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. UF CLASS REVIEWS—NASAL ALLERGY DRUGS

P&T Comments

A. Nasal Allergy Drugs—Relative Clinical Effectiveness and Conclusion

The P&T Committee evaluated the clinical effectiveness of the Nasal Allergy Drugs, which includes the nasal corticosteroids, nasal antihistamines, and nasal anticholinergics. Three new drugs, ciclesonide hydrofluoroalkane (HFA), (Zetonna), beclomethasone HFA (QNASL), and fluticasone/azelastine (Dymista) have been marketed since the last UF review in May 2011. Triamcinolone (Nasacort OTC) is available over-the-counter (OTC) and is not included in the review.

The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) with the following conclusions:

1. There is no new evidence that substantively changes the conclusions of the class review completed in 2011. Nasal corticosteroids are first-line agents in reducing allergic rhinitis symptoms of congestion, rhinorrhea, congestion, and itching.
2. Available data from placebo-controlled trials and head-to-head trials is not sufficient to clearly show superiority of one nasal allergy drug over another with regard to symptom relief or lower risk of harm.
3. Nasal steroid HFA aerosol formulations (ciclesonide [Zetonna] and beclomethasone [QNASL]) have advantages over aqueous formulations of no post nasal drip, longer retention in the nasal cavity, potentially better taste, once daily dosing, and inclusion of a dose counter. The disadvantages include a higher incidence of epistaxis and burning, and U.S. Food and Drug Administration (FDA) approval only for children older than 12 years.
4. Fluticasone/azelastine (Dymista) is the first combination nasal corticosteroid/nasal antihistamine. It has not been compared with individual

components given separately or with concomitant use of another nasal steroid/oral antihistamine.

5. The nasal antihistamines are generally less effective than nasal corticosteroids for treating allergic rhinitis, but may be used as first-line therapy, and in non-allergic rhinitis. Nasal antihistamines have a quicker onset of effect than the nasal steroids. They are associated with a clinically significant effect on reducing nasal congestion. Somnolence is considered a class effect.

B. Nasal Allergy Drugs—Relative Cost-Effectiveness Analysis and Conclusion

A pharmacoeconomic analysis and budget impact analysis (BIA) were performed to evaluate the Nasal Allergy Drugs. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Cost minimization analysis (CMA) results showed generic formulations of fluticasone propionate (Flonase), ipratropium (Atrovent), flunisolide (Nasarel), and azelastine 137 mcg (Astelin) were the most cost-effective agents in this class, followed by the branded agents mometasone (Nasonex), fluticasone furoate (Veramyst), azelastine 205 mcg (Astepro), budesonide (Rhinocort Aqua), beclomethasone (QNASL), ciclesonide 50 mcg (Omnaris), olopatadine (Patanase), ciclesonide 37 mcg (Zetonna), beclomethasone (Beconase AQ), and fluticasone/azelastine (Dymista).
- A BIA was performed to evaluate the potential impact of scenarios with selected agents designated with formulary or NF status on the UF. BIA results showed that the scenario with azelastine 137 mcg, flunisolide, fluticasone propionate, and ipratropium all designated as formulary and step-preferred, and with all branded agents designated as NF and non step-preferred, was the most cost-effective for the Military Health Service (MHS).

C. Nasal Allergy Drugs—UF Recommendation

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following for the Nasal Allergy Drugs, based on the high degree of therapeutic interchangeability and on cost effectiveness:

- UF and step-preferred ("in front of the step"): azelastine 137 mcg, flunisolide, fluticasone propionate, and ipratropium
- NF and non-preferred ("behind the step"): azelastine 205 mcg (Astepro), beclomethasone (QNASL and Beconase AQ), ciclesonide (Omnaris and Zetonna), budesonide (Rhinocort Aqua), fluticasone furoate (Veramyst), fluticasone/azelastine (Dymista), mometasone (Nasonex), and olopatadine (Patanase)

- This recommendation includes step therapy, which requires a trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium in all new and current users of the Nasal Allergy Drugs who are older than 4 years.
- Generic formulations of mometasone (Nasonex) are expected later in 2014. When the generics to Nasonex become cost-effective relative to the step-preferred agents, the generic will become step-preferred without further action by the P&T Committee, BAP, or Director, DHA. A generic agent is cost-effective relative to step-preferred agents when its total weighted average cost per day of treatment is less than or equal to the total weighted average cost per day of treatment for the step-preferred agent.

D. Nasal Allergy Drugs—Prior Authorization (PA) Criteria

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) automated (step therapy) and manual PA criteria in all new and current users of Astepro, QNASL, Beconase AQ, Omnaris, Zetonna, Rhinocort Aqua, Veramyst, Dymista, Nasonex, and Patanase who are older than 4 years of age. A trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is required before the non step-preferred drugs.

Automated PA criteria: The patient has filled a prescription for azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium at any MHS pharmacy point of service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

AND

Manual PA criteria: Astepro, Beconase AQ, QNASL, Rhinocort Aqua, Zetonna, Omnaris, Veramyst, Dymista, Nasonex, or Patanase is approved (e.g., trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is NOT required) if:

- Patient has experienced any of the following issues with **at least one** of the following step-preferred Nasal Allergy Drugs (fluticasone propionate, flunisolide, azelastine, or ipratropium), which is not expected to occur with the non-preferred Nasal Allergy Drug:
    - inadequate response to the step-preferred drugs
    - intolerable adverse effects (persistent epistaxis, significant nasal irritation, pharyngitis)
    - contraindication
    - no formulary alternative for the following
        - » for budesonide (Rhinocort Aqua): patient is pregnant (pregnancy category B)

» for beclomethasone (Beconase AQ) and mometasone (Nasonex): patient has nasal polyps and cannot be treated with one of the step-preferred products

E. Nasal Allergy Drugs—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service (POS); and, 2) DHA send a letter to beneficiaries affected by the UF decision.

III. UF CLASS REVIEWS—NASAL ALLERGY DRUGS

BAP Comments

A. Nasal Allergy Drugs—UF Recommendation

The P&T Committee recommended the following for the Nasal Allergy Drugs, based on the high degree of therapeutic interchangeability and on cost effectiveness:

- UF and step-preferred ("in front of the step"): azelastine 137 mcg, flunisolide, fluticasone propionate, and ipratropium
- NF and non-preferred ("behind the step"): azelastine 205 mcg (Astepro), beclomethasone (QNASL and Beconase AQ), ciclesonide (Omnaris and Zetonna), budesonide (Rhinocort Aqua), fluticasone furoate (Veramyst), fluticasone/azelastine (Dymista), mometasone (Nasonex), and olopatadine (Patanase)
- This recommendation includes step therapy, which requires a trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium in all new and current users of the Nasal Allergy Drugs who are older than 4 years.
- Generic formulations of mometasone (Nasonex) are expected later in 2014. When the generics to Nasonex become cost-effective relative to the step-preferred agents, the generic will become step-preferred without further action by the P&T Committee, BAP, or Director, DHA. A generic agent is cost-effective relative to step-preferred agents when its total weighted average cost per day of treatment is less than or equal to the total weighted average cost per day of treatment for the step-preferred agent.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Nasal Allergy Drugs—PA Criteria

The P&T Committee recommended automated (step therapy) and manual PA criteria in all new and current users of Astepro, QNASL, Beconase AQ, Omnaris, Zetonna, Rhinocort Aqua, Veramyst, Dymista, Nasonex, and Patanase who are older than 4 years of age. A trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is required before the non step-preferred drugs.

Automated PA criteria: The patient has filled a prescription for azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria: Astepro, Beconase AQ, QNASL, Rhinocort Aqua, Zetonna, Omnaris, Veramyst, Dymista, Nasonex, or Patanase is approved (e.g., trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is NOT required) if:

- Patient has experienced any of the following issues with **at least one** of the following step-preferred Nasal Allergy Drugs (fluticasone propionate, flunisolide, azelastine, or ipratropium), which is not expected to occur with the non-preferred Nasal Allergy Drug:
    - inadequate response to the step-preferred drugs
    - intolerable adverse effects (persistent epistaxis, significant nasal irritation, pharyngitis)
    - contraindication
    - no formulary alternative for the following
        - for budesonide (Rhinocort Aqua): patient is pregnant (pregnancy category B)
        - for beclomethasone (Beconase AQ) and mometasone (Nasonex): patient has nasal polyps and cannot be treated with one of the step-preferred products

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Nasal Allergy Drugs—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

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

IV. UF CLASS REVIEWS—INHALED CORTICOSTEROIDS (ICS)

P&T Comments

A. ICS—Relative Clinical Effectiveness and Conclusion

The P&T Committee evaluated the clinical effectiveness of the ICS, which were last reviewed for UF status in February 2009. Mometasone (Asmanex HFA) metered dose inhaler was recently approved and has an August 2014 launch date; it will be reviewed at an upcoming meeting.

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

1. There is no new evidence that substantively changes the conclusions of the class review completed in 2009.
2. In patients with asthma, there is fair-to-moderate evidence that ICS agents do not differ with regard to symptom control, need for rescue medication, and exacerbations.
3. There is insufficient evidence to conclude there are clinically relevant differences in efficacy among the ICS products for treating COPD. The ICS products are not indicated for COPD treatment.
4. In terms of safety, there is insufficient evidence to determine whether there are clinically relevant differences among the ICS products in terms of minor adverse events or systemic adverse events.

B. ICS—Relative Cost-Effectiveness Analysis and Conclusion

A pharmacoeconomic analysis and BIA were performed to evaluate the ICS. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- The pharmacoeconomic analysis showed budesonide (Pulmicort Flexhaler) and fluticasone (Flovent Diskus and HFA) were the most cost-effective agents in this class, followed by beclomethasone (QVAR) and mometasone furoate (Asmanex Twisthaler), ciclesonide (Alvesco) and flunisolide (Aerospan).
- BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and formulary or non-preferred and NF on the UF. BIA results showed that the scenario with Flovent Diskus and Flovent HFA designated as step-preferred and formulary on the UF, with Aerospan, Alvesco, Asmanex Twisthaler, Pulmicort Flexhaler and QVAR designated as non-preferred and NF on the UF, was the most cost-effective option for the MHS.

C. ICS—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following for the ICS, based on the high degree of therapeutic interchangeability and cost effectiveness:

- UF and step-preferred ("in front of the step"): fluticasone (Flovent Diskus and Flovent HFA)
- NF and non-preferred ("behind the step"): beclomethasone (QVAR), budesonide (Pulmicort Flexhaler), ciclesonide (Alvesco), flunisolide (Aerospan), and mometasone (Asmanex Twisthaler)
- This recommendation includes step therapy, which requires a trial of Flovent Diskus or Flovent HFA in all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, or Asmanex Twisthaler who are older than 12 years.
- Budesonide nebulized solution (Pulmicort) was reviewed in 2009 and was not part of the class review for this meeting; it remains on the UF and is not subject to step therapy.

D. ICS—PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) and manual PA criteria in all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, or Asmanex Twisthaler who are older than 12 years of age. A trial of Flovent Diskus or Flovent HFA is required before the non-step preferred drugs.

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

AND

Manual PA criteria: QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, and Asmanex Twisthaler is 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 ICS:
    - inadequate response to the step preferred drugs
    - intolerable adverse effects (patient has a history of adrenal suppression and the request is for Alvesco)
    - contraindication
    - patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk
    - No formulary alternative for the following: Pulmicort Flexhaler: patient is pregnant

E. ICS—UF Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

V. UF CLASS REVIEWS—ICS

BAP Comments

A. ICS—UF Recommendation

The P&T Committee recommended the following for the ICS, based on the high degree of therapeutic interchangeability and cost effectiveness:

- UF and step-preferred ("in front of the step"): fluticasone (Flovent Diskus and Flovent HFA)
- NF and non-preferred ("behind the step"): beclomethasone (QVAR), budesonide (Pulmicort Flexhaler), ciclesonide (Alvesco), flunisolide (Aerospan), and mometasone (Asmanex Twisthaler)
- This recommendation includes step therapy, which requires a trial of Flovent Diskus or Flovent HFA in all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, or Asmanex Twisthaler who are older than 12 years.
- Budesonide nebulized solution (Pulmicort) was reviewed in 2009 and was not part of the class review for this meeting; it remains on the UF and is not subject to step therapy.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. ICS—PA Criteria

The P&T Committee recommended automated (step therapy) and manual PA criteria in all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, or Asmanex Twisthaler who are older than 12 years of age. A trial of Flovent Diskus or Flovent HFA is required before the non-step preferred drugs.

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

AND

Manual PA criteria: QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, and Asmanex Twisthaler is 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 ICS:
    - inadequate response to the step preferred drugs
    - intolerable adverse effects (patient has a history of adrenal suppression and the request is for Alvesco)
    - contraindication
    - patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk
    - No formulary alternative for the following: Pulmicort Flexhaler: patient is pregnant

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. ICS—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

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

VI. UF CLASS REVIEWS—OSTEOPOROSIS DRUGS

P&T Comments

A. Osteoporosis Drugs: Oral Bisphosphonates Subclass—Relative Clinical Effectiveness and Conclusion

The oral bisphosphonates are a subclass of the Osteoporosis drugs, which were last reviewed for UF placement in June 2008. Generic formulations are available for alendronate (Fosamax) and ibandronate (Boniva). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

1. There was no new significant efficacy data since the last review; however, there is substantial new safety information for the bisphosphonates.
2. Relative superiority of one agent versus another cannot be determined by bone mineral density data alone. For fracture prevention, available data from placebo-controlled trials and head-to-head trials is not sufficient to clearly establish superiority of one bisphosphonate versus another.
3. Clinical guidelines list ibandronate (Boniva, generics) as second-line therapy due to the lack of data for hip fracture prevention and lack of long-term data. However, ibandronate has the convenience of once monthly dosing and an MHS study showing improved persistence with the once monthly ibandronate formulation over the other bisphosphonates.
4. The risedronate formulations of Atelvia (once weekly regimen) and Binosto (effervescent tablet) offer no clinically compelling advantages over the other bisphosphonate formulations.
5. Potential adverse events of osteonecrosis of the jaw, atrial fibrillation, esophageal cancer, and atypical femur fractures are considered a class effect by the FDA.

B. Osteoporosis Drugs: Oral Bisphosphonates Subclass—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate the bisphosphonate subclass. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed generic alendronate was the most cost-effective agent, followed by generic ibandronate, branded risedronate (Actonel), risedronate DR (Atelvia), alendronate/vitamin D (Fosamax Plus D), and alendronate effervescent tablet (Binosto).

- BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and UF or non-preferred and NF on the UF. BIA results showed the scenario with generic alendronate designated as formulary and step-preferred, generic ibandronate as UF and non step-preferred for new users, and all branded agents (Actonel, Atelvia, Binosto, and Fosamax Plus D) designated as NF and non step-preferred for new and current users was the most cost-effective option for the MHS.

C. Osteoporosis Drugs: Oral Bisphosphonates Subclass—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following, based on the high degree of therapeutic interchangeability and cost-effectiveness:

- UF and step-preferred (e.g., "in front of the step"): alendronate (Fosamax, generic)
- UF and non step-preferred (e.g., "behind the step"): ibandronate (Boniva, generic)
- NF and non step-preferred: risedronate (Actonel), risedronate DR (Atelvia), alendronate effervescent (Binosto), and alendronate/Vitamin D (Fosamax Plus D)
- This recommendation includes step therapy, which requires a trial of alendronate prior to use of ibandronate only in new users, as the patient impact is less than if all current and new users were affected by the step. A trial of alendronate is required prior to use of risedronate (Actonel), risedronate DR (Atelvia), alendronate effervescent (Binosto), and alendronate/Vitamin D (Fosamax Plus D) in all new and current users.

D. Osteoporosis Drugs: Oral Bisphosphonates Subclass—PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) and manual PA criteria in all new users of ibandronate, and all new and current users of Actonel, Atelvia, Binosto, and Fosamax Plus D. A trial of alendronate is required before the non step-preferred drugs.

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

AND

Manual PA criteria—ibandronate, Actonel, Atelvia, Binosto, and Fosamax Plus D is approved (e.g., trial of alendronate is NOT required) if:

- Patient has experienced any of the following issues with alendronate, which is not expected to occur with the non-preferred oral bisphosphonates:
  - Intolerable adverse effects
    - » Patient requires once monthly ibandronate or Actonel 150 mg due to gastrointestinal adverse events from alendronate weekly dosing
    - » Patient has experienced significant adverse effects from formulary agents
    - » For Binosto: No alternative formulary agent and patient has swallowing difficulties and cannot consume 8 oz of water and has no sodium restrictions
    - » For Fosamax Plus D: No alternative formulary agent and patient cannot take alendronate and vitamin D separately
  - Contraindication

E. Osteoporosis Drugs: Oral Bisphosphonates Subclass—UF Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

VII. UF CLASS REVIEWS—OSTEOPOROSIS DRUGS

BAP Comments

A. Osteoporosis Drugs: Oral Bisphosphonates Subclass—UF Recommendation

The P&T Committee recommended the following, based on the high degree of therapeutic interchangeability and cost-effectiveness:

- UF and step-preferred (e.g., "in front of the step"): alendronate (Fosamax, generic)
- UF and non step-preferred (e.g., "behind the step"): ibandronate (Boniva, generic)
- NF and non step-preferred: risedronate (Actonel), risedronate DR (Atelvia), alendronate effervescent (Binosto), and alendronate/Vitamin D (Fosamax Plus D)
- This recommendation includes step therapy, which requires a trial of alendronate prior to use of ibandronate only in new users, as the patient impact is less than if all current and new users were affected by the step. A trial of alendronate is

required prior to use of risedronate (Actonel), risedronate DR (Atelvia), alendronate effervescent (Binosto), and alendronate/Vitamin D (Fosamax Plus D) in all new and current users.

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

B. Osteoporosis Drugs: Oral Bisphosphonates Subclass—PA Criteria

The P&T Committee recommended automated (step therapy) and manual PA criteria in all new users of ibandronate, and all new and current users of Actonel, Atelvia, Binosto, and Fosamax Plus D. A trial of alendronate is required before the non step-preferred drugs.

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

AND

Manual PA criteria—ibandronate, Actonel, Atelvia, Binosto, and Fosamax Plus D is approved (e.g., trial of alendronate is NOT required) if:

- Patient has experienced any of the following issues with alendronate, which is not expected to occur with the non-preferred oral bisphosphonates:
  - Intolerable adverse effects
    - » Patient requires once monthly ibandronate or Actonel 150 mg due to gastrointestinal adverse events from alendronate weekly dosing
    - » Patient has experienced significant adverse effects from formulary agents
    - » For Binosto: No alternative formulary agent and patient has swallowing difficulties and cannot consume 8 oz of water and has no sodium restrictions
    - » For Fosamax Plus D: No alternative formulary agent and patient cannot take alendronate and vitamin D separately
  - Contraindication

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Osteoporosis Drugs: Oral Bisphosphonates Subclass—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VIII. RECENTLY APPROVED U.S. FDA AGENTS—HEPATITIS C VIRUS DRUGS

P&T Comments

A. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi)—Relative Clinical Effectiveness and Conclusion

Sofosbuvir (Sovaldi) is a new oral direct acting antiviral (DAA) indicated for the treatment of chronic hepatitis C virus (HCV) infection. The American Association for the Study of Liver Diseases and the Infectious Disease Society of America (AASLD/IDSA) released new HCV treatment guidelines in February 2014 (*www.hcvguidelines.org*). Several drugs are in the pipeline, including interferon-free regimens; consult the guidelines for updated recommendations.

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

- The AASLD/IDSA guidelines consider sofosbuvir as the standard of care for HCV infection. Sofosbuvir should be a component of a combination antiviral regimen (e.g., including ribavirin with or without peginterferon); it must not be used as monotherapy. Sustained virologic response (SVR) rates of 90% are achieved in HCV genotypes 1 through 6 when sofosbuvir is combined with ribavirin (dual therapy) and interferon (triple therapy).

- Advantages of sofosbuvir over the other DAAs [telaprevir (Incivek) and boceprevir (Victrelis)] include reduced frequency of administration, lower tablet burden, higher SVR rates, shorter treatment courses, fewer drug interactions, and improved tolerability profile.

- Telaprevir (Incivek) and boceprevir (Victrelis) are no longer recommended in the AASLD/IDSA guidelines as they are inferior to sofosbuvir and should not be used.

B. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi)—Relative Cost-Effectiveness Analysis and Conclusion

Initial CMA and cost-effectiveness analysis (CEA) were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Cost analysis showed that sofosbuvir (Sovaldi) is the most costly DAA currently available for treating HCV.
- CEA evaluated the potential benefit associated with improved efficacy data and improved tolerability associated with sofosbuvir (Sovaldi) compared to other HCV treatment regimens. Preliminary findings suggested that the cost per SVR achieved with sofosbuvir was comparable with previously prescribed DAAs for HCV infection.

C. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi)—UF Recommendation

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

- Sofosbuvir (Sovaldi) be designated with formulary status on the UF. Patients are encouraged to fill Sovaldi prescriptions at MTFs or Mail Order Pharmacy POS, and
- Sovaldi, and the other DAAs telaprevir (Incivek) and boceprevir (Victrelis), be added to the TRICARE Specialty Drug list to facilitate recapture from the Retail Network to the Mail Order Pharmacy.

D. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi)—PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) PA criteria for sofosbuvir (Sovaldi) for new users, consistent with AASLD/IDSA guidelines and FDA-approved labeling. Prior authorization will expire after 12 or 24 weeks for sofosbuvir (Sovaldi).

PA Criteria for Hepatitis C Drugs:

Sofosbuvir (Sovaldi)
Direct Acting Antiviral Subclass

- New users of sofosbuvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their Sovaldi prescriptions.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

  Manual PA Criteria:
  - Age ≥ 18
  - Has laboratory evidence of chronic HCV infection
  - Has laboratory evidence of HCV genotype 1, 2, 3, or 4 HCV infection
    1. State the HCV infection genotype on the PA form.
  - Sofosbuvir (Sovaldi) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
  - The patient is not co-infected with Hepatitis B virus (HBV).
  - Sofosbuvir (Sovaldi) is not prescribed as monotherapy; ribavirin with or without PEG-interferon is also prescribed. (Exception: sofosbuvir may be used with simeprevir (Olysio) in genotype 1 HCV patients who are ineligible for interferon; see below.)

  Treatment Regimens and Duration of Therapy
  - Treatment and duration of therapy is approved for one of the following regimens outlined below, based on HCV genotype or unique population.
  - Prior authorization will expire after 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1

- Approved in patients who meet ONE of the following criteria:
  (1 or 2)
  1. Interferon eligible: sofosbuvir + interferon + ribavirin for 12 weeks
  2. Interferon ineligible: sofosbuvir + simeprevir for 12 weeks

     - Interferon ineligible is defined as ONE of the following:
       - intolerance to interferon (patient has previously taken interferon)
       - autoimmune hepatitis or other autoimmune disorders
       - hypersensitivity to peginterferon or any of its components
       - decompensated hepatic disease

- history of depression or clinical features consistent with depression
- baseline CBC: neutrophil count < 1,500/µ or PLTs < 90,000/µ or Hgb<10 g/dl
- history of preexisting cardiac disease

- NOTE: Sofosbuvir + ribavirin for 24 weeks is an alternative regimen recommended by the AASLD/IDSA but is not as effective at the sofosbuvir + simeprevir in interferon-ineligible patients. If utilizing this treatment regimen, consider future highly effective pan-genotypic direct acting antiviral (DAA) combination that are interferon-free.

Genotype 2

- Sofosbuvir + ribavirin approved for 12 weeks

Genotype 3

- Approved in patients who meet ONE of the following criteria: (1 or 2):
  1. Sofosbuvir + ribavirin approved for 24 weeks
  2. Sofosbuvir + ribavirin + interferon approved for 12 weeks as an alternative in cirrhotic individuals or treatment experienced

Genotype 4

- Sofosbuvir + ribavirin+ interferon approved for 12 weeks
- NOTE: Sofosbuvir + ribavirin for 24 weeks is an interferon-ineligible alternative regimen recommended by the AASLD/IDSA, but is not as effective as sofosbuvir + interferon for 12 weeks. If utilizing this treatment regimen, consider future highly effective pan-genotypic DAA combinations that are interferon-free.

Regimen other than those listed above:

- Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates and guidelines.

Prior Authorization Criteria for Boceprevir (Victrelis) and Telaprevir (Incivek) Direct Acting Antiviral Subclass

- The revised PA will apply to new users of boceprevir or telaprevir.
- Current users of boceprevir or telaprevir are allowed to complete the course of therapy without interruption.

Manual PA Criteria:

Telaprevir and Boceprevir are NO LONGER RECOMMENDED for ANY HCV treatment by the (AASLD/IDSA). See www.hcvguidelines.org.

- Although regimens of PEG-interferon and ribavirin plus telaprevir or boceprevir for 24 to 48 weeks using response-guided therapy are also FDA-approved; they are **markedly inferior** to the currently available regimens.
- Telaprevir and boceprevir regimens are associated with higher rates of serious adverse events than recommended current regimens with sofosbuvir (Sovaldi).
- Consider treatment with sofosbuvir-containing regimens OR future highly effective pan-genotypic direct acting antiviral combination regimens that are interferon-free.
- The justification and dosing/duration for boceprevir or telaprevir must be documented (e.g., allergic to all other known regimens; inability to wait for treatment).

Prior authorization will expire after 12 weeks for telaprevir and 44 weeks for boceprevir.

Simeprevir (Olysio)
Direct Acting Agent Subclass

- New users of simeprevir for HCV are required to undergo the PA process.
- The FDA-approved indication of simeprevir + PEG-interferon + ribavirin for 24 to 48 weeks is no longer recommended for HCV treatment by the AASLD/IDSA. See www.hcvguidelines.org.
- The current AASLD/IDSA recommendation for simeprevir is for patients with HCV genotype 1 who are ineligible for interferon; simeprevir is given with sofosbuvir and either with or without ribavirin for 12 weeks.

Manual PA Criteria:

- Age ≥18
- Has laboratory evidence of chronic HCV (quantified viral load above undetectable)
- Has laboratory evidence of genotype 1 HCV infection
- If HCV genotype 1a, the patient is negative for NS3 Q80K polymorphism at baseline
- Is not co-infected with HIV or HBV
- The patient has not previously used HCV protease inhibitor (boceprevir, telaprevir, or simeprevir)
- Simeprevir is not approved for monotherapy

- AASLD/IDSA guidelines recommend a regimen of simeprevir plus sofosbuvir either with or without ribavirin for 12 weeks.

- The patient is interferon ineligible. Interferon ineligible is defined as ONE of the following:
  - Intolerance to interferon (patient has previously taken interferon)
  - Autoimmune hepatitis or other autoimmune disorders
  - Hypersensitivity to peginterferon or any of its components
  - Decompensated hepatic disease
  - History of depression or clinical features consistent with depression
  - A baseline CBC: neutrophil count < 1,500/µ or PLTs < 90,000/µ or HgB <10 g/dl
  - History of preexisting cardiac disease

Prior authorization will expire after 12 weeks.

E. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi), Telaprevir (Incivek), Boceprevir (Victrelis), Simeprevir (Olysio)—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of no later than the first Wednesday after a 30-day implementation period in all POS.

IX. RECENTLY APPROVED U.S. FDA AGENTS—HEPATITIS C VIRUS DRUGS

BAP Comments

A. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi)—UF Recommendation

The P&T Committee recommended the following:

- Sofosbuvir (Sovaldi) be designated with formulary status on the UF. Patients are encouraged to fill Sovaldi prescriptions at MTFs or Mail Order Pharmacy POS, and
- Sovaldi, and the other DAAs telaprevir (Incivek) and boceprevir (Victrelis), be added to the TRICARE Specialty Drug list to facilitate recapture from the Retail Network to the Mail Order Pharmacy.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi)—PA Criteria

The P&T Committee recommended PA criteria for sofosbuvir (Sovaldi) for new users, consistent with AASLD/IDSA guidelines and FDA-approved labeling. Prior authorization will expire after 12 or 24 weeks for sofosbuvir (Sovaldi).

PA Criteria for Hepatitis C Drugs:

Sofosbuvir (Sovaldi)
Direct Acting Antiviral Subclass

- New users of sofosbuvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their Sovaldi prescriptions.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

  Manual PA Criteria:
  - Age ≥ 18
  - Has laboratory evidence of chronic HCV infection
  - Has laboratory evidence of HCV genotype 1, 2, 3, or 4 HCV infection
    1. State the HCV infection genotype on the PA form.
  - Sofosbuvir (Sovaldi) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
  - The patient is not co-infected with Hepatitis B virus (HBV).
  - Sofosbuvir (Sovaldi) is not prescribed as monotherapy; ribavirin with or without PEG-interferon is also prescribed. (Exception: sofosbuvir may be used with simeprevir (Olysio) in genotype 1 HCV patients who are ineligible for interferon; see below.)

  Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy is approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1

- Approved in patients who meet ONE of the following criteria: (1 or 2)
    3. Interferon eligible: sofosbuvir + interferon + ribavirin for 12 weeks
    4. Interferon ineligible: sofosbuvir + simeprevir for 12 weeks

        - Interferon ineligible is defined as ONE of the following:
            - intolerance to interferon (patient has previously taken interferon)
            - autoimmune hepatitis or other autoimmune disorders
            - hypersensitivity to peginterferon or any of its components
            - decompensated hepatic disease
            - history of depression or clinical features consistent with depression
            - baseline CBC: neutrophil count < 1,500/µ or PLTs < 90,000/µ or Hgb<10 g/dl
            - history of preexisting cardiac disease

- NOTE: Sofosbuvir + ribavirin for 24 weeks is an alternative regimen recommended by the AASLD/IDSA but is not as effective at the sofosbuvir + simeprevir in interferon-ineligible patients. If utilizing this treatment regimen, consider future highly effective pan-genotypic direct acting antiviral (DAA) combination that are interferon-free.

Genotype 2

- Sofosbuvir + ribavirin approved for 12 weeks

Genotype 3

- Approved in patients who meet ONE of the following criteria: (1 or 2):
    3. Sofosbuvir + ribavirin approved for 24 weeks
    4. Sofosbuvir + ribavirin + interferon approved for 12 weeks as an alternative in cirrhotic individuals or treatment experienced

Genotype 4

- Sofosbuvir + ribavirin+ interferon approved for 12 weeks
- NOTE: Sofosbuvir + ribavirin for 24 weeks is an interferon-ineligible alternative regimen recommended by the AASLD/IDSA, but is not as effective as

sofosbuvir + interferon for 12 weeks. If utilizing this treatment regimen, consider future highly effective pan-genotypic DAA combinations that are interferon-free.

Regimen other than those listed above:

- Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates and guidelines.

Prior Authorization Criteria for Boceprevir (Victrelis) and Telaprevir (Incivek) Direct Acting Antiviral Subclass

- The revised PA will apply to new users of boceprevir or telaprevir.
- Current users of boceprevir or telaprevir are allowed to complete the course of therapy without interruption.

Manual PA Criteria:

Telaprevir and Boceprevir are NO LONGER RECOMMENDED for ANY HCV treatment by the (AASLD/IDSA). See www.hcvguidelines.org.

- Although regimens of PEG-interferon and ribavirin plus telaprevir or boceprevir for 24 to 48 weeks using response-guided therapy are also FDA-approved; they are **markedly inferior** to the currently available regimens.
- Telaprevir and boceprevir regimens are associated with higher rates of serious adverse events than recommended current regimens with sofosbuvir (Sovaldi).
- Consider treatment with sofosbuvir-containing regimens OR future highly effective pan-genotypic direct acting antiviral combination regimens that are interferon-free.
- The justification and dosing/duration for boceprevir or telaprevir must be documented (e.g., allergic to all other known regimens; inability to wait for treatment).

Prior authorization will expire after 12 weeks for telaprevir and 44 weeks for boceprevir.

Simeprevir (Olysio)
Direct Acting Agent Subclass

- New users of simeprevir for HCV are required to undergo the PA process.
- The FDA-approved indication of simeprevir + PEG-interferon + ribavirin for 24 to 48 weeks is no longer recommended for HCV treatment by the AASLD/IDSA. See www.hcvguidelines.org.

- The current AASLD/IDSA recommendation for simeprevir is for patients with HCV genotype 1 who are ineligible for interferon; simeprevir is given with sofosbuvir and either with or without ribavirin for 12 weeks.

Manual PA Criteria:

- Age ≥18
- Has laboratory evidence of chronic HCV (quantified viral load above undetectable)
- Has laboratory evidence of genotype 1 HCV infection
- If HCV genotype 1a, the patient is negative for NS3 Q80K polymorphism at baseline
- Is not co-infected with HIV or HBV
- The patient has not previously used HCV protease inhibitor (boceprevir, telaprevir, or simeprevir)
- Simeprevir is not approved for monotherapy
    - AASLD/IDSA guidelines recommend a regimen of simeprevir plus sofosbuvir either with or without ribavirin for 12 weeks.
- The patient is interferon ineligible. Interferon ineligible is defined as ONE of the following:
    - Intolerance to interferon (patient has previously taken interferon)
    - Autoimmune hepatitis or other autoimmune disorders
    - Hypersensitivity to peginterferon or any of its components
    - Decompensated hepatic disease
    - History of depression or clinical features consistent with depression
    - A baseline CBC: neutrophil count < 1,500/µ or PLTs < 90,000/µ or HgB <10 g/dl
    - History of preexisting cardiac disease

Prior authorization will expire after 12 weeks.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Hepatitis C Virus Drugs: Sofosbuvir Tablets (Sovaldi), Telaprevir (Incivek), Boceprevir (Victrelis), Simeprevir (Olysio)—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of no later than the first Wednesday after a 30-day implementation period in all POS.

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

X. RECENTLY APPROVED U.S. FDA AGENTS

P&T Comments

A. Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq)—Relative Clinical Effectiveness and Conclusion

Background—Mirabegron (Myrbetriq) is a beta-3 receptor agonist, which promotes urine storage by increasing bladder capacity. This mechanism of action is unique from the antimuscarinic OAB drugs [e.g., tolterodine (Detrol LA), oxybutynin, solifenacin (Vesicare), and trospium (Sanctura), etc.]. Compared to placebo, mirabegron produced statistically significant reductions in incontinence episodes, but the clinical effect is small and there is a high placebo response rate. An analysis of Military Health System (MHS) prescription data showed that the medication possession ratio was higher at six months with mirabegron than the OAB drugs (72% versus 61%).

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) that although there do not appear to be clinically relevant differences in efficacy between mirabegron and the antimuscarinic OAB drugs, it is well-tolerated and does not produce the anticholinergic effects of dry mouth and constipation seen with the other OAB drugs.

B. Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq)—Relative Cost-Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—A CMA was performed to evaluate mirabegron (Myrbetriq), a new entrant in the OAB Drug Class. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic oxybutynin IR (Ditropan) was the most cost-effective agent, followed by oxybutynin ER (Ditropan XL, generic), trospium IR (Sanctura, generic), oxybutynin 10% gel (Gelnique), tolterodine ER (Detrol LA), tolterodine IR (Detrol; generic), solifenacin (Vesicare), mirabegron (Myrbetriq), oxybutynin transdermal

system (Oxytrol), darifenacin (Enablex), trospium ER (Sanctura XR), fesoterodine (Toviaz), and oxybutynin pump (Gelnique Pump).

C. Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq)—UF Recommendation

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

- Mirabegron (Myrbetriq) be designated UF and non step-preferred ("behind the step"). Step therapy will require that all new users of mirabegron try Detrol LA or a preferred generic (oxybutynin IR, oxybutynin ER, or trospium IR) prior to the use of the other OAB drugs.
- Automated PA criteria (step therapy) and manual PA criteria for all new users of mirabegron were recommended at the February 2014 P&T Committee meeting and implemented on June 11, 2014. (See February 2014 DoD P&T Committee minutes.)

XI. RECENTLY APPROVED U.S. FDA AGENTS

BAP Comments

A. Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq)—UF Recommendation

The P&T Committee recommended the following:

- Mirabegron (Myrbetriq) be designated UF and non step-preferred ("behind the step"). Step therapy will require that all new users of mirabegron try Detrol LA or a preferred generic (oxybutynin IR, oxybutynin ER, or trospium IR) prior to the use of the other OAB drugs.
- Automated PA criteria (step therapy) and manual PA criteria for all new users of mirabegron were recommended at the February 2014 P&T Committee meeting and implemented on June 11, 2014. (See February 2014 DoD P&T Committee minutes.)

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XII. RECENTLY APPROVED U.S. FDA AGENTS

P&T Comments

A. Oral Anticoagulants: Apixaban (Eliquis)—Relative Clinical Effectiveness and Conclusion

Background—Apixaban is a new oral anticoagulant (NOAC) and is the second oral factor Xa inhibitor to reach the market. Similar to the other NOACs, [(rivaroxaban (Xarelto) and dabigatran (Pradaxa)], apixaban has the advantages of predictable anticoagulant effect, fixed dosing, and fewer drug interactions compared to warfarin, and the convenience of no laboratory monitoring and no dietary restrictions. Apixaban was superior to poorly controlled warfarin at preventing stroke and systemic embolism in patients with atrial fibrillation (ARISTOTLE trial). Apixaban was non-inferior to enoxaparin when used for prevention of venous thromboembolism following hip or knee replacement surgery.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (12 for, 0 against, 0 abstained, 5 absent) the main benefit of apixaban and the other NOACs over warfarin is the reduced rate of intracranial hemorrhage when used for stroke prevention in patients with non-valvular atrial fibrillation. The NOACs and warfarin (Coumadin, generic) will be re-reviewed at an upcoming meeting for UF and BCF placement.

B. Oral Anticoagulants: Apixaban (Eliquis)—Relative Cost-Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate apixaban (Eliquis) with other oral anticoagulants in the prevention of stroke and systemic embolism in atrial fibrillation and prevention of VTE in patients undergoing orthopedic surgery. The P&T Committee concluded (12 for, 0 opposed, 0 abstained, 5 absent) the following:

- CMA showed that warfarin (Coumadin, generic), including drug monitoring costs, remains the least costly agent in the class. Among NOACs, apixaban (Eliquis) was less costly than rivaroxaban (Xarelto) and more costly than dabigatran (Pradaxa).

C. Oral Anticoagulants: Apixaban (Eliquis)—UF Recommendation

The P&T Committee recommended (12 for, 0 against, 0 abstained, 5 absent) apixaban (Eliquis) be designated formulary on the UF.

XIII. RECENTLY APPROVED U.S. FDA AGENTS

BAP Comments

A. Oral Anticoagulants: Apixaban (Eliquis)—UF Recommendation

The P&T Committee recommended apixaban (Eliquis) be designated formulary on the UF.

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

XIV. RECENTLY APPROVED U.S. FDA AGENTS

P&T Comments

A. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—Relative Clinical Effectiveness and Conclusion

Background—Dapagliflozin (Farxiga) is the second FDA-approved SGLT2 inhibitor. SGLT2 inhibitors are a relatively new subclass of the Non-Insulin Diabetes Drug Class and have a novel mechanism of action. Dapagliflozin is effective in lowering hemoglobin A1c (A1c) by about 0.4% to 1% when used as monotherapy, by about 0.5% to 2% as part of dual therapy, and about 0.3% to 1% as part of triple therapy. It is similar to canagliflozin (Invokana) in terms of decreasing triglycerides, increasing LDL cholesterol, increasing HDL cholesterol, and decreasing systolic blood pressure and body weight.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) dapagliflozin offers no clinically compelling advantages over the existing UF non-insulin diabetes drugs, given the modest decrease in A1c; risk of adverse reactions, including female genital mycotic infections and urinary tract infections; and unknown long-term cardiovascular safety profile.

B. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed to evaluate dapagliflozin (Farxiga) with other oral products on the Uniform Formulary used in the treatment of diabetes. The P&T Committee concluded (16 for, 0 opposed, 1abstained, 0 absent) the following:

- CMA results showed that dapagliflozin (Farxiga) was not cost-effective compared with existing formulary agents in the non-insulin diabetes class including metformin, sulfonylureas, thiazolidinediones, and dipeptidyl-dipeptidase-4 (DPP-4) inhibitors.

- Current costs for dapagliflozin (Farxiga) show it was comparable to canagliflozin (Invokana), the other product available in the SGLT2 subclass.

C. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) dapagliflozin (Farxiga) be designated NF, due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcome, and cost disadvantage compared to UF products.

D. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—Prior Authorization (PA) Criteria

Existing automated PA (step therapy) for the SGLT2 inhibitors requires a trial of metformin, or a sulfonylurea, and a DPP-4 inhibitor first, based on positive long-term outcomes data with metformin and the sulfonylureas.

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) a trial of metformin or a sulfonylurea and a DPP-4 inhibitor in all new and current users of dapagliflozin (Farxiga), due to the modest hemoglobin Alc lowering and safety concerns.

All new and current users of dapagliflozin (Farxiga) are required to try metformin, a sulfonylurea (SU), and a dipeptidyl-dipeptidase-4 (DPP-4) inhibitor before dapagliflozin (Farxiga).

Automated PA criteria: The patient has filled a prescription for metformin, a SU, AND a DPP-4 inhibitor at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria: If automated criteria are not met, dapagliflozin (Farxiga) is approved (e.g., trial of metformin or SU AND a DPP-4 inhibitor is NOT required) if:

- 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 sulfonylurea:
  - hypoglycemia requiring medical treatment
- The patient has had inadequate response to metformin or a SU or a DPP-4 inhibitor

The patient has a contraindication to metformin or a SU or DPP-4 inhibitor

E. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 against, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

XV. RECENTLY APPROVED U.S. FDA AGENTS

BAP Comments

A. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—UF Recommendation

The P&T Committee recommended dapagliflozin (Farxiga) be designated NF, due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcome, and cost disadvantage compared to UF products.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—Prior Authorization (PA) Criteria

Existing automated PA (step therapy) for the SGLT2 inhibitors requires a trial of metformin, or a sulfonylurea, and a DPP-4 inhibitor first, based on positive long-term outcomes data with metformin and the sulfonylureas.

The P&T Committee recommended a trial of metformin or a sulfonylurea and a DPP-4 inhibitor in all new and current users of dapagliflozin (Farxiga), due to the modest hemoglobin Alc lowering and safety concerns.

All new and current users of dapagliflozin (Farxiga) are required to try metformin, a sulfonylurea (SU), and a dipeptidyl-dipeptidase-4 (DPP-4) inhibitor before dapagliflozin (Farxiga).

Automated PA criteria: The patient has filled a prescription for metformin, a SU, AND a DPP-4 inhibitor at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

AND

Manual PA criteria: If automated criteria are not met, dapagliflozin (Farxiga) is approved (e.g., trial of metformin or SU AND a DPP-4 inhibitor is NOT required) if:

- 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 sulfonylurea:
  - hypoglycemia requiring medical treatment
- The patient has had inadequate response to metformin or a SU or a DPP-4 inhibitor

The patient has a contraindication to metformin or a SU or DPP-4 inhibitor

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XVI. RECENTLY APPROVED U.S. FDA AGENTS

P&T Comments

A. Long-Acting Beta Adrenergic (LABA) Inhalers: Indacaterol (Arcapta Neohaler)—Relative Clinical Effectiveness and Conclusion

Background—Indacaterol (Arcapta) is a LABA that is dosed once daily. It is not available in a fixed-dose combination with an inhaled corticosteroid (ICS). The U.S. approved dose of 75 mcg QD was based on two trials showing indacaterol produced statistically and clinically significant improvement in forced expiratory volume in one second compared to placebo; there are no comparative trials available with this dose. The safety profile appears similar to the other LABAs, including a black box warning against use in patients with asthma.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 against, 0 abstained, 0 absent) that although indacaterol is the only LABA dosed once daily, other drug classes, including the ICS/LABA combinations and long-acting muscarinic agents, are more effective than LABAs at improving pulmonary function, and decreasing hospitalizations or exacerbations in patients with chronic obstructive pulmonary disease (COPD).

B. Long-Acting Beta Adrenergic (LABA) Inhalers: Indacaterol (Arcapta Neohaler)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed to evaluate indacaterol (Arcapta) with other LABAs available on the UF that are used in the treatment of COPD. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

CMA results showed that indacaterol (Arcapta) was not cost-effective compared to salmeterol (Serevent) and formoterol (Foradil).

C. Long-Acting Beta Adrenergic (LABA) Inhalers: Indacaterol (Arcapta Neohaler)—UF Recommendation

Despite the convenience of once daily dosing, the P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) indacaterol (Arcapta) be designated NF due to the lack of compelling advantages over the other LABAs and cost effectiveness. Additionally, the P&T Committee recommended reclassifying the LABAs to the Pulmonary II drug class, which includes other drug classes used for treating COPD.

D. Long-Acting Beta Adrenergic (LABA) Inhalers: Indacaterol (Arcapta Neohaler)—UF Implementation Plan

The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

XVII. RECENTLY APPROVED U.S. FDA AGENTS

BAP Comments

A. Long-Acting Beta Adrenergic (LABA) Inhalers: Indacaterol (Arcapta Neohaler)—UF Recommendation

Despite the convenience of once daily dosing, the P&T Committee recommended indacaterol (Arcapta) be designated NF due to the lack of compelling advantages over the other LABAs and cost effectiveness. Additionally, the P&T Committee recommended reclassifying the LABAs to the Pulmonary II drug class, which includes other drug classes used for treating COPD.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Long-Acting Beta Adrenergic (LABA) Inhalers: Indacaterol (Arcapta Neohaler)—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XVIII. RECENTLY APPROVED U.S. FDA AGENTS

P&T Comments

A. Gastrointestinal (GI-1s): GI steroid subclass—Budesonide Extended Release (ER) Tablets (Uceris)—Relative Clinical Effectiveness and Conclusion

Background—Budesonide ER tablets (Uceris) differs from the budesonide capsules (Entocort; generics) currently on the market in its delivery mechanism and FDA-approved indication. The Uceris tablet releases budesonide in the distal colon, making it effective for ulcerative colitis, while generic budesonide is released in the distal ileum

and right colon and is only indicated for the treatment of Crohn's disease. There are no head-to-head studies comparing Uceris to the oral aminosalicylates, but an indirect comparison to mesalamine (Lialda) suggests reduced efficacy at inducing remission after eight weeks of treatment.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 against, 0 abstained, 0 absent) that although Uceris offers a locally-acting steroid option for patients with mild to moderate ulcerative colitis, it failed to demonstrate clinically compelling advantages over existing UF agents for this indication.

B. Gastrointestinal (GI-1s): GI steroid subclass—Budesonide Extended Release (ER) Tablets (Uceris)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed to evaluate budesonide ER tablets (Uceris) with other oral GI steroids and mesalamine products on the UF for induction of remission in patients with mild to moderate ulcerative colitis. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) budesonide ER (Uceris) was not cost-effective compared with other GI steroid alternatives and mesalamine products on the UF.

C. Gastrointestinal (GI-1s): GI steroid subclass—Budesonide Extended Release (ER) Tablets (Uceris)—UF Recommendation

The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) budesonide ER tablets (Uceris) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

D. Gastrointestinal (GI-1s): GI steroid subclass—Budesonide Extended Release (ER) Tablets (Uceris)—UF Implementation Plan

The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

XIX. RECENTLY APPROVED U.S. FDA AGENTS

BAP Comments

A. Gastrointestinal (GI-1s): GI steroid subclass—Budesonide Extended Release (ER) Tablets (Uceris)—UF Recommendation

The P&T Committee recommended budesonide ER tablets (Uceris) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Gastrointestinal (GI-1s): GI steroid subclass—Budesonide Extended Release (ER) Tablets (Uceris)—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XX. RECENTLY APPROVED U.S. FDA AGENTS

P&T Comments

A. Non-Steroidal Anti-inflammatory Drugs (NSAIDs): Diclofenac Low Dose (Zorvolex)—Relative Clinical Effectiveness and Conclusion

Zorvolex is a low dose formulation of diclofenac available in 18 mg and 35 mg capsules. The formulation is intended for faster dissolution and absorption compared to other diclofenac products (diclofenac potassium 50 mg and 100 mg; e.g., Cataflam). According to the FDA, the manufacturer failed to demonstrate these theoretical advantages, as there were no differences in the pharmacokinetic profile when Zorvolex was compared to diclofenac potassium. In the clinical trial used to obtain FDA approval, over 80% of patients received rescue narcotics for pain control. The Zorvolex package insert contains usual black box warnings and precautions for NSAIDs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 against, 0 abstained, 4 absent) that there were no clinical compelling advantages between Zorvolex and the other UF NSAIDs.

B. Non-Steroidal Anti-inflammatory Drugs (NSAIDs): Diclofenac Low Dose (Zorvolex)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed to evaluate diclofenac (Zorvolex) with other oral NSAIDs available on the UF used in the treatment of mild to moderate pain. The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 4 absent) the following:

- CMA results showed that diclofenac low dose 18 mg and 35 mg capsules (Zorvolex) were not cost-effective compared to generic formulations of meloxicam (Mobic), ibuprofen (Motrin), diclofenac sodium (Voltaren), and diclofenac potassium (Cataflam).

Zorvolex was comparable in cost to celecoxib (Celebrex). However, generic formulations of celecoxib are expected later this year and should result in further cost reductions for celecoxib.

C. Non-Steroidal Anti-inflammatory Drugs (NSAIDs): Diclofenac Low Dose (Zorvolex)—UF Recommendation

The P&T Committee recommended (13 for, 0 against, 0 abstained, 4 absent) diclofenac low dose 18 mg and 35 mg capsules be designated NF, based on clinical and cost effectiveness.

D. Non-Steroidal Anti-inflammatory Drugs (NSAIDs): Diclofenac Low Dose (Zorvolex)—UF Implementation Plan

The P&T Committee recommended (13 for, 0 against, 0 abstained, 4 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

XXI. RECENTLY APPROVED U.S. FDA AGENTS

BAP Comments

A. Non-Steroidal Anti-inflammatory Drugs (NSAIDs): Diclofenac Low Dose (Zorvolex)—UF Recommendation

The P&T Committee recommended diclofenac low dose 18 mg and 35 mg capsules be designated NF, based on clinical and cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Non-Steroidal Anti-inflammatory Drugs (NSAIDs): Diclofenac Low Dose (Zorvolex)—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXII. UTILIZATION MANAGEMENT

P&T Comments

A. Cystic Fibrosis Drugs: Ivacaftor (Kalydeco)—PA Criteria

Ivacaftor (Kalydeco) is a potentiator of the cystic fibrosis transmembrane conductance regulator (CFTR). The drug initially targeted a specific subgroup of patients with cystic fibrosis (CF) who had a G551D gene mutation. The FDA has expanded Kalydeco's approved indication to include additional mutations in the CFTR gene. PA criteria were recommended by the P&T Committee for Kalydeco in February 2012 and were implemented in July 2012. There are several FDA-approved in-vitro molecular diagnostic tests designed to simultaneously detect and identify mutations in the CFTR gene.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) updating the existing PA criteria to include the expanded FDA-approved indication.

1. Coverage will be approved for the treatment of CF patients aged 6 years and older who have a G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the CFTR gene, detected by an FDA-approved test.

2. Coverage is not approved for patients who are homozygous for the F508del mutation in the CFTR gene.

3. The approved PA limits coverage of the drug to its labeled use. DHA will expedite review of the required test to determine its coverage under 32 CFR 199.4(g)(15). Providers and beneficiaries will be advised to retain receipts for the test to submit for reimbursement following the coverage determination.

XXIII. UTILIZATION MANAGEMENT

BAP Comments

A. Cystic Fibrosis Drugs: Ivacaftor (Kalydeco)—PA Criteria

Ivacaftor (Kalydeco) is a potentiator of the cystic fibrosis transmembrane conductance regulator (CFTR). The drug initially targeted a specific subgroup of patients with cystic fibrosis (CF) who had a G551D gene mutation. The FDA has expanded Kalydeco's approved indication to include additional mutations in the CFTR gene. PA criteria were recommended by the P&T Committee for Kalydeco in February 2012 and were implemented in July 2012. There are several FDA-approved in-vitro molecular diagnostic tests designed to simultaneously detect and identify mutations in the CFTR gene.

The P&T Committee recommended updating the existing PA criteria to include the expanded FDA-approved indication.

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2. Coverage is not approved for patients who are homozygous for the F508del mutation in the CFTR gene.

3. The approved PA limits coverage of the drug to its labeled use. DHA will expedite review of the required test to determine its coverage under 32 CFR 199.4(g)(15). Providers and beneficiaries will be advised to retain receipts for the test to submit for reimbursement following the coverage determination.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXIV. UTILIZATION MANAGEMENT

P&T Comments

A. Targeted Immunomodulatory Biologics (TIBSs): Tofacitinib (Xeljanz) and Apremilast (Otezla)—PA Criteria

PA criteria currently apply to the TIBs. Tofacitinib (Xeljanz) is a janus kinase inhibitor approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had inadequate response or intolerance to methotrexate. Xeljanz is the first oral TIB to reach the market. Apremilast (Otezla) is an oral phosphodiesterase-4 inhibitor approved for the treatment of psoriatic arthritis. PA criteria were proposed for Xeljanz and Otezla, consistent with FDA-approved product labeling.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) PA criteria for tofacitinib (Xeljanz) and apremilast (Otezla), consistent with the product's labeling. (See Appendix C for full criteria.)

XXV. UTILIZATION MANAGEMENT

BAP Comments

A. Targeted Immunomodulatory Biologics (TIBSs): Tofacitinib (Xeljanz) and Apremilast (Otezla)—PA Criteria

PA criteria currently apply to the TIBs. Tofacitinib (Xeljanz) is a janus kinase inhibitor approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had inadequate response or intolerance to methotrexate. Xeljanz is the first oral TIB to reach the market. Apremilast (Otezla) is an oral phosphodiesterase-4 inhibitor approved for the treatment of psoriatic arthritis. PA criteria were proposed for Xeljanz and Otezla, consistent with FDA-approved product labeling.

The P&T Committee recommended PA criteria for tofacitinib (Xeljanz) and apremilast (Otezla), consistent with the product's labeling. (See Appendix C for full criteria.)

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXVI. UTILIZATION MANAGEMENT

P&T Comments

A. Niacin ER (Niaspan)—PA Criteria

AB-rated generic formulations for niacin ER (Niaspan) were launched in August 2013; however, pricing for the branded product is lower than the generic formulations. The manufacturer of Niaspan offered a Voluntary Agreement for Retail Refunds, and the Tier 1 (generic) copayment was assigned to the branded product at the November 2013 P&T Committee meeting.

The mandatory generic drug policy is in place at the Retail Network; however, brand Niaspan is the preferred product for the MHS. PA criteria allowing for a patient to receive generic niacin ER instead of branded Niaspan is needed as a result of the generic to brand change (i.e., the reverse of the current brand to generic policy).

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) manual PA criteria for generic niacin ER in the Retail Network. The prescriber will provide patient-

specific justification as to why the brand Niaspan product cannot be used. Acceptable reasons include the following, which have occurred or are likely to occur with the branded Niaspan product: allergy to the branded Niaspan; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues.

XXVII. UTILIZATION MANAGEMENT

BAP Comments

A. Niacin ER (Niaspan)—PA Criteria

AB-rated generic formulations for niacin ER (Niaspan) were launched in August 2013; however, pricing for the branded product is lower than the generic formulations. The manufacturer of Niaspan offered a Voluntary Agreement for Retail Refunds, and the Tier 1 (generic) copayment was assigned to the branded product at the November 2013 P&T Committee meeting.

The mandatory generic drug policy is in place at the Retail Network; however, brand Niaspan is the preferred product for the MHS. PA criteria allowing for a patient to receive generic niacin ER instead of branded Niaspan is needed as a result of the generic to brand change (i.e., the reverse of the current brand to generic policy).

The P&T Committee recommended manual PA criteria for generic niacin ER in the Retail Network. The prescriber will provide patient-specific justification as to why the brand Niaspan product cannot be used. Acceptable reasons include the following, which have occurred or are likely to occur with the branded Niaspan product: allergy to the branded Niaspan; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXVIII. UTILIZATION MANAGEMENT

P&T Comments

A. Esomeprazole (Nexium)—PA Criteria

Esomeprazole (Nexium) and omeprazole (generic Prilosec) are BCF and step-preferred in the Proton Pump Inhibitor (PPI) drug class. The patent for Nexium expired in May 2014; however, the launch date for generic formulations is unknown, due to manufacturing issues with the company granted exclusivity by the FDA. Market research indicates generic esomeprazole entrants will be less cost-effective than the branded formulation, leaving branded

Nexium as the preferred product in the MHS. Therefore, PA criteria are needed to allow a patient to receive the generic esomeprazole instead of branded Nexium (i.e., the reverse of the current brand to generic policy).

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) manual PA criteria for generic esomeprazole in the Retail Network. The prescriber will provide patient-specific justification as to why the branded Nexium product cannot be used. Acceptable reasons include the following, which have occurred or are likely to occur with the branded Nexium product: allergy to branded Nexium; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues. Implementation will occur when generic esomeprazole products reach the market.

XXIX. UTILIZATION MANAGEMENT

BAP Comments

A. Esomeprazole (Nexium)—PA Criteria

Esomeprazole (Nexium) and omeprazole (generic Prilosec) are BCF and step-preferred in the Proton Pump Inhibitor (PPI) drug class. The patent for Nexium expired in May 2014; however, the launch date for generic formulations is unknown, due to manufacturing issues with the company granted exclusivity by the FDA. Market research indicates generic esomeprazole entrants will be less cost-effective than the branded formulation, leaving branded Nexium as the preferred product in the MHS. Therefore, PA criteria are needed to allow a patient to receive the generic esomeprazole instead of branded Nexium (i.e., the reverse of the current brand to generic policy).

The P&T Committee recommended manual PA criteria for generic esomeprazole in the Retail Network. The prescriber will provide patient-specific justification as to why the branded Nexium product cannot be used. Acceptable reasons include the following, which have occurred or are likely to occur with the branded Nexium product: allergy to branded Nexium; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues. Implementation will occur when generic esomeprazole products reach the market.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XXX. FISCAL YEAR 2008 NDAA, Section 703

P&T Comments

A. Fiscal Year 2008 NDAA, Section 703—The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not in compliance with the Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity in the MTFs. These NF drugs will remain available in the Mail Order POS without preauthorization.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) that the following products be designated NF on the UF:

CorePharma:	dextroamphetamine sulfate capsules
Lupin:	fenofibrate capsules; Wymzya Fe tablets
Royal:	Derma-Smoothe/FS Body Oil topical oil; DermOtic Oil otic drops
Savient:	Oxandrin tablets

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) the following pre-authorization criteria for the drugs recommended NF above: 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any POS other than retail network pharmacies.

B. Fiscal Year 2008 NDAA, Section 703—Implementation Period for Pre-Authorization Criteria

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by these decisions.

XXXI. FISCAL YEAR 2008 NDAA, Section 703

BAP Comments

A. Fiscal Year 2008 NDAA, Section 703—The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not in compliance with the Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity in the MTFs. These NF drugs will remain available in the Mail Order POS without preauthorization.

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Royal:	Derma-Smoothe/FS Body Oil topical oil; DermOtic Oil otic drops
Savient:	Oxandrin tablets

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) the following pre-authorization criteria for the drugs recommended NF above: 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any POS other than retail network pharmacies.

B. Fiscal Year 2008 NDAA, Section 703—Implementation Period for Pre-Authorization Criteria

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by these decisions.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention