DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

November 2014

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 19 and 20, 2014, at the Defense Health Agency (DHA) Formulary Management Branch, Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of August Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes from the August 2014 DoD P&T Committee meeting on November 13, 2014.

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 Basic Core Formulary (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. Insulin Drugs: Miscellaneous Insulin Delivery Devices—Valeritas V-Go (V-Go)

Background—V-Go is a disposable insulin delivery device approved for patients with diabetes mellitus. Unlike an insulin pump, V-Go does not require any tubing or catheters. The device is filled daily with rapid-acting insulin, allowing for continuous administration of basal insulin and optional bolus dosing. After 24 hours, the device is discarded and replaced with a new unit.

The advantages of using V-Go include convenience for the patient who desires increased control over their blood glucose levels and elimination of the need for multiple daily insulin injections. Compared to multiple insulin injections, V-Go may reduce prandial glycemic excursions.

There are no randomized controlled trials using the V-Go insulin delivery device compared to usual care with basal or basal/bolus insulin dosing using pens or vials. Limitations of the V-Go studies include small sample sizes (<140 patients enrolled), varied efficacy endpoints, short trial duration, and lack of published studies. Another limitation is that reports of patients requiring overall reduced total daily insulin doses was based on subjective patient-reported data and not on objective endpoints. Additionally, the discontinuation rates in the V-Go studies were high. Although the V-Go studies reported improvements in hemoglobin A1c- lowering, it is difficult to attribute those improvements to the V-Go device due to the lack of control groups and limitations in study design. Long-term data on whether the V-Go device improves patient adherence is lacking.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that the V-Go delivery device offers patient convenience because multiple daily insulin injections are not needed; however, it offers no clinically compelling advantages over existing UF insulin agents administered with pens or vials.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) was performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that the CMA showed V-Go was more costly than other combinations of basal/bolus insulin (e.g., Lantus/Novolog) currently on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) V-Go be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for V-Go. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***
Manual PA criteria were recommended at the August 2014 DoD P&T Committee meeting and implemented on November 14, 2014. The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) clarifying the PA criteria for V-Go. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is April 8, 2015.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Chronic Obstructive Pulmonary Disease (COPD) Drugs—Umeclidinium/Vilanterol (Anoro Ellipta)

Background—Umeclidinium/vilanterol is the first fixed dose combination of a long-acting muscarinic agent (LAMA) with a long-acting beta agonist (LABA) to reach the market. Anoro Ellipta is indicated for maintenance treatment of COPD; in contrast, other products have the additional indication for reducing COPD exacerbations (Spiriva, Advair, and Breo Ellipta).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the main clinical benefits of umeclidinium/vilanterol are its superior improvements in forced expiration volume in 1 second (FEV_1) compared to single ingredient inhalers, the convenience to patients of combining two long-acting bronchodilators into one inhaler, and once daily dosing. The COPD agents will be re-reviewed at an upcoming meeting for UF and BCF placement. Additionally, the P&T Committee recommended adding the LAMA/LABA combinations to the Pulmonary II Drug Class, which includes other chemical entities used for treating COPD.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate umeclidinium/vilanterol (Anoro Ellipta) with other LAMA and LABA therapies in the treatment of COPD. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA showed that the Anoro Ellipta fixed dose combination bronchodilator offers a cost-effective alternative to combining available LAMA and LABA inhalers.

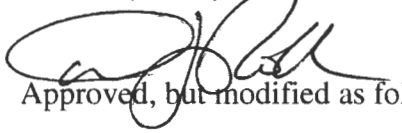
1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) umeclidinium/vilanterol (Anoro Ellipta) be designated formulary on the UF, based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) the following QLs for umeclidinium/vilanterol (Anoro Ellipta), consistent with the FDA-approved package labeling:

    - Retail Network: 1 inhaler per 30 days
    - Mail Order Pharmacy: 3 inhalers per 90 days

3. ***COMMITTEE ACTION: TRICARE FOR LIFE PHARMACY DRUG LIST***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) adding Anoro Ellipta to the TRICARE for Life Pharmacy Drug List due to the potential for additional cost avoidance, and for consistency with other inhaled bronchodilators on the UF that are already included on the Pharmacy Drug List.

Director, DHA, Decision: ☑ Approved □ Disapprov



Approved, but modified as follows:

C. Glaucoma Drugs: Brinzolamide 1%/Brimonidine 0.2% Ophthalmic Suspension (Simbrinza)

Background—Brinzolamide/brimonidine ophthalmic suspension (Simbrinza) is the first fixed dose combination product for glaucoma that has components other than a beta blocker. It contains a carbonic anhydrase inhibitor (brinzolamide, Azopt) and an alpha 2 adrenergic receptor agonist (brimonidine, Alphagan).

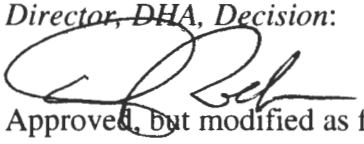
Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) Simbrinza's fixed combination offers a convenience to the patient versus using two drugs concomitantly, even though it requires dosing three times a day. Simbriniza also decreases intraocular pressure to a greater extent than the individual components administered alone.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate brinzolamide/brimonidine (Simbrinza) with other drugs used in the treatment of glaucoma. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA showed that brinzolamide/brimonidine (Simbrinza) was comparable to the UF carbonic anhydrase inhibitors and alpha 2 adrenergic receptor agonists when taken in combination.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) brinzolamide 1%/brimonidine 0.2% ophthalmic suspension (Simbrinza) be designated with formulary status on the UF, based on clinical and cost effectiveness.

Director, DHA, Decision: ☑ Approved □ Disapproved



Approved, but modified as follows:

D. Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)—Bromfenac 0.07% Ophthalmic Solution (Prolensa)

Background—Bromfenac 0.07% (Prolensa) is FDA-indicated for the treatment of postoperative inflammation and pain in patients following cataract surgery. It is the third bromfenac formulation to obtain FDA approval. The branded formulations of bromfenac 0.09% (Xibrom)

dosed twice daily and bromfenac 0.09% (Bromday) dosed once daily (QD) have been discontinued by the manufacturer.

There are no head-to-head clinical trials comparing Prolensa with another ophthalmic NSAID. There is no data to show that Prolensa is better tolerated when compared to generic bromfenac 0.09% (Bromday) QD. While Prolensa offers the convenience of once daily dosing, generic Bromday is also dosed once daily.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that Prolensa does not offer clinically relevant advantages over the other UF ocular NSAIDs that are FDA-approved for use following cataract surgery.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate bromfenac 0.07% ophthalmic solution (Prolensa) with other ophthalmic NSAIDs on the UF. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) that Prolensa was the most costly ocular NSAID.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) bromfenac 0.07% ophthalmic solution (Prolensa) be designated NF due to the lack of compelling clinical advantages and the cost disadvantage compared to the other UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for bromfenac 0.07% ophthalmic solution (Prolensa). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 6, 2015.

Director, DHA Decision ☑ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Self-Monitoring Blood Glucose System (SMBGS) Test Strips

Background—The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips. See Appendix D for a full list of the SMBGS test strips in the class. SMBGS

glucometers are not included as part of the TRICARE outpatient pharmacy benefit (they are included under the medical benefit) and are not the focus of the review.

U.S. Federal Government contracting requirements stated the following:

> The Company shall ensure test strips are made available to all three Points of Service (Military Treatment Facilities, TRICARE Mail Order Pharmacy, and Retail Network). In accordance with industry practice, the Company shall make meters available to DoD beneficiaries at no additional charge or cost to the DoD beneficiary.

The FDA classifies SMBGS test strips and glucometers as medical devices rather than drugs. The clinical effectiveness review focused on differences in the technical aspects/attributes among the test strips and glucometers. The P&T Committee recommended that the potential test strips considered for inclusion on the UF should meet standards relating to such factors as FDA requirements for accuracy based on the International Organization for Standardization (ISO) 15197 guidelines from 2003, sample size, alternate site testing, result time, memory capacity, ease of calibration, customer support, downloading capabilities, and data management capabilities.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following for the SMBGS test strips:

- Potential SMBGS test strips considered for inclusion on the UF must meet all U.S. Federal Government contracting requirements and the technical factors listed above.
- Potential SMBGS test strips considered for inclusion on the UF included FreeStyle Lite; FreeStyle InsuLinx; Precision Xtra; ACCU-CHEK Aviva Plus; OneTouch Ultra Blue; OneTouch Verio; CONTOUR NEXT; TRUEtest; Nova Max; GLUCOCARD 01-SENSOR; GLUCOCARD Vital; and Prodigy No Coding.
- *Overall relative clinical effectiveness conclusion:* The P&T Committee concluded there were no clinically relevant differences between the 12 SMBGS test strips that were reviewed and met the contracting requirements and technical factors, and that any of the 12 test strips were acceptable for inclusion on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed to evaluate the SMBGS test strips that were considered for inclusion on the UF. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- Results from a comprehensive cost analysis, which included a CMA and considered the cost of patient switching and related DoD administrative costs in addition to SMBGS test strip per unit costs, showed FreeStyle Lite and Precision Xtra test strips were the most cost-effective SMBGS test strips, followed by ACCU-CHEK Aviva Plus, GLUCOCARD Vital and GLUCOCARD 01-SENSOR, TRUEtest, Prodigy No Coding, CONTOUR NEXT, Nova Max, and all other SMBGS test strips. OneTouch Ultra Blue test strips were the least cost-effective.

- BIA was performed to evaluate the potential impact of scenarios, with selected test strips designated step-preferred and UF or non-preferred and NF on the UF. BIA results showed the scenario with FreeStyle Lite and Precision Xtra designated as step-preferred on the UF and all remaining test strips designated NF and non-step preferred, where all current and new users are required to try FreeStyle Lite or Precision Xtra first, was the most cost-effective option for the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) the following:

    - UF and step-preferred:
        - FreeStyle Lite
        - Precision Xtra

    - NF and non-step preferred:
        - ACCU-CHEK Aviva Plus
        - GLUCOCARD 01-SENSOR
        - GLUCOCARD Vital
        - CONTOUR NEXT
        - FreeStyle InsuLinx
        - Nova Max
        - TRUEtest
        - Prodigy No Coding
        - OneTouch Verio
        - OneTouch Ultra Blue
        - All other test strips listed in Appendix D with the exception of FreeStyle Lite and Precision Xtra

    - This recommendation includes step therapy, which requires a trial of FreeStyle Lite or Precision Xtra prior to use of a NF test strip. The recommendation requires all current and new users of a non-preferred test strip try FreeStyle Lite or Precision Xtra, or meet the PA criteria for the non-preferred strips.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) maintaining Precision Xtra test strips on the BCF and adding FreeStyle Lite test strips to the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for the SMBGS test strips. See Appendix B for full criteria.

4. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for all new and current users of NF test strips. The manual PA criteria requires a trial of FreeStyle Lite or Precision Xtra prior to the use of a NF test strip. See Appendix C for the full criteria.

5. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) QLs for the SMBGS test strips, limiting use to 100 strips per 30-day supply in the Retail Network and 300 strips per 90-day supply in the Mail Order and MTF points of service. See Appendix F for the full criteria.

   Quantity Limits for the SMBGS test strips may be exceeded in the following situations: patient is receiving insulin; using an insulin pump; has gestational diabetes; requires more frequent testing due to endocrine disorders (e.g., insulinoma, endogenous hyperinsulinism, non-islet cell tumor); or, has a history of poorly controlled blood glucose levels with adverse outcomes (e.g., ketoacidosis or hypoglycemic episode), requiring medical intervention.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 120-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is June 3, 2015.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: implement in 180 days.

B. Multiple Sclerosis (MS)

Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of the MS Drug Class, which is comprised of the following injectable and oral disease-modifying drugs:

- **Injectable:** Interferon beta-1b (Betaseron and Extavia subcutaneous (SC) injections), interferon beta-1a (Avonex intramuscular (IM) injection; Rebif SC injection), and, glatiramer (Copaxone 20 mg SC daily injection and 40 mg three times a week (TIW) SC injection)

- **Oral**: dimethyl fumarate (Tecfidera), fingolimod (Gilenya), and teriflunomide (Aubagio)

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following conclusions for the MS drugs:

1. For the injectables, no one interferon product is preferred over the other in terms of efficacy and safety. Interferon beta-1a IM (Avonex) is possibly less effective than the other interferons, based on the Oregon Drug Effectiveness Review Project (DERP, 2010).
2. In a Cochrane review (2014), similar outcomes (including clinical and magnetic resonance imaging activity measures) were reported when the interferons were compared to glatiramer (Copaxone) for treating patients with relapsing-remitting forms of MS. These findings differ from the DERP 2010 report, where Avonex was presented as less effective.
3. The Copaxone 40 mg TIW formulation has the convenience of less frequent administration than the 20 mg daily Copaxone formulation. However, the 40 mg TIW product has not been directly compared to the 20 mg daily formulation for efficacy or safety; trials are ongoing.
4. There are no head-to-head trials of one oral drug with another oral drug; placebo controlled studies were used to obtain FDA approval. Limited data from head-to-head trials of the injectables versus oral medications report the following:
    - Fingolimod produces a greater reduction in the annualized relapse rate (ARR) compared to interferon beta-1a IM (Avonex).
    - Teriflunomide (Aubagio) 14 mg and interferon beta-1a SC (Rebif) produced similar reductions in the ARR, while teriflunomide 7 mg was less effective than the 14 mg dose and Rebif.
    - There were no clinically relevant differences in the ARR when glatiramer (Copaxone) was compared to dimethyl fumarate (Tecfidera).
5. The Canadian Agency for Drugs in Technology and Health (CADTH, October 2013) reported the relative ARRs of the various MS treatments compared to placebo. Fingolimod (Gilenya) and dimethyl fumarate (Tecfidera) had the lowest ARRs; teriflunomide, interferon beta-1b SC (Betaseron), interferon beta-1a SC (Rebif), and glatiramer (Copaxone) all had similar ARRs; and, interferon beta-1a (Avonex) had the highest ARR.
6. The MS drugs have distinctly different adverse event profiles. Copaxone has the advantage of a pregnancy category B rating.
7. Dalfampridine (Ampyra) is an orally administered drug that is not disease-modifying; it is solely approved for symptom management to improve walking distance.

8. Due to their differing safety profiles and low degree of therapeutic interchangeability, several MS products are required on the UF to meet the needs of the MHS population.

Relative Cost-Effectiveness Analysis and Conclusion—A cost-effectiveness analysis (CEA) and BIA were performed to evaluate the MS Drug Class. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CEA results showed that, when considering the incremental cost-effectiveness ratios per relapse avoided, all scenarios were within a range considered to be cost-effective to the MHS. Ampyra was not included in the CEA as it is not a disease-modifying drug.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that all modeled scenarios demonstrated a similar level of cost avoidance for the MHS, with only slight differences between evaluated scenarios.

1. ***COMMITTEE ACTION: UF RECOMMENDATIONS***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) the following:
    - UF:
        - Interferon beta-1a SQ (Rebif and Rebif Rebidose)
        - Interferon beta-1a IM (Avonex IM)
        - Interferon beta-1b SC (Betaseron)
        - Interferon beta-1b SC (Extavia)
        - Dalfampridine (Ampyra)
        - Dimethyl fumarate (Tecfidera)
        - Fingolimod (Gilenya)
        - Glatiramer (Copaxone)
        - Teriflunomide (Aubagio)
    - NF: None
2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The MS Drugs Class is now a BCF class; it was previously an Extended Core Formulary (ECF) drug class. The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) interferon beta-1b SC (Betaseron) be designated with BCF status since it is the most cost-effective MS drug. As a result of this action, interferon beta-1a IM (Avonex) is no longer ECF; it remains on the UF.
3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Manual PA criteria recommended in November 2010 and November 2013 currently apply to fingolimod (Gilenya) and dimethyl fumarate (Tecfidera), respectively. The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) maintaining the current PA criteria for Tecfidera and

revising the PA criteria for Gilenya due to recent updates in the package insert for cardiovascular toxicity. See Appendix C for full criteria.

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date no later than 30 days after signing of the minutes in all POS.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VI. UTILIZATION MANAGEMENT

A. Prior Authorizations and Medical Necessity

1. **Hepatitis C Virus (HCV) Agents, Direct Acting Antivirals (DAAs): Ledipasvir/Sofosbuvir (Harvoni) Manual PA Criteria and QLs**—Ledipasvir 90 mg/sofosbuvir 400 mg (Harvoni) is a once daily fixed dose combination tablet that was approved by the FDA in October 2014 for the treatment of HCV genotype 1. It is the first FDA-approved interferon-free regimen indicated to treat HCV genotype 1. Harvoni will be reviewed as a new drug at an upcoming meeting.

   a) ***COMMITTEE ACTION: HARVONI MANUAL PA CRITERIA***—PA criteria currently apply to the DAAs. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users of ledipasvir/sofosbuvir (Harvoni), consistent with FDA-approved labeling. Prior authorization will expire after 8–24 weeks based on the treatment regimen. See Appendix E for the full criteria.

2. **Hepatitis C Virus Agents, Direct Acting Antivirals (DAAs): Simeprevir (Olysio) Manual PA Criteria**—PA criteria were recommended for Simeprevir (Olysio) at the May 2014 DoD P&T Committee meeting. Simeprevir received a new FDA indication in November 2014 as a component of an interferon-free combination treatment for chronic HCV genotype 1.

   a) ***COMMITTEE ACTION: SIMEPREVIR (OLYSIO) PA CRITERIA***
   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) revising the existing PA criteria for Olysio to include the expanded FDA-approved indication. See Appendix E for the full criteria.

3. **Targeted Immunomodulatory Biologics (TIBs): Adalimumab (Humira), Apremilast (Otezla), and Etanercept (Enbrel)**—The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria

were recommended for the class. Recently, adalimumab (Humira) received FDA approval for pediatric Crohn's disease in patients as young as six years and juvenile idiopathic arthritis (JIA) in patients as young as four years; apremilast (Otezla) received FDA approval for plaque psoriasis. PA criteria were updated for Humira and Otezla to reflect their new respective FDA indications. See Appendix C for the full criteria.

Accordingly, step therapy criteria and MN criteria for etanercept (Enbrel) were also revised since Enbrel and Humira are now indicated for the same age range in patients with JIA.

a) ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA) AND APREMILAST (OTEZLA) PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) revised manual and step therapy PA criteria for Humira and Otezla, consistent with the new FDA-approved product labeling. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: ETANERCEPT (ENBREL) MN AND PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an update to the MN and PA criteria for Enbrel since Humira is now indicated for JIA. See Appendices B and C for the full criteria.

4. **Prostate Cancer: Enzalutamide (Xtandi)**—Xtandi is an androgen receptor inhibitor that prolongs survival of metastatic castration-resistant prostate cancer. Manual PA criteria were recommended at the November 2012 P&T Committee meeting. The package insert for Xtandi was updated to state that prior treatment with docetaxel is no longer required.

a) ***COMMITTEE ACTION: ENZALUTAMIDE (XTANDI) PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an update to the manual PA criteria for Xtandi, consistent with the product's labeling for treatment of metastatic castration-resistant prostate cancer. See Appendix C for the full criteria.

5. **Non-Insulin Diabetes Mellitus Drugs: Glucagon-Like Peptide-1 Receptor Agonist (GLP1RAs); Exenatide Once Weekly Pen (Bydureon Pen)**—Exenatide (Bydureon) is now available in a pre-filled pen, in addition to the original vial formulation. The manufacturer states that they do not intend to discontinue the original vial formulation. Both products are dosed once weekly. However, the cost of the Bydureon pen formulation is significantly higher than the Bydureon vials despite having the same dosing and FDA-approved indications. Exenatide (Byetta) is also available in a pen formulation that is dosed twice daily. Manual PA criteria were recommended for the Bydureon pen due to the cost and because other exenatide products (Bydureon vials and Byetta) are available on the UF. The GLP1RA Drug Subclass, including the Bydureon

pen formulation, is scheduled for review at an upcoming meeting.

a) ***COMMITTEE ACTION: EXENATIDE PEN (BYDUREON PEN) PA CRITERIA***—The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 1 absent) manual PA criteria for the Bydureon pen, requiring use of Bydureon vials first. Additionally, a trial of metformin or a sulfonylurea is also required, consistent with the PA criteria for other GLP1RAs. See Appendix C for the full criteria.

B. QLs—QLs for several drugs were reviewed, including the HCV direct acting antiviral ledipasvir/sofosbuvir (Harvoni); the pulmonary fibrosis drugs nintedanib (Ofev) and pirfenidone (Esbriet); and, the LABA olodaterol (Striverdi Respimat). QLs apply to the other products in these drug classes.

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for ledipasvir/sofosbuvir (Harvoni), nintedanib (Ofev), pirfenidone (Esbriet), and olodaterol (Striverdi Respimat), consistent with the product labeling. See Appendix F for QLs.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VII. SECTION 716 OF THE NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FISCAL YEAR 2013 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM

A. Medication Drug List for the Pilot Program: Updates—The Medication Drug list for the Pilot Program for TRICARE for Life beneficiaries was recommended at the November 2013 P&T Committee meeting. An update to the drug list is required due to products discontinuations from the market, availability issues, and to ensure consistency within the drug classes. See the TRICARE Formulary Search Tool at *http://pec.ha.osd.mil/TFL_maintenance_drug_list.php* for the full medication drug list.

1. ***COMMITTEE ACTION: MAINTENANCE MEDICATION PROGRAM DRUG LIST UPDATE***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) changes to the list of covered maintenance medications for the Section 716 pilot program. Implementation will occur upon signing of the minutes. See Appendix H for the full list of changes.

☒ Approved □ Disapproved

Director, DHA, Decision:

Approved, but modified as follows:

VIII. LINE EXTENSIONS

A. Formulary Status Clarification—The P&T Committee clarified the formulary status for one product line extension ("follow-on product") by the original manufacturer. Line extensions have the same FDA indications and pricing as the "parent" drug.

1. ***COMMITTEE ACTION: LINE EXTENSIONS FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) clarifying the formulary status of insulin detemir (Levemir Flextouch). The Levemir Flextouch formulation is replacing the Levemir Flexpen formulation, which was discontinued from the market in the summer of 2014. Implementation will occur upon signing of the minutes.

    - Insulin detemir (Levemir Flextouch): NF, similar to Levemir Flexpen

Director, DHA, Decision: ☒ Approved □ Disapproved

Approved, but modified as follows:

IX. COMPOUND PRESCRIPTIONS

A. PA Criteria—The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant and increasing, and compounded medications have a high potential for inappropriate use. From June 2013 through May 2014, 140,000 beneficiaries filled 360,000 compounded prescriptions that totaled over $410 million in expenditures at the Retail Network and Mail Order POS. In an effort to decrease inappropriate use and ensure safety for beneficiaries, PA criteria were proposed.

1. ***COMMITTEE ACTION: COMPOUND PRESCRIPTIONS MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for all new and current users of compounds. Coverage will be approved if the prescriber provides the following information listed below and implementation of the PA will occur when a final recommendation is made.

    a) What is the diagnosis?

b) Has the patient tried commercially available products for the diagnosis provided? Please state all products tried.

c) Is there a current national drug shortage of an otherwise commercially available product?

d) What is the proposed duration of therapy?

AND

The patient meets the following criteria:

(1) Each active ingredient(s) is/are a chemical entity of an FDA-approved drug for marketing in the United States AND the drugs have not been withdrawn for safety reasons from the U.S. market. (If True, proceed to (2); if False, claim rejects.)

(2) Each active ingredient(s) used in this compound is indicated by the FDA to treat the diagnosis provided. (If True, proceed to (3); if False, claim rejects.)

(3) An FDA-approved commercially available product is not appropriate because the patient requires a unique dosage form or concentration (e.g., inability to take a solid dosage form, dose based on age or weight) and/or an FDA-approved product cannot be taken due to allergies or contraindication. (If True, Approved; if False, claim rejects.

Director, DHA, Decision: □ Approved ☒ Disapproved

Approved, but modified as follows: pending consideration of BAP recommendations

X. SPECIALTY MEDICATIONS

A. Clinical Services Drug List and DoD Specialty Agent Reporting List—The P&T Committee was briefed on two separate drug lists for specialty medications, the Clinical Services Drug List and the DoD Specialty Agent Reporting List.

Drugs are assigned to the DoD Specialty Agent Reporting List when they generally meet at least two of these four criteria: cost $500 or more per dose or $6,000 or more per year, have a difficult or unusual process of delivery, require patient management beyond traditional dispensing practices, or as defined by DoD. The DoD Specialty Agent Reporting List is used internally for reporting purposes to monitor drug spend and trends in utilization of specialty medications.

The Clinical Services Drug List is a subset of the DoD Specialty Agent Reporting List and identifies drugs for which contractor-provided pharmacy services at the Retail Network and Mail Order Pharmacy will be provided in conjunction with the new TRICARE Pharmacy contract effective in May 2015.

The P&T Committee reviewed the list of drugs recommended for the Clinical Services Drugs List and voted to remove drugs that are no longer marketed, remove drugs that do not require enhanced clinical services, remove certain drugs classes to allow consideration at future P&T Committee meetings, and add drugs to the list that meet the definition above and require enhanced clinical services.

The Clinical Services Drug List comprises 79 products from a variety of drug classes, including bleeding disorders (hemophilia), MS, HCV, rheumatoid arthritis and other inflammatory conditions, oncology, osteoporosis, neutropenia, acromegaly, iron overload, and hormonal therapies.

The P&T Committee also recommended that additions or deletions to the Clinical Services Drug List be made administratively when new products are approved or when market discontinuations occur to maintain the currency of the list and to ensure timely patient access to specialty medications. The P&T Committee will then review any administrative actions at the next scheduled P&T Committee meeting.

1. ***COMMITTEE ACTION: CLINICAL SERVICES DRUG LIST AND DOD SPECIALTY AGENT REPORTING LIST***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the changes to the Clinical Services Drug List outlined above, and recommended the List be maintained administratively, with any additions or deletions reported at the next scheduled DoD P&T Committee meeting.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

XI. ITEMS FOR INFORMATION

A. Naloxone—The P&T Committee was briefed on an executive action by President Obama to expand the availability of opioid overdose reversal kits for first responders on military bases and other areas under DoD control to improve patient safety and prevent suicides. In April 2014, the FDA approved the first naloxone auto-injectable (Evzio) formulation intended for caregiver administration in emergency situations. The potential implications of wider access of Evzio to patients/family members using opioids who are at increased risk for opioid overdose were discussed. Updates to the P&T Committee will be provided as new information becomes available.

B. UF Proposed Rule—A Proposed Pharmacy TRICARE Rule published in the CFR on September 19, 2014 (http://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22276.pdf) proposes administrative changes to align the Pharmacy Benefit Program regulation with the statute (10 U.S.C. 1074g), clarifies some uniform formulary procedures, and designates the over-the-counter demonstration program as permanent. The main points of the Proposed Rule are to limit NF drugs to one point of service, place new drugs approved by the FDA in a provisional status for 120 days, and allow generic drugs to be placed in the third tier co-pay. The review period is scheduled to end on January 19, 2015.

XII. ADJOURNMENT

The meeting adjourned at 1130 hours on November 20, 2014. The next meeting will be in February 2015.

Appendix A—Attendance: November 2014 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Self-Monitoring Blood Glucose System Test Strips

Appendix E—Table of Prior Authorization Criteria for Hepatitis C Drugs

Appendix F—Table of Quantity Limits

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

Appendix H—Section 716 Maintenance Medication Program Drug List

Appendix I—Table of Abbreviations

SUBMITTED BY:

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

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

3 Feb 2015
Date

Appendix A—Attendance: November 2014 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
George Jones, PharmD, M.S.	Chief, DHA Pharmacy Operations Division
LTC Robert Conrad, MS	DHA Pharmacy Operations Division (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer Alternate
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
COL Ted Cieslak, MC	Army, Physician at Large
Col Michael Wynn, MC	Army, Family Practice Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
COL Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Voting Members Absent	
Col Michael Spilker, BSC	DHA Deputy Chief, Pharmacy Operations Division
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. Paul Hutter	Principal Deputy General Counsel, DHA
Mr. Bryan Wheeler via DCO	Deputy General Counsel, DHA
Guests	
Mr. Bill Davies via DCO	DHA Pharmacy Operations Division
MAJ Kevin Ridderhoff	DHA, Pharmacy Operations Division
CDR Ryan Schupbach	Indian Health Service
LT Kendra Jenkins via DCO	DHA, Pharmacy Operations Division

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	DHA Pharmacy Operations Division
CDR Joshua Devine, USPHS	DHA Pharmacy Operations Division
CDR Edward Vonberg, BSC	DHA Pharmacy Operations Division
LTC Misty Cowan, MC	DHA Pharmacy Operations Division
LCDR Marisol Martinez, USPHS	DHA Pharmacy Operations Division
Maj David Folmar, BSC	DHA Pharmacy Operations Division
Maj Ronald Khoury, MC	DHA Pharmacy Operations Division
Angela Allerman, PharmD, BCPS	DHA Pharmacy Operations Division
Shana Trice, PharmD, BCPS	DHA Pharmacy Operations Division
Amy Lugo, PharmD, BCPS via DCO	DHA Pharmacy Operations Division
Eugene Moore, PharmD, BCPS	DHA Pharmacy Operations Division
Brian Beck, PharmD, BCPS	DHA Pharmacy Operations Division
David Meade, PharmD, BCPS	DHA Pharmacy Operations Division
Ms. Deborah Garcia	DHA Pharmacy Operations Division contractor
Mr. Kirk Stocker	DHA Pharmacy Operations Division contractor
Esmond Nwokeji, PhD	DHA Pharmacy Operations Division contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Valeritas Insulin Delivery Device (V-Go) **Insulin–Miscellaneous Insulin Delivery Devices**	• Formulary agents result or are likely to result in therapeutic failure **Formulary alternative:** Uniform Formulary insulin products (insulin glargine, insulin lispro, insulin aspart) pens and vials
• Bromfenac 0.07% ophthalmic solution (Prolensa) **Ophthalmic NSAIDS**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents **Formulary alternatives:** bromfenac, diclofenac, flurbiprofen, ketorolac, nepafenac ophthalmic NSAIDs
• ACCU-CHEK Aviva Plus • GLUCOCARD 01-SENSOR • GLUCOCARD Vital • CONTOUR NEXT • FreeStyle InsuLinx • Nova Max • TRUEtest • Prodigy No Coding • One Touch Verio • One Touch Ultra Blue • Plus all other SMBGS test strips listed in Appendix D, except for FreeStyle Lite and Precision Xtra **Self-Monitoring Blood Glucose System (SMBGS) test strips**	• No alternative formulary – applies in the following situations: • Patient is blind/severely visually impaired and requires a test strip used in a talking meter – Prodigy Voice, Prodigy AutoCode, Advocate Redicode • Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter o Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump o Nova Max strip with Nova Max Link meter for Medtronic pump o For Retail Network Only: One Touch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump o For Retail Network Only: One Touch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump • The patient has a documented physical or mental health disability requiring a special strip or meter. For example, the patient requires ACCU-CHEK Aviva Plus strip due to manual dexterity issues (Arthritis Association Seal of Approval) **Formulary alternatives:** Freestyle Lite and Precision Xtra
• Etanercept (Enbrel) **Targeted Immunomodulatory Biologics (TIBs)**	• Use of adalimumab (Humira) is contraindicated • The patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira) • Adalimumab (Humira) resulted or is likely to result in therapeutic failure. • The patient previously responded to the nonformulary agent and changing to adalimumab (Humira) would incur unacceptable risk • No alternative formulary agent applies only to: 1. Abatacept (Orencia): The patient is transitioning from IV abatacept or has symptomatic congestive heart failure (CHF). 2. Anakinra (Kineret): The patient has neonatal onset multisystem inflammatory disease (NOMID), a subtype of cryopyrin associated periodic syndrome (CAPS). 3. Etanercept (Enbrel): The patient has hepatitis C infection. 4. Tocilizumab (Actemra): The patient is transitioning from IV abatacept or has symptomatic CHF. **Formulary alternative: adalimumab (Humira)**

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Valeritas Insulin Delivery Device (V-Go) **Insulin–Miscellaneous Insulin Delivery Devices**	PA criteria apply to all new users of the V-Go device. Manual PA criteria: (1) Patient has Type 2 diabetes mellitus (2) Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily (3) Patient does not need less than 2 unit increments of bolus dosing (4) Patient has been maintained on stable basal insulin for at least 3 months (at dosages ranging from 20U to 40U) (5) Patient has been using prandial insulin for at least 3 months
• Fingolimod (Gilenya) **Multiple Sclerosis Drugs (MS)**	Manual PA criteria: • A documented diagnosis of relapsing forms of MS • No current use of a disease-modifying therapy (e.g., interferon 1a or 1b or Copaxone) • Avoid use in patients with significant cardiac history, including: o Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization o Those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker o Patients with a baseline QTc interval ≥500 ms o Those receiving treatment with class Ia or class III antiarrhythmic drugs
• ACCU-CHEK Aviva Plus • GLUCOCARD 01-SENSOR • GLUCOCARD Vital • CONTOUR NEXT • FreeStyle InsuLinx • Nova Max • TRUEtest • Prodigy No Coding • One Touch Verio • One Touch Ultra Blue • Plus all other SMBGS test strips listed in Appendix D **Self-Monitoring Blood Glucose System (SMBGS) test strips**	New and current users of the nonformulary test strips are required to try FreeStyle Lite or Precision Xtra Manual PA Criteria—Non-preferred test strip allowed if: • Patient is blind/severely visually impaired and requires a test strip used in a talking meter – Prodigy Voice, Prodigy AutoCode, Advocate Redicode • Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter o Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump o Nova Max strip with Nova Max Link meter for Medtronic pump o For Retail Network Only: One Touch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump o For Retail Network Only: One Touch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump • The patient has a documented physical or mental health disability requiring a special strip or meter. For example, the patient requires ACCU-CHEK Aviva Plus strip due to manual dexterity issues (Arthritis Association Seal of Approval)
• Adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with: (Changes highlighted in bold) • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically

Drug / Drug Class	Prior Authorization Criteria
• Adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs)**	less appropriate • Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade • Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants **Pediatric patients with** • **Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric patients: 2–17 years)** • **Moderate to severely active Crohn's disease (≥ 6 years)** who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate Coverage is NOT provided for concomitant use with other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)
• Apremilast (Otezla) **Targeted Immunomodulatory Biologics (TIBs)**	Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Otezla if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Adverse reactions to Humira not expected with requested non-step preferred TIB AND Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis • **Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy** Coverage is NOT provided for concomitant use with other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)
• Etanercept (Enbrel) **Targeted Immunomodulatory Biologics (TIBs)**	Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Enbrel if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF)

Drug / Drug Class	Prior Authorization Criteria
• Etanercept (Enbrel) **Targeted Immunomodulatory Biologics (TIBs)**	• Adverse reactions to Humira not expected with requested non-step preferred TIB • There is no formulary alternative (Enbrel is prescribed for a patient with hepatitis C virus) AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy Coverage approved for pediatric patients (age 2–17) with: • Moderate to severe active polyarticular Juvenile Idiopathic Arthritis Coverage is NOT provided for concomitant use with other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)
• Enzalutamide (Xtandi) **Prostate Cancer Drugs**	Coverage is approved if: • Documented diagnosis of metastatic castration-resistant prostate cancer No expiration date for the PA
• Exenatide once weekly pen (Bydureon pen) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	New GLP1RA users are required to try metformin or a sulfonylurea (SU) before receiving Byetta, Bydureon, or Victoza. Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days, AND Manual PA criteria, if automated criteria are not met: Byetta, Bydureon, or Victoza is approved (e.g., trial of metformin or SU is NOT required) if: 1) The patient has a confirmed diagnosis of Type 2 Diabetes Mellitus 2) The patient has experienced any of the following adverse events while receiving metformin: impaired renal function that precludes treatment with metformin or history of lactic acidosis. 3) The patient has experienced the following adverse event while receiving a SU: hypoglycemia requiring medical treatment. 4) The patient has a contraindication to both metformin and a SU. 5) The patient has had an inadequate response to metformin and a SU. 6) **Also for exenatide once weekly (Bydureon pen)** ▪ **Coverage approved if patient has first tried Bydureon 2mg vial/cartridge first AND** ▪ **Patient has dexterity issues and cannot assemble the Bydureon vial/cartridge**

Appendix D—Table of Self-Monitoring Blood Glucose System Test Strips in the Class

FreeStyle Lite	Easy Touch	Reveal test strip
Precision Xtra	Easy Touch glucose	Relion Confirm Micro
ACCU-CHEK Aviva Plus	Easy Gluco	Relion Prime
GLUCOCARD 01-SENSOR	Easy Gluco G2 test strip	Rightest GS100 test strips
GLUCOCARD Vital	Element test strips	Rightest GS 300 test strips
CONTOUR NEXT	Element Plus	Rightest GS 550 test strips
FreeStyle Insulinx	Embrace	SmartDiabetes Xpres
Nova Max	Evencare test strip	Smartest test
TRUEtest	Evencare G2	Surechek test strips
Prodigy No Coding	EZ Smart	Surestep
OneTouch Verio	EZ Smart Plus Fast Take	Surestep Pro
OneTouch Ultra Blue	Fifty50 test strip	Sure test
ACCU-CHEK	Fora G20	Solus v2
ACCU-CHEK Active	Fora test strip	Telcare test strips
ACCU-CHEK Advantage	Fora v10	Tracer BG
ACCU-CHEK Aviva	Fora V12	TRUEtrack
ACCU-CHEK Comfort Curve	Fora V30a	TRUEtrack Smart System
ACCU-CHEK Instant	G-4 test strip	Ultima
ACCU-CHEK Smartview	GE blood glucose test	Ultratrak
AccuTrend glucose	GE100 blood glucose test strip	Ultratrak Pro
Acura test strips	GLUCOCARD Expression	Ultratrak Ultimate test strip
Advance test strips	GLUCOCARD X sensor	Victory
Advocate test strip	Glucolab	Wavesense AMP
Advocate Redi-Code	Glucose test strip	Wavesense Jazz
Advocate Redi-Code+	Glucometer Encore	Wavesense Presto
Ascensia Elite	Glucostix	
Assure 3	Infinity	
Assure 4	Keynote	
Assure Platinum	Liberty test strips	
Assure Pro	Micro	
BD test strips	Microdot	
BG-star	Neutek 2Tek test strips	
Blood glucose test strips	On Call Vivid test strip	
Blood glucose test strips – Leader	Optium	
Chemstrip BG	Optium EZ	
ChoiceDM G20	Pocketchem EZ	
ChoiceDM GD20	Precision PCX	
Clever Check	Precision PCX Plus	
Clever Choice test strips	Precision Point Of Care	
Clever Choice Pro	Precision QID	
Contour	Premium blood glucose	
Control	Prestige test	
Dextrostix reagent	Prestige smart system	
Easymax	Prodigy	
EasyPlus glucose test strips	Quintet	
EasyPlus mini strip	Quintet AC	
Easy Pro Plus	RefuAH Plus test strip	

Appendix E—Table of Prior Authorization (PA) Criteria for Hepatitis C Drugs

Prior Authorization Criteria

Ledipasvir/sofosbuvir (Harvoni)
Direct Acting Antiviral Subclass

- New users of ledipasvir/sofosbuvir (Harvoni) 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 Harvoni 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 genotype 1 infection
    1. State the HCV genotype and HCV RNA viral load on the PA form
- Ledipasvir/sofosbuvir (Harvoni) 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).

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype, prior treatment, and presence of cirrhosis.
- Prior authorization will expire after 8 weeks or 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1 Patient Populations	***Treatment Duration***
Treatment naïve with or without cirrhosis	8* - 12 weeks
Treatment experienced** without cirrhosis	12 weeks
Treatment experienced** with cirrhosis	24 weeks
*Consider treatment duration of 8 weeks in treatment-naïve patients without cirrhosis who have a pretreatment HCV RNA less than 6 million IU/mL. **Treatment-experienced patients who have failed treatment with either (a) peginterferon alfa plus ribavirin or (b) HCV protease inhibitor plus peginterferon alfa plus ribavirin	

Prior Authorization Criteria

Simeprevir (Olysio)
Direct Acting Antiviral Subclass

- New users of simeprevir (Olysio) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- The FDA-approved indication of simeprevir + PEG-interferon + ribavirin for 24 to 48 weeks is not recommended for HCV treatment by the AASLD/IDSA. See www.hcvguidelines.org.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their simeprevir 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 genotype 1 infection
- State the HCV genotype and HCV RNA viral load on the PA form
- If HCV genotype 1a, the patient is negative for NS3 Q80K polymorphism at baseline
- Simeprevir (Olysio) 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 HIV or Hepatitis B virus (HBV).
- Not recommended for monotherapy
- The patient has not previously used a HCV protease inhibitor (boceprevir, telaprevir, or simeprevir)

Treatment Regimens and Duration of Therapy

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

Genotype 1 Patient Populations	Treatments	Treatment Duration
Treatment naïve or experienced* without cirrhosis	simeprevir 150 mg once daily sofosbuvir 400 mg once daily	12 weeks
Treatment naïve or experienced* with cirrhosis	simeprevir 150 mg once daily sofosbuvir 400 mg once daily	24 weeks
*Treatment-experienced patients who have failed treatment with peginterferon alfa plus ribavirin but not a HCV protease inhibitor Prior Authorization expires at the end of treatment duration (12–24 weeks)		

Appendix F—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
Self-Monitoring Blood Glucose Test Strips (all products)	▪ Retail Network: 100 strips/30-day supply ▪ Mail Order and MTF: 300 strips/90-day supply Override criteria include the following situations: ▪ receiving insulin ▪ using an insulin pump ▪ gestational diabetes ▪ requires more frequent testing due to endocrine disorders (e.g., insulinoma, endogenous hyperinsulinism, non-islet cell tumor) ▪ history of poorly-controlled blood glucose levels with history of adverse outcomes (e.g., ketoacidosis or hypoglycemic episode) requiring medical intervention
• Umeclidinium/vilanterol (Anoro Ellipta) **Pulmonary II Drugs for COPD**	▪ Retail Network: 1 inhaler per 30 days ▪ Mail Order and MTF: 3 inhalers per 90 days
• Ledipasvir/sofosbuvir (Harvoni **Hepatitis C Drugs–Direct Acting Agents**	▪ Retail Network, Mail Order and MTF: 28 tablets per 28 days
• Nintedanib (Ofev) **Pulmonary Fibrosis**	▪ Retail Network, Mail Order, and MTF: 50/100 mg capsules, 60 tabs (30-day supply)
• Pirfenidone (Esbriet) **Pulmonary Fibrosis**	▪ Retail Network, Mail Order, and MTF: 267 mg caps, 270 capsules (30-day supply)
• Olodaterol (Striverdi Respimat) **Pulmonary Fibrosis Long-Acting Beta Agonist (LABA)**	▪ Retail Network: 1 inhaler (60 actuations) per 30 days ▪ Mail Order and MTF: 3 inhalers (180 actuations) per 90 days

Appendix G—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
Nov 2014	**Multiple Sclerosis Drugs**	UF class review Previously reviewed	▪ Interferon beta-1b SC (Betaseron)	▪ Interferon beta-1a SC (Rebif and Rebif Rebidose) ▪ Interferon beta-1a IM (Avonex) ▪ Interferon beta 1b SC (Extavia) ▪ Dalfampridine (Ampyra) ▪ Teriflunomide (Aubagio) ▪ Glatiramer (Copaxone) ▪ Fingolimod (Gilenya) ▪ Dimethyl fumarate (Tecfidera)	▪ None	Pending singing of the minutes / 30 days	▪PA required for Gilenya and Tecfidera (See Appendix C)	▪ MS drugs s are no longer an ECF class; Betaseron is now BCF and Avonex is removed from the ECF.
Nov 2014	**Pulmonary II: Chronic Obstructive Pulmonary Disease**	New Drug Review	▪ Ipratropium bromide (Atrovent HFA) ▪ Ipratropium bromide/albuterol nebulized solution (Duoneb) ▪ Salmeterol (Serevent) ▪ Tiotropium (Spiriva)	**May 2013** ▪ Aclidinium (Tudorza) ▪ Arformoterol (Brovana) ▪ Formoterol (Foradil) ▪ Ipratropium bromide/albuterol (Combivent Respimat) ▪ Roflumilast (Daliresp) **Nov 2014** ▪ **Umeclidinium/ vilanterol (Anoro Ellipta) Nov 2014**	▪ Formoterol (Perforomist) ▪ Indacaterol (Arcapta)	Pending signing of the minutes	▪QL apply	▪ BCF, UF, and NF choices are designated for COPD drugs for LABAs, LAMAs, SABA/SAMA, SAMAs, and oral PDE-4 inhibitors. See DoD P&T Minutes for Feb 2009, May 2013, and May 2014.
Nov 2014	**Ophthalmic NSAIDs**	New Drug Review	▪ None	**Aug 2010** ▪ Bromfenac 0.9%, generic ▪ Diclofenac (Voltaren) ▪ Flurbiprofen (Ocufen) ▪ Ketorolac 0.4% (Acular LS) ▪ Ketorolac 0.45% (Acuvail) ▪ Ketorolac 0.5% (Acular) ▪ Nepafenac (Nevanac)	**Nov 2014** ▪ **Bromfenac 0.07% (Prolensa)**	Pending singing of the minutes / 90 days	▪None	▪ Medical Necessity Criteria apply. See Appendix B

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
Nov 2014	**Ophthalmic Glaucoma Agents**	New Drug Review	▪ Latanoprost, generic ▪ Timolol, generic ▪ Brimonidine 0.15%, 0.2%, generic	**Nov 2014** ▪ **brinzolamide 1% /brimonidine 0.2% (Simbrinza)** **Feb 2007** ▪ Bimatoprost (Lumigan) ▪ Betaxolol (Betoptic, Betoptic-S) ▪ Carteolol (Ocupress) ▪ Levobunolol (Betagan) ▪ Metipranolol (Optipranolol) ▪ Timolol maleate (Timoptic) ▪ Timolol maleate gel forming solution (Timoptic XE) ▪ Dorzolamide (Trusopt) ▪ Dorzolamide / timolol (Cosopt) ▪ Brimonidine purite 0.1% (Alphagan P) ▪ Apraclonidine (Iopidine) ▪ Dipivefrin (Propine) ▪ Acetylcholine (Miochol-E) ▪ Carbachol (Isopto Carbachol) ▪ Pilocarpine (Pilocar, Pilopine HS) ▪ Echothiophate (Phospholine iodide)	▪ travoprost (Travatan and Travatan Z) ▪ tafluprost (Zioptan) ▪ timolol (Betimol) ▪ timolol (Istalol) ▪ brinzolamide (Azopt)	Pending singing of the minutes / 90 days	▪None	▪ None

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
Nov 2014	**Self-Monitoring Blood Glucose System (SMBS) test strips**	UF Class Review	▪ FreeStyle Lite (Abbott) ▪ Precision Xtra (Abbott)	Uniform Formulary and Step-Preferred ▪ FreeStyle Lite (Abbott) ▪ Precision Xtra (Abbott)	Nonformulary and non-step preferred ▪ACCU-CHEK Aviva Plus (Roche) ▪GLUCOCARD 01-SENSOR (Arkray) ▪GLUCOCARD Vital (Arkray) ▪CONTOUR NEXT (Bayer) ▪ FreeStyle InsuLinx (Abbott) ▪NovaMax (Nova) ▪TRUEtest (Nipro) ▪Prodigy No Coding (Prodigy) ▪One Touch Ultra Blue (Lifescan) ▪One Touch Verio (Lifescan) ▪For a V2 (For a) ▪Solus V12 (Biosense) ▪All other test strips listed in Appendix D, with the exception of Freestyle Lite, and Precision Xtra	Pending signing of the minutes / 120 days	Step therapy requires a trial of an FreeStyle Lite, or Precision Xtra in all new and current users of the nonformulary strips	▪ FreeStyle Lite added to the BCF; Precision Xtra remains on the BCF

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

Appendix H—Section 716 Maintenance Medication Program Drug List

- Removed from list due to manufacturer discontinuation:
  - ANTARA 45 mg, 130 mg CAPS
  - CENESTIN 0.3, 0.45 mg TABS
  - LEVATOL 20 mg TABs
  - LUVOX CR 150 mg CAPS
  - SANCTURA 20 mg TABS
  - UNIRETIC 7.5 mg/12.5 mg TABS

- Added to the list, due to consistency with the drug class (new strengths or dosage formulations):
  - ACTONEL 30 mg TABLET
  - ANGELIQ 0.25 mg–0.5 mg TABLET
  - ARICEPT 23 mg TABLET
  - BETAPACE 160 mg TABLET
  - CARAFATE 1 g/10 ml ORAL SUSP
  - CLORPRES 0.1 mg–15 mg TABLET
  - EFFER-K 25 mEq TABLET EFF
  - EXELON 13.3 mg/24 hours PATCH TD24
  - KLOR-CON 20 mEq PACKET
  - K-TAB ER 20 mEq TABLET ER
  - LANOXIN 62.5 mcg and 1875 mcg TABLET
  - LUPRON DEPOT 45 mg SYRINGE KIT
  - LUPRON DEPOT-PED 30 mg and 11.25 mg SYRINGE KIT
  - MINITRAN 0.4 mg/hr PATCH TD24
  - NAPROSYN 250 mg TABLET
  - NEUPRO 1 mg/24 hour, 3 mg/24 hour and 8 mg/24 hour PATCH TD24
  - NEXIUM 2.5 mg and 5 mg SUSPDR PKT
  - NORDITROPIN FLEXPRO 10 mg/1.5 ml PEN
  - NUTROPIN AQ 20 mg/2 ml CARTRIDGE and NUTROPIN AQ NUSPIN 5 mg/2 ml CARTRIDGE
  - RAZADYNE ER 8 mg CAP 24 hour PEL
  - SAIZEN 8.8 mg VIAL and 8.8 mg/1.5 CARTRIDGE
  - SPRYCEL 140 mg TABLET
  - TRELSTAR 3.75 mg/2 ml SYRINGE
  - NAMENDA 5 mg–10 mg TAB DS PK

Appendix I—Table of Abbreviations

ARR	annualized relapse rate
BCF	Basic Core Formulary
BIA	budget impact analysis
CADHT	Canadian Agency for Drugs in Technology and Health
CEA	cost-effectiveness analysis
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
DAAs	direct acting antivirals
DCO	Defense Connect Online
DERP	Oregon Drug Effectiveness Review Project
DHA	Defense Health Agency
DoD	Department of Defense
ECF	Extended Core Formulary
ER	extended release
FDA	U.S. Food and Drug Administration
FEV_1	forced expiration volume in 1 second
GLP1RA	glucagon-like peptide-1 receptor agonist
HCV	hepatitis C virus
IM	intramuscular
IOP	intraocular pressure
ISO	International Organization for Standardization
JIA	juvenile idiopathic arthritis
LABA	long-acting beta agonist
LAMA	long-acting muscarinic agent
MHS	Military Health System
MN	medical necessity
MS	multiple sclerosis
MTF	Military Treatment Facility
NF	nonformulary
NDAA	National Defense Authorization Act
NSAIDs	nonsteroidal anti-inflammatory drugs
P&T	Pharmacy and Therapeutics
PA	prior authorization
POS	points of service
QD	once daily
QLs	quantity limits
SC	subcutaneous
SMBGS	self-monitoring blood glucose system
TIBs	targeted immunomodulatory biologics
TIW	three times a week
UF	Uniform Formulary
V-Go	Valeritas V-Go insulin delivery device