Physician's Perspective*:**

These two drugs are new variations of existing medications. The Committee did recognize that patients with Alzheimer's disease require assistance with care and taking their medications.

These two products will be reviewed as new drugs in November, and updates to the PA criteria can be provided if necessary.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Manual Prior Criteria Authorization and Implementation Plan for Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric).

- **Alzheimer's Disease Drugs – Namenda XR and Namzaric – Manual Prior Authorization Criteria:**

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

  Director, DHA:

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

- **Alzheimer's Disease Drugs – Namenda XR and Namzaric – Implementation Plan:**

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

  Director, DHA:

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

6. SEDATIVE HYPNOTICS

A. Sedative Hypnotics: Tasimelteon (Hetlioz)—Renewal Prior Authorization Criteria:

Hetlioz is approved for treatment of blind patients with non-24 hour sleep-wake disorder. The P&T Committee reviewed Hetlioz in February 2015 and designated it with nonformulary status; prior authorization was also established at that time. Currently, prior authorization criteria will expires after six months, as patients who do not respond after a six-month Hetlioz trial are unlikely to show therapeutic benefit. The P&T Committee recommended adding additional criteria to the existing prior authorization to allow for the renewal of the prior authorization after six months, based on patient response.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** revising the manual prior authorization criteria for Hetlioz to assess response after six months of therapy.

The full prior authorization (PA) criteria are as follows:

For patients who have completed the initial six-month trial of Hetlioz, renewal PA criteria will be determined.

Renewal Manual PA criteria: Tasimelteon (Hetlioz) will be approved indefinitely

if:

- The patient is totally blind and has a documented diagnosis of non-24 sleep wake disorder

  AND

- The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers)

  AND

- The patient has been receiving Hetlioz for 6 months and has had a documented response to therapy.

PA will not be approved if the patient has not had a documented response to therapy. If the patient has not responded after 6 months, they will be deemed a non-responder.

B. Sedative Hypnotics: Tasimelteon (Hetlioz)—Implementation Plan

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Tasimelteon (Hetlioz) become effective on the first Wednesday after a 90-day implementation period in all points of service.

***Summary of Physician's Perspective*:**

This is an example where the P&T Committee wanted to have a mechanism for patients who have had a beneficial response to continue therapy with Hetlioz. If patients have not responded to therapy after 6 months, it is unlikely that they will ever respond.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Renewal Prior Criteria Authorization and Implementation Plan for Sedative Hypnotics: Tasimelteon (Hetlioz).

- **Hetlioz – Renewal Prior Authorization Criteria:**

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

Director, DHA:

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

- **Hetlioz – Implementation Plan:**

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

Director, DHA:

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

7. CYSTIC FIBROSIS DRUGS

A. Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi)—Manual Prior Authorization Criteria:

Orkambi is a fixed-dose combination product containing lumacaftor with ivacaftor (Kalydeco). Both drugs are potentiators of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Orkambi was FDA-approved in July 2015 for treatment of cystic fibrosis in patients at least 12 years of age who are homozygous for the F508del mutation in the CFTR gene. Currently, prior authorization criteria apply to the ivacaftor component of Orkambi.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual prior authorization criteria for Orkambi, consistent with the FDA-approved product labeling.

The full prior authorization (PA) criteria are as follows:

Prior Authorization applies to all new and current users of lumacaftor/ivacaftor (Orkambi).

Manual PA criteria: Orkambi is approved if:

- Orkambi is prescribed for the treatment of cystic fibrosis in an age-appropriate patient population according to the product label.

  AND

- The patient is homozygous for the F508del deletion mutation in the cystic fibrosis transmembrane conductance regulator gene, detected by an FDA-approved test.

B. Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Lumacaftor/Ivacaftor (Orkambi) become effective on the first Wednesday after a 90-day implementation period in all points of service.

***Summary of Physician's Perspective*:**

This panel has seen several updates to the PA for the cystic fibrosis drug Kalydeco, and now Kalydeco has been combined into the product called Orkambi. Once again, we've kept current with changes to the package insert and the approved pediatric age ranges.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Manual Prior Criteria Authorization and Implementation Plan for Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi).

- **Orkambi – Manual Prior Authorization Criteria:**

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

  Director, DHA:

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

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual prior authorization criteria for Orkambi, consistent with the FDA-approved product labeling.

The full prior authorization (PA) criteria are as follows:

Prior Authorization applies to all new and current users of lumacaftor/ivacaftor (Orkambi).

Manual PA criteria: Orkambi is approved if:

- Orkambi is prescribed for the treatment of cystic fibrosis in an age-appropriate patient population according to the product label.

  AND

- The patient is homozygous for the F508del deletion mutation in the cystic fibrosis transmembrane conductance regulator gene, detected by an FDA-approved test.

B. Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Lumacaftor/Ivacaftor (Orkambi) become effective on the first Wednesday after a 90-day implementation period in all points of service.

***Summary of Physician's Perspective*:**

This panel has seen several updates to the PA for the cystic fibrosis drug Kalydeco, and now Kalydeco has been combined into the product called Orkambi. Once again, we've kept current with changes to the package insert and the approved pediatric age ranges.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Manual Prior Criteria Authorization and Implementation Plan for Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi).

- **Orkambi – Manual Prior Authorization Criteria:**

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

Director, DHA:

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

- **Orkambi – Implementation Plan:**

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

Director, DHA:

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

8. TOPICAL PAIN PRODUCTS

A. Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel)—Manual PA Criteria:

Solaraze is FDA-approved for the topical treatment of actinic keratosis. The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual PA criteria for Solaraze 3% Gel in all new users, consistent with the FDA-approved product labeling for use in actinic keratosis.

The full prior authorization (PA) criteria are as follows:

Prior Authorization criteria apply to all new users of Solaraze 3% Gel.

Manual PA criteria: Diclofenac 3% topical gel (Solaraze Gel) is approved if:

The patient has a documented diagnosis of actinic keratosis. Only apply to new patients

B. Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Diclofenac Gel (Solaraze 3% Gel) become effective on the first Wednesday after a 90-day implementation period in all points of service

***Summary of Physician's Perspective*:**

A review of Solaraze found that there was some inappropriate use, so a manual PA was recommended to limit Solaraze to the FDA-approved indication of actinic keratosis.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization and Implementation Plan for Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel).

- **Solaraze 3% Gel – Manual Prior Authorization Criteria:**

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

Director, DHA:

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

- **Solaraze 3% Gel – Implementation Plan:**

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

Director, DHA:

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

9. COMPOUND PRESCRIPTIONS

A. Compound Prescriptions – Prior Authorization Criteria:

The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant, but decreasing. There has been a decrease in the number of compounded prescriptions filled; however, compounded medications continue to have a high potential for inappropriate use.

Manual prior authorization criteria for compounds were recommended by the DoD P&T Committee in November 2014, and presented to the Beneficiary Advisory Panel in January 2015. In March, 2015, Lt Gen Robb modified the prior authorization criteria. The current prior authorization criteria for compounded prescriptions require documentation of the diagnosis and route of administration; a trial of commercially available products; and the results of therapy for commercially available products. Allowances are made for national drug shortages or commercial products. Providers can submit supporting clinical documentation to be considered.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent) that** the current prior authorization criteria should expire after one year. Prior authorization approval will last for 12 months, or for the duration of therapy, if less than 12 months.

B. Compound Prescriptions – Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 60-day implementation period in all points of service; and, DHA send a letter to all beneficiaries with a prior authorization currently in place.

***Summary of Physician's Perspective*:**

This latest recommendation is to have the compounded prescriptions PA expire after one year. A review of utilization data found that less than 7% of patients are on a compounded prescription for more than one year, so there will be a limited number of beneficiaries affected by this change.

Patients will be notified of this update to the PA via mailed letters.

***Summary of Panel Questions and Comments*:**

Ms. Buchanan states that she is seeing consistent trending in the voting among the Panel members. She asks if it is appropriate to inquire about the reason for the one (1) committee member that abstained.

CAPT VonBerg responded the the VA representative abstained.

There were no more questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization Criteria and Implementation Plan for Compound Prescriptions.

- **Compound Prescriptions – Prior Authorization Criteria:**

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

  Director, DHA:

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

- **Compound Prescriptions – Implementation Plan:**

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

  Director, DHA:

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

SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAL 2008 (FY 08)

1. **Section 703, NDAA FY08—Uniform Formulary Recommendation:**

   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 Section 703 of the Fiscal Year 2008 National Defense Authorization Act. The law stipulates that if a drug is not compliant with Section 703, it will be designated non-formulary on the Uniform Formulary and will require pre-authorization prior to use in the Retail point of service and medical necessity at the Military Treatment Facilities. These non-formulary drugs will remain available in the Mail Order point of service without preauthorization.

   The P&T Committee recommended **(13 for, 0 opposed, 2 abstained, 2 absent)** the following product be designated non-formulary on the Uniform Formulary:

   - Neos Therapeutics: Hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL.

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

   The P&T Committee recommended **(13 for, 0 opposed, 2 abstained, 2 absent)** the following pre-authorization criteria for hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL by Neos Therapeutics:

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

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

3. **Section 703, NDAA FY08—Implementation Plan for Pre-Authorization Criteria:**

   The P&T Committee recommended **(13 for, 0 opposed, 2 abstained, 2 absent)** an effective date of the first Wednesday after a 90-day implementation period in the Retail Network and DHA send a letter to beneficiaries affected by this decision.

   ***Summary of Physician's Perspective*:**

   There is no physician perspective for Section 703 information:

***Summary of Panel Questions and Comments*:**

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

- **Section 703, NDAA FY08 – UF Recommendation:**

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

  Director, DHA:

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

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

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

  Director, DHA:

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

- **Section 703, NDAA FY08 – Implementation Plan for Pre-Authorization Criteria:**

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

  Director, DHA:

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

4. **Additional Panel questions and comments**:

Dr. Delgado asks if the language in Section IV-A-2, bullet 2 of the Pre-Authorization criteria can be changd in the minutes. The current language is as follows:

- Change from: For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.
- Change to: For branded products with products with AB-rated generic availability, use of the generic product could be detrimental to the patient.

Dr. Allerman stated that a recommended change can be suggested as part of the official documentation but this is the language that has been used for several years. However, the change will be noted as a recommendation from the Panel.

- **The Panel vote of the recommended substitute the work "could" for "would":**

Concur: 5 Non-Concur: 1 Abstain: 0 Absent: 1

Director, DHA:

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

OVER-THE-COUNTER DRUGS

1. OVER-THE-COUNTER DRUGS

Section 702 of the Fiscal Year 2013 National Defense Authorization Act provides legislative authority for the Over-the-Counter (OTC) Drug Program. The Final Rule published in the Federal Register on July 27, 2015, establishes the process for identifying OTC products for coverage under the TRICARE pharmacy benefit and the rules for making these products available to eligible DoD beneficiaries.

A. OTC Drugs—Relative Cost-Effectiveness and Patient Access:

The P&T Committee evaluated the relative cost-effectiveness and patient access considerations for the following over-the-counter drug currently covered as part of the OTC Demonstration Project: omeprazole 20 mg (Prilosec, Prilosec OTC, generics)

The P&T Committee recommended (**14 for, 0 opposed, 1 abstained, 2 absent):**

- Removing coverage of branded omeprazole (Prilosec OTC), as it is not cost effective, relative to comparable generic and prescription proton pump inhibitors.

- Generic formulations of omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics), and levonorgestrel (Plan B, generics) will remain designated formulary on the Uniform Formulary.

***Summary of Physician's Perspective*:**

Several new regulations that affect the pharmacy benefit were recently enacted. Now, the P&T Committee will be able to make formulary recommendations for OTC drugs, and the Panel will be seeing more OTC clinical and cost reviews in the future.

***Summary of Panel Questions and Comments*:**

There were no questions or comments from the Panel. The Chair called for the vote on Relative Cost-Effectiveness and Patient Access for OTC Drugs.

- **OTC Drugs – Relative Cost-Effectiveness:**

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

Director, DHA:

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

Brief Listing of Acronyms Used in this Summary

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

- ASCVD - Atherosclerotic Cardiovascular Disease
- BIA – Budget Impact Analysis
- BID – Dosed Twice Daily
- CFR – Code of Federal Regulations
- CFTR – Cystric Fybrosis Transmembrane Conductance Regulator
- CK – Creatinine Kinase
- CML – Chronic Myelogenous Leukemia
- CTM - Cholpheniramine
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DoD – Department of Defense
- DPP-4 - Dipeptidyl Peptidase 4
- ER – Extended Release
- ER/LA – Extended Relase/Long Acting
- FDA – Food Drug Administration
- FEV1 – Forced Expiratory Volume in 1 Second
- GLP1-RA - Glucagon Like Peptide-1 Receptor Agonist
- HeFH - Heterozygous Familial Hypercholestolemia
- HFA - Hydrofluoroalkane
- HoFH - Homozygous Familial Hypercholestrolemia
- IPF - Idiopathic Pulmonary Fibrosis
- IR – Interventional Radiology
- IU/L – International Unites per Unit
- LAMA – Long Acting Muscarinic Antagonist
- LDL - Lipoprotein Cholesterol
- MS - Morphine Sulfate
- NDAA – National Defense Authorization Act
- OTC - Over-the-Counter
- P&T Committee - Pharmacy & Therapeutics Committee
- PA - Prior Authorization
- PCSK9 - Proprotein Convertase Subtilisin/Kexin Type 9
- QT - Quart
- SLGT2 - Sodium Glucose Co-transporter 2

- SU - Sulfonylurea
- TIB – Targeted Immunomodulatory Biologics
- TRICARE – Military Health Care System
- ULN – Upper Limits of Normal
- XR – Extended Release

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
September 30, 2015
Washington, D.C.

Present Panel Members

- Robert Duane Tackitt, the Association of Military Surgeons US, Chairperson
- Sandra S. Delgado, Humana
- Theresa Buchanan, the National Military Family Association
- Michael Anderson, United Healthcare
- John Wagoner, HealthNet Federal Services
- Katherine O. Tracy, the Military Officers Association of America

Absent

- Robert Lewis, Chief Warrant and Warrant Officers Association

Agenda

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

- Welcome and Opening Remarks
- Public Citizen Comments
- Therapeutic Class Review
    - Designated Newly Approved Drugs
        - Long-Acting Muscarinic Antagonists (LAMAs) – Umeclidinium (Incruse)
        - Targeted Immunomodulatory Biologics (TIBs) – Secukinumab injection (Cosentyx)
    - Drug Class Reviews
        - Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
        - Non-Insulin Diabetes Drugs: Glucagon-Like Peptide 1 (Receptor Agonists (GLP1RAs)
        - Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)
        - Narcotic Analgesics: Long Acting High Potency Narcotic Analgesics
    - Utilization Management Issues – Prior Authorization Criteria
        - Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors – Alirocumab (Praluent) and evolocumab (Repatha) Injections

- Inhaled Corticosteroids/Long-Flutcasone furotate (Arnuity Ellipta) and mometasone (Asmanex HFA) inhalers
- Inhaled Corticosteroids/Long-Acting Beta Agonists Combinations – Fluticasone fuoate/vilanterol (Breo Ellipta) Inhaler
- Pulmonary Fibrosis Drugs – Nintedanib (Ofev) and Pirfenidone (Esbriet)
- Alzheimer's Disease Drugs – Memantine extended release (Namednda XR) and memantine extended release/donepezil (Namzaric)
- Sedative Hypnotics – Tasimelteon (Hetlioz)
- Cystic Fibrosis Drugs – Lumacaftor/ivacaftor (Orkambi)
- Topical Pain Products – Diclofenac Gel (Solaraze 3% Gel)
- Compound Prescriptions

- National Defense Authorization Act Fiscal Year 2008, Section 703 Actions

- Over-the-Counter (OTC) Drugs: UF Recommendations

- Panel Discussions:

  The Uniform Formulary Beneficiary Advisory Panel will have the opportunity to ask questions to each of the presenters. Upon completions 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 introduces himself as the Designated Federal Officer (DFO) for the Uniform Formulary Beneficiary Advisory Panel. The panel has convened to comment on the recommendations of the DoD P&T Committee meeting, which occurred on August 12-13, 2015.

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 establish 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 prepare comments of the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared for the Director of DHA. As guidance to the Panel regarding this meeting, CAPT Norton said the role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the department appreciates that the BAP maybe interested in the drug class the selected for review, drugs recommended for the basic core formulary (BCF) or specific pricing data, these titles 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 Pharmacoeconomic 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

Mr. Tackitt welcomes CAPT Norton and greets the audience.

DRUG CLASS REVIEW PRESENTATION

(PEC Script – CAPT VONBERG)

Good Morning. I am CAPT Edward VonBerg, Chief of the Formulary Management Branch. Joining me is doctor and retired Army Colonel (Ret) 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 Dr. Angela Allerman, a clinical pharmacist and Deputy Chief of the P&T Section; I would also like to recognize Mr. Bryan Wheeler, David Hurt Acting General Counsel for the DHA.

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

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

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

- 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).

- 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

    a. 2 newly approved drugs. They are:

        - Umeclidinium (Incruse Ellipta) in the Long Acting Muscarinic Antagonist (LAMA) drug class;
        - Secukinumab (Cosentyx) in the Targeted Immunomodulatory Biologics (TIB) drug class;

b. Finally, the P&T Committee reviewed four (4) Uniform Formulary Drug Classes:

- Diabetes Non-insulin, Sodium glucose Co-transporter 2 (SLGT2) drugs subclass and
- Diabetes Non-Insulin, Glucagon Like Peptide-1 Receptor Agonist (GLP1-RA) drugs subclass;
- Oral Oncologic Agents, Chronic Myelogenous Leukemia (CML) drug subclass;
- Long Acting Narcotic Analgesics, drug subclass.

c. We will also discuss nine (9) Prior Authorizations (PA):

- PCSK9 Inhibitors - Alirocumab (Praluent)
- Inhaled corticosteroids - Fluticasone furoate (Arnuity Ellipta) and Mometasone furoate (Asmanex HFA)
- Inhaled corticosteroids/long acting beta agonists combinations - Fluticasone / vilanterol (Breo Ellipta)
- Drugs for Idiopathic pulmonary fibrosis - Nintedanib (Ofev) andPirfenidone (Esbriet)
- Drugs for Alzheimer's disease - Memantine (Namenda XR) and Memantine ER and donepezil (Namzaric)
- Tasimelteon (Hetlioz)
- Diclofenac 3% (Solaraze)
- Cystic Fibrosis Drug: Lumacaftor /ivacaftor (Orkambi)
- Update the current compounds Prior Authorization criteria to expire after one year.

d. There was ONE drug under Section 703, National Defense Authorization Act (NDAA) for Fiscal Year 2008 reviewed at this meeting.

e. There was several drugs under Section 702, National Defense Authorization Act (NDAA) for Fiscal Year 2013 reviewed. (this statue provides legislative authority for the Over-the-Counter Drug Program)

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.

We have given you a handout that includes the Uniform Formulary recommendations for all the drugs discussed today; these are found on pages 2 through 5. We will be using trade names as much as possible, so you can refer to your handout throughout the presentation.

I. RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. LONG-ACTING MUSCARINIC ANTAGONIST

(Dr. Allerman)

1. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)—Relative Clinical Effectiveness and Conclusion:

Umeclidinium (Incruse Ellipta) is an oral inhaler approved for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). There are no studies evaluating reduction in COPD exacerbations as a primary endpoint. Similar to tiotropium (Spiriva), umeclidinium has a long duration of action. The FDA-approved dose of 62.5 mcg was based on trials showing umeclidinium produced statistically and clinically significant improvements in the forced expiratory volume in one second (FEV_1). The safety profile is similar to the other LAMAs. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** that the main clinical benefits of umeclidinium are its one puff, once daily dosing, and the ease of use of the Ellipta device. Based on active controlled trials, the changes in FEV_1 with umeclidinium appear similar to that achieved with tiotropium.

2. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)—Relative Cost-Effectiveness Analysis and Conclusion:

Cost minimization analysis was performed. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** that umeclidinium (Incruse Ellipta) was cost effective compared with other LAMA inhalers on the Uniform Formulary.

3. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)—Uniform Formulary Recommendation:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** umeclidinium (Incruse Ellipta) be designated formulary on the Uniform Formulary, based on clinical and cost effectiveness.

4. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** implementation upon signing of the minutes.

5. Physician's Perspective:

There is a high degree of therapeutic interchangeability between the three LAMAs – Incruse Ellipta, Spiriva, and Tudorza. Although there are no head-to head trials between the LAMAs, the effect on FEV1 appears similar when the results of placebo-controlled trials are compared.

The Ellipta device is a new device that is very easy for the patient to use, and it only requires one inhalation once daily.

Several COPD drugs have been recently approved by the FDA, including fixed dose combinations of two drugs in once inhaler, containing a LAMA and a long-acting beta agonist. The P&T Committee is considering whether to review the LAMAs and the fixed dose combination LAMA/LABA drugs sometime in 2016.

6. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta).

- **LAMA: Umeclidinium (Incruse Ellipta) – UF Recommendation:**

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

- **LAMA: Umeclidinium (Incruse Ellipta) – Implementation Plan:**

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

B. TARGETED IMMUNOMODULATORY BIOLOGICS

(CAPT Vonberg)

1. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)—Relative Clinical Effectiveness and Conclusion:

Secukinumab (Cosentyx) has a unique mechanism of action and is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

The TIBs were previously reviewed for Uniform Formulary placement in August 2014; adalimumab (Humira) was selected as the step-preferred drug. Step therapy and manual prior authorization (PA) apply to all the TIBs. In February 2015, the P&T Committee recommended manual PA criteria for secukinumab, consistent with the class.

- Five (5) TIBs are approved for treating psoriasis: adalimumab (Humira), etanercept (Enbrel), ustekinumab (Stelara), apremilast (Otezla), and secukinumab (Cosentyx).
- In clinical trials, secukinumab demonstrated superior efficacy to placebo, etanercept (Enbrel), and ustekinumab (Stelara) in treating moderate to severe plaque psoriasis. There are no head-to-head trials comparing secukinumab (Cosentyx) and adalimumab (Humira).
- Secukinumab is well tolerated. The rates of adverse events do not differ significantly for secukinumab and other TIBs.
- The FDA-approved 300 mg dose requires administration of two 150 mg injections, which is a potential inconvenience to the patient.

The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent),** despite its unique mechanism of action, secukinumab (Cosentyx) offers no clinically compelling advantages over the existing TIBs on the Uniform Formulary approved for plaque psoriasis.

2. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)—Relative Cost-Effectiveness Analysis and Conclusion:

Cost minimization analysis was performed. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** that secukinumab (Cosentyx) was cost effective compared with other TIBs on the Uniform Formulary approved for treating plaque psoriasis.

3. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)—Uniform Formulary Recommendation:

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

- Secukinumab (Cosentyx) be designated formulary and non-preferred based on cost effectiveness and the previously accepted solicitation condition sets from the August 2014 P&T Committee TIBs Drug Class review. A trial of adalimumab (Humira) is required prior to use of Cosentyx.
- The current prior authorization criteria for Cosentyx, previously approved at the February 2015 P&T Committee meeting will be continued.

4. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)—Implementation Plan:

The P&T Committee recommended **(17 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 90-day implementation period in

all points of service and DHA send a letter to beneficiaries affected by the Uniform Formulary decision.

5. Physician's Perspective:

The Committee recommended UF status for Cosentyx, but it will be behind the step and require a trial of Humira first. Humira has the largest number of FDA-approved indications for the TIBs.

Cosentyx does have a unique mechanism of action, but there are several other TIBs approved for treating psoriasis.

For Cosentyx, the FDA approved dose has to be administered as two injections once daily, as the volume is too large to be given in one injection. There is the potential that a patient could be under-dosed, if only one syringe is used inadvertently.

6. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx).

- **(TIBs): Secukinumab (Cosentyx) – UF Recommendation:**

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

- **(TIBs): Secukinumab (Cosentyx) – Implementation Plan:**

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

II. UNIFORM FORMULARY CLASS REVIEWS

A. NON-INSULIN DIABETES DRUGS: SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS:

(Dr. Allerman)

1. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Relative Clinical Effectiveness and Conclusion:

The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** the following with regard to the SGLT2 inhibitors and their fixed-dose combinations:

- There are no head-to-head trials between any of the SGLT inhibitors, although there do not appear to be clinically relevant differences in their effects on lowering A1c when used as monotherapy or added on to other diabetes drugs.
- The most common adverse drug reactions for all the SGLT2 inhibitors are female genital mycotic infections and urinary tract infections. The SGLT2 inhibitors are contraindicated in patients that have severe renal impairment, although empagliflozin and canagliflozin can be used in patients moderate renal impairment.
- Empagliflozin and dapagliflozin have a lower risk of drug-drug interactions than canagliflozin. (Invokana)
- The cardiovascular (CV) safety profile of SGLT2 inhibitors is currently unknown. At the time of the August 2015 DoD P&T Committee meeting there were no published long-term CV outcomes trials.
- There is a high degree of therapeutic interchangeability between the SGLT2 inhibitors.
- The SGLT2 inhibitors have a limited role in treating T2DM due to a lack of clinically, compelling advantages over alternative therapies in lowering A1c, an unknown CV safety profile, and undesirable side effects, including genital mycotic and urinary tract infections.

Overall Relative Clinical Effectiveness Conclusion*:* Other than their potential for weight loss, the SGLT2 inhibitors offer no additional clinical advantages over the other non-insulin diabetes drugs on the Uniform Formulary.

2. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Relative Cost-Effectiveness Analysis and Conclusion:

Cost minimization analysis and budget impact analyses were performed. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** the following:

- Cost minimization analysis results showed that empagliflozin (Jardiance) and empagliflozin/linagliptin (Glyxambi) were the most cost-effective SGLT2 inhibitors, followed by dapagliflozin (Farxiga), dapagliflozin/metformin (Xigduo XR), and lastly followed by canagliflozin (Invokana) and canagliflozin/metformin (Invokamet).
- Budget impact analyses (BIA) was performed to evaluate the potential impact of designating selected agents as formulary (and step-preferred) or non-formulary (and non-step-preferred) on the Uniform Formulary. BIA results showed that designating empagliflozin (Jardiance) and empagliflozin/linagliptin (Glyxambi) as formulary and step-preferred resulted in the greatest cost avoidance for the Military Health System.

3. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Uniform Formulary Recommendation:

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

- Uniform Formulary and step-preferred:

  a. Empagliflozin (Jardiance)
  b. Empagliflozin/linagliptin (Glyxambi)

- Non-formulary and non-step-preferred:

  a. Canagliflozin (Invokana)
  b. Canagliflozin/metformin (Invokamet)
  c. Dapagliflozin (Farxiga)
  d. Dapagliflozin/metformin extended release (Xigduo XR)

This recommendation includes step therapy (automated prior authorization), which requires a trial of empagliflozin or empagliflozin/metformin prior to use of the non-formulary, non-step-preferred SGLT2 inhibitors in all new and current users. Prior authorization criteria currently apply to the entire SGLT2 inhibitors subclass.

4. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Automated Prior Authorization (Step Therapy) and Manual Prior Authorization Criteria:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** to modify the existing prior authorization criteria to require a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses prior to use of an SGLT2 inhibitor in new users. The P&T Committee also recommended step therapy criteria for Invokana, Invokamet, Farxiga, and Xigduo XR.

The full prior authorization (PA) criteria are as follows:

All new users of an SGLT2 inhibitor are required to try metformin and at least one drug from two 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 two additional different oral non-insulin diabetes drug classes at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days.

  OR

- The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 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 two additional different oral non-insulin diabetes drug classes are NOT required) if:

- The patient has had an inadequate response to metformin and at least one drug from two 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 two additional different oral non-insulin diabetes drug classes; or
- The patient has a contraindication to metformin and at least one drug from two additional different oral non-insulin diabetes drug classes.

  AND

In addition to the above criteria regarding metformin and at least one drug from two additional different oral non-insulin diabetes drug classes, the following prior authorization criteria would apply specifically to all new and current users of canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/metformin ER (Xigduo XR):

- The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance or Glyxambi) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.

5. **Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Uniform Formulary and Prior Authorization Implementation Plan:**

   The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 90-day implementation period in all points of service and DHA send a letter to beneficiaries affected by the Uniform Formulary decision.

6. **Physician's Perspective:**

   This is the first time the Committee has reviewed the SGLT2 inhibitors for formulary status. The three "parent" drugs (Invokana, Farxiga, and Jardiance) had previously been reviewed individually as newly approved drugs.

   Fixed dose combinations of an SGLT2 inhibitor with other drugs, including metformin and the DPP-4 inhibitors, are starting to enter the market. However, the utilization of the fixed dose combination products only represent about 3% of the total market share for the subclass. Last month the fixed dose combination of empagliflozin with metformin was approved by the FDA, and will be reviewed at an upcoming meeting.

   The SGLT2 inhibitors do have a unique mechanism of action –they primarily work in the kidneys to prevent reabsorption of glucose back into the bloodstream, and increase the excretion of glucose into the urine. However, this mechanism may be associated with adverse effects of female genital fungal infections and urinary tract infections.

   The drugs do have some positive effects, including a slight reduction in blood pressure and about a four pound weight loss.

   The major Diabetes guidelines, including the American Diabetes Association and the American Association of Clinical Endocrinologists, all mention the SGLT2 inhibitors can be used as second or third line. However there is agreement in the guidelines that metformin should still be used first.

   We conducted a survey of DoD providers for the SGLT2 inhibitors. Over 400 providers responded to the survey. There was no clear agreement on whether an SGLT2 inhibitor needed to be on the formulary, with 26% of responders undecided, 41% wanting a formulary agent, and 33% not wanting a formulary agent. Most providers felt that patients should try other drugs or drug classes before using a SGLT2 including metformin, a sulfonylurea, a DPP-4 inhibitor, a GLP1, or insulin. Additionally, the responders did mention the risk of adverse effects.

The Committee did feel that there was a high degree of therapeutic interchangeability between the products, and that is why a preferred product was chosen for the subclass (Jardiance and Glyxambi).

The Committee also suggested some changes to the existing step therapy criteria, and now recommends that a trial of metformin and two additional diabetes drug classes be tried before using an SGLT2 inhibitor. The step therapy recommendation was based on the major Diabetes Guidelines and because of the efficacy and safety data available with the other oral diabetes classes.

Last week, the Jardiance cardiovascular outcome study was published in the New England Journal of Medicine so we will review this study and determine if any changes to the Prior Authorization criteria are needed.

7. BAP Comments:

Dr. Anderson asked if the data, referenced by Dr. Allerman, would align with the recommendation of the Committee because there was some outcomes data.

Dr. Allerman responded, we were not expecting the cardiovascular outcomes study for any of these drugs but all of them have studies underway. Jardiance products did have their study published in the New England Journal. It did show a beneficial effect on a composite employee group re: cardiovascular death. As always we will go back and review the study in detail. Unfortunately that there was not study completed on the drugs the P&T Committee preferred.

There were no more questions from the Panel. The Chair called for the vote on UF recommendation, Automated Prior Authorization (Step Therapy) and Manual Prior Authorization, UF and PA Implementation Plan for Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 Inhibitors.

- **(SGLT2) Inhibitors – Uniform Formulary Recommendation:**

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

- **SGLT2 Inhibitors – Automated PA (Step Therapy) and Manual PA Criteria:**

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

- **SGLT2 Inhibitors – UF and PA Implementation Plan:**

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

B. GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs)

(Dr. Allerman)

1. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Relative Clinical Effectiveness and Conclusion:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** the following conclusions for the GLP-1RA subclass:

- Metformin remains the first-line treatment in all patients with type 2 diabetes mellitus, unless contraindications exist.
- The GLP1RAs are all indicated for monotherapy as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus. They are not first-line therapies.
- The GLP1RAs are self-injectable medications that differ in the frequency of administration. Trulicity, Tanzeum, and Bydureon have the advantage of once weekly dosing; Victoza is dosed once daily; and, Byetta is dosed twice daily (BID).
- The results of seven (7) head-to-head trials between the GLP1RAs do not show clinically significant differences in effects on glycemic control.
- Weight loss was observed in all seven head-to-head studies. When used as monotherapy or as an add-on agent, a 2 kg to 3 kg weight loss is expected with the GLP1RAs.
- The reported incidence of hypoglycemia with GLP1RAs is low, ranging from 3% to 9%. Tanzeum has the lowest incidence of hypoglycemia when used with a sulfonylurea or as monotherapy.
- Nausea is the most common adverse event among all the GLP1RAs. Tanzeum has the lowest incidence of nausea (11.1%) compared to Bydureon (14.4%), Victoza (22.7%), Trulicity (12.1 % to 21.1%), or Byetta (29.9%).
- All the GLP1RAs are contraindicated for use in patients with pancreatitis. All the GLP1RAs except Byetta carry black box warnings for medullary thyroid cancer and multiple endocrine neoplasia syndrome type 2.
- There are no completed trials with any FDA-approved GLP1RA that assess long-term cardiovascular outcomes; cardiovascular safety studies are underway.
- Tanzeum and Trulicity have an advantage in offering a smaller needle size for patient convenience.
- Trulicity, Byetta, and Victoza have an advantage as they do not require mixing prior to administration.

Overall Relative Clinical Effectiveness Conclusion—The GLP1RAs have a high degree of therapeutic interchangeability, with no clinically relevant differences between the individual products.

2. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Relative Cost-Effectiveness Analysis and Conclusion:

Cost minimization analysis and budget impact analyses were performed. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** the following:

- Cost minimization analysis results showed that exenatide twice daily (Byetta) was the most cost-effective GLP1RA, followed by albiglutide (Tanzeum), exenatide once weekly (Bydureon), dulaglutide (Trulicity), and liraglutide (Victoza).
- Budget impact analyses (BIA) was performed to evaluate the potential impact of designating selected agents as step-preferred, formulary, or non-formulary on the Uniform Formulary. BIA results showed that designating exenatide once weekly (Bydureon) and albiglutide (Tanzeum) as formulary and step-preferred agents, with no grandfathering (i.e., step therapy would apply to all new and current users of a GLP1RA), demonstrated significant cost avoidance for the Military Health System.

3. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Uniform Formulary Recommendation:

The P&T Committee recommended **(13 for, 2 opposed, 2 abstained, 0 absent)**

- Uniform Formulary and step-preferred:

  a. Exenatide once weekly (Bydureon)
  b. Albiglutide (Tanzeum)

- Non-formulary and non-step-preferred:

  a. Exenatide twice daily (Byetta)
  b. Dulaglutide (Trulicity)
  c. Liraglutide (Victoza)

This recommendation includes step therapy (automated prior authorization), which requires a trial of exenatide once weekly (Bydureon) and albiglutide (Tanzeum) prior to use of the nonformulary, non-preferred GLP1RA drugs, in all new and current users. Additionally, prior authorization criteria currently apply to the entire GLP1RAs subclass.

4. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Automated Prior Authorization (Step Therapy) and Manual Prior Authorization Criteria Recommendation:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** maintaining the existing PA criteria, requiring a trial of metformin or sulfonylurea prior to use of a GLP1RA in all current and new users. The P&T Committee also recommended step therapy criteria for Byetta, Trulicity, and Victoza.

The full prior authorization (PA) criteria are as follows:

- All new and current users of a Bydureon, Tanzeum, Byetta, Trulicity, and Victoza are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA.

- Additionally, all new and current users of Victoza, Byetta, and Trulicity are required to try Bydureon or Tanzeum first.

Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days,

AND

Manual PA criteria: If automated prior authorization criteria are not met, Bydureon, Tanzeum, Byetta, Trulicity, or Victoza is approved (e.g., trial of metformin or SU is NOT required) if:

- The patient has a confirmed diagnosis of type 2 diabetes mellitus
- The patient has experienced any of the following issues on metformin:

  a. impaired renal function precluding treatment with metformin
  b. history of lactic acidosis

- The patient has experienced any of the following issues on a SU:

  a. hypoglycemia requiring medical treatment

- The patient has had inadequate response to metformin or a SU
- The patient has a contraindication to metformin or a SU

AND

In addition to the above criteria regarding metformin and SU, the following prior authorization criteria would apply specifically to new and current users of Byetta, Trulicity, and Victoza:

- The patient has had an inadequate response to Bydureon and Tanzeum.

5. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—Uniform Formulary and Prior Authorization Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 90-day implementation period in all points of service and DHA send a letter to beneficiaries affected by the Uniform Formulary decision.

6. Physician's Perspective:

The P&T Committee has previously reviewed the GLP-1RAs in 2010 and 2012, and we wanted to review the class again, due to the market entry of new products.

When we surveyed the providers for the SGLT2 inhibitors, we also asked the about the GLP-1RAs. Overall, 42% of providers felt that 2 agents were needed on the uniform formulary. Most providers chose Victoza as the drug they wanted on formulary, followed by Byetta, then Bydureon; but the reasons for these preferences were due to having the most experience with Victoza and Byetta.

The Committee did realize that the majority of the market share currently in DoD is with Victoza. Victoza is dosed once daily, and was the easiest product to use for several years, since Byetta required twice a day dosing and Bydureon was previously only available in a cartridge that was difficult to activate.

The Committee did recognize the advantages of the once weekly dosing with Bydureon and Tanzeum. Bydureon is now available in a prefilled syringe, and Tanzeum has a small needle size. Additionally, choosing Bydureon and Tanzeum allows for having products with two different chemical entities, instead of having Bydureon and Byetta, which have the same active ingredient of exenatide.

The overall goal of the step therapy is to continue to promote the use of metformin or sulfonylurea prior to the GLP1RAs, which is consistent with the guidelines, and to promote use of the preferred GLP1RAs – Bydureon and Tanzeum.

The formulary recommendation is for "no grandfathering" so the patients currently receiving Victoza will need to try Bydureon or Tanzeum. However, now patients have the opportunity for a once weekly injection instead of a once daily product.

Several products are in the pipeline, including formulations with long durations of action that could potentially be dosed once monthly. So it is likely that we will be reviewing the class again in a couple of years.

7. BAP Comments:

Dr. Anderson asked for the beneficiary count of Victoza users that are affected by the Committee recommendation.

Dr. Allerman responded approximately 21, 000 patients and the beneficiary count was taken into consideration by the P&T committee. The Committee believed that since these products were self-injected it would provide an opportunity for the patients switch to a product that is injected once a week would be beneficial to the patients. For several years there has been an attending endocrinologists that sits on the Committee and he believes that the once a week dosing would be beneficial to the patients.

Dr. Kugler interjected that the endocrinologists did agree with the step therapy.

Dr. Allerman stated that she forgot to mention that there were two (2) opposing votes who wanted Byetta and Bydureon but they both have the same active ingredients. The committee members wanted two different active ingredients.

Dr. Anderson asked Dr. Allerman to clarify the statement regarding the reformulation of Bydureon.

Dr Allerman responded that the original Bydureon formulation was very complicated to put together. The patient had to wait several minutes but now it is in a prefilled syringe. The patient has to wait approximately10 minutes for it to mix but it is much more user friendly. It the drug had been available in the older formulation the committee would not have recommended it.

There were no more questions or comments from the Panel. The Chair called for the vote on UF recommendation, Automated Prior Authorization (Step Therapy) and Manual Prior Authorization, UF and PA Implementation Plan for Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs).

- **GLPR1RAs – Uniform Formulary Recommendation:**

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

- **GLPR1RAs – Automated PA (Step Therapy) and Manual PA Criteria:**

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

- **GLPR1RAs – UF and PA Implementation Plan:**

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

C. **ORAL ONCOLOGY DRUGS: CHRONIC MYELOGENOUS LEUKEMIA**

(CAPT Vonberg)

1. **Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)—Relative Clinical Effectiveness and Conclusion:**

   The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** the following:

   - Imatinib (Gleevec), nilotinib (Tasigna), and dasatinib (Sprycel) are approved in the United States for first-line therapy of chronic phase CML. Guidelines from the National Cancer Care Network and international guidelines also support the use of these three TKIs as first-line therapies.
   - Imatinib (Gleevec) advantages include pending generic availability, a well-known safety profile, and additional FDA indications other than CML. Adverse events include fatigue, myalgias, and fluid retention.
   - Advantages of dasatinib (Sprycel) and nilotinib (Tasigna) compared to imatinib include fewer progressions to acute phase CML or blast phase CML, based on head-to-head trials. The second generation tyrosine kinase inhibitors are preferred for use in moderate to high risk patients. However, to date, there are no statistically significant differences in overall survival between Gleevec and the second generation tyrosine kinase inhibitors.
   - Sprycel has been associated with pleural effusions and pulmonary arterial hypertension.
   - Tasigna requires twice daily administration and a fasting window. It has a black box warning for QT interval prolongation, and has been associated with pancreatitis and hyperglycemia.
   - Bosutinib (Bosulif) and ponatinib (Iclusig) have unique adverse reactions and there use is limited to second-line settings.

   Overall Relative Clinical Effectiveness Conclusion: The P&T Committee concluded that the choice of chronic myelogenous leukemia drug depends on patient comorbidities, provider experience, and continued response to initial treatment, prior treatment, and adverse event profiles.

2. **Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)—Relative Cost-Effectiveness Analysis and Conclusion:**

   Cost minimization analysis and budget impact analyses were performed. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** the following:

   - Cost minimization analysis results showed imatinib (Gleevec) was the most cost-effective tyrosine kinase inhibitor for chronic myelogenous leukemia.

   - Budget impact analyses (BIA) was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and formulary, non-preferred and formulary, and formulary without a step-therapy requirement. BIA results showed that all scenarios modeled were similar in projected cost avoidance to the Military Health System.

3. **Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)—Uniform Formulary Recommendation:**

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

   - Uniform Formulary (no-step scenario):

     a. Imatinib (Gleevec)
     b. Dasatinib (Sprycel)
     c. Nilotinib (Tasigna)
     d. Bosutinib (Bosulif)
     e. Ponatinib (Iclusig)

   - Non-formulary: None

4. **Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)—Implementation Plan**:

   The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** the Uniform Formulary implementation plan become effective upon signing of the minutes.

5. **Physician's Perspective:**

   This was the second oral oncology drug class that has been reviewed. There are differences in the safety profiles between the drugs, and based on individual patient factors, one product can be preferred over another.

Overall, this was a win-win situation for the DoD – all the products resulted in a cost avoidance, and were recommended to be added to the formulary.

6. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Oral Oncology Drugs: Chronic Myelogenous Leukemia.

- **Chronic Myelogenous Leukemia – Uniform Formulary Recommendation:**

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

- **Chronic Myelogenous Leukemia – Implementation Plan:**

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

D. NARCOTIC ANALGESIC DRUGS: LONG ACTING HIGH POTENCY NARCOTIC ANALGESICS

(CAPT Vonberg)

1. Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics—Relative Clinical Effectiveness and Conclusion:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** the following for the long acting narcotic analgesics:

- The long acting opioids are recognized as the mainstay of chronic pain management, with well-documented evidence of their efficacy in the short-term.
- Current guidelines do not state a preference for the use of one long acting high potency narcotic analgesic over another in the treatment of moderate to severe pain.
- Tapentadol ER (Nucynta ER) is the only long acting narcotic analgesic with an FDA-approved indication for the treatment of neuropathic pain associated with diabetic peripheral neuropathy.
- There is no new evidence regarding the comparative effectiveness of the long acting high potency narcotics. Clinical trials differ significantly in terms of study designs, patient characteristics, types of pain treated, and titration schedules.
- Meaningful conclusions cannot be drawn from indirect comparisons of the drugs. Two systematic reviews concluded that there is insufficient evidence to suggest clinically relevant differences in efficacy and safety among the long acting narcotics.

- While abuse-deterrent formulations offer a potential barrier to abuse via intravenous and intranasal routes, they have yet to demonstrate the ability to prevent abuse altogether. Abusers can still overcome the technologies in these formulations via over consumption.

2. Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics—Relative Cost-Effectiveness Analysis and Conclusion:

Cost minimization analysis and budget impact analyses were performed. The P&T Committee concluded **(17 for, 0 opposed, 0 abstained, 0 absent)** the following:

- Cost minimization analysis results showed that generic sustained release morphine sulfate (MS Contin) was the most cost-effective ER/LA opioid.

- Budget impact analyses (BIA) was performed to evaluate the potential impact of scenarios designating selected extended release/long acting opioid agents as formulary or non-formulary on the Uniform Formulary. BIA results showed that scenarios where all generic and branded formulations of the long acting high potency narcotic analgesics are designated formulary on the Uniform Formulary demonstrated cost avoidance for the Military Health System.

3. Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics—Uniform Formulary Recommendation:

The P&T Committee recommended **(17 for, 0 opposed, 0 abstained, 0 absent)** the following:

- Uniform Formulary (no step scenario):

  a. Fentanyl transdermal system (Duragesic, generics)
  b. Hydrocodone ER (Hysingla ER, Zohydro ER)
  c. Hydromorphone ER (Exalgo, generics)
  d. Morphine sulfate sustained release (MS Contin, generics)
  e. Morphine ER (Avinza, Kadian, generics)
  f. Morphine ER/naltrexone (Embeda)
  g. Oxycodone controlled release (Oxycontin)
  h. Oxymorphone ER (Opana ER, generics)
  i. Tapentadol ER (Nucynta ER)

- Non-formulary: None

4. **Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics—Implementation Plan:**

   The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** the Uniform Formulary implementation plan become effective upon signing of the minutes.

5. **Physician's Perspective:**

   There has been a lot of publicity given to the new "abuse deterrent' formulations of narcotics. Ideally these new formulations prevent the drugs from being inhaled or injected, but they do not prevent all cases of inappropriate use – patients can always ingest multiple tablets. The data does not yet show that these abuse deterrent formulations result in measurable decreases in abuse.

   There are several DoD resources for providers to help ensure safe opioid prescribing. Some of the programs include the Sole Provider Program, the Prescription Monitoring Program, "Do no harm" mandatory training, Project ECHO (Extension for Community Healthcare Outcomes), and the VA/DoD Clinical Practice Guidelines "Management of Opioid Therapy for Chronic Pain" Toolkit.

6. **BAP Comments:**

   There were no questions or comments from the Panel. The Chair called for the vote on UF recommendation and Implementation Plan for Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics.

   - **Long Acting High Potency Narcotic Analgesics – Uniform Formulary Recommendation:**

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

   - **Long Acting High Potency Narcotic Analgesics – Implementation Plan:**

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

III. UTILIZATION MANAGEMENT

A. PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITORS:

(Dr. Allerman)

1. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Alirocumab (Praluent) – Prior Authorization Criteria:

The PCSK9 inhibitors are a new class of biologic drugs that lower low-density lipoprotein (LDL) cholesterol. Alirocumab (Praluent) was approved on July 24, 2015, and is administered as biweekly subcutaneous injections. At the time of the August P&T Committee meeting, the second drugs in the class, evolocumab (Repatha) was anticipated to obtain FDA approval on August 27, 2015. Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional LDL lowering. The product labeling states that the effect of Praluent on cardiovascular morbidity and mortality has not been determined. Prior authorization criteria were recommended for the PCSK9 inhibitors due to the lack of data on cardiovascular morbidity and mortality, unknown long-term safety profile, and anticipated high cost.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual prior authorization criteria for alirocumab (Praluent) in all new and current users. Prior authorization will be approved for patients with heterozygous familial hypercholesterolemia or patients with atherosclerotic cardiovascular disease with LDL levels greater than 100 mg/dL despite maximally tolerated statins doses (atorvastatin 40 mg to 80 mg and rosuvastatin 20 mg to 40 mg, or any statin at maximally tolerated doses in combination with ezetimibe).

The full prior authorization (PA) criteria are as follows:

Manual PA criteria apply to all new and current users of alirocumab (Praluent).

Manual PA criteria—Alirocumab is approved if:

- A cardiologist, lipidologist, or endocrinologist prescribes the drug.
- The patient is at least 18 years of age.
- The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.

- The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below:

    a. The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR
    b. The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR
    c. If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND
    d. The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy.

- For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:

    a. Intolerance

- The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND
- The patient has undergone at least two trials of statin re-challenges with reappearance of muscle symptoms, OR
- The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.

    a. Contraindication to statin

- The contraindication must be defined.
- Praluent is not approved for any indication other than heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease.
- Praluent is not approved for patients who are pregnant or lactating.
- The dosage must be documented on the Prior Authorization Form as either:

    a. 75 mg every 2 weeks, or
    b. 150 mg every 2 weeks.

- PA expires in one year.
- PA criteria for renewal: After one year, prior authorization must be resubmitted. Continued use of Praluent will be approved for the following:

    a. The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
    b. The patient has documented adherence.

2. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Evolocumab (Repatha)—Prior Authorization Criteria:

Due to the impending FDA approval of evolocumab, the P&T Committee also recommended (**16 for, 0 opposed, 1 abstained, 0 absent),** contingent upon FDA approval, manual prior authorization criteria for evolocumab (Repatha) in all new and current users. The product labeling for Repatha is similar to Praluent, with the exception that in addition to patients with heterozygous familial hypercholesterolemia and clinical atherosclerotic heart disease, Repatha is also approved for treating patients with homozygous familial hypercholesterolemia, including pediatric patients from the ages of 13 to 17 years.

The full prior authorization (PA) criteria are as follows: Manual prior authorization criteria apply to all new and current users of evolocumab (Repatha).

Manual PA criteria—Evolocumab is approved if:

- A cardiologist, lipidologist, or endocrinologist prescribes the drug.
- The patient is at least 18 years of age for heterozygous familial hypercholesterolemia (HeFH) and clinical atherosclerotic cardiovascular disease (ASCVD). For homozygous familial hypercholesterolemia (HoFH), patients as young as 13 years of age can receive the drug.
- The patient has HoFH and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol.
- The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.
- The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below:

    a. The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR
    b. The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR
    c. If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND
    d. The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy.

- For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:

  a. Intolerance

- The patient has experienced intolerable and persistent (for longer than two weeks) muscle symptoms (muscle pain, weakness, cramps), AND
- The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR
- The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.

  a. Contraindication to statin

- The contraindication must be defined.
- Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD.
- Repatha is not approved for patients who are pregnant or lactating.
- The dosage must be documented on the PA Form as either:

  a. 140 mg every 2 weeks, or
  b. 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose.

- PA expires in one year.
- PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Repatha will be approved for the following:

  a. The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
  b. The patient has documented adherence.

3. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Alirocumab (Praluent) and Evolocumab (Repatha)—Implementation Plans:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** the PA implementation plans for alirocumab (Praluent) and evolocumab (Repatha) become effective upon signing of the minutes in all points of service.

4. Physician's Perspective:

Although this new therapy is a promising treatment for patients with elevated LDL levels, it has yet to be established whether these drugs will cause a reduction in heart attacks or stroke.

Prior Authorization criteria were recommended, since there is limited data on outcomes with these products, and also because the statins have a large body of evidence of their benefits. Additionally, several civilian health plans and the VA are recommending Prior Authorization criteria.

The PA criteria are consistent with the FDA-approved indications in the package inserts. The P&T Committee did want to ensure that statin therapy had been maximized, and they also did define what constituted a statin failure.

Since these drugs do require injections by the patient, and are very expensive, we want to be sure that patients will be compliant and achieve the most beneficial effects possible. This was the reasoning as to why the PA will expire in one year – we want to be sure that the patient's response to therapy is assessed.

5. BAP Comments:

Dr. Anderson asked if the committee discussed the controversial criteria for this drug class and the LDL threshold of 100. Can you speak to has that was established?

Dr. Allerman responded in November 2013 the American College of Cardiology and the American Heart Association stated or published that is was not necessary to treat to a target LDL anymore. However when the drugs put on the market, there was a recommendation for LDL monitoring on the label. The committee did reach out to the cardiology consultants but there with the dilemma the there is no recommended monitoring for LDL and asked for guidance. The threshold of the 100 LDL was recommended by the cardiology consultants and agreed on by the committee. The traditional treatment for patients who have already had a cardiovascular event is that their LDL remains less than 100. After the patient has had treatment the LDL should to be below 70.

Dr. Kugler and Dr. Allerman provided comments regarding patient adherence.

Dr. Anderson asked if the adherence documented or achieved by looking a claims data.

Dr. Allerman responded that a lot of health plans will be evaluating and the Committee will conduct another drug class review for these products. She further states that there are a lot of things the committee would like to do from a research perspective to make sure patients are responding appropriately. Unfortunately, the committee does not have easy access on client data and would be relying on the Specialist to say that the patients LDL has dropped and they are compliant. She asks Dr. Anderson is he had any recommendations on how to assess adherence the committee would be happy to discuss.

There were no more questions or comments from the Panel. The Chair called for the vote on Prior Authorization Criteria and Implementation Plan for Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors: Alirocumab (Praluent) and Evolocumab (Repatha).

- **PCSK9 - Alirocumab (Praluent) – Prior Authorization Criteria:**

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

- **PCSK9 – Evolocumab (Repatha) – Prior Authorization Criteria:**

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

- **PCSK9 – Alirocumab (Praluent) – Implementation Plan:**

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

- **PCSK9 – Evolocumab (Repatha) – Implementation Plan:**

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

B. INHALED CORTICOSTEROIDS

(Dr. Allerman)

1. Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Prior Authorization Criteria:

The FDA approved Arnuity Ellipta and Asmanex HFA in August and April 2014, respectively. The ICS products were reviewed by the P&T Committee in May 2014 and automated prior authorization (step therapy) and manual prior authorization criteria were approved. Fluticasone propionate (Flovent Diskus and Flovent HFA) are the step-preferred ICS products; the remaining ICS products are non-step-preferred.

Arnuity Ellipta and Asmanex HFA are approved for treating asthma in patients 12 years of age and older; Flovent Diskus is approved in patients as young as four years of age. Arnuity Ellipta and Asmanex HFA were recommended to follow the same prior authorization criteria as the other non-step-preferred ICS products.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** step therapy and manual prior authorization criteria for all new users of Arnuity Ellipta and Asmanex HFA, consistent with the current prior authorization for the other non-step-preferred inhaled corticosteroids products.

The full prior authorization (PA) criteria are as follows:

PA criteria apply to all new users of **Arnuity Ellipta** and **Asmanex HFA** who are older than 12 years of age.

Automated PA criteria: The patient has filled a prescription for Flovent Diskus or Flovent HFA at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria: Arnuity Ellipta and Asmanex HFA are approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if:

- Patient has experienced any of the following issues with Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred inhaled corticosteroids:

  a. inadequate response to the step preferred drugs
  b. contraindication
  c. patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk

2. Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Implementation Plan

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA) become effective on the first Wednesday after a 90-day implementation period in all points of service.

3. Physician's Perspective:

These updates to the prior authorization criteria for the inhalers are consistent with the FDA-approved indications and age ranges listed in the package inserts.

These are examples of the Committee keeping up to date with new data that becomes available with the drug classes that already have step therapy in place.

4. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization for Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA).

- **ICS Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Prior Authorization Criteria – Prior Authorization Criteria:**

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

- **ICS Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA)—Prior Authorization Criteria – Implementation Plan:**

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

C. INHALED CORTICOSTEROIDS (ICS) AND LONG-ACTING BETA2-ADRENERGIC AGONIST (LABA) COMBINATIONS: FLUTICASONE FUROATE/VILANTEROL (BREO ELLIPTA) *(Dr. Allerman)*

1. Inhaled Corticosteroids (ICS) and Long-Acting Beta2-Adrenergic Agonist (LABA) Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)—Manual Prior Authorization Criteria:

Fluticasone furoate/vilanterol (Breo Ellipta) is indicated for the long-term treatment of chronic obstructive pulmonary disease (COPD). In April 2015, the FDA-approved indication was further expanded to include the daily treatment of asthma in patients aged 18 years and older. The ICS/LABA products were reviewed by the P&T Committee in February 2014, where automated prior authorization (step therapy) and manual prior authorization criteria were approved for patients older than 12 years. Fluticasone propionate/salmeterol (Advair Diskus and Advair HFA) are the step-preferred ICS/LABA products; the remaining ICS/LABA products are non-step-preferred.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** updating the manual PA criteria for Breo Ellipta to include the expanded FDA-approved indication.

The full prior authorization (PA) criteria are as follows:

Existing step therapy criteria apply to all new and current users of Breo Ellipta who are older than 12 years of age.

New PA criteria for Breo Ellipta will apply to patients who are at least 18 years of age for treating asthma.

Automated PA criteria: The patient has filled a prescription for Advair or Advair HFA at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria:

- Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) if:
  a. Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with the non-preferred ICS/LABA combination drug:
     - inadequate response to Advair Diskus or Advair HFA
     - intolerable adverse effects
     - contraindication
     - patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk
- **Additionally, Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) in patients who are 18 years of age and older for treating asthma if:**
  a. Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with Breo Ellipta:
     - inadequate response to Advair Diskus or Advair HFA
     - intolerable adverse effects

2. Inhaled Corticosteroids (ICS) and Long-Acting Beta2-Adrenergic Agonist (LABA) Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)— Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Fluticasone Furoate/Vilanterol (Breo Ellipta) become effective on the first Wednesday after a 90-day implementation period in all points of service.

3. Physician's Perspective:

These updates to the prior authorization criteria for the inhalers are consistent with the FDA-approved indications and age ranges listed in the package inserts.

These are examples of the Committee keeping up to date with new data that becomes available with the drug classes that already have step therapy in place.

4. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization and the Implementation Plan for Inhaled Corticosteroids (ICS): Fluticasone Furoate/Vilanterol (Breo Ellipta)—Manual Prior Authorization Criteria:

- **ICS and LABA Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)—Manual Prior Authorization Criteria**:

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

- **ICS and LABA Combinations: Fluticasone Furoate/Vilanterol (Breo Ellipta)—Implementation Plan:**

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

D. **PULMONARY FIBROSIS DRUGS**

(CAPT Vonberg)

1. Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Prior Authorization:

Ofev and Esbriet are two oral drugs that were FDA-approved in October 2014 for treatment of idiopathic pulmonary fibrosis (IPF). Ofev and Esbriet improve symptoms in IPF, as measured by a reduction in the decline in forced vital capacity, but have not been shown to decrease mortality. Manual PA criteria were recommended to ensure appropriate use of the drug for IPF diagnoses.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual prior authorization criteria for Ofev and Esbriet, consistent with the FDA-approved product labeling for use in idiopathic pulmonary fibrosis. Prior authorization will expire after one year.

The full prior authorization (PA) criteria are as follows:

Manual prior authorization criteria will apply to all new and current users of nintedanib (Ofev) and pirfenidone (Esbriet).

Manual PA criteria:

Ofev or Esbriet is approved if:

- The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND
- The patient is being actively managed by a pulmonologist, AND
- The patient is only receiving one therapy—either Ofev or Esbriet. The patient cannot receive both drugs concomitantly (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa).

PA will expire after one year. Subsequent PA approval (Renewal PA) will require clinical documentation of efficacy, and will be limited to one year.

2. **Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Implementation Plan:**

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Nintedanib (Ofev) and Pirfenidone (Esbriet) become effective on the first Wednesday after a 90-day implementation period in all points of service.

3. **Physician's Perspective:**

Ofev and Esbriet are new therapies for pulmonary fibrosis, however, they don't cure the condition, and have only been found to have an effect on pulmonary function testing and improve symptoms.

The Committee recommended Prior Authorization criteria, to ensure that the patient has been correctly diagnosed.

Currently there are about 750 patients in the DoD with idiopathic pulmonary fibrosis.

4. **BAP Comments:**

There were no questions or comments from the Panel. The Chair called for the vote on Manual Prior Criteria Authorization and Implementation Plan for Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Prior Authorization

- **Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Prior Authorization:**

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

- **Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet)—Implementation Plan:**

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

E. ALZHEIMER'S DISEASE DRUGS

(CAPT Vonberg)

1. Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric)—Manual Prior Authorization Criteria:

Namenda XR and Namzaric are both approved for treatment of patients with moderate to severe dementia of Alzheimer's disease. Namenda XR is an ER formulation of memantine that is dosed once daily, in contrast to memantine IR, which is dosed twice daily. There are no studies addressing whether once daily therapy improves efficacy of memantine.

Namzaric contains a fixed-dose combination of memantine ER and donepezil (Aricept, generics). Memantine IR and donepezil are both available in low-cost generic formulations. FDA approval of Namzaric was based on bioequivalence studies and not clinical trial data. These two products will be reviewed as new drugs in November 2015. PA criteria were recommended to ensure appropriate use.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual PA criteria for Namenda XR and Namzaric in new users, consistent with the FDA-approved product labeling for Alzheimer's disease.

The full prior authorization (PA) criteria for <u>Namenda XR</u> are as follows*:* Manual prior authorization criteria apply to all new users of Namenda XR.

<u>Manual PA criteria</u>: Namenda XR is approved:

- The patient is being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia), AND
- Taking Namenda IR (memantine) twice daily causes undue burden to the patient or care provider, AND
- The patient's functional status has not declined while receiving Namenda IR.

The full prior authorization (PA) criteria for <u>Namzaric</u> are as follows: Manual PA criteria apply to all new users of Namzaric.

Manual PA criteria: Namzaric is approved if:

3. The patient is being treated for moderate to severe dementia of the Alzheimer`s type, AND
4. The patient is stabilized on one of the following regimens:

    a. memantine IR 10 mg twice daily or memantine ER 28 mg once daily and donepezil hydrochloride 10 mg, OR
    b. memantine IR 5 mg twice daily or ER 14 mg once daily and donepezil hydrochloride 10 mg, AND

5. The patient is unable to take Namenda (memantine) and Aricept (donepezil) separately, OR
6. The patient has progressive swallowing difficulties.

2. Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric) become effective on the first Wednesday after a 90-day implementation period in all points of service.

3. Physician's Perspective:

These two drugs are new variations of existing medications. The Committee did recognize that patients with Alzheimer's disease require assistance with care and taking their medications.

These two products will be reviewed as new drugs in November, and updates to the PA criteria can be provided if necessary.

4. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on Manual Prior Criteria Authorization and Implementation Plan for Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric).

- **Alzheimer's Disease Drugs – Namenda XR and Namzaric – Manual Prior Authorization Criteria:**

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

- **Alzheimer's Disease Drugs – Namenda XR and Namzaric – Implementation Plan:**

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

F. SEDATIVE HYPNOTICS

(Dr. Allerman)

1. Sedative Hypnotics: Tasimelteon (Hetlioz)—Renewal Prior Authorization Criteria:

Hetlioz is approved for treatment of blind patients with non-24 hour sleep-wake disorder. The P&T Committee reviewed Hetlioz in February 2015 and designated it with nonformulary status; prior authorization was also established at that time. Currently, prior authorization criteria will expires after six months, as patients who do not respond after a six-month Hetlioz trial are unlikely to show therapeutic benefit. The P&T Committee recommended adding additional criteria to the existing prior authorization to allow for the renewal of the prior authorization after six months, based on patient response.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** revising the manual prior authorization criteria for Hetlioz to assess response after six months of therapy.

The full prior authorization (PA) criteria are as follows:

For patients who have completed the initial six-month trial of Hetlioz, renewal PA criteria will be determined.

Renewal Manual PA criteria: Tasimelteon (Hetlioz) will be approved indefinitely

if:

- The patient is totally blind and has a documented diagnosis of non-24 sleep wake disorder

  AND

- The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers)

  AND

- The patient has been receiving Hetlioz for 6 months and has had a documented response to therapy.

PA will not be approved if the patient has not had a documented response to therapy. If the patient has not responded after 6 months, they will be deemed a non-responder.

2. Sedative Hypnotics: Tasimelteon (Hetlioz)—Implementation Plan

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Tasimelteon (Hetlioz) become effective on the first Wednesday after a 90-day implementation period in all points of service.

3. Physician's Perspective:

This is an example where the P&T Committee wanted to have a mechanism for patients who have had a beneficial response to continue therapy with Hetlioz. If patients have not responded to therapy after 6 months, it is unlikely that they will ever respond.

4. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on Renewal Prior Criteria Authorization and Implementation Plan for Sedative Hypnotics: Tasimelteon (Hetlioz).

- **Hetlioz – Renewal Prior Authorization Criteria:**

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

- **Hetlioz – Implementation Plan:**

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

G. CYSTIC FIBROSIS DRUGS

(Dr. Allerman)

1. Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi)—Manual Prior Authorization Criteria:

Orkambi is a fixed-dose combination product containing lumacaftor with ivacaftor (Kalydeco). Both drugs are potentiators of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Orkambi was FDA-approved in July 2015 for treatment of cystic fibrosis in patients at least 12 years of age who are homozygous for the F508del mutation in the CFTR gene. Currently, prior authorization criteria apply to the ivacaftor component of Orkambi.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual prior authorization criteria for Orkambi, consistent with the FDA-approved product labeling.

The full prior authorization (PA) criteria are as follows:

Prior Authorization applies to all new and current users of lumacaftor/ivacaftor (Orkambi).

Manual PA criteria: Orkambi is approved if:

- Orkambi is prescribed for the treatment of cystic fibrosis in an age-appropriate patient population according to the product label.

  AND

- The patient is homozygous for the F508del deletion mutation in the cystic fibrosis transmembrane conductance regulator gene, detected by an FDA-approved test.

2. Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi)—Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Lumacaftor/Ivacaftor (Orkambi) become effective on the first Wednesday after a 90-day implementation period in all points of service.

3. Physician's Perspective:

This panel has seen several updates to the PA for the cystic fibrosis drug Kalydeco, and now Kalydeco has been combined into the product called Orkambi. Once again, we've kept current with changes to the package insert and the approved pediatric age ranges.

4. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on Manual Prior Criteria Authorization and Implementation Plan for Cystic Fibrosis Drugs: Lumacaftor/Ivacaftor (Orkambi).

- **Orkambi – Manual Prior Authorization Criteria:**

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

- **Orkambi – Implementation Plan:**

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

H. TOPICAL PAIN PRODUCTS

(Dr. Allerman)

1. **Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel)—Manual PA Criteria:**

   Solaraze is FDA-approved for the topical treatment of actinic keratosis.
   The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** manual PA criteria for Solaraze 3% Gel in all new users, consistent with the FDA-approved product labeling for use in actinic keratosis.

   The full prior authorization (PA) criteria are as follows:

   Prior Authorization criteria apply to all new users of Solaraze 3% Gel.

   Manual PA criteria: Diclofenac 3% topical gel (Solaraze Gel) is approved if:

   The patient has a documented diagnosis of actinic keratosis. Only apply to new patients

2. **Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel)—Implementation Plan:**

   The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 1 absent)** the PA implementation plan for Diclofenac Gel (Solaraze 3% Gel) become effective on the first Wednesday after a 90-day implementation period in all points of service

3. **Physician's Perspective:**

   A review of Solaraze found that there was some inappropriate use, so a manual PA was recommended to limit Solaraze to the FDA-approved indication of actinic keratosis.

4. **BAP Comments:**

   There were no questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization and Implementation Plan for Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel).

   - **Solaraze 3% Gel – Manual Prior Authorization Criteria:**

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

   - **Solaraze 3% Gel – Implementation Plan:**

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

I. COMPOUND PRESCRIPTIONS

(CAPT Vonberg)

1. Compound Prescriptions – Prior Authorization Criteria:

The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant, but decreasing. There has been a decrease in the number of compounded prescriptions filled; however, compounded medications continue to have a high potential for inappropriate use.

Manual prior authorization criteria for compounds were recommended by the DoD P&T Committee in November 2014, and presented to the Beneficiary Advisory Panel in January 2015. In March, 2015, Lt Gen Robb modified the prior authorization criteria. The current prior authorization criteria for compounded prescriptions require documentation of the diagnosis and route of administration; a trial of commercially available products; and the results of therapy for commercially available products. Allowances are made for national drug shortages or commercial products. Providers can submit supporting clinical documentation to be considered.

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent) that** the current prior authorization criteria should expire after one year. Prior authorization approval will last for 12 months, or for the duration of therapy, if less than 12 months.

2. Compound Prescriptions – Implementation Plan:

The P&T Committee recommended **(16 for, 0 opposed, 1 abstained, 0 absent)** an effective date of the first Wednesday after a 60-day implementation period in all points of service; and, DHA send a letter to all beneficiaries with a prior authorization currently in place.

3. Physician's Perspective:

This latest recommendation is to have the compounded prescriptions PA expire after one year. A review of utilization data found that less than 7% of patients are on a compounded prescription for more than one year, so there will be a limited number of beneficiaries affected by this change.

Patients will be notified of this update to the PA via mailed letters.

4. BAP Comments:

Ms. Buchanan states that she is seeing consistent trending in the voting among the Panel members. She asks if it is appropriate to inquire about the reason for the one (1) committee member that abstained.

CAPT VonBerg responded the the VA representative abstained.

There were no more questions or comments from the Panel. The Chair called for the vote on Prior Criteria Authorization Criteria and Implementation Plan for Compound Prescriptions.

- **Compound Prescriptions – Prior Authorization Criteria:**

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

- **Compound Prescriptions – Implementation Plan:**

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

IV. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAL 2008 (FY 08)

(CAPT Vonberg)

A. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAL 2008 (FY 08)

1. Section 703, NDAA FY08—Uniform Formulary Recommendation:

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 Section 703 of the Fiscal Year 2008 National Defense Authorization Act. The law stipulates that if a drug is not compliant with Section 703, it will be designated non-formulary on the Uniform Formulary and will require pre-authorization prior to use in the Retail point of service and medical necessity at the Military Treatment Facilities. These non-formulary drugs will remain available in the Mail Order point of service without preauthorization.

The P&T Committee recommended **(13 for, 0 opposed, 2 abstained, 2 absent)** the following product be designated non-formulary on the Uniform Formulary:

- Neos Therapeutics: Hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL

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

   The P&T Committee recommended **(13 for, 0 opposed, 2 abstained, 2 absent)** the following pre-authorization criteria for hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL by Neos Therapeutics:

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

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

3. **Section 703, NDAA FY08—Implementation Plan for Pre-Authorization Criteria:**

   The P&T Committee recommended **(13 for, 0 opposed, 2 abstained, 2 absent)** an effective date of the first Wednesday after a 90-day implementation period in the Retail Network and DHA send a letter to beneficiaries affected by this decision.

4. **Physician's Perspective:**

   There is no physician perspective for Section 703 information:

5. **BAP Comments:**

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

   - **Section 703, NDAA FY08 – UF Recommendation:**

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

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

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

   - **Section 703, NDAA FY08 – Implementation Plan for Pre-Authorization Criteria:**

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

6. Additional Panel questions and comments:

Dr. Delgado asks if the language Section IV-A-2, bullet 2 of the Pre-Authorization criteria can be changed in the minutes. The current language is as follows:

- Change from: For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.
- Change to: For branded products with products with AB-rated generic availability, use of the generic product could be detrimental to the patient.

Dr. Allerman stated that a recommended change can be suggested as part of the official documentation but this is the language that has been used for several years. However, the change will be noted as a recommendation from the Panel.

- **The Panel vote of the recommended substitute the work "could" for "would":**

Concur: 5 Non-Concur: 1 Abstain: 0 Absent: 1

V. OVER-THE-COUNTER DRUGS

A. OVER-THE-COUNTER DRUGS

(CAPT Vonberg)

Section 702 of the Fiscal Year 2013 National Defense Authorization Act provides legislative authority for the Over-the-Counter (OTC) Drug Program. The Final Rule published in the Federal Register on July 27, 2015, establishes the process for identifying OTC products for coverage under the TRICARE pharmacy benefit and the rules for making these products available to eligible DoD beneficiaries.

1. OTC Drugs—Relative Cost-Effectiveness and Patient Access:

The P&T Committee evaluated the relative cost-effectiveness and patient access considerations for the following over-the-counter drug currently covered as part of the OTC Demonstration Project: omeprazole 20 mg (Prilosec, Prilosec OTC, generics)

The P&T Committee recommended (**14 for, 0 opposed, 1 abstained, 2 absent):**

- Removing coverage of branded omeprazole (Prilosec OTC), as it is not cost effective, relative to comparable generic and prescription proton pump inhibitors.

- Generic formulations of omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics), and levonorgestrel (Plan B, generics) will remain designated formulary on the Uniform Formulary.

2. Physician's Perspective:

Several new regulations that affect the pharmacy benefit were recently enacted. Now, the P&T Committee will be able to make formulary recommendations for OTC drugs, and the Panel will be seeing more OTC clinical and cost reviews in the future.

3. BAP Comments:

There were no questions or comments from the Panel. The Chair called for the vote on Relative Cost-Effectiveness and Patient Access for OTC Drugs.

- **OTC Drugs – Relative Cost-Effectiveness:**

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

Mr. Tackitt thanked the Panel for their participation; the PEC for the briefing and welcomed CAPT VonBerg to the group.

CAPT Norton thanks the panel and audience then concludes the meeting.

Mr. Robert Duane Tackitt

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 uses as acronyms in Panel discussions are listed below for easy reference. The term "Panel" in this summary refers to the "Uniform Formulary Beneficiary Panel," the group who's meeting is the subject of this report.

- ASCVD - Atherosclerotic Cardiovascular Disease
- BIA – Budget Impact Analysis
- BID – Dosed Twice Daily
- CFR – Code of Federal Regulations
- CFTR – Cystric Fybrosis Transmembrane Conductance Regulator
- CK – Creatinine Kinase
- CML – Chronic Myelogenous Leukemia
- CTM - Cholpheniramine
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DoD – Department of Defense
- DPP-4 - Dipeptidyl Peptidase 4
- ER – Extended Release
- ER/LA – Extended Relase/Long Acting
- FDA – Food Drug Administration
- FEV1 – Forced Expiratory Volume in 1 Second
- GLP1-RA - Glucagon Like Peptide-1 Receptor Agonist
- HeFH - Heterozygous Familial Hypercholestolemia
- HFA - Hydrofluoroalkane
- HoFH - Homozygous Familial Hypercholestrolemia
- IPF - Idiopathic Pulmonary Fibrosis
- IR – Interventional Radiology
- IU/L – International Unites per Unit
- LAMA – Long Acting Muscarinic Antagonist
- LDL - Lipoprotein Cholesterol
- MS - Morphine Sulfate
- NDAA – National Defense Authorization Act
- OTC - Over-the-Counter
- P&T Committee - Pharmacy & Therapeutics Committee
- PA - Prior Authorization
- PCSK9 - Proprotein Convertase Subtilisin/Kexin Type 9
- QT - Quart
- SLGT2 - Sodium Glucose Co-transporter 2

- SU - Sulfonylurea
- TIB – Targeted Immunomodulatory Biologics
- TRICARE – Military Health Care System
- ULN – Upper Limits of Normal
- XR – Extended Release