DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS—LONG-ACTING MUSCARINIC ANTAGONIST

P&T Comments

A. 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.

B. 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.

C. 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.

D. 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.

III. RECENTLY APPROVED U.S. FDA AGENTS—LONG-ACTING MUSCARINIC ANTAGONIST

BAP Comments

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

The P&T Committee's recommendation for umeclidinium (Incruse Ellipta) is that it be designated formulary on the Uniform Formulary.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee's recommendation is for implementation upon signing of the minutes.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

IV. RECENTLY APPROVED U.S. FDA AGENTS—TARGETED IMMUNOMODULATORY BIOLOGICS

P&T Comments

A. 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 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, and ustekinumab in treating moderate to severe plaque psoriasis. There are no head-to-head trials comparing secukinumab and adalimumab.
- 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. 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)—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.

C. 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.

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

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) implementation upon signing of the minutes.

V. RECENTLY APPROVED U.S. FDA AGENTS—TARGETED IMMUNOMODULATORY BIOLOGICS

BAP Comments

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

The P&T Committee recommended secukinumab (Cosentyx) be designated formulary and non-preferred. A trial of adalimumab (Humira) is required prior to use of Cosentyx.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee recommended an effective date upon signing of the minutes.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VI. UNIFORM FORMULARY CLASS REVIEWS—NON-INSULIN DIABETES DRUGS: SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS

P&T Comments

A. 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:

- The SGLT2 inhibitors are all indicated as adjunctive therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).

- 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 severe renal impairment, although empagliflozin and canagliflozin can be used in patients with moderate renal impairment.
- Empagliflozin and dapagliflozin have a lower risk of drug-drug interactions than canagliflozin.
- The cardiovascular (CV) safety profile of SGLT2 inhibitors is currently unknown. To date, there are 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 (reduction of 1.8 kg), the SGLT2 inhibitors offer no additional clinical advantages over the other non-insulin diabetes drugs on the Uniform Formulary.

B. 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 nonformulary (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.

C. 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:

- Empagliflozin (Jardiance)
- Empagliflozin/linagliptin (Glyxambi)

- Nonformulary and non step-preferred:
  - Canagliflozin (Invokana)
  - Canagliflozin/metformin (Invokamet)
  - Dapagliflozin (Farxiga)
  - 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 nonformulary, non step-preferred SGLT2 inhibitors in all new and current users. Prior authorization criteria currently apply to the entire SGLT2 inhibitors subclass.

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

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.

E. 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.

VII. UNIFORM FORMULARY CLASS REVIEWS—NON-INSULIN DIABETES DRUGS: SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS

BAP Comments

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

The P&T Committee recommended the following:

- Uniform Formulary and step-preferred:
  - Empagliflozin (Jardiance)
  - Empagliflozin/linagliptin (Glyxambi)
- Nonformulary and non step-preferred:
  - Canagliflozin (Invokana)
  - Canagliflozin/metformin (Invokamet)
  - Dapagliflozin (Farxiga)
  - 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 nonformulary, non step-preferred SGLT2 inhibitors in all new and current users. Prior authorization criteria currently apply to the entire SGLT2 inhibitors subclass.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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 modifying 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.

Coverage for an SGLT2 is approved if the patient has had one of the following issues with metformin and at least one drug from 2 different non-insulin diabetes drug classes:

The patient has had an inadequate response

The patient has experienced a significant adverse event

The patient has a contraindication

Additionally, empagliflozin-containing products (Jardiance or Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users must try a preferred empagliflozin product before trying one of the other SGLT2 inhibitors. Coverage for an SGLT2 inhibitor other than Jardiance or Glyxambi is approved if the following has occurred in all new and current users:

The patient has experienced significant adverse events with Jardiance or Glyxambi that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.

The full prior authorization criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

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

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

VIII. UNIFORM FORMULARY CLASS REVIEWS—GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs)

P&T Comments

A. 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:

- 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. Dulaglutide (Trulicity), albiglutide (Tanzeum), and exenatide once weekly (Bydureon) have the advantage of once weekly dosing; liraglutide (Victoza) is dosed once daily; and, exenatide twice daily (Byetta) is dosed twice daily (BID).
- The results of seven 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.

B. 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 nonformulary 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.

C. 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) the following:

- Uniform Formulary and step-preferred:
  - Exenatide once weekly (Bydureon)
  - Albiglutide (Tanzeum)
- Nonformulary and non step-preferred:
  - Exenatide twice daily (Byetta)
  - Dulaglutide (Trulicity)
  - 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.

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

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.

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:
  - impaired renal function precluding treatment with metformin
  - history of lactic acidosis
- The patient has experienced any of the following issues on a SU:
  - 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.

E. 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.

IX. UNIFORM FORMULARY CLASS REVIEWS—GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs)

BAP Comments

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

The P&T Committee recommended the following:

- Uniform Formulary and step-preferred:
  - Exenatide once weekly (Bydureon)
  - Albiglutide (Tanzeum)
- Nonformulary and non step-preferred:
  - Exenatide twice daily (Byetta)
  - Dulaglutide (Trulicity)
  - Liraglutide (Victoza)

This recommendation includes step therapy (automated PA), 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

Existing automated prior authorization (step therapy) criteria for the GLP1RAs requires a trial of metformin or a sulfonylurea first, based on positive long-term outcomes data with metformin and the sulfonylureas.

Additionally, exenatide once weekly (Bydureon) and albiglutide are now recommended as the preferred GLP1RAs. New and current users must try Bydureon and Tanzeum prior to using Byetta, Trulicity, or Victoza.

The P&T Committee recommended maintaining the existing prior authorization 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. Coverage for Byetta, Trulicity, or Victoza will be approved if the patient has had an inadequate response to Bydureon or Tanzeum.

The full prior authorization criteria are listed above.

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

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

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

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

X. UNIFORM FORMULARY CLASS REVIEWS—ORAL ONCOLOGY DRUGS: CHRONIC MYELOGENOUS LEUKEMIA

P&T Comments

A. Oral Oncology Drugs: Chronic Myelogenous Leukemia—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 chronic myelogenous leukemia. Guidelines from the National Cancer Care Network and international guidelines also support the use of these three tyrosine kinase inhibitors as first-line therapies

- Imatinib (Gleevec) advantages include pending generic availability, a well-known safety profile, and additional FDA indications other than chronic myelogenous leukemia. Adverse events include fatigue, myalgias, and fluid retention.

- Advantages of dasatinib (Sprycel) and nilotinib (Tasigna) compared to imatinib include fewer progressions to acute phase chronic myelogenous leukemia or blast phase chronic myelogenous leukemia, 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 imatinib 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 their 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, continued response to initial treatment, prior treatment, and adverse event profiles.

B. Oral Oncology Drugs: Chronic Myelogenous Leukemia—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.

C. Oral Oncology Drugs: Chronic Myelogenous Leukemia—Uniform Formulary Recommendation

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

- Uniform Formulary (no-step scenario):
  - Imatinib (Gleevec)
  - Dasatinib (Sprycel)
  - Nilotinib (Tasigna)
  - Bosutinib (Bosulif)
  - Ponatinib (Iclusig)

- Nonformulary: None

D. Oral Oncology Drugs: Chronic Myelogenous Leukemia—Uniform Formulary Recommendation

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.

XI. UNIFORM FORMULARY CLASS REVIEWS—ORAL ONCOLOGY DRUGS: CHRONIC MYELOGENOUS LEUKEMIA

BAP Comments

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

The P&T Committee recommended the following:

- Uniform Formulary (no-step scenario):
  - Imatinib (Gleevec)
  - Dasatinib (Sprycel)
  - Nilotinib (Tasigna)
  - Bosutinib (Bosulif)
  - Ponatinib (Iclusig)

- Nonformulary: None

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Oral Oncology Drugs: Chronic Myelogenous Leukemia—Uniform Formulary Recommendation

The P&T Committee recommended the Uniform Formulary implementation plan become effective upon signing of the minutes.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XII. UNIFORM FORMULARY CLASS REVIEWS—NARCOTIC ANALGESIC DRUGS: LONG ACTING HIGH POTENCY NARCOTIC ANALGESICS

P&T Comments

A. 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 extended release (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.

B. 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 extended release/long acting 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 nonformulary 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.

C. 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):
  - Fentanyl transdermal system (Duragesic, generics)
  - Hydrocodone extended release (Hysingla ER, Zohydro ER)
  - Hydromorphone extended release (Exalgo, generics)
  - Morphine sulfate sustained release (MS Contin, generics)
  - Morphine extended release (Avinza, Kadian, generics)
  - Morphine extended release/naltrexone (Embeda)
  - Oxycodone controlled release (Oxycontin)
  - Oxymorphone extended release (Opana ER, generics)
  - Tapentadol extended release (Nucynta ER)

- Nonformulary: None

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

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.

XIII. UNIFORM FORMULARY CLASS REVIEWS—NARCOTIC ANALGESIC DRUGS: LONG ACTING HIGH POTENCY NARCOTIC ANALGESICS

BAP Comments

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

The P&T Committee recommended the following:

- Uniform Formulary (no step scenario):
  - Fentanyl transdermal system (Duragesic, generics)
  - Hydrocodone extended release (Hysingla ER, Zohydro ER)
  - Hydromorphone extended release (Exalgo, generics)
  - Morphine sulfate sustained release (MS Contin, generics)
  - Morphine extended release (Avinza, Kadian, generics)
  - Morphine extended release/naltrexone (Embeda)
  - Oxycodone controlled release (Oxycontin)
  - Oxymorphone extended release (Opana ER, generics)
  - Tapentadol extended release (Nucynta ER)

- Nonformulary: None

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee recommended the Uniform Formulary implementation plan become effective upon signing of the minutes.

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

XIV. UTILIZATION MANAGEMENT—PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITORS

P&T Comments

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 P&T Committee meeting, the second drug in the class and 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.

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 and is on concurrent statin therapy at maximal tolerated doses.
- The patient has established atherosclerotic cardiovascular disease with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below:

- The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR
- The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR
- 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
- The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy.

- For both heterozygous familial hypercholesterolemia and atherosclerotic cardiovascular disease: 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:
  - 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 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.
  - 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:
  - 75 mg every 2 weeks, or
  - 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:
  - The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
  - 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 cardiovascular disease, Repatha is also approved for treating patients with homozygous familial hypercholesterolemia, including pediatric patients from ages 13 to 17 years.

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 and clinical atherosclerotic cardiovascular disease. For homozygous familial hypercholesterolemia, patients as young as 13 years of age can receive the drug.
- The patient has homozygous familial hypercholesterolemia 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 and is on concurrent statin therapy at maximal tolerated doses.
- The patient has established atherosclerotic cardiovascular disease with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below:
    - The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR
    - The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR
    - 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
    - The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy.
- For both heterozygous familial hypercholesterolemia and atherosclerotic cardiovascular disease: 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:
    - 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.
            - Contraindication to statin
        - The contraindication must be defined.
    - Repatha is not approved for any indication other than homozygous familial hypercholesterolemia, heterozygous familial hypercholesterolemia, or clinical atherosclerotic cardiovascular disease.
    - Repatha is not approved for patients who are pregnant or lactating.
    - The dosage must be documented on the Prior Authorization Form as either:
        - 140 mg every 2 weeks, or
        - 420 mg every 4 weeks. Note that only patients with homozygous familial hypercholesterolemia 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, prior authorization must be resubmitted. Continued use of Repatha will be approved for the following:
        - The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND
        - The patient has documented adherence.

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

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

XV. UTILIZATION MANAGEMENT—PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITORS

BAP Comments

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

The P&T Committee recommended manual PA criteria for alirocumab (Praluent) in all new and current users. Prior authorization will be approved for patients with the conditions listed in the package insert who have 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 criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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, contingent upon FDA approval, manual prior authorization criteria for evolocumab (Repatha) in all new and current users. Prior authorization will be approved for patients with the conditions listed in the package insert who have 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 criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee recommended the prior authorization implementation plans for alirocumab (Praluent) and evolocumab (Repatha) become effective upon signing of the minutes in all points of service

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XVI. UTILIZATION MANAGEMENT—INHALED CORTICOSTEROIDS

P&T Comments

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

The FDA approved Arnuity Ellipta and Asmanex Hydrofluoroalkane (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:
    - inadequate response to the step preferred drugs
    - contraindication
    - patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk

XVII. UTILIZATION MANAGEMENT—INHALED CORTICOSTEROIDS

BAP Comments

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

The P&T Committee recommended step therapy and manual prior authorization criteria for all new users of Arnuity Ellipta and Asmanex Hydrofluoroalkane (HFA), consistent with the current prior authorization for the other non step-preferred inhaled corticosteroids products. The prior authorization criteria reflect the FDA-approved indications and age ranges from the package inserts.

The full prior authorization criteria are listed above.

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

XVIII. UTILIZATION MANAGEMENT—INALED CORTICOSTEROIDS AND LONG-ACTING BETA2-ADRENERGIC AGONIST COMBINATIONS

P&T Comments

A. Inhaled Corticosteroids and Long-Acting Beta2-Adrenergic Agonist 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 inhaled corticosteroids/long-acting beta2-adrenergic agonist (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

1. Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) if:
    - 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
2. **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:**

    - 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

XIX. UTILIZATION MANAGEMENT—INALED CORTICOSTEROIDS AND LONG-ACTING BETA2-ADRENERGIC AGONIST COMBINATIONS

BAP Comments

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

The P&T Committee recommended updating the manual prior authorization criteria for Breo Ellipta to include the expanded FDA-approved indication.

The full prior authorization criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XX. UTILIZATION MANAGEMENT—PULMONARY FIBROSIS DRUGS

P&T Comments

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.

XXI. UTILIZATION MANAGEMENT—PULMONARY FIBROSIS DRUGS

BAP Comments

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

The P&T Committee recommended manual prior authorization criteria for Ofev and Esbriet, consistent with the FDA-approved product labeling for use in IPF. Prior authorization will expire after one year.

The full prior authorization criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXII. UTILIZATION MANAGEMENT—ALZHEIMER'S DISEASE DRUGS

P&T Comments

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 <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:

- The patient is being treated for moderate to severe dementia of the Alzheimer`s type, AND
- The patient is stabilized on one of the following regimens:
  - memantine IR 10 mg twice daily or memantine ER 28 mg once daily and donepezil hydrochloride 10 mg, OR
  - memantine IR 5 mg twice daily or ER 14 mg once daily and donepezil hydrochloride 10 mg, AND
- The patient is unable to take Namenda (memantine) and Aricept (donepezil) separately, OR
- The patient has progressive swallowing difficulties.

XXIII. UTILIZATION MANAGEMENT—ALZHEIMER'S DISEASE DRUGS

BAP Comments

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

The P&T Committee recommended 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 criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXIV. UTILIZATION MANAGEMENT—SEDATIVE HYNOTICS

P&T Comments

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 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.

XXV. UTILIZATION MANAGEMENT—SEDATIVE HYNOTICS

BAP Comments

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

The P&T Committee recommended revising the manual prior authorization criteria for Hetlioz to assess response after six months of therapy.

The full prior authorization criteria are listed above.

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

XXVI. UTILIZATION MANAGEMENT—CYSTIC FIBROSIS DRUGS

P&T Comments

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 apply 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 mutation in the cystic fibrosis transmembrane conductance regulator gene, detected by an FDA-approved test.

XXVII. UTILIZATION MANAGEMENT—CYSTIC FIBROSIS DRUGS

BAP Comments

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

The P&T Committee recommended manual prior authorization criteria for Orkambi, consistent with the FDA-approved product labeling.

The full prior authorization criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXVIII. UTILIZATION MANAGEMENT—TOPICAL PAIN PRODUCTS

P&T Comments

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.

XXIX. UTILIZATION MANAGEMENT—TOPICAL PAIN PRODUCTS

BAP Comments

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

The P&T Committee recommended manual prior authorization 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 criteria are listed above.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXX. UTILIZATION MANAGEMENT—IMPLEMENTATION PLAN

P&T Comments

A. Prior Authorization Criteria Implementation Plans

For all the prior authorization criteria discussed above (Arnuity Ellipta, Asmanex HFA, Breo Ellipta, Ofev, Esbriet, Namenda XR, Namzaric, Hetlioz, Orkambi, and Solaraze 3% Gel (with the exception of the PCSK9 inhibitors), P&T Committee recommended (16 for,

0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service.

XXXI. UTILIZATION MANAGEMENT – IMPLEMENTATION PLAN

BAP Comments

A. Prior Authorization Criteria Implementation Plans

For all the prior authorization criteria discussed above, with the exception of the PCSK9 inhibitors, P&T Committee recommended an effective date of the first Wednesday after a 90-day implementation period in all points of service.

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

XXXII. UTILIZATION MANAGEMENT—COMPOUND PRESCRIPTIONS

P&T Comments

A. Compound Prescriptions—Prior Authorization Criteria

The P&T Committee was presented with an update on the status of compounded medications. Military Health System expenditures for compounded medications are significant, but decreasing. There has been a decreased 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 was recommended by the DoD P&T Committee meeting in November 2014 and presented to the Beneficiary Advisory Panel in January 2015. In March 2015, Lt Gen Robb modified prior authorization criteria. The current prior authorization criteria for compounds require documentation of the diagnosis and route of administration, a trial of commercially available products, and the results of therapy for the commercially available products. Allowances are made for national drug shortages of 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.

XXXIII. UTILIZATION MANAGEMENT—COMPOUND PRESCRIPTIONS

BAP Comments

A. Compound Prescriptions—Prior Authorization Criteria

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Compound Prescriptions—Implementation Plan

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

P&T Comments

A. 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 nonformulary 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 nonformulary 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 nonformulary on the Uniform Formulary:

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

B. 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:

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

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

C. Section 703, NDAA FY08—Implementation Plan 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.

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

BAP Comments

A. Section 703, NDAA FY08—Uniform Formulary Recommendation

The P&T Committee's recommendation is that the following product be designated nonformulary on the Uniform Formulary:

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

The P&T Committee's recommendation is the following pre-authorization criteria for hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL by Neos Therapeutics:

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

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

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

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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXXVI. OVER-THE-COUNTER DRUGS

P&T Comments

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.

XXXVII. OVER-THE-COUNTER DRUGS

BAP Comments

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

The P&T Committee recommended:

- 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention