DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

February 2016

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 10 and 11, 2016, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November Minutes**—VADM R.C. Bono, MC, USN, Director, DHA, approved the minutes from the November 2015 DoD P&T Committee meeting on January 29, 2016.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including innovator drugs, and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations (CFR) 199.21(e)(1) and (g)(5). 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.

Nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

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

A. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)

Background—Afrezza is rapid-acting inhaled human insulin indicated to improve glycemic control in adult patients with Type 1 or Type 2 diabetes mellitus. It is the only commercially available inhaled insulin. Afrezza has been compared head-to-head with insulin aspart (NovoLog) and was non-inferior in reducing hemoglobin A1c.

Common adverse effects include cough, throat pain or irritation, decreased pulmonary function, bronchitis, and urinary tract infection. Limitations to use of Afrezza include the need for concomitant subcutaneous basal insulin. Patients with dexterity issues may find manipulation of the small pieces of the device to be difficult.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that despite the novel drug delivery system, the inhaled insulin Afrezza offers no clinically compelling advantages over the rapid acting insulin agents currently included on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: insulin aspart (NovoLog), insulin lispro (Humalog), insulin glulisine (Apidra), and inhaled insulin (Afrezza).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) inhaled insulin (Afrezza) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes data, and cost disadvantage compared to the UF non-basal insulins.

2. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) RECOMMENDATION***—Manual PA criteria for Afrezza were approved in May 2015 with an implementation date of October 21, 2015. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) maintaining the current PA criteria for Afrezza. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MN RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for inhaled insulin (Afrezza). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent)
1) an effective date of the first Wednesday after a 90-day implementation period; 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 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)

Background—Tivorbex is a low-dose formulation of indomethacin available in 20 mg and 40 mg capsules. The formulation is intended for faster dissolution and absorption compared to other indomethacin products (indomethacin 25 mg and 50 mg; e.g., Indocin). According to the FDA, the manufacturer failed to demonstrate these theoretical advantages, as there were no significant differences in the pharmacokinetic profile when Tivorbex was compared to indomethacin. In the clinical trial used to obtain FDA approval, over 80% of patients received rescue narcotics for pain control. The Tivorbex package insert contains usual black box warnings and precautions for NSAIDs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that there were no clinical compelling advantages between Tivorbex and the other UF NSAIDs.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: meloxicam (Mobic, generic), ibuprofen (Motrin, generic), naproxen (Naprosyn, generic), diclofenac sodium (Voltaren, generic), indomethacin (Indocin, generic), celecoxib (Celebrex, generic), diclofenac (Zorvolex), and indomethacin (Tivorbex).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) indomethacin low dose 20 mg and 40 mg capsules (Tivorbex) be designated NF, based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: MN RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Tivorbex, as well as revised MN for all current NF NSAIDs, including the following: diclofenac potassium liquid filled capsules 25 mg (Zipsor); diclofenac potassium powder packets 50 mg (Cambia); naproxen sodium 375 mg, 500 mg, and 750 mg extended release (ER) tablets (Naprelan CR, generics); mefenamic acid 250 mg capsules (Ponstel, generic); ketorolac nasal spray (Sprix); famotidine/ibuprofen (Duexis); and, diclofenac low dose 18 mg and 35 mg capsules (Zorvolex). A trial of at least three UF NSAIDs is required before MN is granted for the NF NSAIDs. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period; 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 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Long-Acting Beta Agonists (LABAs): Olodaterol Oral Inhaler (Striverdi Respimat)

Background—Olodaterol (Striverdi Respimat) is the sixth marketed LABA oral inhaler approved for maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD). It has a long duration of action allowing for once daily dosing. There are no head-to-head trials available with olodaterol and other COPD drugs. Indirect comparisons of olodaterol with formoterol (Foradil) do not show clinically relevant differences in terms of changes in forced expiratory volume in one second (FEV_1). None of the LABAs are labeled to reduce COPD exacerbations or hospitalizations.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that other than the convenience of once daily dosing, olodaterol (Striverdi Respimat) offers no clinically compelling advantages over the existing UF LABAs. There is a high degree of therapeutic interchangeability among the LABAs.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed, comparing olodaterol with other Pulmonary II drugs. CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: olodaterol (Striverdi Respimat), salmeterol (Serevent), tiotropium (Spiriva), indacaterol (Arcapta), arformoterol inhalation solution (Brovana), and formoterol inhalation solution (Perforomist). The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that olodaterol (Striverdi Respimat) was cost effective compared with other LABA oral inhalers on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) olodaterol (Striverdi Respimat) be designated formulary on the UF, based on cost effectiveness.

   Note that salmeterol (Serevent) remains on the BCF for the LABA subclass.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

D. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)

Background—Pazeo is a dual action antihistamine/mast cell stabilizer (AH/MCS) ophthalmic agent and is the third strength of olopatadine approved for the prevention of itching associated with allergic conjunctivitis (AC). Several AH/MCS dual action agents are currently on the UF, including olopatadine 0.2% (Pataday) (once daily dosing) and olopatadine 01% (Patanol) (twice daily dosing). Generic formulations of olopatadine 0.1% (Patanol) recently entered the market.

In the placebo-controlled trials used to obtain FDA approval, Pazeo produced statistically and clinically significant results in treating ocular itching associated with AC both at the onset of action, and 24 hours after dosing. Overall, for relief of ocular itching due to AC, there do not appear to be clinically relevant differences in efficacy or safety between olopatadine 0.7% (Pazeo) and the other dual action AH/MCS agents.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that there were no clinically compelling advantages between Pazeo and the other UF AH/MCS dual action ophthalmic agents. A once daily olopatadine product (Pataday) is currently on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following

- CMA results showed the following rankings for the AH/MCS dual action ophthalmic agents from most to least cost-effective for the UF no-step scenario: azelastine 0.1%, olopatadine 0.1% generic, olopatadine 0.2% (Pataday), olopatadine 0.7% (Pazeo), olopatadine 0.1% (Patanol), alcaftadine (Lastacaft), and bepotastine (Bepreve).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) olopatadine 0.7% ophthalmic solution (Pazeo) be designated NF.

2. ***COMMITTEE ACTION: MN RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Pazeo. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period; 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 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Contraceptive Agents

Background—Two of the three Contraceptive Agents subclasses were reviewed for formulary placement; the oral contraceptive products (OCPs) and the miscellaneous contraceptives (comprised of the injection, transdermal patch, and vaginal ring). The OCPs are further sub-divided into eight categories, based on the amount of estrogen and type of progesterone contained in the product. The subclasses are outlined in Table 1 found on pages 11–14. The third subclass—the emergency contraceptives—will be reviewed for formulary placement at an upcoming meeting. The Contraceptive Agents were previously reviewed for UF placement in August 2011.

There are over 170 products in the OCPs and miscellaneous contraceptive subclasses. There is significant generic competition, and only eight branded, proprietary products that do not have generic equivalents remain in the class. The products were further classified based on 46 unique generic code number (GCN) sequence numbers. Recent entrants of note include AB-rated generic equivalents for the transdermal patch (Ortho Evra) and the multiphasic product Ortho Tri-Cyclen Lo.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 against, 0 abstained, 0 absent) the following for the OCPs and miscellaneous contraceptive subclasses:

- There are no new substantial updates to the clinical conclusions from the August 2011 Contraceptive Agents UF class review. Refer to P&T Committee meeting minutes for the full clinical effectiveness conclusion at http://www.health.mil/PandT.

- All oral and miscellaneous contraceptives are highly effective in preventing pregnancy when used as directed and have comparable efficacy benefits, as well as non-contraceptives benefits.

- New market additions since August 2011 include the replacement of former branded products with chewable formulations, introduction of a monophasic category containing 25 mcg ethinyl estradiol (EE) (e.g., Generess Fe chewable tablets), and the addition of supplements to the products, including iron (Fe) or folate. These new products do not provide clinically significant advantages or advancements in contraceptive therapy.

- Some formulations may offer better cycle control (e.g., vaginal ring), reduce adverse events associated with hormone withdrawal (e.g., extended cycle/continuous use OCPs), or provide better control of breakthrough bleeding (e.g., multiphasic OCPs).

- For the miscellaneous contraceptives, the vaginal ring and transdermal patch (NuvaRing; Xulane generic for Ortho Evra patch) offer similar contraceptive effectiveness as the OCPs. In contrast, improved contraceptive effectiveness occurs with the medroxyprogesterone injection (Depo-Provera; generic) compared to OCPs. The miscellaneous products also provide for an alternate route of administration for certain patient populations, result in sustained release of drug delivery, and offer

benefits to the patient by reducing or stopping menstrual bleeding.

- Overall, all contraceptive formulations have similar safety and adverse profiles, such as breakthrough bleeding, bloating, nausea, breast tenderness, headache, migraine, weight changes, and abnormal carbohydrate/lipid metabolism. An increased risk of venous thromboembolism may be associated with OCPs containing certain progestins (desogestrel, drospirenone) and the transdermal patch users.

- Given comparable contraceptive effectiveness among the various available contraceptive formulations and methods, factors which may affect contraceptive choice include individual patients' needs and characteristics, dosing convenience, and non-contraceptive benefits.

- The UF already contains a wide variety of oral contraceptive and miscellaneous products with various types and amounts of estrogen and progestin content, and also includes products with various regimens, phasic formulations, and routes of administration.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed to evaluate the oral and miscellaneous contraceptive subclasses, mentioned above. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed there were significant overlaps in prices across each of the nine contraceptive categories of medications.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 1 against, 1 abstained, 0 absent) the following, based on clinical and cost effectiveness:

    - **Reclassify to NF (previously UF):**
        - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate chewable (Minastrin 24 Fe chewable)
        - norethindrone acetate 0.8 mg/EE 25 mcg ferrous fumarate chewable (Generess Fe chewable; generics)

    - **Continue to Remain NF:**
        - drospirenone 3 mg/EE 20 mcg levomefolate (Beyaz)
        - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Lomedia 24 Fe; generics)
        - drospirenone 3 mg/EE 30 mcg levomefolate (Safyral)
        - norethindrone 0.4 mg/EE 35 mcg (Balziva; generics)

- norethindrone 0.4 mg/EE 35 mcg ferrous fumarate chewable (Wymzya Fe chewable; generics)
- levonorgestrel 0.09 mg/EE 20 mcg extended cycle (Amethyst; generics)
- levonorgestrel 0.15 mg/EE 30/10 mcg extended cycle (Camrese; generics)
- levonorgestrel 0.1 mg/EE 20/10 mcg extended cycle (Camrese Lo; generics)
- norethindrone acetate 1 mg/EE 10 mcg ferrous fumarate (Lo Loestrin Fe)
- norethindrone acetate 1 mg/EE 20/30/35 mcg ferrous fumarate (Tri-Legest Fe; generics)
- dienogest 2/3 mg and estradiol valerate 3/2/2/1 mg (Natazia)

- **Reclassify to UF (previously NF):**
  - levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen AB-rated generics to Jolessa (including Quasense, Introvale, and Setlakin [equivalent to discontinued Seasonale])
- **Remain UF**
  - levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen (Jolessa)
  - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Microgestin Fe 1/20; generics)
  - norethindrone acetate 1 mg/EE 20 mcg (Microgestin 1/20 [21-day]; generics)
  - drospirenone 3 mg/EE 20 mcg (Yaz; generics)
  - levonorgestrel 0.1 mg/EE 20 mcg (Sronyx; Lutera; generics)
  - norgestrel 0.3 mg/EE 30 mcg (Low-Ogestrel; generics [equivalent to discontinued Lo/Ovral 28])
  - norethindrone acetate 1.5 mg/EE 30 mcg ferrous fumarate (Microgestin Fe 1.5/30; generics; [equivalent to Loestrin Fe 1.5/30])
  - norethindrone acetate 1.5 mg/EE 30 mcg (Microgestin 1.5/30; generics; [equivalent to Loestrin 1.5/30])
  - desogestrel 0.15 mg/EE 30 mcg (Reclipsen; Ortho-Cept; generics)
  - levonorgestrel 0.15 mg/EE 30 mcg (Levora-28; generics)
  - drospirenone 3 mg/EE 30 mcg (Yasmin; generics)
  - ethynodiol diacetate 1 mg/EE 35 mcg (Zovia 1-35E; generics)
  - norethindrone 0.5 mg /EE 35 mcg (Nortrel 0.5/35; generics)
  - norgestimate 0.25 mg/EE 35 mcg (Mononessa; generics)
  - norethindrone 1 mg/EE 35 mcg (Norinyl 1+35; generics)
  - norethindrone 1 mg + mestranol 50 mcg/EE 50 mcg (Norinyl 1+50; generics)
  - norgestrel 0.5 mg/EE 50 mcg (Ogestrel; generics)

- ethynodiol diacetate 1 mg/EE 50 mcg (Zovia 1-50E; generics)
- norethindrone 0.5/1 mg + EE 35 mcg (Necon 10/11; [equivalent to discontinued Ortho Novum])
- desogestrel 0.15 mg + EE 20/10 mcg (Azurette; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 25 mcg (Ortho Tri-Cyclen Lo; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 35 mcg (TriNessa; generics)
- norethindrone 0.5/0.75/1 mg + EE 35 mcg (Necon 7/7/7; generics)
- norethindrone 0.5/1/0.5 mg + EE 35 mcg (Leena; generics)
- levonorgestrel 0.05/0.075/0.125 mg + EE 30/40/30 mcg (Trivora-28; generics)
- desogestrel 0.1/0.125/0.15 mg + EE 25 mcg (Velivet; generics)
- levonorgestrel 0.15 mg + EE 20/25/30/10 mcg (Quartette)
- norethindrone 0.35 mg (Nor-Q-D; Ortho Micronor; generics)
- etonogestrel 0.12 mg + EE 15 mcg vaginal ring (per day [NuvaRing])
- norelgestromin 150 mcg + EE 35 mcg transdermal system (per day [Xulane]; equivalent to discontinued Ortho Evra patch)
- depot medroxyprogesterone acetate 150 mg/mL IM vials (Depo-Provera vials; generic)
- depot medroxyprogesterone acetate 150 mg/mL IM syringes (Depo-Provera syringes; generic)
- depot medroxyprogesterone acetate 104 mg/0.65 mL SC (Depo-SubQ Provera 104)

[Refer to Table 1 on pages 11–14 for a complete list of the contraceptives.]

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) the contraceptive subclasses previously designated with BCF status in August 2011 should be retained on the BCF. The current BCF agents offer a wide variety of cost-effective oral progestin and estrogen contraceptives, including multiphasic formulations, which account for the highest utilization in the Military Treatment Facility (MTF) point of service (POS). The BCF products are as follows:

   - levonorgestrel 0.15 mg/EE 30 mcg extended cycle Jolessa branded generic formulation of the discontinued Seasonale remains BCF, while all other AB-rated generics to Jolessa (Quasense, Introvale, Setlakin, and generics) are reclassified as UF instead of NF
   - drospirenone 3 mg/EE 20 mcg (Yaz or equivalent)
   - levonorgestrel 0.1 mg/EE 20 mcg (Sronyx, Lutera or equivalent)
   - levonorgestrel 0.15 mg/EE 30 mcg (Levora-28 or equivalent)
   - drospirenone 3 mg/EE 30 mcg (Yasmin- or equivalent)
   - norgestimate 0.25 mg/EE 35 mcg (Mononessa or equivalent)

- norethindrone 1 mg/EE 35 mcg (Norinyl 1+35 or equivalent)
- norgestimate 0.18/0.215/0.25 mg + EE 35 mcg (TriNessa or equivalent)
- norethindrone 0.35 mg (Nor-Q-D or equivalent)

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) manual PA criteria for new users of Minastrin 24 Fe, Generess Fe, and Wymzya Fe chewable tablets, and their respective generics, to allow use for patients with special needs or those patients whose needs cannot be met with one of the formulary alternatives. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) MN criteria for the NF contraceptives. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: NF TO MAIL PROGRAM***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) adding the NF contraceptives to the list of medications excluded from the Nonformulary to Mail program.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period after signing of the minutes; and, 2) DHA send a letter to beneficiaries affected by the UF decision (applies to current users of Minastrin 24 FE and Generess Fe chewable tablets). Based on the P&T Committee's recommendation, the effective date is August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Oral Contraceptives												
Monophasics with 20 mcg EE	BCF	*Alesse*	Aubra, Aviane, Falmina, Lutera, Orsythia, Levonorgestrel and Ethinyl Estradiol	AB1	Monophasic 28-days (21act + 7inert)	0.1 mg levonorgestrel	EE 20		Alesse	Low	Low	Low
	BCF	*Levlite*	Lessina, Sronyx, Levonorgestrel and Ethinyl Estradiol	AB2					Levlite	Low	Low	Low
	BCF	*Yaz*	Gianvi, Loryna, Nikki, Vestura	AB	Monophasic 28-days (24act + 4inert)	3 mg drospirenone	EE 20	Yaz		Low	Low/ Unclear	No
	UF	*Loestrin 1/20 (21)*	Gildess 1/20, Junel 1/20, Larin 1/20, Microgestin 1/20, Norethindrone and Ethinyl Estradiol	AB	Monophasic 21-days (21act)	1 mg norethindrone acetate	EE 20		Loestrin 1/20 (21)	Low	High	Medium
	UF	*Loestrin Fe 1/20*	Blisovi Fe 1/20, Gildess Fe 1/20, Junel Fe 1/20, Larin Fe 1/20, Microgestin Fe 1/20, Tarina Fe 1/20, Norethindrone and Ethinyl Estradiol Fe	AB	Monophasic 28-days (21act + 7Fe)	1 mg norethindrone acetate	EE 20	Loestrin Fe 1/20		Low	High	Medium
	NF	*Loestrin 24 Fe*	Gildess 24 Fe, Junel 24 Fe, Larin 24 Fe, Lomedia 24 Fe, Norethindrone and Ethinyl Estradiol Fe	AB	Monophasic 28-days (24act + 4Fe)	1 mg norethindrone acetate	EE 20		Loestrin 24 Fe	Low	High	Medium
	NF	*Minastrin 24 Fe*	Minastrin 24 Fe	-	Monophasic 28-days (24act + 4Fe) CHEWABLE TABLET	1 mg norethindrone acetate	EE 20	Minastrin 24 Fe		Low	High	Medium
	NF	*Beyaz*	Beyaz	-	Monophasic 28-days (24act w/ levomefolate 0.451mg + 4 levomefolate 0.451mg) [pts ≥ 14 y/o]	3 mg drospirenone	EE 20	Beyaz		Low	Low/ Unclear	No
Monophasics with 25 mcg EE	NF	*Generess Fe*	Kaitlib Fe, Layolis Fe, Norethindrone and Ethinyl Estradiol Fe	AB	Monophasic 28-days (24act + 4Fe) CHEWABLE TABLET	0.8 mg norethindrone acetate	EE 25	Generess Fe		Low	Medium	Medium
Monophasics with 30 mcg EE	BCF	*Yasmin*	Drospirenone and Ethinyl Estradiol, Ocella, Syeda, Zarah	AB	Monophasic 28-days (21act + 7inert) [patients ≥ 14 y/o]	3 mg drospirenone	EE 30	Yasmin		Low	Low/ Unclear	None
	BCF	*Levlen 28 Nordette 28*	Altavera, Chateal, Kurvelo, Levonorgestrel and Ethinyl Estradiol, Levora 28, Marlissa, Portia 28	AB	Monophasic 28-days (21act + 7inert)	0.15 mg levonorgestrel	EE 30		Levlen 28 Nordette 28	Low	Medium	Medium
	UF	*Lo-Ovral 28*	Cryselle, Elinest, Low-Ogestrel	AB	Monophasic 28 days (21act;7inert)	0.3 mg norgestrel	EE 30	Lo Ovral 28	Lo Ovral 28	Low	Medium	Medium
	UF	*Desogen Ortho-Cept*	Cyred, Apri, Desogestrel and Ethinyl Estradiol , Emoquette, Enskyce, Juliber, Isibloom, Reclipsen	AB	Monophasic 28 days (21act;7inert)	0.15 mg desogestrel	EE 30	Desogen Ortho-Cept		Low	High	Low
	UF	*Loestrin 1.5/30*	Gildess 1.5/30, Junel 1.5/30, Larin 1.5/30, Microgestin 1.5/30	AB	Monophasic 21-days (21act) [patients ≥ 15 y/o]	1.5 mg norethindrone acetate	EE 30		Loestrin 1.5/30	Low	High	High
	UF	*Loestrin Fe 1.5/30*	Blisovi Fe 1.5/30, Gildess Fe 1.5/30, Junel Fe 1.5/30, Larin Fe 1.5/30, Microgestin Fe 1.5/30	AB	Monophasic 28-days (21act + 7inert) [patients ≥ 15 y/o]	1.5 mg norethindrone acetate	EE 30	Junel Fe 1.5/30 Larin Fe 1.5/30	Loestrin Fe 1.5/30	Low	High	High
	NF	*Safyral*	Safyral	-	Monophasic 28-days (24act w/ levomefolate 0.451mg + 4 levomefolate 0.451mg) [patients ≥ 14 y/o]	3 mg drospirenone	EE 30	Safyral		Low	Low/ Unclear	None

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Monophasics with 35 mcg EE	BCF	*Norinyl 1+35 Ortho-Novum 1/35*	Alyacen, Cyclafem, Dasetta, Necon, Nortrel, Pirmella	AB	Monophasic 28-days (21act + 7inert) [patients ≥ 15 y/o]	1 mg norethindrone	EE 35	Norinyl 1+35 Ortho-Novum 1/35		Medium	High	Medium
	BCF	*Ortho-Cyclen*	Estarylla, Mono-Linyah, Mononessa, Norgestimate and Ethinyl Estradiol, Previfem, Sprintec	AB	Monophasic 28-days (21act + 7inert)	0.25 mg norgestimate	EE 35	Ortho-Cyclen		Medium	Low	Low
	UF	*Brevicon Modicon*	Cyclefem 0.5/35, Necon 0.5/35, Nortrel 0.5/35, Wera	AB	Monophasic 28-days (21act + 7inert)	0.5 mg norethindrone	EE 35	Brevicon		Medium	Low	Low
	UF	*Demulen 1-35*	Kelnor 1-35, Zovia 1-35E	AB	Monophasic 28-days (21act + 7inert)	1 mg ethynodiol diacetate	EE 35	Demulen 1-35	Demulen 1-35	Medium	High	Low
	NF	*Femcon Fe Wymzya Fe*	Zenchent Fe	AB	Monophasic 28-days (21act + 7inert) CHEWABLE TABLET	0.4 mg norethindrone	EE 35	Femcon Fe Wymzya Fe		Medium	Low	Low
	NF	*Ovcon-35*	Balziva, Briellyn, Gildagia, Philith, Vyfemla, Zenchent	AB	Monophasic 28-days (21act +7inert)	0.4 mg norethindrone	EE 35		Ovcon 35	Medium	Low	Low
Monophasics with 50 mcg Estrogen	UF	*Norinyl 1+50 Ortho-Novum*	Necon	AB	Monophasic 28-days (21act + 7inert)	1 mg norethindrone	Mestranol 50	Norinyl 1+50 Ortho-Novum	Ortho-Novum	Medium	Medium	Medium
	UF	*Demulen 1/50*	Zovia 1/50E	AB	Monophasic 28-days (21act + 7inert)	1 mg ethynodiol diacetate	EE 50		Demulen 1/50	High	High	Medium
	UF	*Ovral-28*	Ogestrel	AB	Monophasic 28-days (21act + 7inert)	0.5 mg norgestrel	EE 50		Ovral-28	High	High	High
Extended Cycle/ Continuous Use Regimen	BCF	*Seasonale*	Jolessa (Only Jolessa is BCF)	AB	Extended cycle 91-day (84act + 7inert)	0.15 mg levonorgestrel	EE 30		Seasonale	Low	Medium	Medium
	UF		Introvale, Quasense, Setlakin, Levonorgestrel and Ethinyl Estradiol									
	NF	*LoSeasonique*	Amethia Lo, Camrese Lo, Levonorgestrel and Ethinyl Estradiol	AB	Extended cycle 91-day (84act-EE20 + 7EE10 only)	0.1 mg levonorgestrel	EE 20/10	LoSeasonique		Low	Low	Low
	NF	*Lybrel*	Amethyst, Levonorgestrel and Ethinyl Estradiol	AB	Continuous 28-days regimen (Non-cyclic) (28act)	0.09 mg levonorgestrel	EE 20		Lybrel	Low	Low	Low
	NF	*Seasonique*	Amethia, Ashlyna, Camrese, Daysee, Levonorgestrel and Ethinyl Estradiol	AB	Extended cycle 91-days (84act-EE30 + 7EE10 only)	0.15 mg levonorgestrel	EE 30/10	Seasonique		Low	Medium	Medium
Multiphasics	Biphasics											
	UF	*Ortho-Novum*	Necon 10-11	-	Biphasic 28-days (10act 0.5mg + 11act 1mg + 7inert)	0.5 mg/1 mg norethindrone	EE 35		Ortho-Novum	Medium	Medium	Medium
	UF	*Mircette*	Azurette, Bekyree, Desogestrel and Ethinyl Estradiol, Kariva, Kimidess, Pimtrea, Viorele	AB	Biphasic 28-days (21act-0.15mg w/EE20 + 2inert + 5EE10 only)	0.15 mg desogestrel	EE 20/10	Mircette		Low	High	Low
	NF	*Lo Loestrin Fe*	Lo Loestrin Fe	-	Biphasic 28-day cycle (24/2/2 cycle regimen) (24act + 2EE10 only + 2Fe)	1 mg norethindrone acetate	EE 10	Lo Loestrin Fe		Low	High	Medium

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Multiphasics (Cont'd)	**Triphasics**											
	BCF	*Ortho Tri-Cyclen*	Norgestimate and Ethinyl Estradiol, Tri-Estarylla, Tri-Linyah, Trinessa, Tri-Previfem, Tri-Sprintec	AB	Triphasic 28-day cycle (7act-0.18mg; 7act 0.21mg; 7act 0.25mg; 7inert)	0.18/0.215/0.25 mg norgestimate	EE 35	Ortho Tri-Cyclen		Medium	Low	Low
	UF	*Ortho Tri-Cyclen Lo*	Tri-Lo-Estarylla, Tri-Lo-Marzia, Tri-Lo-Sprintec	AB	Triphasic 28-day cycle (7act-0.18mg; 7act 0.21mg; 7act 0.25mg; 7inert)	0.18/0.215/0.25 mg norgestimate	EE 25	Ortho Tri-Cyclen Lo		Low	Low	Low
	UF	*Cyclessa*	Caziant, Velivet	AB	Triphasic 28-day cycle (7act 0.1mg;7act 0.125mg, 7act 0.15mg, 7inert)	0.1/0.125/0.15 mg desogestrel	EE 25	Cyclessa		Low	High	Low
	UF	*Tri-Levlen 28 Triphasil-28*	Enpresse, Levonest, Elifemme, Myzilra, Trivora	AB	Triphasic 28-day cycle (6act-0.5mg+30EE; 5act 0.75mg+ 40EE; 10act 0.125mg+30EE; 7inert)	0.05/0.075/0.125 mg levonorgestrel	EE 30/40/30		Tri-Levlen 28 Triphasil-28	Medium	Low	Low
	UF	*Tri-Norinyl*	Aranelle, Leena	AB	Triphasic 28-day cycle (7act 0.5mg;9act 1mg, 5act 0.5mg; 7inert) (patients > 15 y/o)	0.5/1/0.5 mg norethindrone	EE 35	Tri-Norinyl		Medium	Medium	Medium
	UF	*Ortho-Novum 7/7/7*	Alyacen 7/7/7, Cyclafem 7/7/7, Dasetta 7/7/7, Necon 7/7/7, Nortrel 7/7/7, Pirmella 7/7/7	AB	Triphasic 28-day cycle (7act 0.5mg;7act 0.75mg, 7act 1mg, 7inert) (patients > 15 y/o)	0.5/0.75/1 mg norethindrone	EE 35	Ortho-Novum 7/7/7		Medium	Medium	Medium
	NF	*Estrostep FE*	Tilia FE, Tri-Legest FE	AB	Triphasic 28-day cycle (5act 20EE;7act 30EE, 9act 35EE, 7Fe) (patients ≥ 15 y/o)	1 mg norethindrone acetate	EE 20/30/35	Estrostep FE		Low	High	Medium
	Quadriphasics											
	UF	*Quartette*	Quartette	-	Quadriphasic 91-day (Extended cycle) (42act-20EE; 21act-25EE; 21act-30EE; 7-10EE only)	0.15 mg levonorgestrel	EE 20/25/30/10	Quartette		Low	Medium	Medium
	NF	*Natazia*	Natazia	-	Quadriphasic 28-day (2act-3mg EV only; 5act-2mg+2mg EV; 17act-3mg+2mg EV; 2act-1mg EV only; 2inert)	2 mg/3 mg dienogest	Estradiol valerate 3/2/2/1 mg	Natazia		Low	Low/ Unclear	None
Progestogen Only	BCF	*Nor-QD*	Camila, Deblitane, Heather, Nora-BE, Norethindrone, Norlyroc	AB1	Progestin Only 28-day cycle (28act)	0.35 mg norethindrone	-	Nor-QD		-	Low	Low
		Ortho Micronor Micronor	Errin, Jencycla, Jolivette, Lyza, Norethindrone, Sharobel	AB2				Ortho Micronor Micronor				

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Non Oral Contraceptives (Transdermal Patch, Vaginal Ring, Injection)												
Miscellaneous Contraceptives	**Transdermal Patch (estrogen/progestin combination)**											
	UF	*Ortho Evra*	Xulane	AB	28 day regimen (3 patches/box) 1 patch/wk x 3 weeks; 7 days off	150 mcg/day norelgestromin	EE 35 mcg/day	Ortho Evra	Ortho Evra			
	Vaginal Ring (estrogen/progestin combination)											
	UF	*NuvaRing*	Nuvaring	-	28 day regimen (3 rings/box) 1 ring/wk x 3 weeks; 7 days off	0.12 mg/day etonogestrel	EE 15 mcg/day	Nuvaring				
	Injection (SubQ/IM) (progestin only)											
	UF	*Depo-SubQ Provera 104*	Depo-SubQ Provera 104	-	SubQ/90 days (12-14 weeks)	DMPA 104 mg/0.65mL	-	Depo-SubQ Provera 104				
	UF	*Depo-Provera*	Depot Medroxyprogesterone Acetate (DMPA)	AB	IM/90 days (13 weeks) Available as vial or syringe	DMPA 150 mg/mL	-	Depo Provera				

NOTES:

1. Drug names in GREEN are recently approved drugs with little to no DoD utilization data
2. "Brand Name" drug is for reference only; it may or may not be available on the market.
3. "Drug Name" identifies the currently available AB-rated generic equivalent products. If a generic is not available, the brand name is duplicated in this column as the sole available product.
4. "Branded NDC" indicates that there may be utilization data for a "Brand" drug. Consider dispensing a cost-effective AB-rated generic product if it is available at the Prime Vendor.
5. "Obsolete Drug" indicates that an NDC for a discontinued drug is still being used (primarily at the MTF); recommend switching to correct NDC to ensure accurate DoD utilization data.

B. Antifungals: Topical Lacquers

Background—The topical antifungal lacquers used for onychomycosis were reviewed for formulary placement, including ciclopirox 8% topical solution (Penlac, generic), efinaconazole 10% topical solution (Jublia), and tavaborole 5% topical solution (Kerydin). Comparisons to other treatment options used for onychomycosis (including oral terbinafine) were also reviewed by the P&T Committee but were not included in the formulary decision.

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

- The complete cure rates at one year with efinaconazole (Jublia) in the two pivotal trials were 17.8% and 15.2% for the active arms versus 3.3% and 5.5% in the vehicle arms, respectively. In comparison, complete cure rates at one year in the two pivotal trials with tavaborole (Kerydin) were 6.5% and 9.1% for the active arms versus 0.5% and 1.5% in the vehicle arms, respectively. Efficacy data with ciclopirox supports complete cure rates ranging from 5.5% to 8.5%. The variations in the complete cure rates achieved with Jublia, Kerydin, and ciclopirox may be explained by differences in the maximum percentage of nail involvement allowed in the trials

- Oral terbinafine (Lamisil, generics) is more effective than the topical antifungal lacquers, with complete cure rates ranging from 38% to greater than 50%.

- There is only minimal follow-up data beyond one year for Jublia and Kerydin, which limits the ability to assess recurrence rates with the newer agents, compared to other onychomycosis treatments. Data with ciclopirox show a 40% relapse rate at three months while terbinafine has a five-year relapse rate of 20%.

- The safety profiles for the topical antifungal lacquers appear similar and do not differ significantly from placebo vehicle. Both Jublia and Kerydin contain a warning regarding flammability, due to high alcohol content.

- Differences among the medication dispensers for the newer agents may result in product wastage. While tavaborole uses a simple dropper method, efinaconazole uses a brush applicator method. Ciclopirox requires removal after each continuous week of application and, unlike the newer agents, creates a tacky effect after application.

Overall Relative Clinical Effectiveness Conclusion: The treatment effect of the topical antifungals is modest at best, with complete cure rate failures exceeding 80%. The topical agents ciclopirox, efinaconazole, and tavaborole are not as effective as oral terbinafine. Overall, the newer entrants Jublia and Kerydin have a benign safety profile, but their modest clinical effectiveness should limit their use to patients who are unable to tolerate oral antifungal agents and who fail topical ciclopirox.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that oral terbinafine was the most cost-effective antifungal agent for onychomycosis, followed by ciclopirox 8% topical solution (Penlac; generic), and lastly followed by efinaconazole 10% topical solution (Jublia) and tavaborole 5% topical solution (Kerydin).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. Designating efinaconazole (Jublia) and tavaborole (Kerydin) as NF resulted in cost avoidance for the Military Health Service (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following:
   - UF:
     - Ciclopirox 8% topical solution (Penlac; generic)
   - NF:
     - Efinaconazole10% topical solution (Jublia)
     - Tavaborole 5% topical solution (Kerydin)

   Jublia and Kerydin were selected for NF status due to their minimal clinical advantages over ciclopirox, overall modest clinical effectiveness, and lack of cost effectiveness, particularly when compared to the clinically superior oral antifungal agent terbinafine.

   Note that as part of this recommendation, a topical lacquer was not added to the BCF. The BCF selection for the Antifungals includes clotrimazole cream (Topical Antifungals Subclass).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Jublia and Kerydin. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) modifying the current PA criteria for efinaconazole (Jublia) and tavaborole (Kerydin) originally recommended at the February 2015 P&T Committee meeting (and implemented August 19, 2015). PA criteria revisions were made to ensure a trial of both a topical antifungal agent and an oral antifungal agent, prior to utilization of Jublia or Kerydin. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 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 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Ophthalmic Anti-Inflammatory/Immunomodulatory Agents—Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)

Background—The ophthalmic immunomodulatory agents have not previously been reviewed for UF placement. Restasis is the only drug currently in this subclass. There are several pipeline products in this subclass, which will be reviewed upon FDA approval. Over-the-counter (OTC) ophthalmic wetting products (artificial tears) including carboxy- and hydroxypropyl-methylcellulose (Refresh, Celluvisc); polyvinyl alcohol (Hypotears), and high viscosity formulations (Systane, glycerin, and Refresh Endura) are used for mild to moderate dry eye symptoms, but were only reviewed for cost comparisons, and are not part of the UF decision.

Restasis is FDA-approved to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. In 2013, the American Academy of Ophthalmology stated that cyclosporine is appropriate for use in patients who have moderate to severe dry eye disease. In two clinical studies, Restasis 0.05% demonstrated efficacy in the treatment of moderate to severe dry eye disease, showing improvements in both objective and subjective measures. Restasis is safe in the treatment of moderate to severe dry eye diseases, with ocular burning and stinging occurring most commonly.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that Restasis demonstrated improvements in both signs and symptoms of dry eye disease.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that OTC ophthalmic wetting agents are the most cost effective, followed by cyclosporine 0.05% ophthalmic emulsion (Restasis).
- BIA was performed to evaluate the potential impact of designating cyclosporine 0.05% ophthalmic emulsion (Restasis) as formulary or NF on the UF. BIA results showed that designating Restasis as formulary demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 1 opposed, 0 abstained, 0 absent) cyclosporine 0.05% ophthalmic emulsion (Restasis) be designated UF.

   Note that the BCF drugs will remain Pred Forte and Pred Mild in the Ophthalmic Anti-Inflammatory/Immunomodulatory Agents—Ophthalmic Steroids Subclass.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) PA criteria for Restasis to ensure appropriate use. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD*** The P&T Committee recommended (15 for, 0 opposed, 0 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 August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VI. INNOVATOR DRUGS

Background—Section 702 of the FY15 National Defense Authorization Act (NDAA) established new authority for the P&T Committee's review process of FDA newly-approved innovator drugs. The P&T Committee is provided up to 120 days to recommend tier placement for innovator drugs on the UF. During this period, innovator drugs will be assigned a classification pending status; they will be available under terms comparable to NF drugs, unless medically necessary, in which case they would be available under terms comparable to formulary drugs. For additional information, see the August 2015 DoD P&T Committee meeting minutes at http://www.health.mil/PandT.

Drugs subject to the Innovator Rule are defined as new drugs that are approved by the FDA under a Biologic License Application (BLA) or New Drug Application (NDA). The NDA innovator drugs will be further defined by their chemical types to include, but not limited to, new molecular entities, new active ingredients, new dosage formulations, and new combinations.

A. Newly-Approved Innovator Drugs

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost effectiveness analysis presented for the innovator drugs. For the complete list of innovator drugs reviewed at the February 2016 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations, see Appendix E.

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

   - UF:
     - Asfotase alfa injection (Strensiq)
     - Elvitegravir/cobicistat/emtricitabine/tenofovir/alafenamide (Genvoya)
     - Naloxone nasal spray (Narcan Nasal)
     - Selexipag (Uptravi)
     - Patiromer (Veltassa)
     - Cobimetinib (Cotellic)
     - Ixazomib (Ninlaro)
     - Osimertinib (Tagrisso)
     - Alectinib (Alecensa)
     - Coagulation Factor X injection (Coagadex)
     - Antihemophilic factor, recombinant (rFVIII) injection (Adynovate)

   - NF:
     - Aspirin ER 162.5 mg (Durlaza)
     - Meloxicam low dose 5 mg and 10 mg (Vivlodex)
     - Rolapitant (Varubi)
     - Insulin degludec (Tresiba)
     - Amphetamine ER oral suspension (Dyanavel XR)
     - Glycopyrrolate oral inhaler (Seebri Neohaler)
     - Indacaterol/glycopyrrolate oral inhaler (Utibron Neohaler)

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for aspirin ER 162.5 mg (Durlaza), meloxicam low dose 5 mg and 10 mg (Vivlodex), rolapitant (Varubi), insulin degludec (Tresiba), amphetamine ER oral suspension (Dyanavel XR), glycopyrrolate oral inhaler (Seebri Neohaler), and indacaterol/glycopyrrolate oral inhaler (Utibron Neohaler). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) PA criteria for asfotase alfa injection (Strensiq). Strensiq is an orphan drug indicated for treatment of perinatal/infantile and juvenile-onset hypophosphatasia (HPP). This rare disease has a 50% mortality rate in infants who manifest within six months. No formulary alternative is available. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) an effective date upon signing of the minutes in all points of service.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Newly-Approved Innovator Drugs—Program Updates

Two administrative function updates were proposed for the innovator drug process, as outlined below.

1. **INNOVATOR DRUGS WITH NO FORMULARY ALTERNATIVE TO ADJUDICATE AS UF**—Currently, the DHA's Pharmacy Operations Division (POD) defines drug classes and assigns drugs to a UF class as part of the administrative processes required for the day-to-day operation of the UF. When a drug is assigned to a specific UF drug class, the formulary alternatives for the drug are also identified. A formulary agent is defined as a drug from the same drug class or used for the same indication as the NF drug.

   Innovator drugs are designated as NF (Tier 3 copayment) upon market entry. All NF medications, including innovator drugs, have MN criteria that establish clinical necessity based on 32 CFR Sec. 199.2. One of the criteria for MN approval is that there is no alternative pharmaceutical agent on the formulary. Some innovator drugs may have no UF alternatives, and a provider must document clinical necessity to obtain the drug when clinically necessary for each individual patient. The recommended authority below removes this requirement and the associated NF copayments when no alternative pharmaceutical agent exists on the UF.

   a) ***COMMITTEE ACTION: INNOVATOR DRUGS WITH NO FORMULARY ALTERNATIVE TO ADJUDICATE AS UF***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent):

      (1) The DHA POD, after consultation with a physician who is a DoD P&T Committee member or MHS specialist, may direct innovator products with no formulary alternative be made available under Tier 2 terms of the TRICARE pharmacy benefit, prior to a formal vote from the P&T Committee; and,

      (2) All innovator products, including those that the POD has determined have no formulary alternative, be reviewed by the P&T Committee at the next available meeting.

2. **DESIGNATION OF TEMPORARY SPECIFIC MN AND PA CRITERIA FOR INNOVATOR DRUGS**—General MN criteria for the Innovator program were approved at the August 2015 DoD P&T Committee meeting. While the general MN criteria are applicable to many of the innovator drugs, in certain cases more specific MN criteria are needed. Current DoD P&T processes may result in lengthy implementation periods for both MN and PA criteria for innovator drugs when they are formally reviewed by the DoD P&T Committee. The recommended authority below will allow the DHA POD to develop specific MN criteria (and PA criteria, if needed) for certain innovator drugs immediately after FDA approval and prior to market launch.

   a) ***COMMITTEE ACTION: DESIGNATION OF TEMPORARY SPECIFIC MN AND PA CRITERIA FOR INNOVATOR DRUGS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent):

      (1) The DHA POD has authority to administratively implement temporary specific MN/PA criteria on select innovator drugs at the time of product launch, using information available from the FDA (e.g., product labeling, FDA advisory committee recommendations, FDA drug safety board), from peer-reviewed national guidelines, or from the manufacturer.

      (2) Physicians who are P&T Committee members or MHS specialists will be consulted prior to implementation.

      (3) The temporary specific MN/PA criteria will only be active until the formal P&T Committee review process is complete (i.e., P&T Committee recommendations made during the next available meeting are implemented after approval by the DHA Director).

      (4) Implementation of permanent criteria will become effective upon signing of the minutes. All users who have established temporary specific MN/PA criteria will be grandfathered when the permanent criteria become effective, unless directed otherwise.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VII. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Gastrointestinal-2 (GI-2) Miscellaneous Drugs: Eluxadoline (Viberzi) Manual PA Criteria**—The GI-2 Miscellaneous Drug Class was reviewed by the P&T Committee in

November 2015. At the time of the November 2015 meeting, eluxadoline (Viberzi) was approved by the FDA but not yet commercially available.

Eluxadoline is a mixed mu-opioid receptor agonist that is FDA-approved for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). Because of the mechanism of action, several contraindications and warnings exist for the product, in addition to the potential for abuse. PA criteria was recommended for Viberzi due to the safety issues. Additionally, PA criteria also apply for rifaximin for treatment of IBS-D.

a) ***COMMITTEE ACTION: ELUXADOLINE (VIBERZI) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Viberzi in all new patients, consistent with the new FDA-approved product labeling and safety warnings. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: ELUXADOLINE (VIBERZI) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 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 August 10, 2016.

2. **Atypical Antipsychotics (AAPs): Brexpiprazole (Rexulti) Manual PA Criteria**
The AAPs, also known as the second generation antipsychotics, were reviewed by the P&T Committee in May 2011. Brexpiprazole is a new entrant to the class, and is FDA-approved for treating schizophrenia and as adjunct to antidepressant therapy for major depressive disorder. Brexpiprazole has serotonergic and dopaminergic effects similar to other AAPs.

   Manual PA criteria were recommended for Rexulti due to the similar mechanism of action and FDA labeling as aripiprazole (Abilify), which recently became available in generic formulations. The AAPs will be re-reviewed for formulary status at the May 2016 DoD P&T Committee meeting.

   a) ***COMMITTEE ACTION: BREXPIPRAZOLE (REXULTI) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for brexpiprazole (Rexulti) in all new patients. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: BREXPIPRAZOLE (REXULTI) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 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 August 10, 2016.

3. **Anticonvulsants: Lacosamide (Vimpat) Manual PA Criteria**—Lacosamide (Vimpat) was approved in 2008 and only has one FDA-approved indication for treating partial onset seizures. Because of the concern for off-label use, PA criteria were recommended. The Anticonvulsant Drug Class has not been previously reviewed by the P&T Committee, but will be reviewed for formulary placement at the May 2016 DoD P&T Committee meeting.

    a) ***COMMITTEE ACTION: LACOSAMIDE (VIMPAT) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for lacosamide (Vimpat) in all new patients, consistent with the new FDA-approved product labeling. See Appendix C for the full criteria.

    b) ***COMMITTEE ACTION: LACOSAMIDE (VIMPAT) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 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 August 10, 2016.

4. **Renin-Angiotensin-Antihypertensive Agents (RAAs): Sacubitril/Valsartan (Entresto) Automated and Manual PA Criteria**—The RAAs class was previously reviewed by the P&T Committee in May 2010. Automated (step therapy) criteria apply, requiring a generic angiotensin converting enzyme (ACE) inhibitor or preferred angiotensin receptor blocker (ARB), prior to use of a non-step preferred ACE inhibitor or ARB.

    Entresto is a new fixed-dose combination product containing the ARB valsartan (Diovan) and sacubitril, a neprilysin inhibitor. Sacubitril is a prodrug that inhibits neprilysin (neutral endopeptidase) through the active metabolite, leading to increased levels of peptides, including natriuretic peptides.

    Entresto is FDA-approved to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (New York Heart Association [NYHA] class II-IV) and a decreased left ventricular ejection fraction (LVEF). Several ACE inhibitors and the ARBs valsartan and candesartan (Atacand, generic) are indicated for patients with heart failure due to decreased LVEF.

    a) ***COMMITTEE ACTION: SACUBITRIL/VALSARTAN (ENTRESTO) AUTOMATED AND MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) automated and manual PA for Entresto in all new and current users, consistent with the current step therapy requirements for the RAAs class, and FDA labeling for Entresto. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: SACUBITRIL/ VALSARTAN (ENTRESTO) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 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 August 10, 2016.

5. **Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx) Manual PA Criteria**—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 (implemented on December 17, 2014). Secukinumab (Cosentyx) was reviewed by the P&T Committee in February 2015; automated and manual PA criteria were recommended (and implemented on May 4, 2015). In August 2015, Cosentyx was reviewed as a newly-approved drug for treating plaque psoriasis and was recommended for formulary status on the UF, requiring a trial of adalimumab (Humira), the step-preferred TIB, first.

   Secukinumab (Cosentyx) received a new FDA indication in January 2016 for treatment of psoriatic arthritis and ankylosing spondylitis in adults. The PA criteria were updated for Cosentyx to reflect the new FDA indication.

   a) ***COMMITTEE ACTION: SECUKINUMAB (COSENTYX) PA CRITERIA*** The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) revised manual PA criteria for secukinumab (Cosentyx) in new patients, consistent with the new FDA-approved product labeling for psoriatic arthritis and ankylosing spondylitis. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: SECUKINUMAB (COSENTYX) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) implementation of the PA for secukinumab (Cosentyx) become effective upon signing of the minutes.

B. Quantity Limits (QLs)

Quantity limits were reviewed for eight drugs: cobimetinib (Cotellic) for unresectable or metastatic melanoma, osimertinib (Tagrisso) and alectinib (Alecensa) for non-small cell lung cancer (NSCLC), ixazomib (Ninlaro) for relapsed or refractory multiple myeloma, and four inhalers for COPD including glycopyrrolate oral inhaler (Seebri Neohaler), glycopyrrolate/indacaterol oral inhaler (Utibron Neohaler), tiotropium bromide (Spiriva Respimat), and fluticasone/vilanterol (Breo Ellipta Institutional Pack).

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) QLs for cobimetinib (Cotellic), osimertinib (Tagrisso), alectinib (Alecensa), ixazomib (Ninlaro), glycopyrrolate oral inhaler (Seebri Neohaler), glycopyrrolate/indacaterol oral inhaler (Utibron Neohaler),

tiotropium bromide (Spiriva Respimat), and fluticasone/vilanterol (Breo Ellipta Institutional Pack). See Appendix D for the QLs.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

The P&T Committee reviewed two drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with the FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will require pre-authorization prior to use in the retail point of service (POS) and medical necessity at MTFs. These NF drugs will remain available in the Mail Order POS without pre-authorization.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended maintaining the current NF status for the following two products:
   - 13 for, 0 opposed, 0 abstained, 2 absent: Sebela Pharmaceuticals: calcitonin-salmon (Miacalcin), 200 International Units (3.7 mL) nasal spray. Note that Miacalcin nasal spray was designated NF when the osteoporosis drugs were reviewed at the June 2008 DoD P&T Committee meeting. Miacalcin will now require pre-authorization at the retail POS.
   - 14 for, 0 opposed, 0 abstained, 1 absent: Vanda Pharmaceuticals: tasimelteon (Hetlioz), 20 mg capsule. Note that Hetlioz was designated as NF at the February 2015 DoD P&T Committee meeting, with manual PA criteria and MN criteria.

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA FOR MIACALCIN NASAL SPRAY***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) the following pre-authorization criteria for Miacalcin 200 International Units (3.7 mL) nasal spray.

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

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

C. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA FOR HETLIOZ***
Note that tasimelteon (Hetlioz) will not be available in the Mail Order Pharmacy, as it

is only available in the Retail Network via a restricted distribution process, thus pre-authorization criteria do not apply.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) to maintain the existing PA criteria and MN criteria for tasimelteon (Hetlioz) from the February 2015 DoD P&T Committee meeting. See the February 2015 P&T Committee meeting minutes at http://www.health.mil/PandT.

D. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA FOR MIACALCIN***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday after a 30-day implementation period in the Retail Network for Miacalcin nasal spray; and 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation the effective date is June 8, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

IX. OTC DRUG REVIEW

A. Doxylamine

Section 702 of the FY13 NDAA provides legislative authority for the OTC Drug Program. The Final Rule published in the Federal Register on July 27, 2015, establishes the process for identifying OTC products for coverage under the TRICARE pharmacy benefit and the rules for making these products available to eligible DoD beneficiaries. The Final Rule can be found at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy.

The approved OTC drugs will comply with the mandatory generic policy stated in 32 CFR 99.21(j)(2) and be available under terms similar for generic drugs, except that the need for a prescription and/or a copayment may be waived in some circumstances. No cost-sharing for OTC drugs is required at any of the three POS for a uniformed service member on active duty.

Background—The P&T Committee evaluated the relative clinical and cost effectiveness and patient access considerations of adding doxylamine 25 mg (Unisom, generic) to the UF via the OTC Drug Program. Doxylamine has not previously been covered as a TRICARE pharmacy benefit under the OTC Demonstration Project; it is the first OTC drug to be considered under the new legislation.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) the following

- Doxylamine 25 mg (Unisom, generics) is available OTC as a sleep aid but is frequently used for treating nausea and vomiting of pregnancy (NVP), along with pyridoxine (vitamin B6). A prescription product, Bendectin, containing doxylamine and pyridoxine was discontinued from the market in the 1980s.
- In May 2015, the P&T Committee recommended NF status for Diclegis, a prescription product containing delayed release doxylamine succinate and pyridoxine, based on clinical and cost effectiveness. Manual PA criteria were also recommended, requiring a trial of nonpharmacologic interventions and OTC pyridoxine, and consideration of alternate antiemetics.
- The May 2015 P&T Committee also found the OTC ingredients of doxylamine with or without pyridoxine were therapeutically equivalent to Diclegis.
- Input from MTF obstetrics and gynecology providers voiced concern regarding worldwide availability of OTC doxylamine at all MTFs, and the potential for confusion due to the various OTC formulations of the product available in the retail setting (other products with the name "sleep aid" contain diphenhydramine).
- A trial conducted by the manufacturer of Bendectin in 1975 showed doxylamine monotherapy to be as effective and, in some endpoints, more effective than any other combination or monotherapy agent (e.g., doxylamine/pyridoxine, pyridoxine) for treating NVP.
- The September 2015 American College of Obstetrics and Gynecology (ACOG) Practice Bulletin also supports doxylamine for first-line use in the treatment of nausea and vomiting of pregnancy.
- Advantages of OTC doxylamine include its pregnancy category A rating, and the long history of efficacy and safety in both the OTC and prescription setting for treating NVP. Disadvantages include the sedating effects and need for multiple daily dosing, which may be a significant concern for some patients in setting of NVP.
- Providing doxylamine as an OTC TRICARE pharmacy benefit allows uniform availability of the product, and would enhance obstetric care and be consistent with the recently updated ACOG guidelines.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) OTC doxylamine 25 mg was less costly than the NF product Diclegis.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) adding OTC doxylamine 25 mg to the UF, based on clinical and cost effectiveness. As part of this recommendation, a prescription will be required for OTC doxylamine. Additionally, an age limit of patients less than 65 years of age was also recommended, to ensure appropriate use in accordance with Beers Criteria (a list of medications considered inappropriate for use in patients older than 65 years, due to the risk of adverse effects).

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) adding OTC doxylamine 25 mg to the BCF to ensure uniform patient access at all MTFs.

3. ***COMMITTEE ACTION: COPAYMENT WAIVER***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) waiving the copayment requirement for OTC doxylamine 25 mg. The copayment waiver was recommended because doxylamine is considered an acute use drug, with the majority of utilization expected at the MTFs and Retail Network pharmacies. Additionally, waiving the copayment would encourage use of the most cost-effective option for NVP and potentially shift utilization from agents with concerning safety profiles.

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period. Based on the P&T Committee's recommendation, the effective date is July 6, 2016

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

X. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM (EXPANDED MTF/MAIL PHARMACY INITIATIVE), AND NF (TIER 3) PHARMACEUTICALS AT MAIL ORDER

The P&T Committee was briefed on the initial implementation of the Expanded MTF/Mail Pharmacy Initiative, which began October 1, 2015, as well as ongoing implementation of the requirement that NF pharmaceutical agents be generally not available at MTFs or the Retail Network, but available in the Mail Order program.

For more information on these two programs, refer to the August 2015 and November 2015 DoD P&T Committee meeting minutes, available at http://www.health.mil/PandT. Page 10 also discusses the recommended exception to the latter requirement for NF contraceptives that would allow their continued availability at the retail POS.

The P&T Committee reviewed four drugs and agreed that the branded agents gabapentin (Gralise) and ibuprofen/famotidine (Duexis) are suitable for mail order dispensing (the acute use exception does not apply), and that tasimelteon (Hetlioz) and V-Go (a disposable insulin delivery device) are unable to be dispensed at mail order due to availability limitations.

XI. ITEMS FOR INFORMATION

The P&T Committee was briefed on the draft DoD/Veterans Affairs (VA) Continuity of Care Drug List, a joint list of medications for pain, sleep disorders, psychiatric, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by FY16 NDAA, Section 715.

XII. ADJOURNMENT

The meeting adjourned at 1145 hours on February 11, 2016. The next meeting will be in May 2016.

Appendix A—Attendance: February 2016 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Innovator Drugs: Formulary Recommendations

Appendix F—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary

Appendix G—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.

R.C. Bono
VADM, MC, USN
Director

160505
Date

Appendix A—Attendance: February 2016 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood for George Jones, PharmD, M.S.	Chief, DHA Operations Management Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
COL Jack Lewi, MC	Army, Internal Medicine Physician
Col William Hannah, MC	Air Force, Internal Medicine Physician
CDR Brian King, MC	Navy, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Shaun Carstairs, MC	Navy, Physician at Large
MAJ John Poulin, MC	Army, Physician at Large
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Guests	
Mr. Bruce Mitterer	DHA Contract Operations Division
Ms. Tammera Cardinal	DHA Contract Operations Division
MAJ Randall Sweeney	Defense Logistics Agency Troop
Ms. Amanda Doherty	Defense Logistics Agency Troop
CAPT Matt Baker	Indian Health Service
Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
CDR Marisol Martinez, USPHS	DHA Formulary Management Branch
MAJ Aparna Raizada, MS	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch

Appendix A—Attendance (continued)

Others Present	
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
David Meade, PharmD via DCS	DHA Integrated Utilization Branch
Robert Conrad, PharmD via DCS	DHA Operations Management Branch
LT Teisha Robertson via DCS	DHA Purchased Care Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Diana Loffgren	University of Texas Pharmacy Student
Caroline Kim	University of Maryland Pharmacy Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• Inhaled human insulin (Afrezza) **Non-Basal Insulins**	• Patient has experienced significant adverse effects from the formulary alternatives that are not expected to occur with Afrezza **Formulary Alternatives:** insulin aspart (NovoLog), insulin aspart 70/30 (NovoLog Mix), insulin lispro (Humalog), and insulin glulisine (Apidra),
• **Indomethacin low Dose 20 mg and 40 mg Capsules (Tivorbex)** • **Meloxicam Low Dose 5 mg and 10 mg Capsules (Vivlodex)** • Diclofenac potassium liquid filled capsules 25 mg (Zipsor) • Diclofenac potassium powder packets 50 mg (Cambia) • Naproxen sodium ER 375-, 500, & 750 mg (Naprelan CR, generics) • Mefenamic acid 250 mg (Ponstel, generic) • Ketorolac nasal spray (Sprix) • Famotidine/ibuprofen (Duexis) • Diclofenac low dose 18 mg and 35 mg capsules (Zorvolex) **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**	• Patient has experienced significant adverse effects from at least three formulary NSAIDs **Formulary Alternatives:** ibuprofen 400, 600 & 800 mg tablets and 125 mg/5 mL suspension (generic), indomethacin 25 & 50 mg (generic), meloxicam 7.5 mg & 15 mg (generic), naproxen 250 mg & 500 mg (generic), celecoxib (Celebrex generics), diclofenac potassium tablets (Cataflam generic), diclofenac sodium tablets (Voltaren generic), diclofenac/misoprostol (Arthrotec), naproxen sodium 275 mg & 550 mg (Anaprox, generic), naproxen/esomeprazole (Vimovo), diflunisal, etodolac, fenoprofen, flurbiprofen, ketoprofen, ketorolac, meclofenamate, nabumetone, oxaprozin, piroxicam, sulindac, tolmetin
• Olopatadine 0.7% ophthalmic solution (Pazeo) **Ophthalmic-1 Class: Ophthalmic Antihistamines/ Mast Cell Stabilizers**	• Use of formulary ophthalmic antihistamine/mast cell stabilizers are contraindicated • Use of formulary ophthalmic antihistamine/mast cell stabilizers have resulted in therapeutic failure **Formulary Alternatives:** olopatadine 0.1% (Patanol, generic), olopatadine 0.2% (Pataday), azelastine (Optivar), bepotastine (Bepreve), emedastine (Emadine), epinastine (Elestat)
• Efinaconazole 10% topical solution (Jublia) • Tavaborole 5% topical solution (Kerydin) **Antifungals: Topical Lacquers**	• Use of formulary agents is contraindicated **Formulary Alternatives:** ciclopirox 8% topical solution (Penlac, generic), oral terbinafine (Lamisil)
• Aspirin extended release 162.5 mg (Durlaza) **Antiplatelets**	• Patient cannot take over the counter (OTC) aspirin, clopidogrel, prasugrel (Effient), or ticagrelor (Brilinta) due to the following reasons: (Prescriber must supply a reason on the Medical Necessity Form.) **Formulary Alternatives:** OTC aspirin 325 mg and 81 mg, OTC enteric coated aspirin (Ecotrin, generic), OTC buffered aspirin (Bufferin, generic), clopidogrel (Plavix, generic), prasugrel (Effient), ticagrelor (Brilinta); aspirin 25 mg/dipyridamole 200 mg (Aggrenox); persantine

Drug / Drug Class	Medical Necessity Criteria
• Rolapitant (Varubi) **Antiemetic-Antivertigo Agents**	• Patient has experienced or is likely to experience significant adverse effects from the formulary agent. • Use of formulary agent has resulted in therapeutic failure. • Patient previously responded to Varubi and changing to a formulary agent would incur unacceptable risk. **Formulary Alternatives:** aprepitant (Emend)
• Insulin degludec (Tresiba) **Basal Insulins**	• Use of all the formulary long-acting (basal) insulins have resulted in therapeutic failure. **Formulary Alternatives:** insulin glargine (Lantus), insulin detemir (Levemir), Novolin N, Humulin N
• Amphetamine ER oral suspension (Dynavel XR) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	• Use of formulary ADHD stimulants is contraindicated • Patient has experienced significant adverse effects from formulary ADHD stimulants • Use of the formulary stimulants has resulted in therapeutic failure **Formulary Alternatives:** mixed amphetamine salts XR (Adderall XR, generic), methylphenidate ER oral suspension (Quillivant XR)
• Glycopyrrolate oral inhaler (Seebri Neohaler) **Long-Acting Muscarinic Antagonist (LAMAs)**	• The patient has experienced significant adverse effects from formulary drugs. **Formulary Alternatives:** tiotropium (Spiriva), aclidinium (Tudorza), umeclidinium (Incruse Ellipta)
• Indacaterol/Glycopyrrolate oral inhaler (Utibron Neohaler) **Long-Acting Beta Agonist (LABA)/LAMA**	• The patient has experienced significant adverse effects from formulary drugs. **Formulary Alternatives:** vilanterol/umeclidinium (Anoro Ellipta), olodaterol (Incruse Ellipta) used with tiotropium (Spiriva), olodaterol/tiotropium (Stiolto Respimat)
• Norethindrone acetate 1mg/ EE 20 mcg (Minastrin 24 Fe chewable) **Oral Contraceptive Products**	• No alternative formulary agent—Patient requires the nonformulary chewable contraceptive due to established swallowing difficulties. **Formulary Alternatives:** See Table 1 on pages 11–14 for the list of other contraceptive products available on the Uniform Formulary containing EE 20 mcg.
• Norethindrone acetate 0.8 mg/ EE 25 mcg (Generess Fe chewable, generics) **Oral Contraceptive Products**	• No alternative formulary agent—Patient requires the nonformulary chewable contraceptive due to established swallowing difficulties. • No alternate formulary agent—Patient's needs cannot be met with either a monophasic contraceptive with EE 20 mcg or EE 30 mcg, OR a multiphasic with EE 25 mcg. **Formulary Alternatives:** **Monophasic + EE 20 mcg**—norethindrone acetate 1 mg/EE 20 mcg (Microgestin Fe 1/20, generics; Microgestin 1/20, generics); levonorgestrel 0.1 mg/EE 20 mcg (Sronyx, Lutera, generics); drospirenone 3 mg/EE 20 mcg (Yaz, generics)

Drug / Drug Class	Medical Necessity Criteria
	Formulary Alternatives: (continued) **Monophasic + EE 30 mcg**—norethindrone acetate1.5 mg/EE 30 mcg (Microgestin Fe 1.5/30, generics; Microgestin 1.5/30, generics); levonorgestrel 0.15mg/EE 30 mcg (Levora-28, generics); drospirenone 3 mg/EE 30mcg (Yasmin, generics); norgestrel 0.3 mg/EE 30 mcg (Low-Ogestrel, generics); desogestrel 0.15 mg/EE 30 mcg (Reclipsen, Ortho Cept, generics) **Multiphasic + EE 25 mcg**—desogestrel 0.1/0.125/0.15 mg/EE 25 mcg (Velivet, generics); norgestimate 0.18/0.215/0.25 mg/EE 25 mcg (Ortho Tri-Cyclen Lo, Tri-Lo-Sprintec, generics)
• Norethindrone 0.4 mg/EE 35 mcg (Wymzya Fe chewable, generics) **Oral Contraceptive Products**	• No alternative formulary agent—Patient requires the nonformulary chewable contraceptive due to established swallowing difficulties. • No alternate formulary agent—Patient's needs cannot be met with either a monophasic contraceptive with EE 35 mcg OR a multiphasic with EE 35 mcg **Formulary Alternatives:** **Monophasic + EE 35 mcg**—norethindrone 0.5 mg/EE 35 mcg (Nortrel, 0.5/35, generics); norethindrone 1 mg/EE 35 mcg (Norinyl 1+35, generics); norgestimate 0.25 mg/EE 35 mcg (Mononessa, generics); ethynodiol diacetate 1 mg/EE 35 mcg (Zovia 1-35E, generics) **Multiphasic + EE 35 mcg**—norethindrone 0.5/1/0.5 mg/EE 35mcg (Leena and generics); norethindrone 0.5/0.75/1 mg/EE 35 mcg (Necon 7/7/7, Ortho-Novum 7/7/7, generics); norgestimate 0.18/0.215/0.25 mg/EE 35 mcg (TriNessa, Tri-Sprintec, generics)
• Drospirenone 3 mg/EE 20 mcg (Beyaz) • Norethindrone acetate 1 mg/EE 20 mcg (Lomedia 24 Fe; generics) • Drospirenone 3 mg/EE 30 mcg (Safyral) • Norethindrone 0.4 mg/EE 35 mcg (Balziva; generics) • Levonorgestrel 0.09 mg/EE 20 mcg (Amethyst; generics) • Levonorgestrel 0.15 mg/EE 30/10 mcg (Camrese; generics) • Levonorgestrel 0.1 mg/EE 20/10 mcg (Camrese Lo; generics) • Norethindrone acetate 1 mg/EE 10 mcg (Lo Loestrin Fe) • Norethindrone acetate 1 mg/EE 20/30/35 mcg (Tri-Legest Fe; generics) • Dienogest 2/3 mg and estradiol valerate 3/2/2/1 mg (Natazia) **Oral Contraceptive Products**	• The patient cannot be treated with formulary oral contraceptives due to the following reasons: (Prescriber must supply a reason on the Medical Necessity Form.) **Formulary Alternatives:** See Table 1 on pages 11–14 for the list of other contraceptive products available on the Uniform Formulary

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Inhaled insulin (Afrezza) **Insulins**	Manual PA criteria apply to all new and current users of Afrezza. Coverage is approved for non-smoking patients with either: **Type 1 Diabetes Mellitus (diagnosed)** • Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting subcutaneous (SC) insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin • Afrezza is used as adjunctive treatment to current basal insulin therapy • Spirometry testing [baseline forced expiratory volume in the first second (FEV_1) upon initiation with repeated FEV_1 at 6 months after initiation and repeated annually thereafter] has been performed **Type 2 Diabetes Mellitus (diagnosed)** • Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting SC insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin • Failure of or clinically significant adverse effect to two oral anti-diabetic agents (i.e., sulfonylurea, TZD, or DPP-4 inhibitor) if metformin is contraindicated • Spirometry testing (baseline FEV_1 upon initiation with repeated FEV_1 at 6 months after initiation and repeated annually thereafter) has been performed. Contraindications to the use of Afrezza: hypoglycemia, chronic lung disease [asthma, chronic obstructive pulmonary disease (COPD)], hypersensitivity to regular human insulin, or any Afrezza excipients PA does not expire.
• Efinaconazole 10% (Jublia) and tavaborole 5% (Kerydin) topical solutions **Topical Antifungals**	PA criteria apply to all new and current users of efinaconazole (Jublia) and tavaborole (Kerydin). (Updates are bolded.) Manual PA criteria: Jublia and Kerydin are approved if all of the following criteria apply: 1. The patient must have diagnostically confirmed onychomycosis by either potassium hydroxide (KOH) preparation, fungal culture, nail biopsy, or other assessment to confirm diagnosis. 2. The patient is immunocompromised, has diabetes mellitus or peripheral vascular disease and has swelling and/or redness in the surrounding nail tissue or pain in affected nail(s). 3. **The patient must have tried ciclopirox (Penlac) and had therapeutic failure AND** 4. **The patient must have tried one of the following oral agents: itraconazole (Sporonax) or terbinafine (Lamisil) and had therapeutic failure OR** • the patient has a contraindication (renal impairment, pre-existing liver disease, or evidence of ventricular dysfunction such as CHF) to one of the above antifungal agents, OR • the patient has had an adverse event/intolerance to one of the above antifungal agents 5. Treatment is requested due to a medical condition and not for cosmetic

Drug / Drug Class	Prior Authorization Criteria
	purposes. Examples include the following: • patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis • diabetic patients with additional risk factors for cellulitis • patients who experience pain/discomfort associated with the infected nail 6. The patient's condition is causing debility or a disruption in their activities of daily living. 7. . Have Jublia or Kerydin been used in the previous 24 months? If no, PA not approved. If yes, then proceed to next question. 8. Have Jublia or Kerydin been used in the past 30 days? If no, PA not approved; if yes, then PA is approved. PA expires after 1 year.
• Norethindrone acetate 1mg/ EE 20 mcg (Minastrin 24 Fe chewable) **Oral Contraceptive Products**	Manual PA criteria apply to all new users of Minastrin 24 Fe chewable tablets. Manual PA criteria: Coverage is approved for Minastrin 24 Fe chewable tablets if: • The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty. PA does not expire.
• Norethindrone acetate 0.8 mg/ EE 25 mcg (Generess Fe chewable, generics) **Oral Contraceptive Products**	Manual PA criteria apply to all new users of Generess Fe chewable tablets and generics. Manual PA criteria: Coverage is approved for Generess Fe chewable and generics if: • The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty. OR • Patient's needs cannot be met with either (1) a monophasic contraceptive containing ethinyl estradiol (EE) 20 mcg or EE 30 mcg, OR (2) a multiphasic contraceptive containing EE 25 mcg. PA does not expire.
• Norethindrone 0.4 mg/ EE 35 mcg (Wymzya Fe chewable, generics) **Oral Contraceptive Products**	Manual PA criteria apply to all new users of Wymzya Fe chewable tablets and generics. Manual PA criteria: Coverage is approved for Wymzya Fe chewable generics if: • The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty. OR • The patient's needs cannot be met with either (1) a monophasic contraceptive containing EE 35 mcg OR (2) a multiphasic with containing 35 mcg. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Cyclosporine 0.05% ophthalmic emulsion (Restasis) **Ophthalmic Anti-Inflammatory/ Immunomodulatory Agents—Ophthalmic Immunomodulatory Agents**	<u>PA criteria apply to all new users of Restasis.</u> • Current User is defined as a patient who has had Restasis dispensed during the previous 365 days at a Military Treatment Facility (MTF), a retail network pharmacy, or the mail order pharmacy. o If there is a Restasis prescription in the past 365 days (automated lookback with Restasis as the qualifying drug), the claim goes through and no manual PA is required. • New User is defined as a patient who has no had Restasis dispensed in the past 365 days. o If there is no Restasis prescription in the past 365 days, a manual PA is required. <u>Manual PA Criteria</u>: • Coverage is approved if one of the following is fulfilled: o Patient has diagnosis of Keratoconjunctivitis Sicca (KCS) with lack of therapeutic response to at least two OTC artificial tears agents o Patient has ocular graft vs. host disease o Patient has corneal transplant rejection o Patient has experienced documented corneal surface damage while using frequent artificial tears • Coverage is not approved for off-label uses such as, but not limited to: o Atopic keratoconjunctivitis (AKC)/vernal keratoconjunctivitis (VKC) o Pterygia o Blepharitis o Ocular rosacea o LASIK associated dry eye o Contact lens intolerance Prior Authorization expires in one year. • If there is a break in therapy, the patient will be subject to the PA again.
• Eluxadoline (Viberzi) **GI-2 Miscellaneous Drugs**	All new users of eluxadoline (Viberzi) are required to undergo manual prior authorization criteria. <u>Manual PA criteria</u>: Coverage will be approved if: • The patient is ≥ 18 years; AND • Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink ≤ 3 alcoholic beverages per day; AND • Patient has no history of marijuana use or illicit drug use in the previous 6 months; AND • Patient does not have severe hepatic impairment (Child-Pugh C); AND • Patient has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D); AND o The patient has had failure, intolerance, or contraindication to at least one antispasmodic agent; e.g., dicyclomine (Bentyl), Librax, hyoscyamine (Levsin), Donnatal, loperamide (Imodium) AND o The patient has had failure, intolerance, or contraindication to at least one tricyclic antidepressant (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline • Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Brexpiprazole (Rexulti) **Atypical Antipsychotics (AAPs)**	All new users of brexpiprazole (Rexulti) are required to undergo manual prior authorization criteria. Manual PA criteria: Coverage will be approved if: • Diagnosis of Major Depressive Disorder o The patient is ≥ 18 years; AND o The patient has had treatment failure of at least two other antidepressant augmentation therapies (one of which must be aripiprazole); OR o Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti) AND o Patient has concurrent use of an antidepressant • Diagnosis of schizophrenia o The patient is ≥ 18 years; AND o The patient has had treatment failure of at least two other atypical antipsychotics (one of which must be aripiprazole); OR o Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti) • Non-FDA approved uses are not approved. • Prior Authorization does not expire.
• Lacosamide (Vimpat) **Anticonvulsants**	All new users of lacosamide (Vimpat) are required to undergo manual prior authorization criteria. Manual PA criteria: • Coverage will be approved if the patient has a diagnosis of Seizure Disorder and Vimpat is used as monotherapy or adjunctive therapy in the treatment of partial-onset seizure in patients ≥ 17 years of age. • Coverage is not approved for the following: o Non-FDA approved indications o Diabetic neuropathic pain o Essential tremor • Prior Authorization does not expire.
• Sacubitril/valsartan (Entresto) **Renin-Angiotensin-Antihypertensive Agents (RAAs)**	Automated or manual PA criteria apply to all new and current users of Entresto. Automated PA criteria: • The patient has filled a prescription for a step-preferred RAA drug at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. • Step-preferred RAAs include lisinopril +/- hydrochlorothiazide (HCTZ), captopril +/- HCTZ, ramipril, losartan +/- HCTZ, valsartan +/- HCTZ, benazepril +/- HCTZ, enalapril +/- HCTZ, fosinopril +/- HCTZ, moexipril +/- HCTZ, perindopril, quinapril +/- HCTZ, telmisartan +/- HCTZ, telmisartan/amlodipine, valsartan/amlodipine, valsartan/amlodipine/HCTZ. Note that a history of candesartan +/- HCTZ also qualifies as meeting the step therapy criteria. Manual PA criteria: if automated PA criteria are not met, Entresto is approved if: • The patient has a documented diagnosis of chronic heart failure (New York Heart Association class II-IV heart failure) with left ventricular ejection fraction ≤40%. AND • The patient is receiving concomitant treatment with a beta blocker, or the patient has a contraindication to a beta blocker. AND • The patient is intolerant to an ACE inhibitor AND • The patient does not have a history of angioedema to ACE inhibitors or ARBs. • Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Secukinumab (Cosentyx) **Targeted Immunomodulatory Biologics (TIBs)**	Prior Authorization criteria originally approved February 2015 and implemented May 4, 2015. February 2016 changes to PA criteria in bold. Manual PA criteria for psoriatic arthritis and ankylosing spondylitis applies to new patients. Manual PA Criteria applies to all new users of secukinumab (Cosentyx). 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 Cosentyx if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • AND Coverage approved for patients > 18 years with: • Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy OR • **Psoriatic arthritis (February 2016) OR** • **Ankylosing spondylitis (February 2016)** Coverage is NOT provided for concomitant use with other TIBs. Prior Authorization does not expire.
• Asfotase alfa injection (Strensiq) **Metabolic Replacement Agents Miscellaneous**	Prior Authorization applies to all new and current users of Strensiq. Automated PA criteria • Strensiq will be approved for patients younger than one year of age Manual PA criteria—applies if patient is older than one year of age • Strensiq will be approved if: o The patient has the FDA-approved indication of perinatal/infantile and juvenile-onset hypophosphatasia (HPP) AND o The diagnosis is supported by confirmatory testing o Off-label uses are NOT approved Prior Authorization does not expire.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Cobimetinib (Cotellic) **Oncologic Agents: Melanoma**	▪ Retail Network: 63 tablets per 21 days ▪ MTF and Mail Order Pharmacy: 126 tablets per 42 days
• Osimertinib (Tagrisso) **Oncologic Agents: Non-small Cell Lung Cancer**	▪ Retail Network: 30 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 45 tabs per 45 days
• Ixazomib (Ninlaro) **Oncologic Agents: Multiple Myeloma**	▪ Retail Network: 3 tabs per 21 days ▪ MTF and Mail Order Pharmacy: 6 tabs per 42 days
• Alectinib (Alecensa) **Oncologic Agents: Non-small Cell Lung Cancer**	▪ Retail Network: 240 caps per 30 days ▪ MTF and Mail Order Pharmacy: 360 caps per 45 days
• Glycopyrrolate oral inhaler (Seebri Neohaler) **Pulmonary II Agents—LAMA**	▪ Retail Network: 1 inhaler (60 actuations) per 30 days ▪ MTF and Mail Order Pharmacy: 3 inhalers (180 actuations) per 90 days
• Glycopyrrolate/indacaterol oral inhaler (Utibron Neohaler) **Pulmonary II Agents—LAMA/LABA**	▪ Retail Network: 1 inhaler (60 actuations) per 30 days ▪ MTF and Mail Order Pharmacy: 3 inhalers (180 actuations) per 90 days
• Tiotropium (Spiriva Respimat) **Pulmonary II Agents—LAMA**	▪ Retail Network: 1 inhaler (60 actuations) per 30 days ▪ MTF and Mail: 3 inhalers (180 actuations) per 90 days
• Fluticasone/ vilanterol (Breo Ellipta) 200 25 mcg Institutional Pack **Pulmonary I Agents—ICS/LABAs**	▪ Retail Network, MTF and Mail Order Pharmacy: 1 Institutional Pack (14 inhalations) per 14 days

Appendix E—Table of Innovator Drugs: Formulary Recommendations

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Alectinib (Alecensa)	• Oral Oncology • Subclass: Lung Cancer • Not previously reviewed	• crizotinib (Xalkori)	• Advanced anaplastic lymphoma kinase positive non-small cell lung cancer (NSCLC) failing crizotinib	• ALK+ accounts for 2-7% of NSCLC • Few oral options after crizotinib failure • Approval based on tumor size reduction, requires additional studies to verify benefit • Approved with documented ALK+ FDA test • Pending Ph III study comparing as 1st line therapy	• UF
Amphetamine ER oral suspension (Dyanavel XR)	• Attention Deficit Hyperactivity Disorder • Subclass: Stimulants • Reviewed Nov 2015	• amphetamine sulfate (Evekeo) • methylphenidate ER suspension (Quillivant XR) • mixed amphetamine salts (Adderall IR and XR generics)	• ADHD	• The first amphetamine XR oral suspension • Other ADHD stimulant agents with a liquid dosage form on the UF	• NF
Antihemophilic factor recombinant (rFVIII) injection (Adynovate)	• Antihemophilic Factor • Subclass: Factor VIII • Reviewed Feb 2010	• Eloctate (extended half-life) • Kogenate FS, Recombinant	• Hemophilia A, Factor VIII deficiency	• New category of longer acting recombinant Factor VIII products • Pegylated FVIII allows extended half-life (14.3 hours with Adynovate vs. 10.4 hours with Advate) • Extended half- life allows for 1 less infusion/week • Uses most popular FVIII, Advate • Used for on demand treatment and prophylaxis	• UF
Asfotase alfa injection (Strensiq)	• Metabolic replacement agents miscellaneous • Not previously reviewed	• None –orphan drug	• Perinatal/infantile and juvenile-onset hypophosphatasia (HPP)	• 1st FDA-approved treatment for HPP • Tissue non-specific alkaline phosphatase (biologic) • In HPP, calcium and phosphate build up in the body causing damage to bones and organs • 50% mortality rate in infants • Strensiq showed statistical improvement in survival (infant/perinatal); and, in radiological scores, mobility, growth, and height (juveniles)	• UF

Aspirin extended release 162.5 mg (Durlaza; New Haven Pharma)	• Antiplatelets • Reviewed Feb 2012	• OTC ASA • clopidogrel	• Secondary Prevention • CV events (MI, unstable angina, chronic angina) • Stroke, TIA	• 505(b)(2) approval using aspirin data • Durlaza Tmax at 2 hours vs. 1 hour with Aspirin • No clinical studies • 1st low-dose prescription ER ASA • Several OTC aspirin (81 mg/325 mg) and prescription antiplatelets are available	• NF
Coagulation Factor X injection (Coagadex)	• Antihemophilic Factor • Subclass: Factor X • Reviewed Feb 2010	• fresh frozen plasma • Bebulin VH, Profilnine SD	• Hereditary Factor X deficiency	• Rare disease, 1 in 1 million • 1st purified Factor X in US/world, but not new practice as fresh frozen plasma (FFP) contains significant amounts of Factor X and provides current treatment choice • Human plasma-derived Factor X concentrate • Used for on-demand treatment and perioperative management of bleeding	• UF
Cobimetinib (Cotellic)	• Oncological Agent • Subclass: metastatic melanoma • Not previously reviewed	• vemurafenib (Zelboraf) • dabrafenib (Tafinlar) • trametinib (Mekinist)	• Unresectable or metastatic melanoma with the BRAF V600E or V600K mutation (combination with Zelboraf)	• Another approved BRAF/MEK inhibitor combination • Others include trametinib (Mekinist)/dabrafenib (Tafinlar) • Cotellic is not indicated for use in patients with wild-type BRAF melanoma	• UF
Elvitegravir,cobicistat, emtricitabine, tenofovir, alafenamide (Genvoya)	• Anti-retrovirals • Not previously reviewed	• Stribild	• HIV-1 in ≥12 years old antiretroviral naïve or to replace regimen in stable virologically-suppressed • Only for patients with pre-antiretroviral therapy CrCl >70 mL/min • No dose adjustment CrCl ≥ 30mL/min	• One of 5 recommended regimens for naïve patients (rating strong based on randomized controlled trial) with increased safety margin over similar combination	• UF

Glycopyrrolate oral inhaler (Seebri Neohaler)	• Pulmonary II • Subclass: LAMA • Reviewed May 2013	• tiotropium (Spiriva) • aclidinium (Tudorza) • umeclidinium (Incruse Ellipta)	• Long-term, maintenance treatment of COPD	• Seebri: Fourth LAMA to reach market. • Utibron: Third combination LAMA/LABA • There is no evidence to suggest that Seebri or Utibron is superior or inferior in safety or efficacy to the LAMAs or LABA/LAMA combinations currently available • Neohaler device requires BID dosing and a higher peak inspiratory flow rate compared to other devices • Seebri and Utibron offer no clinically compelling advantages over existing UF agents used in the long-term maintenance treatment of COPD	• NF
Glycopyrrolate Indacaterol oral inhaler (Utibron Neohaler)	• Pulmonary II • Subclass: LAMA/LABA • Reviewed May 2013	• olodaterol/tiotropium (Stiolto Respimat) • vilanterol/ umeclidinium(Anoro Ellipta)	• Long-term, maintenance treatment of airflow obstruction in COPD		• NF
Insulin degludec (Tresiba)	• Basal Insulins • Reviewed Feb 2010	• glargine (Lantus) • glargine (Basalgar) • detemir (Levemir) • Novolin N • Humulin N	• Diabetes mellitus	• The 1st "ultra-long-acting" basal insulin with a distinct, slow absorption which results in a flat and stable action profile • Dosed subcutaneously daily at any time • Degludec non-inferior to both glargine and detemir in improvement of glycemic control	• NF
Ixazomib (Ninlaro)	• Oral Oncology-Multiple Myeloma • Not previously reviewed	• lenalidomide (Revlimid) • bortezomib (Velcade) IV	• Multiple Myeloma	• 1st oral proteasome inhibitor; all oral regimen • Requires ≥ 1 prior therapy failure • Give in combo with lenalidomide plus steroid • Overall survival benefit yet to be demonstrated • Multiple combination regimens utilized IV/PO	• UF
Meloxicam low dose 5 and 10 mg (Vivlodex)	• NSAIDs • Reviewed May 2014	• meloxicam (Mobic) • celecoxib (Celebrex) • Ibuprofen (Motrin)	• Osteoarthritis pain	• 505(b)(2) approval using meloxicam (Mobic) data • The 3rd "SoluMatrix" NSAID allowing for faster dissolution resulting in similar Cmax and 20% lower AUC at a lower dose • Not interchangeable with other meloxicam (20% lower dose) • FDA review does not support manufacturer claim of improved pharmacokinetic profile	• NF

Naloxone nasal spray (Narcan Nasal)	• Alcohol deterrants-narcotic antagonists • Not previously reviewed	• naloxone hydrochloride IV/IM • naloxone IM/SQ Auto-injector (Evzio)	• Treatment of opioid overdose	• First non-injectable form of naloxone • Eliminates risk for contaminated needle stick	• UF
Osimertinib (Tagrisso)	• Oral Oncology • Subclass: NSCLC • Not previously reviewed	• erlotinib (Tarceva) • gefitinib (Iressa) • afatinib (Gilotrif)	• Advanced epidermal growth factor receptor (EGFR)-positive T790 mutation NSCLC failing EFGR therapy	• EGFR+ accounts for ~15% of NSCLC cases • No other agent approved for T790M mutation • Approved based on tumor size reduction; requires additional studies to verify benefit • Approved with documented T790M test	• UF
Patiromer (Veltassa)	• Binders-chelators-antidotes-overdose agents • Not previously reviewed	• sodium polystyrene sulfonate (Kayexalate)	• Treatment of hyperkalemia	• Can be used in patients with obstructive bowel disease (which is contraindicated with Kayexalate) • May be tolerated for long-term use, no report of GI tract ulceration or necrosis (which has been associated with Kayexalate) • Potential for chronic hyperkalemia management	• UF
Rolapitant (Varubi)	• Anti-Nausea • Reviewed May 2006	• aprepitant (Emend)	• Prevention of delayed nausea and vomiting associated with emetogenic cancer chemotherapy	• The second approved NK1 antagonist after aprepitant (Emend) • Half-life is approximately 7 days (Emend half-life is 9-13 hours) • Varubi only indicated for delayed chemotherapy-induced nausea and vomiting (CINV), whereas Emend is indicated for both acute and delayed CINV	• NF
Selexipag (Uptravi)	• PAH agents • Subclass: Prostacyclins • Reviewed Feb 2015	• treprostinil oral tab (Orenitram ER)	• Pulmonary arterial hypertension	• Selexipag is the 2nd available oral prostacyclin	• UF

Appendix F—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 2016	**Contraceptives: Oral Contraceptives and**	UF class review (previously reviewed Aug 2011)	▪ EE 20 mcg; 0.1 mg levonorgestrel (Lutera, Sronyx or equiv) ▪ EE 20 mcg; 3 mg drospirenone (Yaz or equiv) ▪ EE 30 mcg; 3 mg drospirenone (Yasmin or equiv) ▪ EE 30 mcg; 0.15 mg levonorgestrel (Levora-28, or equiv) ▪ EE 35 mcg; 0.25 mg norgestimate (Mononessa, or equiv) ▪ EE 35 mcg; 1.0 mg norethindrone (Norinyl 1+35, or equiv) ▪ EE 35 mcg; 0.18/0.215/0.25 mg norgestimate (TriNessa, or equiv) ▪ 0.35 mg norethindrone (Nor-QD, Jolivette or equiv) ▪ EE 30 mcg; 0.15 mg levonorgestrel extended cycle **(Jolessa only)**	▪ EE 20 mcg; 1.0 mg norethindrone (Microgestin 1/20 or equiv) ▪ EE 20 mcg; 1.0 mg norethindrone; ferrous fumarate (Microgestin Fe 1/20 or equiv) ▪ EE 30 mcg; 0.3 mg norgestrel (Low-Ogestrel or equiv) ▪ EE 30 mcg; 1.5 mg norethindrone (Microgestin 1.5/30 or equiv) ▪ EE 30 mcg; 1.5 mg norethindrone; ferrous fumarate (Microgestin Fe1.5/30 or equiv) ▪ EE 30 mcg; 0.15 mg desogestrel (Reclipsen or equiv) ▪ EE 35 mcg; 1.0 mg ethynodiol diacetate (Zovia 1-35E; or equiv) ▪ EE 35 mcg; 0.5 mg norethindrone (Nortrel 0.5/35 or equiv) ▪ EE 50 mcg; mestranol 50 mcg; 1 mg norethindrone (Norinyl 1+50 or equiv) ▪ EE 50 mcg; 1 mg ethynodiol diacetate (Zovia 1-50E or equiv) ▪ EE 50 mcg; 0.5 mg norgestrel (Ogestrel or equiv)	▪ EE 20 mcg; 1.0 mg norethindrone acetate ferrous fumarate (Minastrin 24 FE chew) ▪ EE 20 mcg; 3 mg drospirenone; levomefolate calcium 0.451mg (Beyaz) ▪ EE 20 mcg/norethindrone acetate 1 mg ferrous fumarate – 24 day regimen (Loestrin 24 Fe or equiv) ▪ EE 10 mcg; 1.0 mg norethindrone; ferrous fumarate (Lo Loestrin Fe) ▪ EE 25 mcg; 0.8 mg norethindrone acetate ferrous fumarate (Generess Fe chew) ▪ EE 30 mcg; 3 mg drospirenone; levomefolate calcium 0.451mg (Safyral) ▪ EE 35 mcg; 0.4 mg norethindrone (Balziva or equiv) ▪ EE 35 mcg; 0.4 mg norethindrone	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪PA now applies to Minastrin Fe 24 chew, Generess FE chew, and Wymzya Fe chew tablets – See Appendix C	▪No changes made to BCF choices ▪Minastrin Fe 24 and Generess Fe chewables now NF ▪Jolessa generics now UF; Jolessa remains BCF

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
			▪ Norethindrone 0.35 mg (Nor-Q-D or equiv)	▪ EE 30 mcg; 0.15 mg levonorgestrel extended cycle (Quasense, Introvale, Setlakin or equiv); Jolessa only is BCF ▪ EE 35 mcg; 0.5/1.0 mg norethindrone (Necon 10/11) ▪ EE 20/10 mcg; 0.15 mg desogestrel (Azurette or equiv) ▪ EE 25 mcg; 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo or equiv) ▪ EE 35 mcg; 0.18/0.15/0.25 mg norgestimate (TriNessa or equiv) ▪ EE 35 mcg; 0.5/0.75/1 mg norethindrone (Necon 7/7/7 or equiv) ▪ EE 35 mcg; 0.5/1/0.5 mg norethindrone (Leena or equiv) ▪ EE 30/40/30 mcg; 0.05/0.075/0.125 mg levonorgestrel (Trivora-28 or equiv) ▪ EE 25 mcg; 0.1/0.125/0.15 mg desogestrel (Velivet or equiv) ▪ EE 20/25/30/10 mcg/levonorgestrel 0.15 mg (Quartette)	acetate ferrous fumarate (Wymzya Fe chew or equiv) ▪ EE 20 mcg/levonorgestrel 0.9 mg – 28 day continuous regimen (Amethyst or equiv) ▪ EE 30/10 mcg; 0.15 mg levonorgestrel (Camrese or equiv ▪ EE 20/10 mcg; 0.10 mg levonorgestrel (Camrese Lo or equiv) ▪ EE 20/30/35 mcg; norethindrone 1 mg ferrous fumarate (Tri-Legest Fe or equiv) ▪ Estradiol valerate 3/2/2/1 mg; dienogest 2/3 mg (Natazia)			

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 2016	**Contraceptives: Miscellaneous Contraceptives**	UF class review (previously reviewed Aug 2011)	Miscellaneous Contraceptives (None)	▪ norelgestromin 150 mcg + EE 35 mcg transdermal (Xulane, equiv to discontinued Ortho-Evra) ▪ etonogestrel 0.12 mg +EE 15 mcg vaginal ring (NuvaRing) ▪ 104 mg/0.65mL depot medroxyprogesterone acetate injection (Depo-Subq Provera 104) ▪ 150 mg/mL depot medroxyprogesterone acetate injection IM and SC (Depo-Provera; generics)	▪ None	Pending signing of the minutes / 90 days The effective date is August 10, 2016.		
Feb 2016	**Antifungals Topical Lacquers Subclass**	UF class review	BCF: None (BCF selections from the Antifungals Drug Class include clotrimazole)	▪ ciclopirox 8% topical solution (Penlac, generic)	▪ efinaconazole 10% topical solution (Jublia) ▪ tavaborole 5% topical solution (Kerydin)	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪Prior authorization applies for Jublia and Kerydin (revised from Feb 2015) – See Appendix C	
Feb 2016	**Ophthalmic Anti-Inflammatory/ Immuno-modulatory Agents: Ophthalmic Immuno-modulatory Agents Subclass**	UF class review	BCF: None (BCF Ophthalmic Anti-Inflammatory Drugs include Pred Mild and Pred Forte)	▪ cyclosporine 0.05% ophthalmic emulsion (Restasis)	▪ None	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪Prior authorization applies for Restasis – See Appendix C	

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 2016	**Non-Basal Insulins**	New Drug Class previously reviewed in 1999 and Aug 2003 (Pre-UF Rule decision)	**August 2003** ▪ insulin aspart (NovoLog vials) ▪ 70% insulin aspart protamine suspension/30% insulin aspart (NovoLog Mix vials) **May 2010** ▪ insulin aspart pen and cartridges (NovoLog FlexPen; NovoLog PenFill cartridges) ▪ 70% insulin aspart protamine suspension/30% insulin aspart pen injection device (NovoLog Mix 70/30 FlexPen)	Aug 2003 Pre-UF Rule decision ▪ Insulin lispro (Humalog)	**Feb 2016** ▪ **Inhaled insulin (Afrezza)**	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪Afrezza PA applies from May 2015 – See Appendix C	

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 2016	**NSAIDs**	New Drug Class previously reviewed Aug 2011	▪ ibuprofen 400 mg, 600 mg & 800 mg tablets & 125 mg/5 mL susp (generic) ▪ indomethacin 25 mg & 50 mg (generic) ▪ meloxicam 7.5 mg & 15 mg (generic) ▪ naproxen 250 mg & 500 mg (generic) & 125 mg/5 mL susp (generic)	▪ celecoxib (Celebrex) ▪ diclofenac/misoprostol (Arthrotec) ▪ diclofenac potassium tablets (Cataflam generic) ▪ diclofenac sodium tablets (Voltaren generic) ▪ diflunisal ▪ etodolac ▪ fenoprofen ▪ flurbiprofen ▪ ketoprofen ▪ ketorolac ▪ meclofenamate ▪ nabumetone ▪ naproxen sodium 275 mg & 550 mg (Anaprox, generic) ▪ oxaprozin ▪ piroxicam ▪ sulindac ▪ tolmetin ▪ naproxen/esomeprazole (Vimovo)	**Feb 2016** ▪ **indomethacin low dose 20 and 40 mg capsules (Tivorbex)** ▪ **meloxicam low dose 5 and 10 mg capsules (Vivlodex)** May 2014 ▪ diclofenac low dose 18 and 35 mg capsules (Zorvolex) Aug 2011 ▪ diclofenac potassium liquid filled capsules (Zipsor) 25 mg ▪ diclofenac potassium powder packets 50 mg (Cambia) ▪ naproxen sodium ER (Naprelan CR, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card ▪ mefenamic acid (Ponstel, generic) 250 mg	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	N/A	▪ New MN Criteria applies to all NF NSAIDs. 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
Feb 2016	**Ophthalmic-1s – Dual Action Ophthalmic Antihistamines and Mast Cell Stabilizers**	New Drug Class previously reviewed Aug 2010	▪ olopatadine 0.1% (Patanol; generics)	▪ bepotastine (Bepreve) ▪ olopatadine 0.2% (Pataday) ▪ azelastine (Optivar, generics) ▪ Epinastine (Elestat)	**Feb 2016** ▪ **olopatadine 0.7% (Pazeo)** **Feb 2012** ▪ alcaftadine (Lastacaft)	Pending signing of the minutes / 90 days The effective date is August 10, 2016.		
Feb 2016	**Long-Acting Beta Agonists (LABAs)**	New Drug Class previously reviewed Feb 2009	▪ Salmeterol (Serevent Diskus)	**Feb 2016** ▪ **olodaterol (Striverdi Respimat)** **Feb 2009** ▪ formoterol (Foradil) ▪ arformoterol nebulized solution (Brovana)	**May 2014** ▪ formoterol nebulized solution (Arcapta Neohaler) **Feb 2009** ▪ formoterol nebulized solution (Perforomist)	N/A	▪QL apply	

TRICARE Formulary Search tool: http://www.express-scripts.com/tricareformulary

BCF: Basic Core Formulary
ECF: Extended Core Formulary
ER: extended release
IR: immediate release

Appendix G—Table of Abbreviations

AAPs	atypical antipsychotics
AC	allergic conjunctivitis
ACE	angiotensin converting enzyme
ARB	angiotensin receptor blocker
ACOG	American College of Obstetrics and Gynecology
ADHD	attention deficit hyperactivity disorder
AH/MCS	antihistamine/mast cell stabilizer
AKC	atopic keratoconjunctivitis
AUC	area under the curve
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
CD	controlled delivery
CFR	Code of Federal Regulations
CINV	chemotherapy-induced nausea and vomiting
CMA	cost minimization analysis
Cmax	maximum (peak) plasma concentration
COPD	chronic obstructive pulmonary disease
CrCl	creatinine clearance
CV	cardiovascular
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DoD	Department of Defense
DPP4	dipeptidyl peptidase-4 inhibitor
ECF	Extended Core Formulary
EE	ethinyl estradiol
EGFR	epidermal growth factor receptor
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
Fe	iron
FEV_1	forced expiratory volume in one second
FFP	fresh frozen plasma
FY	fiscal year
GCN	generic code number
GI-2	Gastrointestinal-2 Miscellaneous Drugs
HCTZ	hydrochlorothiazide
HF	heart failure
HPP	hypophosphatasia
IBS	irritable bowel syndrome
IBS-D	diarrhea-predominant irritable bowel syndrome
IM	intramuscular
IR	immediate release
KCS	keratoconjunctivitis sicca

KOH	potassium hydroxide
LABA	long-acting beta agonist
LAMA	long-acting muscarinic antagonists
LVEF	left ventricular ejection fraction
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDA	New Drug Application
NDAA	National Defense Authorization Act
NF	nonformulary
NSAIDs	non-steroidal anti-inflammatory drugs
NSCLC	non-small cell lung cancer
NVP	nausea and vomiting of pregnancy
NYHA	New York Heart Association
OCPs	oral contraceptive products
OTC	over-the-counter
ODT	orally dissolving tablet
P&T	Pharmacy and Therapeutics
PA	prior authorization
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
RAAs	Renin Angiotensin-Antihypertensives Drug Class
QD	once daily
QLs	quantity limits
SC	subcutaneous
Tmax	time to reach maximum (peak) plasma concentration
TFL	TRICARE for Life
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary
VA	U.S. Department of Veterans Affairs
VKC	vernal keratoconjunctivitis