

**DEPARTMENT OF DEFENSE  
PHARMACY AND THERAPEUTICS COMMITTEE  
MINUTES AND RECOMMENDATIONS**

**February 2014**

**I. CONVENING**

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 12, 2014, at the Defense Health Agency (DHA) Pharmacoeconomic 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 for the November 2013 DoD P&T Committee meeting on February 10, 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. Antidepressants (AD-1s)—Bupropion extended release 450 mg (Forfivo XL), desvenlafaxine extended release (ER) (Khedeza), levomilnacipran (Fetzima), and vortioxetine (Brintellix).**

*Background and Relative Clinical Effectiveness Conclusion*—The P&T Committee concluded (16 for, 0 against, 0 absent, 0 abstain) the following with regard to the clinical efficacy and safety of bupropion XL 450 mg (Forfivo XL), desvenlafaxine ER (Khedeza), levomilnacipran (Fetzima), and vortioxetine (Brintellix). All four drugs are indicated solely for the treatment of major depressive disorder (MDD).

## 1. Forfivo XL

- a) Forfivo XL is an extended-release 450 mg formulation of bupropion, a norepinephrine/dopamine reuptake inhibitor (NDRI). Several generic formulations of bupropion (Wellbutrin, Wellbutrin SR, and Wellbutrin XL) are on the BCF. There are no clinical trials with Forfivo XL; FDA approval was based on demonstrated bioequivalence to three tablets of 150 mg Wellbutrin XL.
- b) Limitations to the product include that patients must be titrated with another bupropion formulation first, and the dose cannot be adjusted in renal or hepatic impairment.
- c) Forfivo XL has similar safety and tolerability concerns as other bupropion agents.
- d) While Forfivo XL offers an alternative treatment option of one tablet administered once daily for patients requiring a high dose of bupropion, it offers no compelling clinical advantages over the other bupropion formulations on the BCF or UF.

## 2. Desvenlafaxine ER (Khedeza)

- a) Khedeza is a serotonin/norepinephrine reuptake inhibitor (SNRI) that is an extended-release form of desvenlafaxine (Pristiq). Khedeza differs from Pristiq in the salt form (desvenlafaxine base versus desvenlafaxine succinate). Generic desvenlafaxine formulations are now available.
- b) Khedeza has shown bioequivalence to Pristiq in three studies; there are no clinical trials available.
- c) Khedeza offers no clinically relevant advantages over the venlafaxine products (Effexor, Effexor XR, generic) products on the UF.

## 3. Levomilnacipran (Fetzima)

- a) Levomilnacipran is a SNRI and is an extended-release stereoisomer of milnacipran (Savella). Fetzima is indicated for MDD whereas Savella is indicated for fibromyalgia.
- b) There are no head-to-head studies comparing levomilnacipran with other antidepressants.
- c) In the three placebo-controlled studies used to gain FDA approval, all levomilnacipran doses produced a statistically significant change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS). However, varying effects on response rates (e.g., a 50% reduction in the MADRS score from baseline) have been reported, depending on the dose and study design. There was no difference from placebo in remission rate at any levomilnacipran dose.

- d) The safety profile of levomilnacipran is similar to milnacipran (Savella) and carries the same warnings.
- e) Levomilnacipran offers no clinically compelling advantages over the other AD-1s on the UF.

4. Vortioxetine (Brintellix)

- a) There have been no head-to-head studies between vortioxetine and other antidepressants. In four of seven placebo-controlled studies, vortioxetine was superior to placebo in improving MADRS or HAMD (Hamilton Depression Rating Scale) scores from baseline.
- b) In active comparator studies using duloxetine (Cymbalta) or venlafaxine (Effexor), vortioxetine showed similar clinical results in the endpoints of MADRS, HAMD, response, or remission.
- c) The most common adverse events (AEs) with vortioxetine include nausea and vomiting. Vortioxetine has fewer known AEs and warnings compared to desvenlafaxine, duloxetine (Cymbalta), and levomilnacipran. However, vortioxetine is the newest AD-1 to reach the market and additional AEs may increase during post-marketing surveillance.
- d) Although vortioxetine offers additional serotonergic effects in its mechanism of action and has fewer AEs overall than some of the other AD-1s, this has not translated into greater efficacy in treating depression.

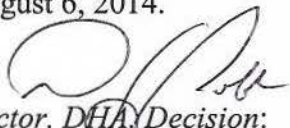
*Relative Cost-Effectiveness Analysis and Conclusion*—Cost minimization analysis (CMA) was performed to evaluate new antidepressants bupropion XL 450 mg (Forfivo XL), desvenlafaxine ER (Khedeza), levomilnacipran (Fetzima), and vortioxetine (Brintellix) compared with other AD-1 subclasses, including selective serotonin reuptake inhibitors (SSRIs), SNRIs, and NDRIs. Based on the CMA results, the P&T Committee concluded (16 for, 0 against, 0 absent, 0 abstain) the following:

- For the NDRIs, the current BCF drugs—generic bupropion IR, sustained release and ER formulations—were the most cost-effective agents, followed by the new entrant Forfivo XL and then followed by the NF branded product bupropion hydrobromide (Aplenzin).
  - For the SNRIs and SSRIs subclasses, the BCF drugs citalopram and sertraline were the most cost-effective drugs, followed by generic venlafaxine IR and ER, and then followed by generic desvenlafaxine, Khedeza, generic duloxetine (Cymbalta), levomilnacipran (Fetzima), vortioxetine (Brintellix), and branded duloxetine (Cymbalta), ranked in order from most to least cost effective.
1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 against, 0 absent, 1 abstain) bupropion XL 450 mg

(Forfivo XL), desvenlafaxine ER (Khedezla), levomilnacipran (Fetzima), and vortioxetine (Brintellix) be designated NF, based on clinical and cost effectiveness. Additionally, the P&T Committee recommended Khedezla, Fetzima, and Brintellix be non-step preferred (“behind the step”), which requires a trial of a formulary AD-1 prior to use in all current and new patients. See Prior Authorization section, below.

2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (15 for, 0 against, 0 absent, 1 abstain) MN criteria for bupropion 450 mg XL (Forfivo XL), desvenlafaxine ER (Khedezla), levomilnacipran (Fetzima), and vortioxetine (Brintellix). (See Appendix B for the full criteria.)
3. **COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA**—The P&T Committee recommended (15 for, 0 against, 0 absent, 1 abstain) PA criteria should apply to Khedezla, Fetzima, and Brintellix. (See Appendix C for the full PA criteria.)
  - a) Desvenlafaxine ER (Khedezla): For all new users of Khedezla, patients are required to try venlafaxine immediate release (IR) or ER (Effexor, Effexor XR; generics) first.
  - b) Levomilnacipran (Fetzima) and vortioxetine (Brintellix): For new users of Fetzima or Brintellix, patients are required to try a generic SSRI, duloxetine, SNRI (except milnacipran), tricyclic antidepressant, mirtazapine, bupropion, serotonin antagonist reuptake inhibitor (trazodone or nefazodone), or mononamine oxidase inhibitor first.

4. **COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD**  
The P&T Committee recommended (15 for, 0 against, 0 absent, 1 abstain) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service (POS); and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee’s recommendation, the effective date is August 6, 2014.



Director, DHA, Decision:

Approved

Disapproved

Approved, but modified as follows:

## V. UF DRUG CLASS REVIEWS

### A. Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs) Combinations

*Background and Relative Clinical Effectiveness Conclusion*—The P&T Committee evaluated the clinical effectiveness of the ICS/LABA combinations, which were last reviewed for UF

status in February 2009. Since the last review, one new drug, fluticasone/vilanterol (Breo Ellipta) has been marketed. Military Health System (MHS) expenditures for the class were \$168 million in calendar year 2013. The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the following conclusions:

1. Fluticasone/salmeterol (Advair) and budesonide/formoterol (Symbicort) are highly therapeutically interchangeable for asthma. For asthma, head-to-head trials and systematic reviews show no significant differences in efficacy.
2. For chronic obstructive pulmonary disease (COPD), there is insufficient evidence to conclude that there are clinically relevant differences in efficacy between Advair and Symbicort.
3. Advair Diskus, Symbicort, and Breo Ellipta are all FDA-approved for maintenance treatment of COPD; however, only Advair Diskus and Breo Ellipta are specifically approved for decreasing COPD exacerbations. Symbicort does have data from observational studies showing decreases in COPD exacerbations.
4. For mometasone/formoterol (Dulera), there are no head-to-head trials with another ICS/LABA in asthma; clinically relevant differences in efficacy are not expected. Dulera is not approved for COPD; two trials have shown benefit in improving spirometric endpoints in COPD.
5. There is only limited data for Breo Ellipta in patients with asthma, and it is not FDA-approved for this indication.
6. Breo Ellipta offers the convenience of once-a-day dosing in COPD. However, the long-term safety of the LABA component vilanterol is not known. One large trial (SUMMIT) evaluating mortality as a primary endpoint is underway.
7. Advair Diskus is the only drug approved for treatment of asthma in children down to the age of four years; however, for this age range, a metered dose inhaler (MDI) with a spacer is more commonly used. It also has the advantage of availability in both a MDI [Advair hydrofluoroalkane (HFA)] and dry powder inhaler (Advair Diskus).
8. For safety, a systematic review did not show clinically relevant differences between Advair and Symbicort in asthma. Advair Diskus, Advair HFA, Symbicort, Dulera, and Breo Ellipta all contain the same black box warnings and precautions. All drugs containing a LABA carry a black box warning for the increased risk of death in asthma.
9. Breo Ellipta and Dulera have a lower degree of interchangeability with Advair and Symbicort, due to their limited FDA-approved indications.
10. The Pharmacy Outcomes Research Team (PORT) presented an analysis of the use of ICS/LABAs by indications and found that asthma represents the majority of MHS use (67% of beneficiaries had ICD-9 diagnosis codes indicative of asthma, while 37% had codes for COPD, and 17% had codes for neither diagnosis). However, there was considerable overlap between the COPD and asthma diagnosis codes.

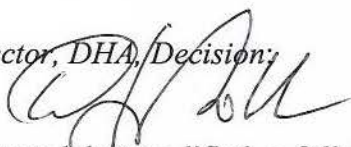
*Relative Cost-Effectiveness Analysis and Conclusion*—A pharmacoeconomic analysis and budget impact analysis (BIA) were performed to evaluate the ICS/LABAs. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- The pharmacoeconomic analysis showed that fluticasone/salmeterol (Advair Diskus/Advair HFA) was the most cost-effective agent in this class, followed by mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort), and fluticasone/salmeterol (Breo Ellipta).
- A BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and formulary or non-preferred and NF on the UF. BIA results showed that the scenario where Advair Diskus and Advair HFA are designated as step-preferred and formulary, with Dulera, Symbicort, and Breo Ellipta designated as non-preferred and NF, was the most cost-effective option for the MHS.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following for the ICA/LABAs, based on clinical and cost effectiveness:
  - UF and step-preferred: fluticasone/salmeterol (Advair Diskus and Advair HFA)
  - NF and non-preferred: budesonide/formoterol (Symbicort), mometasone/formoterol (Dulera), and fluticasone/vilanterol (Breo Ellipta)
  - This recommendation includes step therapy, which requires a trial of Advair Diskus or Advair HFA in all new and current users of Symbicort, Dulera, and Breo Ellipta who are older than 12 years.
2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) that fluticasone/salmeterol (Advair Diskus and Advair HFA) remain on the BCF.
3. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Symbicort, Dulera, and Breo Ellipta. (See Appendix B for full MN criteria.)
4. **COMMITTEE ACTION: PA CRITERIA**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) automated (step therapy) and manual PA criteria in all new and current users of Symbicort, Dulera, and Breo Ellipta who are older than 12 years of age; a trial of Advair Diskus or Advair HFA is required before the non-step preferred drugs.

5. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—QLs currently apply to the ICS/LABAs. The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) QLs for Advair Diskus, Advair HFA, Symbicort, Dulera, and Breo Ellipta of 1 inhaler/30 days in the Retail Network and 3 inhaler/90 days in the Mail Order Pharmacy.
  
6. **COMMITTEE ACTION: UF IMPLEMENTATION PERIOD**—The P&T Committee recommended (13 for, 2 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision; and, 3) that the ICS/LABA Drug Class be added to the safety net program (Rapid Response Program). Based on the P&T Committee's recommendation, the effective date is July 9, 2014.

Director, DHA, Decision:



Approved

Disapproved

Approved, but modified as follows:

#### B. Gastrointestinal-1 (GI-1s) Drug Class: Oral Aminosalicylates Subclass

*Background and Relative Clinical Effectiveness Conclusion*—The P&T Committee evaluated the relative clinical effectiveness of the oral aminosalicylates, a subclass within the GI-1s Drug Class. The subclass is comprised of generic sulfasalazine and the 5-aminosalicylate (5-ASA) products [balsalazide (generic Colazal and Giazol), olsalazine (Dipentum), and mesalamine (Delzicol, Asacol HD, Pentasa, Lialda, and Apriso)].

The GI-1s were previously reviewed for UF placement in February 2011, and mesalamine delayed release (DR) tablets (Asacol), along with generic sulfasalazine, were recommended for BCF addition. Asacol was discontinued from the market in March 2013 due to safety concerns of dibutyl phthalate (DBP) present in the enteric coating of Asacol tablets. A new phthalate-free mesalamine DR formulation, Delzicol is now available. At the May 2013 meeting, Asacol was removed from the BCF, pending a re-review of the subclass. Currently, the only aminosalicylate on the BCF is sulfasalazine.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following conclusions for the aminosalicylates drug class:

1. Sulfasalazine remains the first-line oral aminosalicylate. For the induction of remission in active ulcerative colitis (UC), evidence from two systematic reviews found no clinically relevant differences in efficacy between sulfasalazine and the newer 5-ASA formulations.

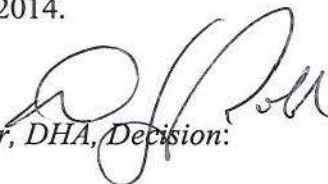
2. For maintenance of remission in UC, another systematic review showed a therapeutic advantage of sulfasalazine over the 5-ASA formulations. This advantage was offset by an increase in adverse events observed with sulfasalazine, due to the sulfapyridine moiety.
3. The newer 5-ASA formulations employ different release mechanisms, which deliver the active drug to various sites in the GI tract. These differences in drug release and site of release do not confer additional benefits in terms of clinical response.
4. The mesalamine product Delzicol is the phthalate-free replacement for Asacol that is bioequivalent to its predecessor; no clinical trials were conducted to evaluate efficacy or safety.
5. Giazio is a new balsalazide product with a higher strength per unit than the other balsalazide formulations (1,100 mg versus 750 mg with Colazal). It is not approved for use in women, and it offers no compelling advantage to the other balsalazide products commercially available.
6. The safety profile is similar for the 5-ASA products, based on systematic reviews. In clinical trials, females treated with Giazio reported more adverse events than males.
7. Lialda and Apriso are dosed once daily, which provides patient convenience, but have not been shown to have clinically relevant benefits in terms of adherence compared to 5-ASAs dosed twice or three times daily. Lialda and Apriso also have the lowest tablet burden.
8. The 5-ASA products are highly therapeutically interchangeable for treating UC. The choice of 5-ASA for UC will depend on other factors, such as location and extent of disease, as well as patient preference in terms of tablet burden and frequency of dosing.

*Relative Cost-Effectiveness Analysis and Conclusion*—CMA and BIA were performed to evaluate the GI-1s Aminosalicylate Subclass. The P&T Committee concluded (15 for, 0 opposed, 1 abstained, 0 absent) the following:

- CMA results showed that generic sulfasalazine was the most cost-effective agent in this subclass, followed by balsalazide 750 mg (Colazal, generics), olsalazine (Dipentum), and the branded mesalamine agents Apriso, Lialda, Delzicol, Asacol HD, and Pentasa. Giazio (branded balsalazide 1,100 mg) was not cost-effective relative to other agents in this class.
- BIA was performed to evaluate the potential impact of scenarios with selected agents designated formulary or NF on the UF. BIA results showed the scenario with Apriso, Delzicol, and Lialda designated as formulary on the UF, with Asacol HD and Pentasa designated as NF, was the most cost-effective for the MHS.



1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following, based on the high degree of therapeutic interchangeability and cost-effectiveness:
  - UF: sulfasalazine, balsalazide 750 mg (Colazal, generics), olsalazine (Dipentum), and the mesalamine products Delzicol, Lialda, and Apriso
  - NF: Pentasa, Asacol HD and the balsalazide 1,100 mg product (Giazo)
  
2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) retaining sulfasalazine on the BCF, and adding mesalamine multimatrix (Lialda) to the BCF.
  
3. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Pentasa, Asacol HD, and Giazo. (See Appendix B for full MN criteria.)
  
4. **COMMITTEE ACTION: UF IMPLEMENTATION PERIOD**—The P&T Committee recommended (15 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) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee’s recommendation, the effective date is August 6, 2014.

*Director, DHA, Decision:* 

Approved

Disapproved

Approved, but modified as follows:

**C. Pancreatic Enzyme Products (PEPs)**

*Background and Relative Clinical Effectiveness*—The P&T Committee evaluated the relative clinical effectiveness of the PEPs. The class was previously an extended core formulary (ECF) class and last reviewed in February 2011. The PEPs were reviewed for the FDA-approved indication of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis or other conditions; other uses (e.g., pain relief from pancreatitis) were not reviewed. Since the last review, three new products, Pertzye, Viokace, and Ultresa, have been marketed. The PEPs all contain various amounts of lipase, amylase, and protease.

*Relative Clinical Effectiveness Conclusion*—The P&T Committee recommended (15 for, 1 opposed, 0 abstained, 0 absent) the following conclusions:

1. Based on clinical efficacy alone, Creon, Pancreaze, Zenpep, Viokace, Ultresa, and Pertzye are effective at increasing coefficient of fat absorption in patients with EPI, compared to placebo. Only limited clinical trial data is available.
2. Creon has the most indications and highest MHS utilization. Among the PEPs, Creon has an additional indication for EPI due to pancreatitis or pancreatotomy, without requiring use of a proton pump inhibitor.
3. Zenpep has the most dosage strengths available.
4. Zenpep and Viokace have information for gastrostomy tube administration.
5. Viokace is an uncoated tablet that is not approved for use in pediatrics; it requires administration with a proton pump inhibitor, to prevent degradation in the stomach.
6. Creon, Pancreaze, and Zenpep have dosing recommendations for infants as young as 12 months of age while Pancreaze has dosing information in infants as young as 6 months.
7. Pertzye and Ultresa have limited data regarding efficacy in treating EPI and have limited dosage strengths available.
8. With regards to safety, the available evidence suggests there are no clinically relevant differences between any of the PEPs.
9. There is a high degree of therapeutic interchangeability among the class.

*Relative Cost-Effectiveness Analysis and Conclusion*—CMA and BIA were performed to evaluate the PEP Drug Class. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that Creon was the most cost-effective agent in this class, followed by Zenpep, Pancreaze, and Viokace. Ultresa and Pertzye were not cost-effective relative to other agents in this class.
- BIA was performed to evaluate the potential impact of scenarios with selected agents designated formulary or NF on the UF. BIA results showed the scenario with Creon, Zenpep, Pancreaze, and Viokace designated as formulary on the UF, with Ultresa and Pertzye designated as NF on the UF, was the most cost-effective for the MHS.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee, recommended (13 for, 2 opposed, 1 abstained, 0 absent) Creon, Pancreaze, Zenpep, and Viokace remain on the UF, and that Pertzye and Ultresa be designated as NF.

2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) reclassifying the PEPs as a BCF class instead of an ECF class, and adding Creon to the BCF. As a result of this action, Pancreaze is removed from the ECF.
3. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Pertzye. (See Appendix B for the full MN criteria.)
4. **COMMITTEE ACTION: UF IMPLEMENTATION PERIOD**—The P&T Committee recommended (15 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) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee’s recommendation, the effective date is August 6, 2014.

Director, DHA, Decision: 

Approved

Disapproved

Approved, but modified as follows:

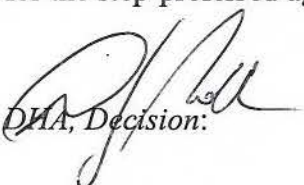
**VI. RE-EVALUATION OF NF AGENTS: DULOXETINE (CYMBALTA)**

On an ongoing basis, the DHA Pharmacoeconomic Branch monitors changes in the clinical information, current costs, and utilization trends to determine whether the UF status of agents designated as NF needs to be readdressed. The P&T Committee’s process for reevaluating NF agents was established at the May 2007 meeting and approved by the Director, TMA, on June 24, 2007.

The P&T Committee reevaluated the UF status of duloxetine (Cymbalta) in light of recent price reductions in generic formulations across all three POS. Additionally, automated PA (step therapy) requires a trial of a generic formulary antidepressant or generic non-opioid pain syndrome drug before receiving Cymbalta. As of the meeting, the generic duloxetine products were not cost-effective relative to the price of branded Cymbalta.

1. **COMMITTEE ACTION: DULOXETINE UF RECOMMENDATION AND IMPLEMENTATION**—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) maintaining Cymbalta as NF and continuing the current step therapy. When generic formulations of Cymbalta become cost-effective relative to the step-preferred agents, generic duloxetine will move to UF status, become step-preferred (e.g., “in front of the step”), and existing PA criteria will be removed without further action by the P&T Committee, Beneficiary Advisory

Panel, or Director, DHA. A generic agent is cost-effective relative to step-preferred agents when the generic agent's total weighted average cost per day of treatment is less than or equal to the total weighted average cost per day of treatment for the step-preferred agent.

Director, DHA, Decision: 

Approved

Disapproved

Approved, but modified as follows:

## VII. UTILIZATION MANAGEMENT

### A. PAs

1. **Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq)**—Mirabegron was FDA-approved for OAB in June 2012 and launched in October 2013. It will be reviewed as a new drug at an upcoming meeting. Mirabegron is a beta-3 agonist, which is a unique mechanism compared to the antimuscarinic OAB drugs (darifenacin, fesoterodine, tolterodine, oxybutynin, solifenacin, and trospium). In placebo-controlled trials, the efficacy of mirabegron on OAB symptoms appears similar to that of the other OAB drugs; however, mirabegron causes less anticholinergic AEs (dry mouth, constipation). The OAB drugs were reviewed for UF placement in November 2012, and automated PA (step therapy) was implemented, requiring a trial of a generic OAB drug or Detrol LA in all new and current users of an OAB drug.
  - a) **COMMITTEE ACTION: MIRABEGRON (MYRBETRIQ) PA CRITERIA**  
The P&T Committee recommended (13 for, 1 opposed, 1 abstained, 1 absent) PA criteria for all new users of mirabegron (Myrbetriq) for OAB. (See Appendix C for full criteria.)
  - b) **COMMITTEE ACTION: MIRABEGRON (MYRBETRIQ) UF IMPLEMENTATION**—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 30-day implementation period in all POS. The effective date is June 11, 2014.
2. **Phosphodiesterase-5 (PDE-5) Inhibitor: Avanafil (Stendra)**—Avanafil is a new PDE-5 inhibitor approved by the FDA in April 2012, but not launched until January 2014. It is only approved for erectile dysfunction (ED). Currently, automated PA (step therapy) applies to the class for ED; Viagra is the step-preferred PDE-5 for ED.
  - a) **COMMITTEE ACTION: AVANAFIL (STENDRA) PA CRITERIA**—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) PA

criteria for all users of Avanafil (Stendra) for ED. A trial of sildenafil (Viagra) for ED is required prior to using Stendra. Uses other than ED, including benign prostatic hypertrophy, following prostatectomy, pulmonary arterial hypertension, or Raynaud's phenomenon are not allowed. (See Appendix C for full criteria.)

## B. QLs

1. **Hepatitis C Drugs: Sofosbuvir (Sovaldi)**—Sofosbuvir (Sovaldi) is a new direct acting agent for hepatitis C approved on December 18, 2013. QLs currently apply to the hepatitis C drugs, including the direct acting antiviral agents. Sofosbuvir efficacy was established in patients with genotype 1, 2, 3, or 4 infection, including those with hepatocellular carcinoma awaiting liver transplantation and those co-infected with HIV. It can be used without interferon in patients with genotype 1, 2, or 3 hepatitis C virus.
  - a) **COMMITTEE ACTION: SOFOSBUVIR (SOVALDI) QLs**—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) QLs for sofosbuvir of 28 tablets per 28 days in all POS [Medical Treatment Facility (MTF), Retail Network, and Mail Order Pharmacy], consistent with the FDA-approved product dosing of one tablet given once daily.
  
2. **PDE-5 Inhibitors: Avanafil (Stendra)**—QLs currently apply to the PDE-5 inhibitors. The P&T Committee evaluated QLs for avanafil for treatment of ED.
  - a) **COMMITTEE ACTION: AVANAFIL (STENDRA) QLs**—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) QLs for Avanafil of 6 tablets per 30 days in the Retail Network and 18 tablets for 90 days in the Mail Order Pharmacy, consistent with the other PDE-5 inhibitors. This is a collective QL, a maximum of 6 tablets (Retail Network) or 18 tablets (Mail Order Pharmacy) of any PDE-5 is allowed.

  
Director, DHA, Decision:

Approved

Disapproved

Approved, but modified as follows:

## VIII. OVERVIEWS

Overviews of the ICS and Nasal Allergy Drugs (nasal antihistamines, nasal corticosteroids, and nasal anticholinergics) drug classes were presented to the P&T Committee. The P&T

Committee provided expert opinion regarding those clinical outcomes considered most important for use in contract solicitation and for completing the clinical effectiveness review and developing the appropriate cost-effectiveness modes. The clinical and economic analyses of these classes will be presented at an upcoming meeting.

## **IX. ITEMS FOR INFORMATION**

**A. Medication Adherence**—The PORT updated the P&T Committee regarding progress in formulating a process and algorithm for measuring medication adherence. The algorithm is intended for use as a DHA quality measure and in coordination with the DHA Health Information Technology Branch for potential inclusion in the Population Health Portal as a practical tool for clinicians and clinic managers at point of care. The overall DHA metrics follow recommendations from the Pharmacy Quality Alliance/National Committee for Quality Assurance and will allow comparison to Center for Medicare Services Star Rating measures for health plans.

## **X. ADJOURNMENT**

The meeting adjourned at 1650 hours on February 12, 2014. The next meeting will be in May 2014.

**Appendix A—Attendance: February 2014 P&T Committee Meeting**

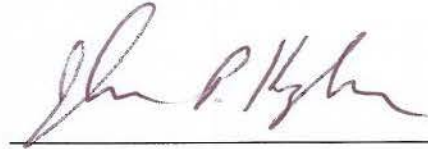
**Appendix B—Table of Medical Necessity Criteria**

**Appendix C—Table of Prior Authorization Criteria**

**Appendix D—Table of Implementation Status of UF Recommendations/Decisions  
Summary**

**Appendix E—Table of Abbreviations**

**SUBMITTED BY:**

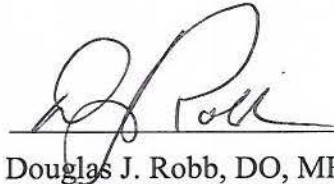


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John P. Kugler, M.D., MPH  
DoD P&T Committee Chair

**DECISION ON RECOMMENDATIONS**

Director, DHA, decisions are as annotated above.



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

*12 May 2014*

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Date

**Appendix A—Attendance: February 2014 P&T Committee Meeting**

<b>Voting Members Present</b>	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
LTC Robert Conrad, MS	Chief, DHA Pharmacoeconomic Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Derrick Clay for CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
LTC Dan Hsu for COL Ted Cieslak, MC	Army, Physician at Large
Col Michael Wynn, MC	Army, Family Practice Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Physician
Col Lowell Sensintaffer, 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
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Mr. Vincent Calebrese for Mr. Joe Canzolino	U.S. Department of Veterans Affairs
<b>Voting Members Absent</b>	
Col Michael Spilker, BSC	DHA Deputy Chief, Pharmacy Operations Division
<b>Nonvoting Members Present</b>	
Mr. David Hurt	Associate General Counsel, DHA
LT Col Dan Castiglia	Defense Logistics Agency Troop Support
LCDR Bob Selvester, MC	VA/DoD Evidence-Based Practice Guideline Work Group
CDR Brandon Hardin by phone	Medical Logistics Division, DLA



**Appendix A—Attendance (continued)**

<b>Guests</b>	
Mr. Bill Davies via DCO	Defense Health Agency, Pharmacy Operations Division
Capt Richard Caballero, via DCO	Defense Logistics Agency Troop Support
Mr. Alexander Quinones	Defense Logistics Agency Troop Support
CAPT Travis Watt	Vice Chair, IHS National P&T Committee
<b>Others Present</b>	
CAPT Walter Downs, MC	DHA Pharmacoeconomic Branch
LCDR Marisol Martinez, USPHS	DHA Pharmacoeconomic Branch
LCDR Joshua Devine, USPHS	DHA Pharmacoeconomic Branch
LCDR Linh Quach, MSC	DHA Pharmacoeconomic Branch
Maj David Folmar, BSC	DHA Pharmacoeconomic Branch
MAJ Misty Cowan, MC	DHA Pharmacoeconomic Branch
Dr. David Meade	DHA Pharmacoeconomic Branch
Dr. Angela Allerman	DHA Pharmacoeconomic Branch
Dr. Shana Trice	DHA Pharmacoeconomic Branch
Dr. Jeremy Briggs	DHA Pharmacoeconomic Branch
Dr. Brian Beck	DHA Pharmacoeconomic Branch
Dr. Amy Lugo via DCO	DHA Pharmacoeconomic Branch
Dr. Teresa Anekwe via DCO	DHA Pharmacy Operations Division
Ms. Deborah Garcia	DHA Pharmacoeconomic Branch contractor
Dr. Esmond Nwokeji	DoD Pharmacoeconomic Branch contractor
Mr. Kirk Stocker	DoD Pharmacoeconomic Branch contractor
Ms. Linda Paul	University of Incarnate Word, Feik School of Pharmacy student
Ms. Jennifer Miller via DCO	Lake Erie College of Osteopathic Medicine, School of Pharmacy student
Ms. Anna Hung via DCO	University of Maryland, School of Pharmacy student

**Appendix B—Table of Medical Necessity Criteria**

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> <li>• Budesonide/formoterol (Symbicort)</li> <li>• Mometasone/formoterol (Dulera)</li> <li>• Fluticasone/vilanterol (Breo Ellipta)</li> </ul> <p><b>Inhaled Corticosteroids/ Long-Acting Beta Agonists (ICS/LABAs) Combinations</b></p>	<ul style="list-style-type: none"> <li>• Use of Advair Diskus or Advair HFA is contraindicated</li> <li>• The patient has experienced or is likely to experience intolerable adverse effects to Advair Diskus or Advair HFA.</li> <li>• The patient has had an inadequate response to Advair Diskus or Advair HFA.</li> <li>• The patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk.</li> </ul>
<ul style="list-style-type: none"> <li>• Bupropion 450 mg XL (Forfivo XL)</li> </ul> <p><b>Antidepressant-1s (AD-1s)</b></p>	<ul style="list-style-type: none"> <li>• Use of formulary agents (bupropion, bupropion SR, bupropion XL) is contraindicated and treatment with other formulary antidepressants is not clinically appropriate. Provider must state why the patients cannot take generic bupropion, bupropion SR, or bupropion XL.</li> </ul>
<ul style="list-style-type: none"> <li>• desvenlafaxine ER (Khedezla)</li> </ul> <p><b>Antidepressant-1s (AD-1s)</b></p>	<ul style="list-style-type: none"> <li>• Use of the formulary agents venlafaxine IR or venlafaxine ER are contraindicated</li> <li>• The patient has experienced or likely to experience significant adverse effects from the formulary agents venlafaxine IR or venlafaxine ER.</li> <li>• Formulary agents resulted or are likely to result in therapeutic failure.</li> <li>• Patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk.</li> </ul>
<ul style="list-style-type: none"> <li>• Levomilnacipran (Fetzima)</li> </ul> <p><b>Antidepressant-1s (AD-1s)</b></p>	<ul style="list-style-type: none"> <li>• Use of formulary AD-1s are contraindicated</li> <li>• Patient has experienced or is likely to experience significant adverse effects from formulary AD-1s.</li> <li>• Formulary AD-1s resulted or are likely to result in therapeutic failure.</li> <li>• Patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk.</li> <li>• No alternative formulary agent</li> </ul> <p><b>Formulary alternatives:</b> (selective serotonin reuptake inhibitors, serotonin/norepinephrine reuptake inhibitor (except milnacipran), tricyclic antidepressants, mirtazapine, bupropion, serotonin antagonist reuptake inhibitors, monoamine oxidase inhibitors)</p>
<ul style="list-style-type: none"> <li>• Brintellix (Vortioxetine)</li> </ul> <p><b>Antidepressant-1s (AD-1s)</b></p>	<ul style="list-style-type: none"> <li>• Use of formulary AD-1s are contraindicated</li> <li>• Patient has experienced or is likely to experience significant adverse effects from formulary AD-1s.</li> <li>• Formulary AD-1s resulted or are likely to result in therapeutic failure</li> <li>• Patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk</li> <li>• No alternative formulary agent</li> </ul> <p><b>Formulary alternatives:</b> (selective serotonin reuptake inhibitors, serotonin/norepinephrine reuptake inhibitor (except milnacipran), tricyclic antidepressants, mirtazapine, bupropion, serotonin antagonist reuptake inhibitors, monoamine oxidase inhibitors)</p>

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> <li>• Balsalazide 1100 mg (Giazo)</li> <li>• Mesalamine high dose (Asacol HD)</li> <li>• Mesalamine (Pentasa)</li> </ul> <p><b>Gastrointestinal-1 Drugs (GI-1s), aminosaliclates</b></p>	<ul style="list-style-type: none"> <li>• Use of formulary oral aminosaliclates are contraindicated</li> </ul>
<ul style="list-style-type: none"> <li>• Pertzye</li> <li>• Ultresa</li> </ul> <p><b>Pancreatic Enzyme Products (PEPs)</b></p>	<ul style="list-style-type: none"> <li>• Use of formulary oral PEPs are contraindicated</li> <li>• No alternative formulary agent; patient requires a strength that is not available with the formulary PEPs</li> </ul>

## Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> <li>• Budesonide/formoterol (Symbicort)</li> <li>• Mometasone/formoterol (Dulera)</li> <li>• Fluticasone furoate/vilanterol (Breo Ellipta)</li> </ul> <p><b>Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs) Combinations</b></p>	<p>PA criteria apply to all new and current users of Symbicort, Dulera, and Breo Ellipta who are older than 12 years of age.</p> <p><u>Automated PA criteria:</u> The patient has filled a prescription for Advair or Advair HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</p> <p>AND</p> <p><u>Manual PA criteria</u>—Symbicort, Dulera, or Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) if:</p> <ul style="list-style-type: none"> <li>• Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with the non-preferred ICS/LABA combination drug: <ul style="list-style-type: none"> <li>○ inadequate response to Advair Diskus or Advair HFA</li> <li>○ intolerable adverse effects</li> <li>○ contraindication</li> <li>○ patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Desvenlafaxine ER (Khedezla)</li> </ul> <p><b>Antidepressant1-s (AD-1s)</b></p>	<p>PA criteria apply to all new users of Khedezla</p> <p><u>Automated PA criteria</u></p> <p>The patient has filled a prescription for venlafaxine IR or venlafaxine ER at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</p> <p>AND</p> <p><u>Manual PA criteria</u>—If automated criteria are not met, Khedezla is approved in new users (e.g., trial of venlafaxine IR or venlafaxine ER is NOT required) if:</p> <ul style="list-style-type: none"> <li>• Use of the formulary SNRI (venlafaxine) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient) and use of any other formulary antidepressant is not clinically appropriate.</li> <li>• The patient has previously responded to Khedezla, and changing to a formulary medication would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Khedezla and changing to a formulary medication would present a risk of destabilization).</li> <li>• The patient is being treated for depression, requires treatment with a SNRI (e.g., due to failure of SSRI therapy), and has failed an adequate trial of venlafaxine. Note: an adequate trial is generally considered to be at least 4–8 weeks in duration, due to the delay in achieving maximal benefit.</li> <li>• The patient requires treatment with a SNRI (e.g., due to failure of SSRI therapy), and has been unable to tolerate venlafaxine.</li> </ul>

<ul style="list-style-type: none"> <li>Levomilnacipran (Fetzima)</li> </ul> <p><b>Antidepressant1-s (AD-1s)</b></p>	<p>PA criteria apply to all new users of Fetzima.</p> <p><u>Automated PA criteria</u></p> <ul style="list-style-type: none"> <li>The patient has filled a prescription for a formulary SSRI, duloxetine, SNRIs (except milnacipran), TCA, mirtazapine, bupropion, trazodone or nefazodone, or an MAOI at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</li> </ul> <p>AND</p> <p><u>Manual PA criteria</u>—For new users, Fetzima is approved (e.g., trial of a formulary AD-1 listed above is NOT required) if:</p> <ul style="list-style-type: none"> <li>Use of a formulary antidepressant (SSRI, duloxetine, SNRI (except milnacipran), TCA, mirtazapine, bupropion, trazodone or nefazodone, or, MAOI) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient) and use of any other formulary antidepressant is not clinically appropriate.</li> <li>The patient has previously responded to Fetzima, and changing to a formulary medication would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Fetzima and changing to a formulary medication would present a risk of destabilization).</li> <li>The patient is being treated for depression and has failed therapy with the formulary antidepressants (SSRI, duloxetine, SNRI (except milnacipran), TCA, mirtazapine, bupropion, trazodone or nefazodone, or, MAOI). Note: an adequate trial is generally considered to be at least 4–8 weeks in duration, due to the delay in achieving maximal benefit.</li> <li>The patient is being treated for depression and has been unable to tolerate the formulary antidepressants (SSRI, duloxetine, SNRI (except milnacipran), TCA, mirtazapine, bupropion, trazodone or nefazodone, or, MAOI).</li> </ul>
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Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> <li>• Vortioxetine (Brintellix)</li> </ul> <p><b>Antidepressant1-s (AD-1s)</b></p>	<p>PA criteria apply to all new users of Brintellix.</p> <p><u>Automated PA criteria</u></p> <ul style="list-style-type: none"> <li>• The patient has filled a prescription for a formulary SSRI, duloxetine, SNRIs (except milnacipran), TCA, mirtazapine, bupropion, trazodone or nefazodone, or an MAOI at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</li> </ul> <p>AND</p> <p><u>Manual PA criteria</u>—For new users, Brintellix is approved (e.g., trial of a formulary AD-1 listed above is NOT required) if:</p> <ul style="list-style-type: none"> <li>• Use of a formulary antidepressant (SSRI, duloxetine, SNRI except milnacipran, TCA, mirtazapine, bupropion, trazodone or nefazodone, or, MAOI) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient) and use of any other formulary antidepressant is not clinically appropriate.</li> <li>• The patient has previously responded to Brintellix, and changing to a formulary medication would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Brintellix and changing to a formulary medication would present a risk of destabilization).</li> <li>• The patient is being treated for depression and has failed therapy with the formulary antidepressants (SSRI, duloxetine, SNRI except milnacipran, TCA, mirtazapine, bupropion, trazodone or nefazodone, or, MAOI). Note: an adequate trial is generally considered to be at least 4–8 weeks in duration, due to the delay in achieving maximal benefit.</li> <li>• The patient is being treated for depression and has been unable to tolerate the formulary antidepressants (SSRI, duloxetine, SNRI except milnacipran, TCA, mirtazapine, bupropion, trazodone or nefazodone, or, MAOI).</li> </ul>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> <li>• Mirabegron (Myrbetriq)</li> </ul> <p><b>Overactive Bladder (OAB) Drugs</b></p>	<p>PA criteria apply to all new users of Myrbetriq</p> <p><u>Automated PA criteria</u></p> <ul style="list-style-type: none"> <li>• The patient has filled a prescription for tolterodine ER (Detrol LA), oxybutynin ER, oxybutynin IR, or generic trospium IR (Sanctuary) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</li> </ul> <p><u>Manual PA criteria</u>—If automated criteria are not met, Myrbetriq is approved if:</p> <ul style="list-style-type: none"> <li>• Coverage is only approved for the FDA-approved indication of OAB with symptoms of urge incontinence, urgency, and urinary frequency</li> <li>• Patient has failed a 12-week trial with at least one of the following step-preferred OAB drugs (Detrol LA, oxybutynin ER, oxybutynin IR, or trospium IR) due to a treatment failure or intolerable adverse effects.</li> <li>• Patient has experienced central nervous system (CNS) adverse effects with oral OAB medications or is at increased risk for such CNS effects due to comorbid conditions or other medications.</li> </ul>
<ul style="list-style-type: none"> <li>• Avanafil (Stendra)</li> </ul> <p><b>Phosphodiesterase-5 (PDE-5) Inhibitor</b></p>	<p>PA applies to all new and current users of avanafil (Stendra).</p> <p><u>Automated PA criteria</u></p> <ul style="list-style-type: none"> <li>• The patient has received a prescription for sildenafil (Viagra) at any MHS point of service (MTFS, Retail Network or Mail Order) during the previous 180 days.</li> <li>• The patient is a male, aged 40 years of older with ED.</li> </ul> <p><u>Manual PA criteria</u>—if automated criteria are not met. Stendra is approved if</p> <ul style="list-style-type: none"> <li>• The patient has tried sildenafil (Viagra) and has had an inadequate response or was unable to tolerate treatment due to adverse effects.</li> <li>• Treatment with Viagra is contraindicated.</li> </ul> <p>Note: Coverage is approved only for erectile dysfunction (ED). Use for benign prostatic hyperplasia (BPH), following prostatectomy, pulmonary arterial hypertension, and Raynaud's phenomenon is not allowed. Additionally, use is not allowed for treatment of ED in males younger than age 18, for ED due to psychogenic origin, or in women for female sexual dysfunction.</p>

**Appendix D—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
Feb 2014	<b>Inhaled Corticosteroids/ Long-Acting Beta Agonists (ICS/LABAs) Combinations</b>	UF class review  Previously reviewed	<ul style="list-style-type: none"> <li>▪ Fluticasone/salmeterol (Advair Diskus)</li> <li>▪ Fluticasone/salmeterol (Advair HFA)</li> </ul>	<ul style="list-style-type: none"> <li>▪ None (Advair Diskus and Advair HFA BCF)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Budesonide/formoterol (Symbicort)</li> <li>▪ Mometasone/formoterol (Dulera)</li> <li>▪ Fluticasone/vilanterol (Breo Ellipta)</li> </ul>	Pending signing of the minutes / 60 days	<ul style="list-style-type: none"> <li>▪ Step therapy required; see comments</li> <li>▪ Quantity Limits apply; see Minutes</li> </ul>	<ul style="list-style-type: none"> <li>▪ Must try Advair before Symbicort, Dulera, or Breo Ellipta in all current and new users older than 12 years. (See Appendix C)</li> </ul>
Feb 2014	<b>GI-1s 5-Amino Salicylate Subclass</b>	UF Class review  Previously reviewed	<ul style="list-style-type: none"> <li>▪ Sulfasalazine</li> <li>▪ Mesalamine multimatrix (Lialda)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Balsalazide 750 mg (Colazal, generic)</li> <li>▪ Olsalazine (Dipentum)</li> <li>▪ Mesalamine DR (Delzicol)</li> <li>▪ Mesalamine (Apriso)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Balsalazide 1100 mg (Giazo)</li> <li>▪ Mesalamine high dose (Asacol HD)</li> <li>▪ Mesalamine (Pentasa)</li> </ul>	Pending signing of the minutes / 90 days	<ul style="list-style-type: none"> <li>▪ None</li> </ul>	<ul style="list-style-type: none"> <li>▪ None</li> </ul>
Feb 2014	<b>Pancreatic Enzyme Products (PEPs)</b>	UF class review	<ul style="list-style-type: none"> <li>▪ Creon</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pancreaze</li> <li>▪ Viokace</li> <li>▪ Zenpep</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pertzye</li> <li>▪ Ultresa</li> </ul>	Pending signing of the minutes / 90 days	<ul style="list-style-type: none"> <li>▪ None</li> </ul>	<ul style="list-style-type: none"> <li>▪ Note Pancreaze removed from the ECF.</li> </ul>



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
Feb 2014	<p>Depression and Non-Opioid Pain Syndrome Agents</p> <p><b>Antidepressant-Is Subclass</b></p> <p>Previous review: Aug 2011</p>	<p>New Drug in Already Reviewed Class</p> <p>Bupropion 450 mg (Forfivo XL)</p> <p>Desvenlafaxine ER (Khedezla)</p> <p>Levomilnacipran (Fetzima)</p> <p>Vortioxetine (Brintellix)</p>	<p>No change from previous review</p> <p><b>SSRIs:</b> citalopram fluoxetine sertraline</p> <p><b>SNRIs:</b> venlafaxine IR venlafaxine ER</p> <p><b>SARIs:</b> trazodone</p> <p><b>NDRIs:</b> bupropion HCl IR bupropion HCl SR bupropion HCl ER</p> <p><b>GABA analogs:</b> gabapentin</p> <p><b>TCAs:</b> amitriptyline doxepin imipramine HCl nortriptyline</p>	<p><b>SSRIs:</b> citalopram fluoxetine escitalopram fluvoxamine paroxetine HCl IR paroxetine HCl CR paroxetine mesylate sertraline</p> <p><b>SNRIs:</b> venlafaxine IR venlafaxine ER venlafaxine ER tablets</p> <p><b>SARIs:</b> nefazodone trazodone</p> <p><b>NDRIs:</b> bupropion HCl IR bupropion HCl SR bupropion HCl ER</p> <p><b>TCAs:</b> amitriptyline desipramine doxepin imipramine HCl imipramine pamoate nortriptyline protriptyline</p> <p><b>A2RAs:</b> mirtazapine tablets mirtazapine ODT</p> <p><b>GABA analogs:</b> gabapentin</p>	<p><i>Feb 2014</i></p> <ul style="list-style-type: none"> <li>▪ bupropion 450 mg (Forfivo XL)</li> <li>▪ desvenlafaxine ER (Khedezla)</li> <li>▪ levomilnacipran (Fetzima)</li> <li>▪ vortioxetine (Brintellix)</li> </ul> <p><i>Nov 2011</i></p> <p><b>SSRIs:</b> fluoxetine (Sarafem) fluoxetine weekly (Prozac Weekly)</p> <p><b>SNRIs:</b> desvenlafaxine (Pristiq) duloxetine (Cymbalta) milnacipran (Savella)</p> <p><b>SARIs:</b> trazodone ER (Oleptro)</p> <p><b>SPARIs:</b> vilazodone (Viibryd)</p> <p><b>NDRIs:</b> bupropion HBr (Aplenzin)</p> <p><b>GABA analogs:</b> pregabalin (Lyrica)</p>	Pending signing of minutes/ 90 days	Step therapy required; see comments	<ul style="list-style-type: none"> <li>▪ Khedezla: Must try venlafaxine IR or ER first</li> <li>▪ Fetzima and Brintellix: Must try a formulary AD-1 first.</li> </ul> <p>(See Appendix C)</p>

TRICARE Formulary Search tool: [http://www.pec.ha.osd.mil/formulary\\_search.php](http://www.pec.ha.osd.mil/formulary_search.php)

## Appendix E—Table of Abbreviations

5-ASA	5-aminosalicylate
AD-1s	Antidepressants Drug Class
AEs	adverse events
BCF	Basic Core Formulary
BIA	budget impact analysis
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
DBP	dibutyl phthalate
DCO	Defense Connect Online
DHA	Defense Health Agency
DoD	Department of Defense
DR	delayed release
ED	erectile dysfunction
EPI	exocrine pancreatic insufficiency
ER	extended release
FDA	U.S. Food and Drug Administration
GI-1s	Gastrointestinal-1 Drug Class
HAMD	Hamilton Depression Rating Scale
HFA	hydrofluoroalkane
ICS/LABAs	Inhaled Corticosteroids/Long-Acting Beta Agonists Drug Class
IR	immediate release
MADRS	Montgomery-Asberg Depression Rating Scale
MAOI	mononamine oxidase inhibitor
MDD	major depressive disorder
MDIs	metered-dose inhalers
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDRI	norepinephrine/dopamine reuptake inhibitor
NF	nonformulary
OAB	overactive bladder
P&T	Pharmacy and Therapeutics
PA	prior authorization
PDE-5	phosphodiesterase-5 inhibitor
PEPs	Pancreatic Enzyme Products
PORT	Pharmacy Outcomes Research Team
POS	points of service
QLs	quantity limits
SARIs	serotonin antagonist reuptake inhibitor
SNRI	serotonin/norepinephrine reuptake inhibitor
SSRIs	serotonin reuptake inhibitors
UC	ulcerative colitis
UF	Uniform Formulary
XL	extended release