DECISION PAPER

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

August 2012

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

A. Targeted Immunomodulatory Biologics (TIBs)—Abatacept Subcutaneous (SC) Injection (Orencia SC)

Relative Clinical Effectiveness Conclusion—The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that although abatacept SC (Orencia SC) provides an alternative to the tumor necrosis factor (TNF) alpha inhibitors used for treatment of rheumatoid arthritis and offers patient convenience over the abatacept intravenous formulation, there is currently insufficient data to conclude that Orencia SC offers improved efficacy, safety, or tolerability compared to the TNF alpha inhibitors in the TIBs class.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that abatacept SC (Orencia SC) was not cost-effective when compared to other TIBs included on the Uniform Formulary (UF).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) abatacept SC (Orencia SC) be designated nonformulary (NF) due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***
Based on the clinical evaluations for abatacept SC (Orencia SC) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for abatacept SC (Orencia SC). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Glaucoma Drugs: Prostaglandin Analogs—Tafluprost Ophthalmic Solution (Zioptan)

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) that tafluprost (Zioptan) offers no compelling clinical advantages over the other prostaglandins available on the UF.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that tafluprost (Zioptan) was not cost-effective when compared to the other ophthalmic prostaglandins currently included on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) tafluprost (Zioptan) be designated NF because it has no compelling clinical advantages over the other ophthalmic prostaglandin analogues and is not cost-effective compared to latanoprost, the most utilized drug in the Military Health System (MHS).

2. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for tafluprost (Zioptan) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for tafluprost (Zioptan). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Oral Non-steroidal Anti-inflammatory Drugs (NSAIDs)—Ibuprofen/Famotidine (Duexis)

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) ibuprofen/famotidine (Duexis) offers no distinct clinical advantages to the combination NSAID/gastroprotective agents already on the UF.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that ibuprofen/famotidine (Duexis) was not cost-effective when compared to other oral NSAIDs agents included on the UF; it was also more costly than the individual components, ibuprofen and famotidine.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) ibuprofen/famotidine (Duexis) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for ibuprofen/famotidine (Duexis) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for ibuprofen/famotidine (Duexis). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9, 2013

Director, TMA, Decision: ☒Approved ☐ Disapproved

Approved, but modified as follows:

D. Oral NSAIDs—Ketorolac Nasal Spray (Sprix)

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) there is no evidence to suggest ketorolac nasal spray

(Sprix) has a compelling clinical advantage over the other oral NSAIDs already on the Basic Core Formulary (BCF) and UF.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that ketorolac nasal spray (Sprix) was more costly, based on an average weighted cost per day of therapy at all three points of service (POS), than the other oral NSAIDs and low-potency narcotic analgesics currently on the BCF and UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee, recommended (16 for, 0 opposed, 1 abstained, 0 absent) ketorolac nasal spray (Sprix) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for ketorolac nasal spray (Sprix) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for ketorolac nasal spray (Sprix). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: QUANTITY LIMITS***—The P&T Committee recommended (16 for, 0 opposed, 1 abstain, 0 absent) restricting the maximum allowable quantity to 5 nasal spray bottles/30 days in the mail order pharmacy and retail network, which is consistent with the recommended dosing from the package labeling.

4. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

E. Non-Insulin Diabetes Drugs: Dipeptidyl Dipeptidase-4 (DPP-4) Inhibitors—Sitagliptin/Metformin ER (Janumet XR) and Linagliptin/ Metformin (Jentadueto)

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) there is no evidence to suggest either sitagliptin/ metformin ER (Janumet XR) or linagliptin/metformin (Jentadueto) have a compelling clinical advantage over the other DPP-4 inhibitor/metformin fixed-dose combinations included on the UF.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that Janumet XR and Jentadueto were cost-effective when compared to other DPP-4 inhibitors included on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee, recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following:

    - sitagliptin/metformin ER (Janumet XR) be designated step-preferred and formulary on the UF; and
    - linagliptin/metformin (Jentadueto) be designated non-preferred and formulary on the UF.
    - This recommendation includes step therapy, which requires a trial of sitagliptin (Januvia), sitagliptin/metformin (Janumet), sitagliptin/ simvastatin (Juvisync), or sitagliptin/metformin ER (Janumet XR) (the preferred drugs) prior to using other DPP-4 inhibitors. Prior authorization for the DPP-4 inhibitors also requires a trial of metformin or sulfonylurea for new patients.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee, recommended (14 for, 1 opposed, 1 abstained, 1 absent) sitagliptin/metformin ER (Janumet XR) be designated with BCF status.

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***
The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following PA criteria should apply to the DPP-4 inhibitors subclass. Coverage would be approved if the patient met any of the following criteria

    a) Automated PA criteria:

        (1) The patient has filled a prescription for metformin or a sulfonylurea at any MHS pharmacy POS [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

(2) The patient has received a prescription for a DPP-4 inhibitor (Januvia, Janumet, Juvisync, Janumet XR, Tradjenta, Jentadueto, Onglyza, or Kombiglyze XR) at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

b) Manual PA criteria, if automated criteria are not met:

The fixed-dose combination product Janumet XR or Jentadueto is approved (eg, a trial of sulfonylurea is not required if):

(1) The patient has had an inadequate response to metformin or sulfonylurea.

(2) The patient has experienced the following adverse event while receiving a sulfonylurea: hypoglycemia requiring medical treatment.

(3) The patient has a contraindication to a sulfonylurea.

c) In addition to the above criteria regarding metformin and sulfonylurea, the following PA criteria would apply specifically to linagliptin/metformin metformin (Jentadueto):

(1) The patient has experienced an adverse event with sitagliptin-containing products, which is not expected to occur with linagliptin-containing products.

(2) The patient has had an inadequate response to a sitagliptin-containing product.

(3) The patient has a contraindication to sitagliptin.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENATION PERIOD***
The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

II. UNIFORM FORMULARY DRUG CLASS REVIEWS

A. Anticoagulants—Heparin and Related Products

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 2 absent) on the following clinical effectiveness conclusions:

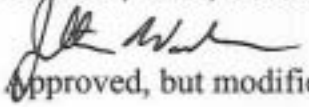
- Enoxaparin (Lovenox, generic) has the widest clinical utility of the subclass, due to its long history of use and largest number of FDA-approved indications.
- Fondaparinux (Arixtra, generic) has fewer FDA-approved indications than enoxaparin. It has a therapeutic niche for patients with a history of heparin-induced thrombocytopenia (HIT).
- The major limitation with dalteparin (Fragmin) is the lack of an FDA-approved indication for treating deep venous thrombosis and pulmonary embolism. The package insert also cautions against use in patients with a history of HIT.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that generic enoxaparin was the most cost-effective agent based on a weighted average cost per unit across all three POS, followed by branded dalteparin (Fragmin), and generic fondaparinux. Budget impact analysis (BIA) results showed that scenarios where generic enoxaparin is included on the BCF and dalteparin (Fragmin) and generic fondaparinux are included on the UF generated the greatest cost-avoidance projection.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee, recommended (15 for, 0 opposed, 1 abstained, 1 absent) enoxaparin, dalteparin (Fragmin), and fondaparinux remain designated as formulary on the UF.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) generic enoxaparin be designated with BCF status, based on clinical and cost effectivness. The BCF recommendation will be implemented upon signing of the minutes.

Director, TMA, Decision: ☒ Approved ☐ Disapproved



Approved, but modified as follows:

B. Androgens Anabolic Steroids—Transdermal and Buccal Testosterone Replacement Therapies (TRTs)

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following concerning the TRT agents:

- Although high-quality comparative data is lacking, there appear to be no clinically relevant differences in efficacy between products.
- Transdermal and buccal testosterone replacement products effectively raise testosterone levels in hypogonadal men to the normal range when used in accordance with product labeling.
- Skin-to-skin transfer of transdermal testosterone to women and children should be minimized due to risk of virilization or premature onset of puberty. Testosterone buccal tablets (Striant) carry the lowest risk while the topically applied products carry the highest risk.
- Transdermal and buccal TRTs have a low overall incidence of systemic adverse events, which are not considered to differ clinically across products.
- The most frequent adverse events are dermal application site reactions for the transdermal products and oral application site reactions for buccal tablets; most are mild or transient in nature.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that transdermal 2% gel pump (Fortesta) was the least costly agent, followed by transdermal solution (Axiron), transdermal patch (Androderm), transdermal 1.62% gel pump (Androgel 1.62%), transdermal 1% gel pump and gel packets (Androgel 1%), transdermal gel tubes (Testim), and testosterone buccal tablets (Striant).

BIA results showed the scenario where transdermal 2% gel (Fortesta) is step-preferred on the UF, all other TRTs are designated non-preferred on the UF or NF, and step therapy is applied to all current and new users of TRTs, was determined to be the most cost-effective scenario.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 3 opposed, 1 abstained, 0 absent) the following scenario for the UF, which is the most clinically and cost-effective option for the MHS:
    - testosterone transdermal 2% gel pump (Fortesta) be designated step-preferred and formulary on the UF;
    - testosterone transdermal patch (Androderm), testosterone transdermal gel tubes (Testim), and testosterone buccal tablets (Striant) be designated non-preferred and formulary on the UF; and
    - testosterone transdermal 1% gel pump and gel packets (Androgel 1%), testosterone transdermal 1.62% gel pump (Androgel 1.62%), and

testosterone transdermal solution (Axiron) be designated non-preferred and NF on the UF.

- This recommendation includes step therapy, which requires a trial of testosterone transdermal 2% gel pump (Fortesta) prior to using other transdermal and buccal TRTs.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) testosterone transdermal 2% gel pump (Fortesta) be designated BCF.

3. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 4 absent) that the following manual PA criteria should apply to all current and new users of the testosterone replacement therapies. Coverage would be approved if the patient met any of the following criteria:

   a) Manual PA criteria for all transdermal and buccal testosterone replacement products:

      - Patient is male and has a diagnosis of hypogonadism evidenced by 2 or more morning testosterone levels in the presence of symptoms usually associated with hypogonadism.
      - Patient is a female and receiving testosterone for the following uses:
        - Treatment of hypoactive sexual desire in menopausal women (whether natural or surgical); or
        - Treatment of menopausal symptoms in women also receiving FDA-approved estrogen products (with or without concomitant progesterone).
        - Note that coverage of transdermal or buccal testosterone replacement therapies is not approved for osteoporosis or urinary incontinence.
        - Note that coverage for use in women will be by appeal only.
      - Note that use in adolescents under the age of 17 is not approved and will be by appeal only.

   b) In addition to the above criteria, the following PA criteria would apply specifically to transdermal gel tubes (Testim), transdermal patch (Androderm), buccal tablets (Striant), transdermal 1% gel pump and gel

packets (Androgel 1%), transdermal 1.62% gel pump (Androgel 1.62%), and transdermal solution (Axiron):

- The patient requires a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members (for Striant and Androderm only).
- The patient has tried transdermal 2% gel pump (Fortesta) for a minimum of 90 days AND failed to achieve total testosterone levels above 400ng/dL (lab must be drawn 2 hours after Fortesta application) AND denied improvement in symptoms.
- The patient has a contraindication or relative contraindication to Fortesta (e.g., hypersensitivity to a component [including alcohol]; concomitant disulfiram use) that does not apply to Testim, Androderm, Striant, Androgel 1%, Androgel 1.62%, or Axiron.
- The patient has experienced a clinically significant skin reaction to Fortesta that is not expected to occur with Testim, Androderm, Striant, Androgel 1%, Androgel 1.62%, or Axiron.

4. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for transdermal 1.62% gel pump (Androgel 1.62%), transdermal 1% gel pump and gel packets (Androgel 1%), the transdermal solution (Axiron), and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Androgel 1.62%, Androgel 1%, and Axiron. (See Appendix B for full MN criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
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 POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is February 6, 2013.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

III. SECTION 703

A. Section 703—The P&T Committee reviewed a list of products—Amicar (branded aminocaproic acid), Kineret (anakinra), Phoslo (branded calcium acetate), Rheumatrex (branded methotrexate), Oxadrin (branded oxandrolone), Denavir (penciclovir), and Transderm-Scop (scopolamine patch)—to determine MN and pre-authorization criteria. These products were identified as not fulfilling refund requirements as required in section 703 of the 2008 National Defense Authorization Act. These drugs were made NF on the UF at previous P&T Committee meetings.

1. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 4 absent) the following should apply to the drugs listed above. Coverage at retail network pharmacies would be approved if the patient met all the following criteria:

    a) Manual Pre-Authorization Criteria:

    (1) Obtaining the product from home delivery would be detrimental to the patient.

    (2) For branded products with AB generic availability, use of the generic product would be detrimental to the patient.

The Pre-Authorization criteria listed above do not apply to any point of service other than retail network pharmacies.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

Jonathan Woodson, M.D.
Director

NOV 8 2012

Date

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE MINUTES AND RECOMMENDATIONS

August 2012

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 15 and 16, 2012, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is found in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May Minutes**—Jonathon Woodson M.D., Director, approved the minutes for the May 2012 DoD P&T Committee meeting on August 8, 2012.
2. **Clarification to the February 2012 Minutes**—The February minutes were clarified to state, for the Sedative Hypnotics-1 class, zolpidem IR is the sole Basic Core Formulary (BCF) drug.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and BCF recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Targeted Immunomodulatory Biologics (TIBs)—Abatacept Subcutaneous Injection (Orencia SC)

Relative Clinical Effectiveness—Abatacept (Orencia) inhibits the activation of T-cells and is approved for treating moderate to severe active rheumatoid arthritis (RA) in adults. It was first marketed in 2005 as an intravenous (IV) infusion, which is only available through the TRICARE medical benefit. A new subcutaneous (SC) abatacept

formulation intended for self-injection is now available. FDA-approval of abatacept SC was based on its demonstrated non-inferiority to abatacept IV. Prior authorization criteria and quantity limits apply to the TIBs and were placed on abatacept SC in November 2011, which are consistent with the FDA-approved package labeling.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that although abatacept SC (Orencia SC) provides an alternative to the tumor necrosis factor (TNF) alpha inhibitors used for treatment of RA and offers patient convenience over the abatacept IV formulation, there is currently insufficient data to conclude that Orencia SC offers improved efficacy, safety, or tolerability compared to the TNF alpha inhibitors in the TIBs class.

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion—A pharmacoeconomic analysis was performed. The weighted average cost per month at all three points of service (POS) was evaluated for abatacept SC (Orencia SC) in relation to the other drugs in the TIBs class indicated for treatment of RA. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that Orencia SC was not cost-effective when compared to other TIBs included on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) abatacept SC (Orencia SC) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for abatacept SC (Orencia SC) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for abatacept SC (Orencia SC). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

B. Glaucoma Drugs: Prostaglandin Analogs—Tafluprost Ophthalmic Solution (Zioptan)

Relative Clinical Effectiveness—Tafluprost ophthalmic solution (Zioptan) is a preservative-free prostaglandin analog indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. In one head-to-head comparison, tafluprost proved inferior to latanoprost in lowering IOP, failing to meet the pre-specified margin for non-inferiority. Whether preservative-free tafluprost is associated with decreased adverse events compared to preservative-containing tafluprost remains to be determined.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) that tafluprost (Zioptan) offers no compelling clinical advantages over the other prostaglandins available on the UF.

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion—A pharmacoeconomic analysis was performed. The weighted average cost per day at all three POS was evaluated for tafluprost (Zioptan) in relation to the other ophthalmic prostaglandin analogues. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that Zioptan was not cost-effective when compared to the other ophthalmic prostaglandins currently included on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) tafluprost (Zioptan) be designated NF because it has no compelling clinical advantages over the other ophthalmic prostaglandin analogues and is not cost-effective compared to latanoprost, the most utilized drug in the Military Health System (MHS).

2. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for tafluprost (Zioptan) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for tafluprost (Zioptan). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9,

2013.

C. Oral Non-steroidal Anti-inflammatory Drugs (NSAIDs)—Ibuprofen/Famotidine (Duexis)

Relative Clinical Effectiveness—Ibuprofen/famotidine (Duexis) is the first fixed-dose combination of a non-selective NSAID with an H2 antagonist. Ibuprofen and famotidine are currently on the BCF and UF, respectively, and are available over-the-counter. Other combination NSAID/gastroprotective agents on the UF include esomeprazole/enteric-coated naproxen (Vimovo), diclofenac/misoprostol (Arthrotec), and the COX-2 inhibitor celecoxib (Celebrex). No studies with Duexis have evaluated clinically important upper GI events (bleeding, perforation, obstruction). Although the fixed-dose combination of famotidine and ibuprofen offers the convenience of a gastroprotective agent with an NSAID, the three-times daily dosing regimen may affect patient compliance. Systematic reviews and national professional guidelines state a preference for NSAID with proton pump inhibitor or NSAID with misoprostol versus an NSAID with H2 antagonist for reducing GI ulcers.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) ibuprofen/famotidine (Duexis) offers no distinct clinical advantages to the combination NSAID/gastroprotective agents already on the UF.

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion—A pharmacoeconomic analysis was performed. The weighted average cost per day at all three POS was evaluated for ibuprofen/famotidine (Duexis) in relation to the other oral gastroprotective NSAIDs. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that Duexis was not cost-effective when compared to other oral NSAIDs agents included on the UF; it was also more costly than the individual components, ibuprofen and famotidine.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) ibuprofen/famotidine (Duexis) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for ibuprofen/famotidine (Duexis) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for ibuprofen/famotidine (Duexis). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

D. Oral NSAIDs—Ketorolac Nasal Spray (Sprix)

Relative Clinical Effectiveness—Ketorolac nasal spray (Sprix) is the first NSAID administered by the intranasal route. There is no direct comparative data with ketorolac nasal spray or other oral NSAIDs or low potency narcotic analgesics. The studies used to obtain FDA-approval were conducted using a placebo control in the in-patient setting where concomitant morphine or rescue analgesia was administered. Reduced morphine requirements were seen at 24 hours in some studies with Sprix—whether these results are clinically relevant is difficult to determine. Opioid-sparing drugs on the UF include other NSAIDs and tramadol. Sprix is limited by a five-day duration of use, and warnings not seen with other NSAIDs, including contraindications for use in patients with a history of GI bleeding or renal dysfunction.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) there is no evidence to suggest ketorolac nasal spray (Sprix) has a compelling clinical advantage over the other oral NSAIDs already on the BCF and UF.

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion—A pharmacoeconomic analysis was performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that ketorolac nasal spray (Sprix) was more costly, based on an average weighted cost per day of therapy at all three POS, than the other oral NSAIDs and low-potency narcotic analgesics currently on the BCF and UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee, recommended (16 for, 0 opposed, 1 abstained, 0 absent) ketorolac nasal spray (Sprix) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for ketorolac nasal spray (Sprix) and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained,

0 absent) MN criteria for ketorolac nasal spray (Sprix). (See Appendix B for full MN criteria.)

3. ***COMMITTEE ACTION: QUANTITY LIMITS***—The P&T Committee recommended (16 for, 0 opposed, 1 abstain, 0 absent) restricting the maximum allowable quantity to 5 nasal spray bottles/30 days in the mail order pharmacy and retail network, which is consistent with the recommended dosing from the package labeling.

4. ***COMMITTEE ACTION: UF AND MN IMPLEMENTATION PERIOD*** The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

E. Non-Insulin Diabetes Drugs: Dipeptidyl Dipeptidase-4 (DPP-4) Inhibitors—Sitagliptin/Metformin ER (Janumet XR) and Linagliptin/Metformin (Jentadueto)

Relative Clinical Effectiveness—Janumet XR and Jentadueto are fixed-dose combination products containing metformin in either an extended release (ER) formulation with sitagliptin (Janumet XR) or an immediate release (IR) formulation with linagliptin (Jentadueto). Sitagliptin is also available in a fixed-dose combination product with metformin IR (Janumet).

Both Janumet XR and Jentadueto were approved via the FDA 505(b)(2) process, requiring only proof of bioequivalence to their respective individual components. There are no efficacy studies with either agent. The combination of sitagliptin with metformin IR reduces hemoglobin A1c by 0.51% to 0.67%, while the combination of linagliptin with metformin IR decreases A1c by 0.4% to 0.5%. No studies evaluating clinical outcomes (e.g., cardiovascular death, myocardial infarction, and stroke) are available for the DPP-4 inhibitors, but trials are underway.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) there is no evidence to suggest either sitagliptin/ metformin ER (Janumet XR) or linagliptin/metformin (Jentadueto) have a compelling clinical advantage over the other DPP-4 inhibitor/metformin fixed-dose combinations included on the UF.

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion—A pharmacoeconomic analysis was performed. The weighted average cost per day at all three POS was evaluated for sitagliptin/metformin ER (Janumet XR) and linagliptin/ metformin (Jentadueto) in relation to the other drugs in the DPP-4 inhibitors subclass. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that Janumet XR and Jentadueto were cost-effective when compared to other DPP-4 inhibitors included on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee, recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following:

    - sitagliptin/metformin ER (Janumet XR) be designated step-preferred and formulary on the UF; and
    - linagliptin/metformin (Jentadueto) be designated non-preferred and formulary on the UF.
    - This recommendation includes step therapy, which requires a trial of sitagliptin (Januvia), sitagliptin/metformin (Janumet), sitagliptin/ simvastatin (Juvisync), or sitagliptin/metformin ER (Janumet XR) (the preferred drugs) prior to using other DPP-4 inhibitors. Prior authorization for the DPP-4 inhibitors also requires a trial of metformin or sulfonylurea for new patients.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee, recommended (14 for, 1 opposed, 1 abstained, 1 absent) sitagliptin/metformin ER (Janumet XR) be designated with BCF status, as sitagliptin-containing products have the majority of the current DPP-4 inhibitor utilization and are the most cost-effective agents.

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***
   Existing automated prior authorization (step therapy) requires a trial of metformin or a sulfonylurea prior to use of a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR, and Juvisync) are the preferred agents in the DPP-4 inhibitors subclass. New users must try a preferred product before trying linagliptin or saxagliptin-containing products.

   The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following PA criteria should apply to the DPP-4 inhibitors subclass. Coverage would be approved if the patient met any of the following criteria

    a) Automated PA criteria:

(1) The patient has filled a prescription for metformin or a sulfonylurea at any MHS pharmacy POS [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

(2) The patient has received a prescription for a DPP-4 inhibitor (Januvia, Janumet, Juvisync, Janumet XR, Tradjenta, Jentadueto, Onglyza, or Kombiglyze XR) at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

b) Manual PA criteria, if automated criteria are not met:

The fixed-dose combination product Janumet XR or Jentadueto is approved (eg, a trial of sulfonylurea is not required if):

(1) The patient has had an inadequate response to metformin or sulfonylurea.

(2) The patient has experienced the following adverse event while receiving a sulfonylurea: hypoglycemia requiring medical treatment.

(3) The patient has a contraindication to a sulfonylurea.

c) In addition to the above criteria regarding metformin and sulfonylurea, the following PA criteria would apply specifically to linagliptin/metformin metformin (Jentadueto):

(1) The patient has experienced an adverse event with sitagliptin-containing products, which is not expected to occur with linagliptin-containing products.

(2) The patient has had an inadequate response to a sitagliptin-containing product.

(3) The patient has a contraindication to sitagliptin.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENATION PERIOD***
The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 9, 2013.

V. UF DRUG CLASS REVIEWS

A. Anticoagulants—Heparin and Related Products

Background and Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of the Heparin and Related Products subclass of the anticoagulants. (The newer oral anticoagulants, including the Factor Xa inhibitors and direct thrombin inhibitors will be discussed at a later date.) The drugs in this subclass include unfractionated heparin, which is available in many generic formulations and will not be discussed further, enoxaparin (Lovenox), dalteparin (Fragmin), and fondaparinux (Arixtra). Two products, tinzaparin (Innohep) and ardeparin (Normiflow), were voluntarily discontinued by their manufacturers due to nonsafety reasons. The subclass has not previously been reviewed for UF placement. Generic biologic formulations of enoxaparin and fondaparinux are available; both are FDA AP-rated (therapeutically equivalent parenteral products) to Lovenox and Arixtra, respectively.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 2 absent) on the following clinical effectiveness conclusions:

- Enoxaparin has the widest clinical utility of the subclass, due to its long history of use, largest number of FDA-approved indications, availability in several dosage strengths, and recommendations by the American College of Chest Physicians for use in special populations (pregnancy, pediatrics). The package labeling cautions against use in patients with a history of heparin-induced thrombocytopenia (HIT).
- Fondaparinux has fewer FDA-approved indications than enoxaparin. It has a therapeutic niche for patients with a history of HIT. The risk of bleeding is increased in patients with low body weight (<50 kg), the elderly, and in patients with decreased renal function.
- The major limitation with dalteparin is the lack of an FDA-approved indication for treating deep venous thrombosis and pulmonary embolism. The package insert also cautions against use in patients with a history of HIT.

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion—Cost minimization (CMA) and budget impact analyses (BIA) were used to evaluate the drugs in this subclass, with corresponding sensitivity analyses. Due to recent availability of generic fondaparinux (Arixtra), an estimated generic drug price was used in the cost analyses. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that generic enoxaparin was the most cost-effective agent based on a weighted average cost per unit across all three POS, followed by branded dalteparin (Fragmin), and generic fondaparinux (ranked in order from most cost-effective to least cost-effective). BIA results showed that, among currently available formulary options, scenarios where generic enoxaparin is included on the BCF and dalteparin (Fragmin) and generic fondaparinux are included on the UF generated the greatest cost-avoidance projection.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee, recommended (15 for, 0 opposed, 1 abstained, 1 absent) enoxaparin, dalteparin (Fragmin), and fondaparinux remain designated as formulary on the UF.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) generic enoxaparin be designated with BCF status, based on clinical and cost effectivness. This clarifies the previous BCF listing for the low-molecular weight heparins stating that MTFs could choose between dalteparin (Fragmin), enoxaparin, or tinzaparin (Innohep). The BCF recommendation will be implemented upon signing of the minutes.

B. Androgens Anabolic Steroids—Transdermal and Buccal Testosterone Replacement Therapies

Background and Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of the transdermal and buccal testosterone replacement therapies (TRTs), which are used for treating adult male hypogonadism. The TRT class is comprised of the following formulations of topical or buccal testosterone: transdermal patch (Androderm), transdermal 1% gel pump and gel packets (Androgel 1%), transdermal 1.62% gel pump (Androgel 1.62%), transdermal solution (Axiron), transdermal 2% gel pump (Fortesta), buccal tablets (Striant), and transdermal gel tubes (Testim).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following concerning the TRT agents:

- Although high-quality comparative data is lacking, there appear to be no clinically relevant differences in efficacy between products.
- Transdermal and buccal testosterone replacement products effectively raise testosterone levels in hypogonadal men to the normal range when used in accordance with product labeling.
- Skin-to-skin transfer of transdermal testosterone to women and children should be minimized due to risk of virilization or premature onset of puberty. Testosterone buccal tablets (Striant) carry the lowest risk while the topically applied products carry the highest risk.
- Transdermal and buccal TRTs have a low overall incidence of systemic adverse events, which are not considered to differ clinically across products.

- The most frequent adverse events are dermal application site reactions for the transdermal products and oral application site reactions for buccal tablets; most are mild or transient in nature.

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion
Pharmacoeconomic analyses were performed for the topical and buccal testosterone class, including CMA and BIA. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that transdermal 2% gel pump (Fortesta) was the least costly agent, followed by transdermal solution (Axiron), transdermal patch (Androderm), transdermal 1.62% gel pump (Androgel 1.62%), transdermal 1% gel pump and gel packets (Androgel 1%), transdermal gel tubes (Testim), and testosterone buccal tablets (Striant).

The analyses also evaluated the potential budgetary impact of cost scenarios where selected TRTs were designated with preferred product status (step therapy) on the UF; i.e., a trial of a preferred TRT would be required before using other TRTs. BIA results showed scenarios implementing step therapy were more cost-effective than scenarios without step therapy. The scenario where transdermal 2% gel (Fortesta) is step-preferred on the UF, all other TRTs are designated non-preferred on the UF or NF, and step therapy is applied to all current and new users of TRTs, was determined to be the most cost-effective scenario.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 3 opposed, 1 abstained, 0 absent) the following scenario for the UF, which is the most clinically and cost-effective option for the MHS:
    - testosterone transdermal 2% gel pump (Fortesta) be designated step-preferred and formulary on the UF;
    - testosterone transdermal patch (Androderm), testosterone transdermal gel tubes (Testim), and testosterone buccal tablets (Striant) be designated non-preferred and formulary on the UF; and
    - testosterone transdermal 1% gel pump and gel packets (Androgel 1%), testosterone transdermal 1.62% gel pump (Androgel 1.62%), and testosterone transdermal solution (Axiron) be designated non-preferred and NF on the UF.
    - This recommendation includes step therapy, which requires a trial of testosterone transdermal 2% gel pump (Fortesta) prior to using other transdermal and buccal TRTs.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) testosterone transdermal 2% gel pump (Fortesta) be designated BCF.

3. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 4 absent) that the following manual PA criteria should apply to all current and new users of the testosterone replacement therapies. Coverage would be approved if the patient met any of the following criteria:

    a) Manual PA criteria for all transdermal and buccal testosterone replacement products:

        - Patient is male and has a diagnosis of hypogonadism evidenced by 2 or more morning testosterone levels in the presence of symptoms usually associated with hypogonadism;
        - Patient is a female and receiving testosterone for the following uses:
            - Treatment of hypoactive sexual desire in menopausal women (whether natural or surgical); or
            - Treatment of menopausal symptoms in women also receiving FDA-approved estrogen products (with or without concomitant progesterone).
            - Note that coverage of transdermal or buccal testosterone replacement therapies is not approved for osteoporosis or urinary incontinence.
            - Note that coverage for use in women will be by appeal only.
        - Note that use in adolescents under the age of 17 is not approved and will be by appeal only.

    b) In addition to the above criteria, the following PA criteria would apply specifically to transdermal gel tubes (Testim), transdermal patch (Androderm), buccal tablets (Striant), transdermal 1% gel pump and gel packets (Androgel 1%), transdermal 1.62% gel pump (Androgel 1.62%), and transdermal solution (Axiron):

        - The patient requires a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members (for Striant and Androderm only).

- The patient has tried transdermal 2% gel pump (Fortesta) for a minimum of 90 days AND failed to achieve total testosterone levels above 400ng/dL (lab must be drawn 2 hours after Fortesta application) AND denied improvement in symptoms.
- The patient has a contraindication or relative contraindication to Fortesta (e.g., hypersensitivity to a component [including alcohol]; concomitant disulfiram use) that does not apply to Testim, Androderm, Striant, Androgel 1%, Androgel 1.62%, or Axiron.
- The patient has experienced a clinically significant skin reaction to Fortesta that is not expected to occur with Testim, Androderm, Striant, Androgel 1%, Androgel 1.62%, or Axiron.

4. ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluations for transdermal 1.62% gel pump (Androgel 1.62%), transdermal 1% gel pump and gel packets (Androgel 1%), the transdermal solution (Axiron), and the conditions for establishing MN for NF medications, the P&T Cominittee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Androgel 1.62%, Androgel 1%, and Axiron. (See Appendix B for full MN criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
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 POS, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the P&T Committee's recommendation, the effective date is February 6, 2013.

VI. SECTION 703

A. Section 703—The P&T Committee reviewed a list of products—Amicar (branded aminocaproic acid), Kineret (anakinra), Phoslo (branded calcium acetate), Rheumatrex (branded methotrexate), Oxadrin (branded oxandrolone), Denavir (penciclovir), and Transderm-Scop (scopolamine patch)—to determine MN and pre-authorization criteria. These products were identified as not fulfilling refund requirements as required in section 703 of the 2008 National Defense Authorization Act. These drugs were made NF on the UF at previous P&T Committee meetings.

1. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 4 absent) the following should apply to the drugs listed above. Coverage at retail network pharmacies would be approved if the patient met all the following criteria:

a) Manual Pre-Authorization Criteria:

(1) Obtaining the product from home delivery would be detrimental to the patient.

(2) For branded products with AB generic availability, use of the generic product would be detrimental to the patient.

The Pre-Authorization criteria listed above do not apply to any point of service other than retail network pharmacies.

VII. ITEMS FOR INFORMATION

A. Pharmacy Outcomes Research Team (PORT)—The PORT updated the P&T Committee on their various activities and research initiatives, and presented data on utilization patterns and effects of formulary changes in four drug classes:

- Antiplatelet agents—This class was reviewed in February 2012, with clopidogrel (Plavix) remaining on the BCF. A key element of the cost-effectiveness evaluation was the anticipated generic availability of clopidogrel. As of July 2012, generic clopidogrel accounted for more than 98% of all use in the retail network, accompanied by an approximately 72% decrease in the average cost per unit compared to April 2012. At least one clopidogrel generic formulation is available to MTFs under a Federal Supply Schedule contract. The P&T Committee acknowledged that MTFs may encounter delayed availability of clopidogrel generics through their prime vendors, but encouraged perseverance, given the volume of use and the potential for cost avoidance.
- Antilipidemics-1—An automated step therapy program/PA was implemented in October 2010, requiring use of the preferred statin agents (atorvastatin, lovastatin, pravastatin, simvastatin) prior to treatment with non-preferred agents (e.g., rosuvastatin, ezetimibe/simvastatin, etc). The P&T Committee noted that step therapy is working, as evidenced by a gradual decline in the use of non-preferred agents (particularly the lower dosage strengths) in the retail and mail POS, and the low percentage (<3%) of rejected claims under the step therapy program relative to total claims (paid claims plus rejected claims).
- Leukotriene Antagonists—A PA requirement for montelukast (Singulair) was implemented in March 2012. The PA allows for the treatment of asthma, but limits use for treatment of allergic rhinitis, unless the patient has failed or experienced an adverse event with nasal corticosteroids. The P&T Committee noted an overall decline in Singulair use, particularly in the retail and mail order POS. Additionally, there was no spike in usage in April 2012, which historically was noticeable and attributed to seasonal usage of Singulair, likely for allergic rhinitis. No information was available at the time of the meeting

concerning impact of the very recent generic approval of montelukast in August 2012.

- Phosphodiesterase-5 inhibitors for Erectile Dysfunction—In November 2011, sildenafil (Viagra) replaced vardenafil (Levitra) on the BCF (effective February 2012) and as the preferred agent under the existing step therapy/PA program (effective April 2012). MTFs are rapidly switching from Levitra to Viagra. It is too early to determine the full effect on relative market share of these agents at retail and mail.

B. TRICARE Formulary Search Tool—Information regarding updates to the TRICARE Formulary Search Tool was provided to the P&T Committee and is available at *http://pec.ha.osd.mil/formulary_search.php*.

VIII. ADJOURNMENT

The meeting adjourned at 1100 hours on August 16, 2012. The next meeting will be in November 2012.

Appendix A—Attendance: August 2012 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria for Newly-Approved Drugs

Appendix C—Table of Implementation Status of UF Recommendations/Decisions Summary

Appendix D—Table of Abbreviations

Appendix A—Attendance: August 2012 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CDR Joe Lawrence, MSC	Director, DoD Pharmacoeconomic Center (Recorder)
Col George Jones, BSC	Deputy Chief, Pharmaceutical Operations Directorate
COL Carole Labadie, MS	Army, Pharmacy Officer
Col Mike Spilker, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG, via DCO	Coast Guard, Pharmacy Officer
CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CAPT Walter Downs, MC	Navy, Internal Medicine Physician
COL Doreen Lounsbery, MC	Army, Internal Medicine Physician
LTC Amy Young, MC for COL Ted Cieslak, MC	Army, Physician at Large
COL Michael Wynn, MC for LTC Bruce Lovins, MC	Army, Family Practice Physician
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Major Jeremy King, MC	Air Force, OB/GYN Physician
CDR Eileen Hoke, MC	Navy, Pediatrics
Dr. Miguel Montalvo	TRICARE Regional Office-South Chief of Clinical Operations Division and Medical Director
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. David Hurt	Associate General Counsel, TMA
COL Todd Williams, MS	Defense Medical Materiel Program Office
CDR Jay Peoloquin, MSC	Defense Logistics Agency Troop Support

Appendix A—Attendance (continued)

Guests	
Mr. Bill Davies via DCO	TRICARE Management Activity, Pharmaceutical Operations Directorate
CDR Matthew Baker, USPHS	Indian Health Service
Others Present	
LTC Chris Conrad, MS	DoD Pharmacoeconomic Center
Lt Col Melinda Henne, MC	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
LCDR Ola Ojo, MSC	DoD Pharmacoeconomic Center
LCDR Marisol Martinez, USPHS	DoD Pharmacoeconomic Center
LCDR Joshua Devine, USPHS	DoD Pharmacoeconomic Center
Maj David Folmar, BSC	DoD Pharmacoeconomic Center
LCDR Linh Quach, MSC	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Teresa Anekwe	DoD Pharmacoeconomic Center
Dr. Eugune Moore	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Dean Valibhai	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacoeconomic Center
Dr. Amy Lugo via DCO	DoD Pharmacoeconomic Center
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor

Appendix B—Table of Medical Necessity Criteria for Newly-Approved Drugs

Drug / Drug Class	Medical Necessity Criteria
• Testosterone transdermal solution pump; 30 mg/actuation; (Axiron) • Testosterone 1%; 25 mg/2.5 gm, 50 mg/5 gm transdermal gel packets, and 12.5 mg /actuation gel pump (Androgel 1%) • Testosterone 1.62% transdermal gel pump; 20.25 mg/actuation (Androgel 1.62%) **Testosterone Replacement Therapies**	• Use of ALL formulary testosterone replacement products is contraindicated (e.g., due to hypersensitivity), and treatment with Axiron, Androgel 1%, or Androgel 1.62% is not contraindicated. • Patient has experienced or is likely to experience significant adverse effects from the formulary agents. • The formulary agents have resulted in therapeutic failure.
• Ibuprofen/famotidine (Duexis) **Non-steroidal Anti-Inflammatory Drugs (NSAIDS)**	• Use of formulary agents is contraindicated.
• Ketorolac nasal spray (Sprix) **Non-steroidal Anti-Inflammatory Drugs (NSAIDS)**	• Use of formulary agents is contraindicated. • The patient requires a nasal NSAID formulation and cannot take NSAIDs via any other route.
• Tafluprost ophthalmic solution (Zioptan) **Ophthalmic Prostaglandins**	• The use of formulary alternatives is contraindicated. • The patient has experienced or is likely to experience significant adverse effects from the formulary agents.
• Abatacept SQ (Orencia) **Targeted Immunomodulatory Biologics (TIBs)**	• The use of formulary alternatives is contraindicated. • The patient has experienced or is likely to experience significant adverse effects from the formulary agents. • The formulary agents have resulted or are likely to result in therapeutic failure. • The patient previously responded to a non-formulary agent, and changing to a formulary agent would incur unacceptable risk. • The patient is currently receiving abatacept IV and is switching to abatacept SQ.

Appendix C—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2012	**Testosterone Replacement Therapies** **Topical and Buccal products subclass**	UF Review	• testosterone transdermal 2% gel pump; 10 mg/actuation (Fortesta)	• testosterone 50 mg/5 gm transdermal gel tubes (Testim) • testosterone 2 mg/24 hr, 4 mg/24 hr transdermal patches (Androderm) • testosterone 30 mg buccal tablets (Striant)	• testosterone transdermal solution pump; 30 mg/actuation; (Axiron) • testosterone 1%; 25 mg/2.5 gm, 50 mg/ 5 gm transdermal gel packets, and 12.5 mg/ actuation gel pump (Androgel 1%) • testosterone 1.62% transdermal gel pump; 20.25 mg/actuation (Androgel 1.62%)	Pending signing of minutes/ 90 days	PA required; see Comments	• All current and new users of topical and buccal testosterone replacement products must go through the PA process to ensure diagnosis of hypogonadism • Fortesta 2% gel pump is the preferred product; all users of topical and buccal testosterone replacement products must have trial of Fortesta 2% gel prior to other products
Aug 2012	**Anticoagulants** **Heparin and related products subclass**	UF Review	• enoxaparin (generic)	• dalteparin (Fragmin) • fondaparinux (generic)	• Not applicable (no products designated as nonformulary)	Pending signing of minutes	-	• enoxaparin generic designated BCF

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2012	**Non-Steroidal Anti-inflammatory Drugs** Previous review: Aug 2011	New Drugs in Already Reviewed Classes Ibuprofen/ famotidine (Duexis) Ketorolac nasal spray (Sprix)	• ibuprofen 400 mg, 600 mg & 800 mg (generic) • indomethacin 25 mg & 50 mg (generic) • meloxicam 7.5 mg & 15 mg (generic) • naproxen 250 mg & 500 mg & 125 mg/5 mL susp (generic)	• celecoxib (Celebrex) • diclofenac/misoprostol (Arthrotec) • diclofenac potassium tablets (Cataflam generic) • diclofenac sodium tablets (Voltaren generic) • diflunisal • etodolac • fenoprofen • flurbiprofen • ketoprofen • ketorolac • meclofenamate • nabumetone • naproxen sodium 275 mg & 550 mg (Anaprox, generic) • oxaprozin • piroxicam • sulindac • tolmetin • naproxen/esomeprazole (Vimovo)	*August 2012* • **ibuprofen/famotidine (Duexis)** • **ketorolac nasal spray (Sprix)** *August 2011* • diclofenac potassium liquid-filled capsules (Zipsor) 25 mg • diclofenac potassium powder packets 50 mg (Cambia) • naproxen sodium ER (Naprelan CR, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card • mefenamic acid (Ponstel, generic) 250 mg	Pending signing of minutes/ 60 days	Quantity Limits for ketorolac nasal spray (Sprix): 5 bottles for 30-day supply in both the Retail Network and Mail Order Pharmacy	• ibuprofen/ famotidine (Duexis) designated nonformulary • ketoralac nasal spray (Sprix) designated nonformulary
Aug 2012	**Glaucoma Agents** **Ophthalmic Prostaglandin Subclass** Previous review: Aug 2011	New Drug in Already Reviewed Class Tafluprost (Zioptan)	• latanoprost (generic)	• bimatoprost (Lumigan)	*August 2012* • **tafluprost (Zioptan)** *February 2007* • travoprost (Travatan Z)	Pending signing of minutes/ 60 days	-	• tafluprost (Zioptan) designated nonformulary
Aug 2012	**Non-Insulin Diabetes Drugs** **DPP-4 Inhibitors Subclass** Previous reviews: Feb 2012 and Nov 2012	New Drug in Already Reviewed Class sitagliptin/ metformin ER (Janumet XR) linagliptin/ metformin IR (Jentadueto)	*August 2012* • **sitagliptin/ metformin ER (Janumet XR)** *Feb 2012* • sitagliptin (Januvia) • sitagliptin/metformin (Janumet)	*August 2012* • **linagliptin/metformin IR (Jentadueto)** *February 2012* • sitagliptin/Simvastatin (Juvisync) • linagliptin (Tradjenta)	*February 2012* • saxagliptin (Onglyza) • saxagliptin/metformin ER (Kombiglyze XR)	Pending signing of minutes/ 60 days	Step therapy required – see comments	• Must try metformin and sulfonylurea 1st before any DPP-4 drug • Must try sitagliptin-containing product 1st before Tradjenta, Jentadueto, Onglyza, or Kombiglyze XR

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2012	**Targeted Immuno-modulatory Biologics** Previous review: Nov 2007	New Drug in Already Reviewed Class abatacept SQ (Orencia SC)	• adalimumab SQ (Humira)	• alefacept (Amevive)	*August 2012* • **abatacept SQ (Orencia)** *Nov 2007 and Aug 2009* • etanercept (Enbrel) (etanercept) • anakinra (Kineret) • certolizumab (Cimzia) • golimumab (Simponi)	60 days	• PA limiting use to FDA-approved indications was approved in Nov 2011 • QLs approved in Nov 2011 • Retail: 4 syringes/28 days • Mail Order: 8 syringes/56 days	• abatacept SQ (Orencia) designated nonformulary • adalimumab (Humira) is the formulary alternative for treating rheumatoid arthritis

* TRICARE Formulary Search tool: http://www.pec.ha.osd.mil/formulary_search.php

Appendix D—Table of Abbreviations

BCF	Basic Core Formulary
BIA	budget impact analysis
C.F.R.	Code of Federal Regulations
CMA	cost minimization analysis
DoD	Department of Defense
DPP-4	dipeptidyl dipeptidase-4
ECF	Extended Core Formulary
ER	extended release
FDA	U.S. Food and Drug Administration
FR	Federal Register
GI	gastrointestinal
HIT	heparin-induced thrombocytopenia
IOP	intraocular pressure
IR	immediate release
IV	intravenous
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NF	nonformulary
NSAIDs	non-steroidal anti-inflammatory drugs
P&T	Pharmacy and Therapeutics
PA	prior authorization
PEC	Pharmacoeconomic Center
PORT	Pharmacy Outcomes Research Team
POS	points of service
QLs	quantity limits
RA	rheumatoid arthritis
SC	subcutaneous
TIBs	targeted immunomodulatory biologics
TNF	tumor necrosis factor
TRTs	transdermal and buccal testosterone replacement therapies
UF	Uniform Formulary
U.S.C.	United States Code
VA	U.S. Department of Veterans Affairs