DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

November 2015

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 18 and 19, 2015, 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 August Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes from the August 2015 DoD P&T Committee meeting on October 30, 2015.

III. REQUIREMENTS

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

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. Alzheimer's Disease Agents: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric)

Memantine extended release (Namenda XR) is an N-methyl-D-aspartate (NMDA) receptor antagonist approved for once daily dosing in the treatment of moderate to severe Alzheimer's disease. The immediate release (IR) formulation of memantine (Namenda IR) is now available in a generic formulation. Namzaric is a fixed-dose combination product containing memantine extended release (ER) and donepezil (Aricept), the most commonly prescribed acetylcholinesterase inhibitor.

Although there are no well-conducted head-to-head studies that compare Namenda XR or Namzaric with other Alzheimer's drugs, the two new drugs appear similar to their IR and individual components in terms of efficacy and safety. Namenda XR and Namzaric provide a modest clinical benefit at best, and some efficacy endpoints in the clinical trials showed no benefit at all. While Namenda XR and Namzaric offer the convenience of once daily dosing, there is no data to support any additional clinical benefit of combining an NMDA receptor antagonist with an acetylcholinesterase inhibitor. There is no data available to support the fixed-dose combination improves adherence.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the main benefits for Namenda XR and Namzaric are their once daily dosing, which provides a convenience to caregivers or patients with swallowing difficulties. Aside from this factor, the memantine IR version and the individual components of memantine and donepezil are clinically interchangeable with the memantine ER version (Namenda XR) and combination product (Namzaric).

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed. The P&T Committee concluded (16 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: donepezil (Aricept, generics), memantine IR (Namenda, generics), galantamine (Razadyne, generic), donepezil orally dissolving tablet (Aricept ODT, generic), rivastigmine (Exelon, generic), galantamine ER (Razadyne ER), memantine ER (Namenda XR), memantine ER/donepezil (Namzaric), rivastigmine transdermal system (Exelon Patch).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) memantine ER (Namenda XR) and memantine ER/donepezil (Namzaric) be designated NF.

2. ***COMMITTEE ACTION: MN RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Namenda XR and Namzaric. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—Manual PA criteria were recommended at the August 2015 DoD P&T Committee meeting, with an implementation date of February 3, 2016. The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) maintaining the previously approved PA criteria for Namenda XR and Namzaric. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF, PA, AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first

Wednesday after a 90-day implementation period; 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 May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Attention Deficit Hyperactivity Disorder (ADHD): Stimulants

Background—The ADHD stimulants were reviewed for formulary placement. The full class, including the nonstimulants and wakefulness promoting agents, was previously reviewed in February 2012. New entrants to the class include amphetamine sulfate tablets (Evekeo), methylphenidate ER capsules (Aptensio XR), and dextroamphetamine tablets (Zenzedi). The only products that do not have generic equivalents include methylphenidate ER oral suspension (Quillivant XR), methylphenidate transdermal system (Daytrana), and lisdexamfetamine (Vyvanse).

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

- The new entrants to the class, Evekeo, Aptensio XR, and Zenzedi do not contain new chemical entities; they were approved by the FDA using data from previously approved drugs. There are no head-to-head studies between any of the new entrants and other ADHD stimulants. The active ingredients for the new drugs are available in generic formulations that are on the UF.
- Quillivant XR is the only long-acting methylphenidate oral suspension on the market and is approved for children as young as six years of age. Immediate release methylphenidate and dextroamphetamine oral solutions are therapeutic alternatives to Quillivant XR, but must be dosed twice daily.
- Daytrana is the only transdermal patch available for ADHD, but is associated with skin reactions.
- Vyvanse is currently designated NF and is approved for children and adults with ADHD. A review of Military Health System (MHS) prescribing habits shows that the vast majority of utilization for all the ADHD drugs, including Vyvanse, is in the population aged five to 14 years. Vyvanse has a new FDA-approved indication for binge eating disorder, but other therapies, including topiramate, zonisamide, and the selective serotonin reuptake inhibitors are also commonly used for this condition.
- For patients with swallowing difficulties, the following products can be used:

- Vyvanse is dissolvable in water.
- Ritalin LA, Metadate CD, Adderall XR, and Focalin XR capsules can be opened and their contents can be sprinkled on food.

- All the stimulants contain a black box warning for potential abuse and dependency.

Overall Relative Clinical Effectiveness Conclusion: There were no significant updates to the previous clinical conclusions from the February 2012 UF class review. The ADHD stimulants have a high degree of therapeutic interchangeability, although there are differences in the duration of action between products. The branded ADHD stimulants: Quillivant XR, Vyvanse, Daytrana, Zenzedi, Evekeo, and Aptensio XR offer no additional clinical advantages over the other stimulant agents on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results for brand-only agents showed that methylphenidate ER capsules (Aptensio XR) was the most cost-effective agent, followed by methylphenidate transdermal system (Daytrana), lisdexamfetamine (Vyvanse), methylphenidate ER oral suspension (Quillivant XR), and amphetamine tablets (Evekeo).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Aptensio XR, Quillivant XR, and Evekeo as formulary, with Daytrana and Vyvanse as NF, demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:
    - UF:
        - amphetamine sulfate tabs (Evekeo)
        - methylphenidate ER oral suspension (Quillivant XR suspension)
        - methylphenidate ER (Aptensio XR)
        - methamphetamine (Desoxyn, generic)
        - dextroamphetamine (Dexedrine spansule, Dextrostat tabs, ProCentra solution, generics; Zenzedi tabs)
        - mixed amphetamine salts ER (Adderall XR; generic)
        - mixed amphetamine salts IR (Adderall, generic)
        - methylphenidate osmotic controlled release oral delivery system (OROS) (Concerta; generic)
        - methylphenidate CD (Metadate CD; generic)
        - methylphenidate IR (Ritalin, generic)
        - methylphenidate LA (Ritalin LA, generic)
        - methylphenidate SR (Ritalin SR, generic)
        - methylphenidate ER (Metadate ER, Methylin ER, generic)

- methylphenidate chewable tablets, solution (Methylin, generic)
- dexmethylphenidate IR (Focalin; generic)

- NF
  - lisdexamfetamine (Vyvanse)
  - methylphenidate transdermal system (Daytrana)
  - dexmethylphenidate ER (Focalin XR, generic)

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:
   - Maintaining the following drugs on the BCF:
     - mixed amphetamine salts ER (Adderall XR; generic)
     - methylphenidate osmotic controlled release oral delivery system (OROS) (Concerta; generic)
   - Removing the following drugs from the BCF; they will remain UF
     - Methylphenidate ER (Ritalin LA, generic)
     - Methylphenidate IR (Ritalin IR, generic)

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) maintaining the current MN criteria for Daytrana and dexmethylphenidate ER (Focalin XR, generic). The P&T Committee also recommended updating the current MN criteria for Vyvanse. The MN criteria for Vyvanse will not include binge eating disorder. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: UF AND IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Antirheumatics: Injectable Methotrexate

Background—Methotrexate received FDA approval for the treatment of rheumatoid arthritis (RA) and psoriasis in 1959. Methotrexate is one of the most studied disease-modifying antirheumatic drugs (DMARD) and is a cornerstone of therapy for treating RA. Currently, injectable methotrexate is available in a generic 50 mg/2 mL vial formulation and two auto-injectors, Otrexup and Rasuvo. Injectable methotrexate products are administered subcutaneously.

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

- Methotrexate low-dose oral and injectable vial formulations:
    - Methotrexate absorption via the oral route is variable, especially at doses greater than 15 mg. In contrast, subcutaneous (SC) methotrexate injections are completely absorbed. Most patients prefer oral over SC methotrexate therapy.
    - Anecdotal observations report that some gastrointestinal toxicities may be avoided by administering methotrexate subcutaneously.
    - A 2014 Cochrane Review concluded there was moderate to high quality evidence demonstrating that oral methotrexate, in doses ranging between 5 mg to 25 mg, has a substantial clinical and statistically significant benefit in efficacy outcomes compared to placebo. There was a 16% discontinuation rate due to adverse events with oral methotrexate compared to 8% with placebo.
    - In 2008, a randomized controlled trial comparing the efficacy and safety of oral and SC methotrexate reported SC administration was significantly more effective than oral administration at the same dosage, with no difference in tolerability profiles.
- Methotrexate low-dose injectable vials and auto-injector formulations:
    - There are no head-to-head trials or systematic reviews comparing the different types of injectable methotrexate formulations.
    - The two new auto-injectors, Otrexup and Rasuvo, were FDA approved through 505(b)(2) applications by demonstrating bioequivalence to the generic injectable methotrexate vial formulations.
    - There are no clinical trials that demonstrate Otrexup or Rasuvo auto-injectors provide greater benefit to patients over oral or conventionally injected methotrexate using vials. There is no comparative effectiveness, safety, or tolerability data.
    - There is a high degree of therapeutic interchangeability for the injectable methotrexate delivery options.

Overall Relative Clinical Effectiveness Conclusion: Except for patient convenience, the methotrexate pre-filled auto-injector formulations of Otrexup and Rasuvo offer no additional clinical advantages over generic methotrexate vials. The benefit of the new products may be limited to a niche group of patients with limited vision, decreased finger dexterity, or impaired

cognition.

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

- CMA results showed that injectable methotrexate in the vial formulation was the most cost-effective injectable agent, followed by Otrexup and Rasuvo.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating methotrexate injectable vials as formulary, with Otrexup and Rasuvo designated NF, demonstrated the largest estimated cost avoidance for the MHS.

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

    - UF:
        - Methotrexate 50 mg/2 mL vials
    - NF:
        - Methotrexate auto-injector (Otrexup)
        - Methotrexate auto-injector (Rasuvo)

    NOTE: As part of this recommendation, generic methotrexate 2.5 mg tablets remain on the BCF in the Antirheumatics Drugs Class (pre-UF Rule decision).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for the methotrexate auto-injectors (Otrexup and Rasuvo). See Appendix B for the full criteria.
3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) PA criteria for the methotrexate auto-injectors (Otrexup and Rasuvo). See Appendix C for the full criteria.
4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) QLs for Otrexup and Rasuvo auto-injectors, consistent with the product labeling. See Appendix D for the QLs.
5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent)

1) an effective date of the first Wednesday after a 90-day implementation period in all points of service (POS); and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Acne Drugs: Oral Isotretinoins

Background—The oral isotretinoin acne agents were reviewed for formulary placement. All the products in the class have the same active ingredient, isotretinoin. The class is comprised of AB-rated generic formulations of Accutane, including Amnesteem, Claravis, Myorisan and Zenatane, and a branded product, Absorica.

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

- The oral isotretinoins, including Absorica, have the same FDA indication, labeling, efficacy, side effect profile, and drug interaction profile. As a subclass, the oral isotretinoins are effective in achieving a ≥70% reduction in total nodular lesion count when taken with meals for up to 20 weeks of therapy.
- Absorica is an oral isotretinoin product specifically formulated to allow for absorption regardless of meals. Absorica has a higher bioavailability in fasting conditions than the other oral isotretinoins. To ensure adequate absorption, the generic formulations must be taken with meals.
- In one head-to-head comparison study of Absorica and generic isotretinoin, there was no difference in efficacy outcomes or adverse reactions between the two products when taken under fed conditions.
- Potential advantages of Absorica include patient convenience due to administration without regard to meals, and the availability of two additional dosage strengths (25 mg and 35 mg) compared to generic oral isotretinoins. However, there are no published head-to-head trials that indicate better compliance or reduced relapse rates with Absorica compared to other isotretinoins.
- The oral isotretinoins are reserved for treating severe nodular recalcitrant acne, due to their significant adverse effects, including teratogenicity, pseudotumor cerebri, and psychiatric problems including suicide risk.
- All the oral isotretinoins, including Absorica, are rated as pregnancy category X, require mandatory enrollment in the Risk Evaluation and Mitigation Strategies (REMS) program iPLEDGE, and are limited to dispensing of a 30-day supply at one time.

- There is a high degree of therapeutic interchangeability among the oral isotretinoins and Absorica.

Overall Relative Clinical Effectiveness Conclusion: Other than the convenience of taking Absorica without regard to meals, it offers no additional clinical advantages over the other oral isotretinoins. Based on clinical issues alone, only one isotretinoin product is required on the UF.

Overall Relative Cost Effectiveness Conclusion: CMA and BIA were performed to evaluate oral isotretinoin agents. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that Myorisan and Amnesteem were the most cost-effective oral isotretinoins, followed by Zenatane, Claravis, and Absorica.
- BIA was performed to evaluate the potential impact of designating selected oral isotretinoins as formulary or NF on the UF. BIA results showed that designating Myorisan, Amnesteem, Zenatane, and Claravis as formulary, with Absorica as NF, demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:
    - UF oral isotretinoins:
        - Myorisan
        - Amnesteem
        - Zenatane
        - Claravis
    - NF oral isotretinoins:
        - Absorica

    NOTE: As part of this recommendation, no oral isotretinoin products were added to the BCF. The topical acne products tretinoin 0.25% and 0.05% (Retin A, generics) and clindamycin 1% and 2% (Cleocin T, generics) remain on the BCF (pre-UF Rule decision).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Absorica. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Absorica. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF, PA, AND IMPLEMENTATION PERIOD***
The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

D. Gastrointestinal-2 (GI-2) Miscellaneous Drugs

Background—The P&T Committee evaluated the GI-2 Miscellaneous Drugs. The drugs in the subclass include metronidazole (Flagyl, generic), oral vancomycin, fidaxomicin (Dificid), nitazoxanide (Alinia), oral neomycin, rifaximin (Xifaxan), alosetron (Lotronex), tegaserod (Zelnorm), linaclotide (Linzess), and lubiprostone (Amitiza). The FDA recently approved eluxadoline (Viberzi) and it will be reviewed as a newly-approved drug at an upcoming meeting. Tegaserod has been discontinued from the market.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following for the GI-2 Miscellaneous agents:

- There are no updates or changes from the previous clinical conclusions made at the November 2012 UF drug class review for the treatment of hepatic encephalopathy, travelers' diarrhea, *Clostridium difficile* associated diarrhea, and *Clostridium difficile* infection (CDI). (See the November 2012 P&T Committee meeting minutes at http://www.health.mil/PandT.)
- There are no head-to-head studies among any of the drugs in the GI-2 miscellaneous subclass for the indications of diarrhea-predominant irritable bowel syndrome (IBS-D), constipation-predominant IBS (IBS-C), or chronic idiopathic constipation. All of the clinical trials for IBS studies showed a significant placebo effect. Treatment for opioid-induced constipation was not a focus of this review.

Diarrhea-Predominant IBS (IBS-D)

- For rifaximin (Xifaxan), the studies for IBS-D are of moderate quality evidence. FDA approval for IBS-D was based on the unpublished TARGET 3 trial, which found that rifaximin was modestly more effective than placebo in relieving IBS-D symptoms but relapses were common. Rifaximin primarily relieves abdominal pain, but does not show a statistically significant improvement in stool consistency. It is also approved for travelers' diarrhea and to decrease the recurrence of hepatic encephalopathy.

- Use of alosetron (Lotronex) for IBS-D is restricted to women with severe refractory IBS-D. It is only available through an FDA-mandated REMS program due to the risk of severe adverse events, including death due to bowel obstruction.

Constipation-Predominant IBS (IBS-C)

- The FDA approved linaclotide (Linzess) for the treatment of IBS-C based on two placebo-controlled clinical trials. Linaclotide showed statistically significant improvements in both abdominal pain and an increase in number of bowel movements per week. The studies are rated as high quality evidence. It is generally well tolerated, although patients may experience diarrhea.
- The FDA approved lubiprostone (Amitiza) for the treatment of IBS-C based on two placebo-controlled trials that showed varying efficacy for IBS-C symptoms. The studies are of moderate quality evidence and were primarily conducted in Caucasian women.
    - The most common adverse events with lubiprostone (Amitiza) are nausea, headache, and diarrhea/abdominal pain. Limitations to use include its drug interaction profile and its FDA approval for use only in women for IBS.

Chronic Idiopathic Constipation (CIC)

- Both linaclotide (Linzess) and lubiprostone (Amitiza) are approved for treating CIC, and both drugs have shown increases in the number or frequency of bowel movements per week.
- Comparative efficacy between the two drugs for CIC cannot be made.

Overall relative clinical effectiveness conclusion: At this time, comparative efficacy statements between the drugs approved for treating IBS cannot be made due to their differing mechanisms of action, lack of head-to-head studies, lack of consistent diagnostic criteria, and variable endpoints. The P&T Committee concluded that even though the studies showed statistically significant results for treating IBS symptoms, whether the results are clinically meaningful remains to be determined due to the significant placebo response and lack of comparative studies.

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

- CMA results for the branded products, for all FDA-approved indications, showed that lubiprostone (Amitiza) and linaclotide (Linzess) were the most cost-effective agents, followed by alosetron (Lotronex), nitazoxanide (Alinia), rifaximin (Xifaxan), and fidaxomicin (Dificid).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF. BIA results showed that designating all agents in the GI-2 Miscellaneous Drug Subclass as formulary demonstrated the largest estimated cost avoidance for the MHS.

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

   - UF
     - alosetron (Lotronex)
     - fidaxomicin (Dificid)
     - linaclotide (Linzess)
     - lubiprostone (Amitiza)
     - nitazoxanide (Alinia)
     - rifaximin (Xifaxan)
     - tegaserod (Zelnorm)—discontinued
     - metronidazole (Flagyl, generic)
     - neomycin
     - vancomycin

   - NF
     - None

   - Notes:
     - Fidaxomicin (Dificid) will continue to be excluded from the Mail Order Pharmacy due to the time constraints for treating acute *C. difficile* infection.
     - There were no changes to the BCF drugs in the class from the November 2012 meeting. Metronidazole 250 mg and 500 mg tablets will remain on the BCF.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Prior authorization was recommended for rifaximin, due to the potential for off-label uses for a wide range of conditions for which there is no supporting clinical data.

   The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

   - Applying new manual PA criteria for new users of rifaximin (Xifaxan) 550 mg tablets for treating IBS-D at a dosage of one tablet three times daily for 14 days. Up to two re-treatment courses will be allowed in six months, for a total of three total treatment courses. See Appendix C for the full criteria.
   - Continuing the existing manual PA criteria for rifaximin (Xifaxan) 550 mg tablets, for hepatic encephalopathy at a dosage of one tablet twice daily. (See November 2012 DoD P&T Committee meeting minutes for full criteria.)

- Continuing the current Prior Authorization for rifaximin 200 mg tablets for travelers' diarrhea, which requires a trial of a fluoroquinolone first. As part of this recommendation, the current quantity limits for rifaximin—200 mg tablets, one tablet three times daily for three days (a total of nine tablets), will be continued. (See November 2012 DoD P&T Committee meeting minutes for full criteria.)

3. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is March 30, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Targeted Immunomodulatory Biologics (TIBs): Adalimumab (Humira) 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. Adalimumab (Humira) was selected as the UF step-preferred agent. In September 2015, adalimumab (Humira) received FDA approval for treatment of moderate to severe hidradenitis suppurativa. The PA criteria were updated for Humira to reflect the new FDA indication.

   a) ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA) PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) revised manual PA criteria for Humira in new patients, consistent with the new FDA-approved product labeling for hidradenitis suppurativa. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) implementation of the PA for adalimumab become effective upon signing of the minutes.

2. **Anti-Malarial Drugs: Mefloquine Manual PA Criteria**—The P&T Committee discussed recent changes to the package insert for the antimalarial drug mefloquine (Lariam, generic) due to the risk of serious psychiatric and neurologic side effects. Mefloquine is primarily utilized as malaria prophylaxis. The P&T Committee has not reviewed the antimalarial drug class; most of the agents are available in generic formulations, with variability in malaria resistance patterns across the world.

   In April 2013, the Assistant Secretary of Defense for Health Affairs made changes to the malaria Force Health Protection program. Atovaquone-proguanil (Malarone, generic) and doxycycline are now first-line choices in areas other than Sub-Saharan Africa. In Sub-Saharan Africa, the first-line choice is atovaquone-proguanil, followed by doxycycline. Mefloquine is third line choice. In July 2013, the FDA added a black box warning to the mefloquine label due to risk of permanent adverse effects, including dizziness, loss of balance, and tinnitus. A Fiscal Year 2014 mefloquine drug utilization review revealed suboptimal documentation for contraindications and patient education in the available records.

   a) ***COMMITTEE ACTION: MEFLOQUINE MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for mefloquine in new users. The PA criteria are consistent with the FDA-approved product labeling to ensure safe and appropriate use of mefloquine. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: MEFLOQUINE PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is March 30, 2016.

3. **Hepatitis C Virus (HCV) Drugs: Direct Acting Antivirals (DAAs) Manual PA Criteria**—The HCV DAAs were reviewed by the P&T Committee in May 2015; manual PA criteria and QLs were recommended for the subclass. In July 2015, the FDA approved two new HCV DAAs for the treatment of HCV genotype 3 (GT3) and HCV genotype 4 (GT4): daclatasvir (Daklinza) and paritaprevir/ritonavir/ombitasvir (Technivie), respectfully. The P&T Committee reviewed the PA criteria and QLs for the DAAs due to the new entrants in the class, changes in the FDA package labeling, FDA drug safety communications, and updated treatment recommendations for HCV by the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA). Consult www.HCVguidelines.org for the most recent update from September 25, 2015.

   a) ***COMMITTEE ACTION: HCV DAAs MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) changes and/or new manual PA criteria for the following DAAs. See Appendix E for the full criteria.

(1) Removing the hepatitis B virus (HBV) co-infection contraindication from all the current HCV DAA manual PA criteria.

(2) Manual PA criteria for new users of paritaprevir/ritonavir/ombitasvir (Technivie). Technivie is contraindicated in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C) and is not indicated for use in patients with cirrhosis. It can cause serious liver injury in patients with underlying advanced liver disease. Prior authorization will expire after 12 weeks, based on the treatment regimen.

(3) Manual PA criteria for new users of daclatasvir (Daklinza). Prior authorization will expire after 12–24 weeks based on the treatment regimen.

(4) Revising the existing manual PA criteria for new users of sofosbuvir (Sovaldi). Prior authorization will expire after 12–48 weeks based on the treatment regimen.

(5) Revising the existing manual PA criteria for new users of paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak). Viekira Pak is contraindicated in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C) and can cause serious liver injury in patients with underlying advanced liver disease. Prior authorization will expire after 12–24 weeks based on the treatment regimen.

(6) Revising the existing manual PA criteria for new users of ledipasvir/sofosbuvir (Harvoni). Prior authorization will expire after 8–24 weeks based on the treatment regimen.

b) ***COMMITTEE ACTION: HCV DAAs QLs***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) QLs for both daclatasvir (Daklinza) and paritaprevir/ritonavir/ombitasvir (Technivie), limiting the quantity to a one-month supply. QLs apply to all the products in the HCV DAAs subclass and are consistent with recommended dosing and product packaging. See Appendix D for the QLs.

c) ***COMMITTEE ACTION: HCV DAAs MANUAL PA CRITERIA AND QLs IMPLEMENTATION PLAN***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) implementation for the manual PA criteria and QLs upon signing of the minutes.

4. **Female Hyposexual Desire Disorder (HSDD) Drugs: Flibanserin (Addyi) Manual PA Criteria**—Flibanserin is the first drug approved for treating HSDD in premenopausal women that is not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance.

The drug is available under a limited distribution program, requiring physician registration, due to the risk of adverse effects.

a) ***COMMITTEE ACTION: FLIBANSERIN (ADDYI) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for flibanserin (Addyi) in all new and current users, due to the risk of severe hypotension, especially if used concomitantly with alcohol. Prior authorization will be limited to the FDA-approved indication. Discontinuation of treatment is warranted if there is no improvement in symptoms after eight weeks. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: FLIBANSERIN (ADDYI) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 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 May 4, 2016.

5. **Basal Insulins: Insulin Glargine 300 U/mL (Toujeo) Manual PA Criteria**—Toujeo is a long-acting human insulin analog indicated for improvement of glycemic control in adults with type 1 or type 2 diabetes mellitus. It contains a concentrated solution of insulin glargine, 300 U/mL. Insulin glargine under the brand name of Lantus has been available since 2000, at a concentration of 100 U/mL. The hemoglobin A1c-lowering effect of Toujeo is similar to Lantus. Other formulations of insulin glargine are expected in 2016.

   a) ***COMMITTEE ACTION: INSULIN GLARGINE 300 U/mL (TOUJEO) PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for Toujeo in all new and current users, to ensure appropriate use and to reduce the risk of insulin dosing errors. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: INSULIN GLARGINE 300 U/mL (TOUJEO) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 4, 2016.

6. **Chronic Heart Failure Drugs: Ivabradine (Corlanor) Manual PA Criteria** Ivabradine (Corlanor) is approved to decrease the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure. The package insert states the drug should only be used in patients who have a left ventricular ejection fraction of less than 35%, who have a heart rate of at least 70 beats per minute, and who are receiving maximum tolerated doses of beta blockers, or who have a contraindication

to beta blockers. Corlanor decreases heart rate without affecting ventricular repolarization or myocardial contractility.

a) ***COMMITTEE ACTION: IVABRADINE (CORLANOR) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for new users of Corlanor, consistent with the FDA-approved product labeling. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: IVABRADINE (CORLANOR) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 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 May 4,2016.

7. **Second Generation Antihistamines: Desloratadine (Clarinex), desloratadine/pseudoephedrine (Clarinex-D), and levocetirizine (Xyzal) MN Criteria**—MN criteria apply to the NF second generation antihistamines Clarinex, Clarinex-D, and Xyzal. The current formulary alternatives listed on the MN form include fexofenadine (Allegra, generic) and fexofenadine/pseudoephedrine (Allegra-D). Several antihistamine formulations are now solely available over-the-counter, including fexofenadine, loratadine (Claritin, generics), and cetirizine (Zyrtec, generics).

   a) ***COMMITTEE ACTION: SECOND GENERATION ANTIHISTAMINES MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) revising the current second generation antihistamines MN criteria to remove fexofenadine as a formulary alternative, and to add generic loratadine and cetirizine with or without pseudoephedrine as appropriate formulary alternatives.

   b) ***COMMITTEE ACTION: SECOND GENERATION ANTIHISTAMINES MN CRITERIA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 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 May 4, 2016.

B. QLs

1. Quantity limits were reviewed for five drugs: idelalisib (Zydelig) for chronic lymphocytic leukemia, gefitinib (Iressa) for metastatic non-small cell lung cancer, sonidegib (Odomzo) for advanced basal cell carcinoma, flibanserin (Addyi) for HSDD and isavuconazonium (Cresemba) for invasive aspergillosis and mucormycosis.

COMMITTEE ACTIONS: QLs—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) QLs for idelalisib (Zydelig), gefitinib (Iressa), sonidegib (Odomzo), flibanserin (Addyi), and isavuconazonium (Cresemba). See Appendix D for the QLs.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

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

The P&T Committee reviewed three 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 POS and medical necessity at military treatment facilities (MTFs). These NF drugs will remain available in the Mail Order POS without preauthorization.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following products be designated NF on the UF:

- Pari Respirator: tobramycin (Kitabis Pak), 300 mg/5 mL inhalation solution
- Libertas Pharm: doxycycline (Doryx), 200 mg delayed release tablet
- Gemini Labs: levothyroxine (Unithroid) 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 137 mcg, 150 mcg, 175 mcg, and 300 mcg tablets

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following preauthorization criteria for Kitabis Pak. Doryx, and Unithroid:

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 preauthorization criteria do not apply to any other POS other than retail network pharmacies.

Note that the following drugs will not be available in the Mail Order Pharmacy:

- Kitabis Pak, 300 mg/5 mL inhalation solution, is only available in the Retail Network via a specialty distributor network of pharmacies.
- Unithroid 25 mcg and 100 mcg tablets are noncompliant with the Trade Agreements Act and, therefore, are only available in retail network pharmacies.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in the Retail Network; and 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation the effective date is May 4, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. INNOVATOR DRUGS

Section 702 of the FY15 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, and new combinations. The definition was further expanded to include new dosage formulations.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following regarding the innovator drugs:

A. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors—Evolocumab (Repatha)

- The PCSK9 inhibitors are a new class of biologic drugs that lower low-density lipoprotein (LDL) cholesterol and are administered by SC injection. The first product, alirocumab (Praluent), was approved on July 24, 2015, prior to implementation of the Innovator Rule on August 25, 2015. Evolocumab (Repatha) is the second PCSK9 inhibitor, and obtained FDA approval on August 27, 2015, after the Innovator Rule went into effect. An interim P&T Committee meeting held on September 3, 2015, recommended PA and MN criteria, and QLs for Repatha. (See August 2015 DoD P&T Committee meeting minutes, found at http://www.health.mil/PandT.)
- The product labeling for Repatha is similar to Praluent, with the exception that, in addition to patients with heterozygous familial hypercholesterolemia (HeFH) and clinical atherosclerotic cardiovascular disease (ASCVD), Repatha is also approved for treating patients with homozygous familial hypercholesterolemia (HoFH), including pediatric patients from ages 13 to 17 years.
- The PCSK9 inhibitors cause reductions in low-density lipoprotein cholesterol (LDL-C) ranging from 40% to 75%. Excluding the additional indication for HoFH, the LDL-lowering benefit for Repatha appears similar to Praluent, based on their individual trials.
- The effect of the PCSK9 inhibitors on cardiovascular (CV) morbidity and mortality has not been determined. CV outcomes studies are expected in 2017, and will aid in defining the clinical benefit of this drug class.
- Praluent is available on the UF and covers the same indication as Repatha. For patients with HoFH, patients can access Repatha via the previously approved PA and MN criteria.
- Relative cost-effectiveness of Repatha was reviewed by the P&T Committee.

B. Oral Oncologic Drugs—Trifluridine/Tipiracil (Lonsurf)

- Lonsurf is a last line, oral treatment for metastatic colorectal cancer. First line treatments are intravenously administered medications.
- Efficacy shows statistical significance for Lonsurf in terms of increased overall survival compared to placebo (7.1 months versus 5.3 months, respectively).
- Relative cost-effectiveness of Lonsurf was reviewed by the P&T Committee.

C. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—Empagliflozin/Metformin IR (Synjardy)

- The SGLT2 inhibitors were reviewed in August 2015. Empagliflozin (Jardiance) and empagliflozin/linagliptin (Glyxambi) were designated formulary and step-preferred,

while the two other products and their combinations (canagliflozin and dapagliflozin with and without metformin) were designated NF and non step-preferred.

- Synjardy is the third available fixed-dose combination containing an SGLT2 inhibitor and metformin. There are no significant clinical differences between the three SGLT2 inhibitors in terms of effect on glycemic control, or changes in weight, blood pressure and lipid parameters.
- Empagliflozin/metformin offers the advantage of a fixed-dose combination with metformin. The parent compound is the step-preferred SGLT2 inhibitor.
- Relative cost-effectiveness of Synjardy was reviewed by the P&T Committee.

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

    - UF:
        - Oncology Drugs: tifluridine/tipiracil (Lonsurf)
        - SGLT2 Inhibitors: empagliflozin/metformin IR (Synjardy); Synjardy will be step-preferred. No changes were recommended for the previously approved step-therapy and manual PA criteria. See Appendices B, C, and D.
    - NF:
        - PCSK9 Inhibitor: evolocumab (Repatha). No changes were recommended for the previously approved manual PA criteria, MN criteria, or QLs. See Appendices B, C, and D.

2. ***COMMITTEE ACTION: UF IMPEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date upon signing of the minutes in all POS.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

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

The Expanded MTF/Mail Pharmacy Initiative (EMMPI) medication program drug list is defined by the P&T Committee, which recommends additions and removals. The program, which began on October 1, 2015, requires that non-Active Duty beneficiaries initiating treatment with drugs on the EMMPI list must fill those prescriptions at MTFs or the Mail Order Pharmacy, following two courtesy fills at the Retail Network. The requirement can be waived based on individual patient needs and other appropriate circumstances. Additionally, recent statutory and regulatory changes mandate that NF pharmaceutical agents are generally not available at MTFs or the Retail Network, but are available in the Mail Order program. For additional information on these two programs, refer to the August 2015 DoD P&T Committee meeting minutes, available at http://www.health.mil/PandT.

The P&T Committee undertook a review of drug classes containing one or more medications currently on the EMMPI list or the list of NF (Tier 3) medications. The review had three purposes: 1) to recommend any additional exceptions to the requirement to fill NF (Tier 3) medications at mail order; 2) to recommend changes to the EMMPI list in order to apply Mail or MTF/Mail requirements consistently within drug classes; and, 3) to define drug classes to be added to the EMMPI list, whenever possible, enabling newly-approved branded, legend agents in those classes that are intended for chronic use to be added to the program automatically.

A. Expanded Maintenance Medication Program Drug List and NF (Tier 3) Medications Available at the Mail Order Pharmacy

- The P&T Committee did not identify any new exceptions to the NF (Tier 3) mail requirement, but did apply already defined exceptions (outlined in Appendix G).
- The P&T Committee also recommended temporarily deferring implementation of the Mail Order requirement for several medications or drug classes until outstanding questions regarding acute versus chronic use, availability at Mail Order, or the need for additional exceptions can be resolved, or until NF (Tier 3) status for medications that are now available in generic formulations can be reviewed. Major drug classes falling into the last category include the calcium channel blockers, proton pump inhibitors, and oral contraceptives.
- The P&T Committee recommended numerous additions to the EMMPI list, as outlined in Appendix G.
- The P&T Committee recommended establishing class definitions as outlined in Appendix G.

1. ***COMMITTEE ACTION: EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) changes to the EMMPI list and the establishment of class definitions applying to the EMMPI list, as outlined in Appendix G.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

X. ITEMS FOR INFORMATION

A. Beneficiary Advisory Panel Comments—The P&T Committee was briefed on comments from the Beneficiary Advisory Panel (BAP) members from the September 30, 2015, meeting regarding pre-authorization criteria for drugs not in compliance with FY08 NDAA, Section 703. Regarding the criterion written as,

> "For branded products with AB-rated generic availability, use of the generic product would be detrimental to the patient,"

the BAP recommended changing "would" to "could." The P&T Committee acknowledged the BAP's comments, but recommended maintaining the criterion as written, since the P&T Committee would have identified those Section 703 medications that may have a unique clinical requirement.

XI. ADJOURNMENT

The meeting adjourned at 1125 hours on November 19, 2015. The next meeting will be in February 2016.

Appendix A—Attendance: November 2015 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 Hepatitis C Virus Drugs Prior Authorization Criteria

Appendix F—Table of Innovator Drugs: Formulary Recommendations

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug List and Nonformulary Medications Excluded from Mail Order Requirements

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

Appendix I—Table of Abbreviations

SUBMITTED BY:

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

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

R.C. Bono
VADM, MC, USN
Director

16 01 29
Date

Appendix A—Attendance: November 2015 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
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
CDR Karl Kronmann, MC	Navy, Physician at Large Alternate
MAJ Dausen Harker, MC	Army, Family Practice 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
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Guests	
CAPT Stephen Rudd	Indian Health Service
LT Teisha Robertson via DCS	DHA Purchased Care Operations
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
MAJ Michele Hudak via DCS	DHA Integrated Utilization Branch
Mr. Henry Gibbs via DCS	Chief, DHA Informatics Integration
Maj Richard Caballero	Defense Logistics Agency Troop Support
Mr. Alexander Quiñones	Defense Logistics Agency Troop Support
Mr. Bruce Mitterer	DHA Contract Operations Division
Ms. Chelsea Lavelle	DHA Contract Operations Division
Ms. Praise Stephenson	DHA Contract Operations Division
CPT Kenesha Pace	Army Medical Department Center and School
CPT Ryan Costantino	Winn Army Community Hospital, Ft. Stewart

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
CDR Marisol Martinez, USPHS	DHA Formulary Management Branch
Lt Col Ronald Khoury, MC	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
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
LTC Misty Carlson, MC	DHA Integrated Utilization Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Dr. David Meade via DCS	DHA Integrated Utilization Branch
Dr. Ingrid Svihla, PharmD, BCPS	DHA Integrated Utilization Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
Dr. Elizabeth Hearin, PharmD, BCPS	DHA Informatics Integration
Emily Griffin	University of North Carolina Eshelman School of Pharmacy Student

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Memantine ER (Namenda XR) • Memantine ER/Donepezil (Namzaric) **Alzheimer's Disease Agents**	• No alternative formulary agent—Patient requires once daily dosing or has difficulty swallowing, or multiple daily dosing causes undue burden to caregiver. **Formulary Alternatives:** memantine IR (Namenda), donepezil (Aricept), galantamine (Razadyne, generic), donepezil orally dissolving tablet (Aricept ODT, generic), rivastigmine (Exelon, generic), galantamine ER (Razadyne ER), memantine ER (Namenda XR), memantine/donepezil (Namzaric), and rivastigmine transdermal system (Exelon Patch)
• Lisdexamfetamine (Vyvanse) **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 for ADHD. Note that the MN criteria does not include Binge Eating Disorder. **Formulary Alternatives:** methylphenidate ER and mixed amphetamine salts, Ritalin LA, Metadate CD, Concerta, Adderall XR
• Methylphenidate Transdermal System (Daytrana) • Dexmethylphenidate ER (Focalin XR) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	No changes to MN criteria recommended in February 2012. • 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 • No alternative formulary agent: For Daytrana only, the patient is unable to take oral medications **Formulary Alternatives:** Extended-release methylphenidate and mixed amphetamine salts, including Ritalin LA, Metadate CD, Concerta, Adderall XR
• Methotrexate auto-injector (Otrexup) • Methotrexate auto-injector (Rasuvo) **Antirheumatics: Injectable Methotrexate**	• No alternative formulary agent. Patient requires an auto-injector due to decreased finger dexterity, limited vision, or impaired cognition. **Formulary Alternatives:** generic methotrexate 50 mg/2 mL vials; generic methotrexate 2.5 mg tablets
• Isotretinoin (Absorica) **Acne Drugs: Oral Isotretinoins**	• No alternative formulary agent. Patient is unable to comply with dietary requirements associated with the formulary oral isotretinoins. **Formulary Alternatives:** Generic formulations of Amnesteem, Claravis, Zenatane, Myorisan
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	No changes to MN criteria recommended September 3, 2015. • Use of statins is contraindicated. The contraindication must be listed on the medical necessity form. • The patient has had an inadequate response to a statin, with an LDL > 100 mg/dL despite statin therapy at maximal tolerated doses. • The patient is intolerant of statins. • No alternative formulary agent. The patient has homozygous familial hypercholesterolemia and requires additional LDL-C lowering, despite maximal doses of statin or other therapies (e.g., ezetimibe, LDL apheresis). **Formulary Alternatives:** statins, ezetimibe

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Memantine ER (Namenda XR) **Alzheimer's Disease Agents**	Manual Prior Authorization criteria originally approved August 2015 with an implementation date of February 3, 2016. No changes recommended to PA criteria November 2015. Manual PA criteria apply to all new users of Namenda XR. Manual PA criteria—Namenda XR is approved if: • The patient is being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia), AND • Taking Namenda IR (memantine) twice daily causes undue burden to the patient or care provider, AND • The patient's functional status has not declined while receiving Namenda IR Prior Authorization does not expire.
• Memantine ER/ Donepezil (Namzaric) **Alzheimer's Disease Agents**	Manual Prior Authorization criteria originally approved August 2015 with an implementation date of February 3, 2016. No changes recommended to PA criteria November 2015. Manual PA criteria apply to all new users of Namzaric. Manual PA criteria—Namzaric is approved if: • The patient is being treated for moderate to severe dementia of the Alzheimer's type, AND • The patient is stabilized on one of the following regimens: o memantine IR 10 mg twice daily or memantine ER 28 mg once daily and donepezil hydrochloride 10 mg, OR o memantine IR 5 mg twice daily or ER 14 mg once daily and donepezil hydrochloride 10 mg, AND • The patient is unable to take Namenda (memantine) and Aricept (donepezil) separately, OR • The patient has progressive swallowing difficulties Prior Authorization does not expire.
• Methotrexate auto-injector (Otrexup) • Methotrexate auto-injector (Rasuvo) **Antirheumatics: Injectable Methotrexate**	Manual PA criteria apply to all new users of Otrexup and Rasuvo methotrexate auto-injectors. Manual PA criteria—Otrexup or Rasuvo are approved if: • The patient has experienced intolerance or significant adverse effects from generic injectable methotrexate vials OR • The patient has decreased finger dexterity, limited vision, or impaired cognition that results in the inability to utilize generic injectable methotrexate vials Prior authorization does not expire.
• Absorica **Acne Drugs: Oral Isotretinoins**	Manual PA criteria apply to all new users of Absorica. Manual PA criteria • Patient is unable to comply with the dietary requirements of an AB-rated generic oral isotretinoin Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Rifaximin (Xifaxan) 550 mg tablets **GI-2 Miscellaneous Drugs**	All new users of rifaximin 550 mg tablets are required to undergo manual prior authorization criteria. <u>Manual PA criteria</u> • Hepatic Encephalopathy: No changes from November 2012 o Patient is ≥18 years of age o Patient has a documented diagnosis of hepatic encephalopathy o Prior Authorization does not expire • Irritable Bowel Syndrome-Diarrhea Predominant (IBS-D) o Patient has clinically documented moderate to severe IBS-diarrhea type, without constipation, and has symptoms of moderate abdominal pain and bloating. 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 o If yes to the above, then treatment will be approved for a single 14-day course of therapy (550 mg tablets, one tablet three times daily for 14 days) o For IBS-D, patients who experience recurrence of symptoms can be retreated up to two more times with the same regimen (total of three treatment courses in 6 months) if the following: • Patient has had a positive response to a previous 14-day course of rifaximin. o Prior authorization expires in 6 months • Non-FDA approved uses, including use of the 200 mg rifaximin tablets for travelers' diarrhea, *C. difficile* infection, inflammatory bowel disease, chronic abdominal pain, hepatitis, diabetes, rosacea, or any other non FDA-approved condition: o Prior Authorization is not approved • Use of rifaximin 200 mg tablets for travelers' diarrhea is subject to prior authorization. See November 2012 P&T Committee meeting minutes.
• Adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs)**	Prior Authorization criteria originally approved August 2014 and implemented February 18, 2015. November 2015 changes to PA criteria in bold. Manual PA criteria for hidradenitis suppurativa applies to new patients. Manual PA Criteria applies to all new users of adalimumab (Humira). Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate • Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade • Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants

Drug / Drug Class	Prior Authorization Criteria
	• **Moderate to severe hidradenitis suppurativa (November 2015)** Pediatric patients with: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pediatric patients: 2–17 years) • Moderate to severely active Crohn's disease (≥ 6 years) who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan) Prior Authorization does not expire.
• Mefloquine **Antimalarial Drugs**	Manual PA Criteria apply to all new users of mefloquine. Coverage approved for patients with the following: • Patients requiring mefloquine for malaria chemoprophylaxis. The PA is not intended for patients requiring treatment of acute malaria infections. • Patients with a contraindication or intolerance to both atovaquone-proguanil (Malarone) and doxycycline (e.g., pregnancy) • Patients do NOT have a major psychiatric disorder to include but not limited to o Active or recent history of depression o Generalized anxiety disorder o Psychosis or schizophrenia o Post-Traumatic Stress Disorder (PTSD) or Traumatic Brain Injury (TBI) • Patients do NOT have a history of seizures or vestibular disorders • Patients do NOT have a cardiac conduction abnormality AND • The total treatment duration (months) must be documented on the PA form. AND • The above information is documented in the medical record and the patient has been educated on mefloquine adverse effects and dosing. Prior Authorization expires after one continuous treatment course.
• Flibanserin (Addyi) **Female Hyposexual Desire Disorder Drugs**	Manual PA criteria apply to all new and current users of flibanserin (Addyi). <u>Manual PA criteria</u>—Flibanserin is approved if: • The drug is prescribed for a premenopausal female with HSDD not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance AND • The patient does not have current alcohol use • The patient does not have hepatic impairment (Child-Pugh score ≥6) • The patient is not receiving concomitant therapy with a moderate or strong CYP3A4 inhibitor (e.g., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil) AND • The prescription is written from a provider who is certified/enrolled in the flibanserin REMS program • Note that contraindications to the use of flibanserin include concurrent alcohol, moderate or strong CYP3A4 inhibitors, and hepatic impairment Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Insulin glargine 300 U/mL (Toujeo) **Basal Insulins**	Manual PA criteria apply to all new and current users of Toujeo. Manual PA criteria—Toujeo is approved if: • The patient is at least 18 years of age AND • The patient has diabetes and is using a minimum of 100 units of Lantus (insulin glargine) per day AND • The patient requires a dosage increase with Lantus and has experienced a clinically significant, severe hypoglycemia episode, despite splitting the Lantus dose AND • The patient has been counseled regarding the risk of dosing errors. • Note that the following are not acceptable reasons for Toujeo: o Non-adherence to previous insulin treatment o Patient or prescriber preference for the use of Toujeo o Patient or prescriber preference for a smaller injection volume Prior Authorization does not expire.
• Ivabradine (Corlanor) **Chronic Heart Failure Drugs**	Manual PA criteria apply to all new users of Corlanor. Manual PA criteria—Corlanor is approved if: • The drug is prescribed by a cardiologist or heart failure specialist. • The patient has a diagnosis of stable, symptomatic heart failure with left ventricular ejection fraction ≤35%, is in sinus rhythm, and has a resting heart rate >70 beats per minute. • The patient has heart failure symptoms despite maximal therapy of a beta blocker therapy that has been shown to have survival benefit in heart failure. o Note that acceptable heart failure beta blockers and target doses include the following: metoprolol succinate ER 200 mg QD; carvedilol 25 mg BID, or 50 mg BID if < 85 kg; carvedilol ER 80 mg QD; bisoprolol 10 mg QD (bisoprolol is not FDA-approved for heart failure but has proven efficacy in a large clinical trial) • OR the patient has a contraindication to beta blocker use o Note that the contraindication must be listed on the Prior Authorization form. Prior Authorization does not expire.
• Canagliflozin (Invokana) • Canagliflozin/metformin (Invokamet) • Dapagliflozin (Farxiga) • Dapagliflozin/metformin ER (Xigduo XR) • Empagliflozin (Jardiance) • **Empagliflozin/ Metformin IR (Synjardy)**	No changes to step therapy and manual PA criteria recommended August 2015; to be implemented February 3, 2016. All new users of an SGLT2 inhibitor are required to try metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin or a sulfonylurea (SU) and a DPP-4 inhibitor first. Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first. Automated PA criteria

Drug / Drug Class	Prior Authorization Criteria
Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors	• The patient has filled a prescription for metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. OR • The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) 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 PA criteria are not met, Jardiance, Synjardy, or Glyxambi is approved (e.g., a trial of metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes are NOT required) if: • The patient has had an inadequate response to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has experienced a significant adverse effect from metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has a contraindication to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes. AND In addition to the above criteria regarding metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes, the following PA criteria would apply specifically to all new and current users of canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/ metformin ER (Xigduo XR): • The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance, Glyxambi, or Synjardy) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	No changes recommended for PA criteria from September 3, 2015, implemented October 30, 2015. Manual PA criteria apply to all new and current users of evolocumab (Repatha). Manual PA criteria—Evolocumab is approved if: • A cardiologist, lipidologist, or endocrinologist prescribes the drug. • The patient is at least 18 years of age for HeFH and clinical ASCVD. For HoFH, patients as young as 13 years of age can receive the drug. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally tolerated statin in combination

Drug / Drug Class	Prior Authorization Criteria
	with ezetimibe, OR o If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. – Contraindication to statin ▪ The contraindication must be defined. • Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 140 mg every 2 weeks, or o 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. • PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Repatha will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Methotrexate auto-injector (Otrexup) • Methotrexate auto-injector (Rasuvo) **Antirheumatics: Injectable Methotrexate**	▪ Retail Network: 4 auto-injectors per 30 days ▪ MTF and Mail Order Pharmacy: 12 auto-injectors per 90 days
• Paritaprevir/ritonavir/ombitasvir (Technivie) **Hepatitis C Drugs—DAAs**	▪ Retail Network, Mail Order Pharmacy and MTF: 1 monthly carton with 4 weekly cartons each containing a 7 daily dose pack with 2 paritaprevir/ritonavir/ombitasvir tablets / 28 days
• Daclatasvir (Daklinza) **Hepatitis C Drugs—DAAs**	▪ Retail Network, Mail Order Pharmacy and MTF: 28 tablets per 28 days
• Idelalisib (Zydelig) **Chronic Lymphocytic Leukemia; B-cell Non-Hodgkin Lymphoma; Small Lymphocytic Lymphoma**	▪ Retail Network: 60 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 120 tabs per 60 days
• Gefitinib (Iressa) **Metastatic Non-Small Cell Lung Cancer**	▪ Retail Network : 30 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 60 tabs per 60 days
• Sonidegib (Odomzo) **Advanced Basal Cell Carcinoma**	▪ Retail Network: 30 caps per 30 days ▪ MTF and Mail Order Pharmacy: 60 caps per 60 days
• Flibanserin (Addyi) **Hypoactive Sexual Desire Disorder**	▪ Retail Network: 30 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 60 tabs per 60 days
• Isavuconazonium (Cresemba) **Invasive Aspergillosis and Mucormycosis**	▪ Retail Network: 56 tabs per 28 days ▪ MTF and Mail Order Pharmacy: 112 tabs per 56 days
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	No changes recommended from September 3, 2015, implemented October 30, 2015. ▪ HeFH and ASCVD o Retail Pharmacy Network: 2 of the 140 mg syringes per 30 days o MTF and Mail Order Pharmacy: 6 of the 140 mg syringes per 90 days. ▪ HoFH o Retail Pharmacy Network: 3 of the 140 mg syringes per 30 days ▪ MTF and Mail Order Pharmacy: 9 of the 140 mg syringes per 90 days

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

Prior Authorization Criteria

Paritaprevir/Ritonavir/Ombitasvir (Technivie)—New PA Criteria November 2015

Direct Acting Antiviral Subclass

- New users of paritaprevir/ritonavir/ombitasvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 4 infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Paritaprevir/ritonavir/ombitasvir (Technivie) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Does not have moderate or severe hepatic impairment (Child-Pugh Class B & C), or cirrhosis

Treatment Regimens and Duration of Therapy

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

Table of Recommended Treatment Regimens and Duration of Therapy for Paritaprevir/Ritonavir/Ombitasvir (Technivie)

Patient Population	Treatment	Duration
Genotype 4 without cirrhosis	TECHNIVIE + ribavirin	12 weeks*
For initial therapy of treatment naïve as well as retreatment of patient with GT4 who previously failed RBV + IFN * Technivie without ribavirin for 12 weeks may be considered for some treatment-naïve patients who cannot tolerate ribavirin		

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Prior Authorization Criteria

Daclatasvir (Daklinza)—New PA Criteria November 2015

Direct Acting Antiviral Subclass

- New users of daclatasvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 3 infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Daclatasvir (Daklinza) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Daclatasvir (Daklinza) is not prescribed as monotherapy

Treatment Regimens and Duration of Therapy

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

Table of Recommended Treatment Regimens and Duration of Therapy for Daclatasvir (Daklinza)

Genotype	Patient Population	Treatment	Duration
3	Treatment naïve or experienced[1] without cirrhosis	DACLATASVIR + SOFOSBUVIR	12 weeks
	Treatment naïve or experienced[1] with cirrhosis	DACLATASVIR + SOFOSBUVIR ± ribavirin	24 weeks
[1]Treatment experienced have failed with peginterferon alpha plus ribavirin			

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Prior Authorization Criteria

Sofosbuvir (Sovaldi)—November 2015 updates are bolded

Direct Acting Antiviral Subclass

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

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1, 2, 3, or 4 HCV infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Sofosbuvir (Sovaldi) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- Sofosbuvir (Sovaldi) is not prescribed as monotherapy

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 12 to 24 week (up to 48 weeks in HCC awaiting transplants), based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for Sofosbuvir (Sovaldi)

HCV genotype	Treatment	Duration
Genotype 1	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks
	SIMEPREVIR 150 mg once daily + SOFOSBUVIR 400 mg once daily (treatment naïve or experienced without cirrhosis)	12 weeks
	SIMEPREVIR 150 mg once daily + SOFOSBUVIR 400 mg once daily (treatment naïve or experienced with cirrhosis)	24 weeks
Genotype 2	SOFOSBUVIR + ribavirin	12 weeks
	SOFOSBUVIR + ribavirin (cirrhotic or treatment experienced)	16 to 24 weeks
	SOFOSBUVIR + peginterferon alfa + ribavirin (treatment experienced)	**12 weeks**
Genotype 3	SOFOSBUVIR + ribavirin	24 weeks
	SOFOSBUVIR + peginterferon alfa + ribavirin (cirrhotic or treatment experienced)	12 weeks
	DACLATASVIR + SOFOSBUVIR (without cirrhosis)	**12 weeks**
	DACLATASVIR + SOFOSBUVIR + ribavirin (cirrhotic)	**24 weeks**
Genotype 4, 5, 6	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks
	SOFOSBUVIR + ribavirin	24 weeks
Hepatocellular carcinoma awaiting transplant	SOFOSBUVIR + ribavirin	up to 48 weeks or at transplant
Treatment-experienced patients who have failed treatment with peginterferon alfa plus ribavirin but not a HCV protease inhibitor		

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Prior Authorization Criteria

Paritaprevir/Ritonavir/Ombitasvir with Dasabuvir (Viekira Pak)—November 2015 updates are bolded

Direct Acting Antiviral Subclass

- New users of paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1 HCV infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Paritaprevir/ritonavir/ombitasvir with dasabuvir (Viekira Pak) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
- **Does not have moderate or severe hepatic impairment (Child-Pugh Class B & C), decompensated cirrhosis, or IL-28B T/T polymorphism**
- If co-infected with HIV, patient is on anti-retroviral therapy

Treatment Regimens and Duration of Therapy

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

Genotype 1 Patient Populations[1,2,3]	***Treatment***	***Duration***
GT1a without cirrhosis	Viekira Pak + ribavirin bid	12 weeks
GT1a with cirrhosis[4]	Viekira Pak + ribavirin bid	24 weeks
GT1b without cirrhosis	Viekira Pak	12 weeks
GT1b with cirrhosis	Viekira Pak	12 weeks
Liver transplant recipients with normal hepatic function and mild fibrosis (Metavir ≤2)	Viekira Pak + ribavirin bid	24 weeks

[1]Follow GT1a dosing recommendation in patients with an unknown GT1 or mixed GT1 infection

[2]Treatment naïve or treatment-experienced with peginterferon alpha plus ribavirin

[3]Contraindicated in moderate and severe hepatic impairment (Child-Pugh Class *B* & C)

[4] Avoid in GT1a patients with cirrhosis and prior null responder to peginterferon/ribavirin

Prior Authorization Criteria

Ledipasvir/Sofosbuvir (Harvoni)—November 2015 updates are bolded

Direct Acting Antiviral Subclass

- New users of ledipasvir/sofosbuvir (Harvoni) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥ 18
- Has laboratory evidence of chronic HCV genotype 1 or 4 infection
  - State the HCV genotype and HCV RNA viral load on the PA form
- Ledipasvir/sofosbuvir (Harvoni) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician

Treatment Regimens and Duration of Therapy

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

Table of Recommended Treatment Regimens and Duration of Therapy for Daclatasvir (Daklinza)

Genotype 1 Patient Populations[1]	Treatment	Duration
Treatment naïve with or without cirrhosis	HARVONI	8-12 weeks[2]
Treatment experienced without cirrhosis	HARVONI	12 weeks
Treatment experienced with cirrhosis	**HARVONI + ribavirin**	**12 weeks**
Treatment experienced with cirrhosis	HARVONI	24 weeks
Genotype 4 Patient Population	**Treatment**	**Duration**
Treatment naïve or experienced with or without cirrhosis	**HARVONI**	**12 weeks**

[1]Treatment-experienced patients who have failed treatment with either (a) peginterferon alfa plus ribavirin or (b) HCV protease inhibitor plus peginterferon alfa plus ribavirin

[2]Consider treatment duration of 8 weeks in treatment-naïve patients without cirrhosis who have a pretreatment HCV RNA less than 6 million IU/mL

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates.

Appendix F—Table of Innovator Drugs: Formulary Recommendations

Generic name, Brand name	DoD PEC Drug Class	FDA Approval Date	FDA Approval Type	FDA Indications	Formulary Alternatives	Recommended UF Status	Comments
Evolocumab (Repatha)	• Antilipidemics-1; PCSK9 Inhibitors	8/27/2015	BLA	Adjunct to diet and maximally tolerated statin therapy in adults with the following conditions, who require additional LDL lowering: • Heterozygous familial hypercholesterolemia (HeFH) • Homozygous familial hypercholesterolemia (HoFH) including pediatric patients ages 13-17 years • Clinical atherosclerotic cardiovascular disease (ASCVD)	• statins • ezetimibe • alirocumab (Praluent)*	▪NF	▪Prior Authorization and Medical Necessity criteria and QLs recommended at interim P&T Committee meeting September 3, 2015, and implemented on October 30, 2015 ▪No changes recommended to PA, MN, or QLs; see Appendices B, C, and D ▪PCSK9 inhibitors drug class not reviewed yet
Trifluridine/ tipiracil (Lonsurf)	• Oncological Agents	9/22/2015	NDA; 1	Metastatic Colorectal Cancer ▪ Patients previously treated with fluoropyrimidine-, oxaliplatin-and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy	• capecitabine (Xeloda), a fluoropyrimidine* • regorafenib (Stivarga)*	▪UF	▪Oral drugs for metastatic colorectal cancer not reviewed yet
Empagliflozin/ metformin IR (Synjardy)	• Non-Insulin Diabetes Drugs; SGLT2 Inhibitors	8/26/2015	NDA; 4	Type 2 diabetes ▪ Adjunct to diet and exercise to improve glycemic control in adults who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin.	• empagliflozin (Jardiance) • empagliflozin /linagliptin (Glyxambi)	▪UF; step-preferred	▪SGLT2 inhibitors reviewed in August 2015; empagliflozin products step-preferred ▪Prior Authorization criteria recommended at August 2015 P&T Committee meeting; implementation on February 3, 2016 ▪No changes recommended to PA criteria

NDA Chemical Types:
1: New molecular entity;
2: New active ingredients;
3: New dosage formulations;
4: New combinations
* Drug Class not previously reviewed for UF status

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug (EMMPI) List and Nonformulary Medications (Tier 3) Medications Excluded from Mail Order Requirements

Notes: This table shows the EMMPI list and the nonformulary (Tier 3) list side-by-side. Please note that the table omits classes where no action is recommended by the P&T Committee (no exceptions to the NF mail order requirement apply, no changes to the current EMMPI list are recommended, and no class definitions are recommended). It is not a complete list of EMMPI or nonformulary (Tier 3) medications. Formulary status is as of the November 2015 P&T Committee meeting.

Legend: capitalized drugs – brand name only; italicized drugs – generics available

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
Alzheimer's	Alzheimer's therapy, NMDA receptor antagonist (H1A) *Namenda* (memantine) **Add NAMENDA XR (memantine)**	-
	Alzheimer's therapy – NMDA receptor antagonists & cholinesterase inhibitors (H1C) **Add NAMZARIC (memantine/donepezil)**	-
	Cholinesterase inhibitors (J1B) *Aricept* (donepezil) *Razadyne, Razadyne ER* (galantamine) *Exelon* (rivastigmine) patch, capsule	*Aricept* (donepezil) 23 MG
	Class Definition – **RECOMMENDATION:** Branded, legend medications in GC3s H1A, H1C, or J1B and intended for chronic use to be added to the EMMPI list	
Androgens–anabolic steroids	Androgenic agents (F1A) - **Add all testosterone products to EMMPI list: FORTESTA, ANDRODERM, TESTIM, STRIANT, VOGELXO, NATESTO (nasal)**	ANDROGEL 1% gel pump and packets ANDROGEL 1.62% gel pump AXIRON transdermal solution
	Class Definition – **RECOMMENDATION**: Branded, legend testosterone products in GC3 F1A and intended for chronic use as testosterone replacement therapy be added to the EMMPI list	
Antibiotics	Aminoglycoside (W1F) Tobi (tobramycin for nebulization) **Add TOBI PODHALER**	ZMAX (azithromycin suspension) KETEK (telithromycin) **ZMAX and KETEK not suitable for mail; acute use exception applies**
Anticoagulants	Heparin and related (M9K) FRAGMIN (dalteparin) *Lovenox* (enoxaparin) *Arixtra* (fondaparinux)	-
	Thrombin inhibitors, selective, direct, reversible (M9T) PRADAXA (dabigatran)	-
	Direct Factor XA inhibitor (M9V) ELIQUIS (apixaban)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	XARELTO (rivaroxaban) SAVAYSA (edoxaban)	
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s M9K, M9T, or M9V and intended for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = SSRIs)	SSRIs – H2S (SSRIs) *Celexa, Lexapro, Prozac, Paxil, Pexeva, Zoloft* **Add Paxil CR (paroxetine 24H)**	*Prozac weekly* (90 mg) *Sarafem* (10,20 mg)
	SSRI & 5HTA partial agonist antidepressant (H8P) -	VIIBRYD (vilazodone)
	SSRI & 5HT receptor modulator (H8T) -	BRINTELLIX (vortioxetine)
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3s H2S, H8P, or H8T that are indicated for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = SNRIs)	SNRIs (H7C) & fibromyalgia agents SNRIs (H0G) *Effexor XR* (venlafaxine 24H) **Add Cymbalta (duloxetine)**	KHEDEZLA, PRISTIQ ER (desvenlafaxine 24H) FETZIMA (levomilnacipran) SAVELLA (milnacipran)
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3S H7C or H0G that are intended for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = MAOIs)	MAO inhibitor (H7H) -	EMSAM patch (selegiline)
	MAOIs-non-selective and irreversible (H7J) MARPLAN (isocarboxazid) *Nardil* (phenelzine) *Parnate* (tranylcypromine)	-
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3s H7H or H7J be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = NDRIs)	NDRIs (H7D) *Wellbutrin, Wellbutrin SR, Wellbutrin XL* (bupropion)	APLENZIN (bupropion HBr ER 24H) FORFIVO XL (bupropion HCl ER 24H)
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3 H7D that are intended for chronic use to be added to the EMMPI list; does not apply to products for smoking cessation	
Antidepressants / non-opioid pain (subclass = SARIs)	Serotonin-2 antagonist/reuptake inhibitor (SARIs) (H7E) -	*Oleptro ER (trazodone ER 24H)*
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3 H7E that are intended for chronic use to be added to the EMMPI list	
Antidepressants / non-opioid pain (subclass = tetracyclic antidepressants)	Alpha-2 receptor antagonist antidepressant (H7B) **Add *Remeron* (mirtazapine)**	-
	Subclass Definition – **RECOMMENDATION:** Branded, legend products in GC3 H7B that are intended for chronic use to be added to the EMMPI list	

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
Antiemetics - antivertigo	Antiemetic/ antivertigo agent (H6J) -	ANZEMET (dolasetron) SANCUSO (granisetron patch) ZUPLENZ (ondansetron film) DICLEGIS (doxylamine/pyridoxine) **Not suitable for mail; acute use exception applies**
Antifungals (subclass = topical antifungals)	Topical antifungals (Q5F) -	*Loprox* (ciclopirox) *Spectazole* (econazole) VUSION (miconazole/zinc oxide oint) OXISTAT (oxiconazole) ERTACZO (sertaconazole) EXELDERM (sulconazole) **Not suitable for mail; acute use exception applies**
Antigout (subclass = chronic agents)	Hyperuricemia tx – xanthine oxidase inhib (C7A) *Zyloprim* (allopurinol)	ULORIC (febuxostat)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 C7A that are intended for chronic use to be added to the EMMPI list	
Antihistamine-2 blockers/other antiulcer	Anti-ulcer preparation (D4E) *Pepcid* (famotidine) *Zantac* (ranitidine) *Cytotec* (misoprostol) *Carafate* (sucralfate)	
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 D4E that are intended for chronic use to be added to the EMMPI list	
Antihypertensives (misc)	Antihypertensives, vasodilator (A4A) -	-
	Antihypertensives, sympatholytic (A4B) *Catapres* (clonidine) patches, tabs *Clorpres* (clonidine/chlorthalidone)	-
	J7B Alpha-adrenergic *Minipress* (prazosin)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s A4A, A4B, and J7B that are intended for chronic use to be added to the EMMPI list	
Antilipidemics-1	M4D – HMG CoA reductase inhibitors *Lipitor* (atorvastatin) *Lescol* (lovastatin) *Pravachol* (pravastatin) CRESTOR (rosuvastatin) *Zocor* (simvastatin)	LESCOL XL (fluvastatin ER 24H) ALTOPREV (lovastatin ER 24H) LIVALO (pitavastatin)
	M4E – lipotropic *Niaspan* (niacin ER 24H) ZETIA (ezetimibe)	-
	M4I – HMG CoA & CCB *Caduet* (amlodipine/atorvastatin)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	M4L – HMG CoA & niacin -	ADVICOR (niacin/lovastatin) SIMCOR (niacin/simvastatin)
	HMG CoA & cholest AB inhibitor (M4M) -	LIPTRUZET (ezetimibe/atorvastatin) VYTORIN (ezetimibe/simvastatin)
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s M4D, M4E, M4I, M4L, or M4M that are intended for chronic use to be added to the EMMPI list	
Antilipidemics-2 (subclass = bile acid sequestrants)	Bile acid sequestrants (D7L) *Questran, Questran Light* (cholestyramine) *Colestid* (colestipol)	WELCHOL (colesevelam) (06)
Antilipidemics-2 (subclass = omega-3 fatty acids)	Lipotropic (M4E) Lovaza (omega-3 acid ethyl esters) **Add VASCEPA (icosapent ethyl)**	
Antilipidemics-2 (subclass = fenofibrates)	Lipotropic (M4E) *Lofibra*, FENOGLIDE, LIPOFEN (fenofibrate) *Tricor*, TRIGLIDE, (fenofibrate, nanocrystallized) *Lofibra* (fenofibrate, micronized) FIBRICOR (fenofibric acid) **Add ANTARA (fenofibrate, micronized),** ***Trilipix* (fenofibric acid (choline)**	-
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3 D7L or M4E that are intended for chronic use to be added to the EMMPI list	
Antiplatelet	Platelet aggregation inhibitor (M9P) AGGRENOX (aspirin/dipyridamole) *Pletal* (cilostazol) *Plavix* (clopidogrel) *Persantine* (dipyridamole) EFFIENT (prasugrel) BRILINTA (ticagrelor)	Zontivity (vorapaxar)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 M9P that are intended for chronic use to be added to the EMMPI list	
Antipsychotic agents	-	SAPHRIS (asenapine) FANAPT (iloperidone) LATUDA (lurasidone) **Not suitable for mail; antipsychotic exception applies**
ADHD (subclass = stimulants)	Treatment for ADHD /narcolepsy (H2V), adrenergics, aromatic, non-catecholamine (J5B) -	Focalin XR (dexmethylphenidate) DAYTRANA (methylphenidate transdermal system) QUILLIVANT XR (methylphenidate 24h susp) VYVANSE (lisdexamfetamine) **Not suitable for mail; C-II exception applies**
ADHD (subclass = wakefulness promoting)	Narcolepsy and sleep disorder therapy (H8Q) -	NUVIGIL (armodafinil)

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
BPH	BPH/micturition agents (Q9B) *Proscar* (finasteride) *Uroxatral* (alfuzosin) *Flomax* (tamsulosin)	AVODART (dutasteride) JALYN (dutasteride/tamsulosin) RAPAFLO (silodosin)
	Alpha-adrenergic blocking agent (J7B) *Cardura* (doxazosin)	CARDURA XL (doxazosin)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Q9B or J7B that are intended for chronic use to be added to the EMMPI list	
Beta blockers & diuretic combos	Alpha/beta adrenergic (J7A) *Coreg*, COREG CR (carvedilol)	
	Beta adrenergic (J7C) & combos (J7H) *Sectral* (acebutolol) *Tenormin* (atenolol), *Tenoretic* (atenolol/chlorthalidone) *Ziac* (bisoprolol/HCTZ) DUTOPROL (metoprolol succinate/HCTZ) *Lopressor HCT* (metoprolol tartrate/HCTZ) *Corgard* (nadolol), *Corzide* (nadolol/bendroflumethiazide) *Inderal LA*, INNOPRAN LA (propranolol) *Betapace, Betapace AF* (sotalol) *Tenoretic* (atenolol/chlorthalidone) *Ziac* (bisoprolol/HCTZ) **Add: Inderal XL (propranolol)**	BYSTOLIC (nebivolol)
CCBs	Calcium channel blocking agent (A9A) *Norvasc* (amlodipine) *Cardizem, Cardizem CD, Tiazac* (diltiazem) *Adalat CC, Procardia, Procardia XL* (nifedipine) *Calan, Calan SR* (verapamil)	*Cardizem LA, Matzim LA* (diltiazem) *Isradipine* *Nicardipine IR* CARDENE SR (nicardipine) *Sular* (nisoldipine) *Verelan, Verelan PM* (verapamil 24H)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 A9A that are intended for chronic use to be added to the EMMPI list	
Diabetes non-insulin	Alpha-glucosidases (C4M) *Precose* (acarbose) GLYSET (miglitol)	-
	Amylin agonist (C4H) SYMLINPEN 60, 120 (pramlintide)	-
	Biguanides (C4L) *Glucophage, Glucophage XR* (metformin) RIOMET solution (metformin)	*Fortamet*, GLUMETZA (metformin ER 24H)
	DPP-4s (C4J) and combos (C4C, C4M, C4W) TRADJENTA (linagliptan) JANUVIA (sitagliptan)	NESINA (alogliptan) ONGLYZA (saxagliptan)
	Dopamine agonists (C4V)	CYCLOSET (bromocriptine)

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug List and Nonformulary Medications Excluded from Mail Order Requirements

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	-	
	GLP-1s (C4I) BYDUREON (exenatide) **Add TANZEUM (albiglutide),** **BYDUREON PEN (exenatide)**	TRULICITY (dulaglutide) VICTOZA (liraglutide) BYETTA (exenatide)
	Meglitinides (C4K) and combos (C4S) *Starlix* (nateglinide) *Prandin* (repaglinide) *Prandimet* (repaglinide/metformin)	-
	SGLT2s (C4D) and combos (C4E) - Add GLYXAMBI (empagliflozin/linagliptan) Add JARDIANCE (empagliflozin)	INVOKANA (canaglifozin) FARXIGA (dapagliflozin) INVOKAMET (canaglifozin/metformin) XIGDUO XR (dapaglifozin/metformin)
	Sulfonylureas (C4K) & combos (C4S) *Amaryl* (glimepiride) Glucotrol, Glucotrol XL (glipizide) *Diabeta* (glyburide) *Glynase* (glyburide, micronized) *Glucovance* (glyburide/metformin)	-
	TZDs (C4N) & combos (C4R, C4T) Actos (pioglitazone) Duetact (pioglitazone/glimepiride) Actoplus Met, ACTOPLUS MET XR (pioglitazone/metformin)	AVANDIA (rosiglitazone) AVANDAMET (rosiglitazone/metformin)
	Class Definition – RECOMMENDATION: Branded, legend products in GC3s C4C, C4D,C4E, C4H, C4I, C4J, C4K, C4L, C4M, C4N, C4R, C4S, C4T, C4V, or C4W that are intended for chronic use to be added to the EMMPI list	
Diuretics	Carbonic anhydrase inhibitor (R1E) *Diamox Sequels* (acetazolamide) *Neptazane* (methazolamide)	-
	Thiazide & related (R1F) DIURIL oral suspension (chlorothiazide) *Microzide* (hydrochlorothiazide)	-
	Potassium-sparing diuretic (R1H) and combos (R1L) *Inspra* (eplerenone) *Aldactone* (spironolactone) DYRENIUM (triamterene) *Aldactazide* (spironolactone/HCTZ) *Dyazide, Maxzide, Maxzide-25mg* (triamterene/HCTZ)	-
	Loop (R1M) EDECRIN (ethacrynic acid) *Lasix* (furosemide) *Demadex* (torsemide)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s R1E, R1F, R1H, R1L, or R1M that are intended for chronic use to be added to the EMMPI list	
Electrolyte-mineral-trace element replacement	Potassium replacement (C1D) *Effer-K* (potassium bicarb/cit ac) *Klor-Con* (potassium chloride) 20, 25 mEq packet *K-tab ER* (potassium chloride) 10 mEq	-
	Other replacement products (calcium, magnesium salts, iron, iodine, misc) -	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 C1D that are intended for chronic use to be added to the EMMPI list	
Estrogens, combos (route = oral, topical or transdermal)	Estrogenic agents (G1A) *Alora, Climara*, MENOSTAR, *Minivelle, Vivelle-Dot* (estradiol patch) DIVIGEL, ELESTRIN, ESTROGEL (estradiol gel) *Estrace* (estradiol tablet) CLIMARA PRO, COMBIPATCH (estradiol/levonorgestrel patch) *Activella* (estradiol/norethindrone tablet) PREFEST (estradiol/norgestimate) PREMPHASE, PREMPRO (conjugated estrogen/m-progest acetate) PREMARIN (conjugated estrogens) ENJUVIA (conjugated estrogens, synthetic) MENEST (esterified estrogens) *FemHRT* (norethindrone/ethinyl estradiol) **Add EVAMIST transdermal spray (estradiol), *Lopreeza* tab (estradiol/norethindrone)**	--
	Estrogen & progestin with antimineralocorticoid (G1D) ANGELIQ (drospirenone/estradiol)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s G1A and G1D that are intended for chronic use to be added to the EMMPI list	
Estrogens, combos (route = vaginal)	Vaginal estrogen preparations (Q4K) ESTRACE cream, ESTRING vaginal ring, VAGIFEM vaginal tablet (estradiol) FEMRING vaginal ring (estradiol acetate) PREMARIN vaginal cream (conjugated estrogens)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Q4K that are intended for chronic use to be added to the EMMPI list	
GI-1 agents	Chronic inflammatory colon dx - 5-aminosalicylates (D6F) APRISO, DELZICOL, LIALDA (mesalamine) DIPENTUM (olsalazine) *Azulfidine* (sulfasalazine)	GIAZO (balsalazide) ASACOL HD, PENTASA (mesalamine)
	Chronic inflammatory colon dx, 5-aminosalicylates, rectal (Q3E) CANASA (mesalamine) rectal supp	-
	Glucocorticoids (P5A)	*Uceris* (budesonide) tablet

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	-	
	IBS agents – 5HT3 antagonists (D6C) *Lotronex* (alosetron)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s D6F, Q3E, and D6C that are intended for chronic use to be added to the EMMPI list	
Glaucoma	Q6G – miotics, other intraocular pressure reducer *Iopidine* (apraclonidine) LUMIGAN (bimatoprost) *Alphagan P* (brimonidine) COMBIGAN (brimonidine/timolol) *Trusopt* (dorzolamide) *Cosopt* (dorsolamide/timolol) COSOPT PF (dorzolamide/timolol/PF) PHOSPHOLINE IODIDE (echothiophate iodide) *Xalatan* (latanoprost) *Betagan* (levobunolol) *Isopto Carpine* (pilocarpine) *Timoptic, Timoptic XE,* TIMOPTIC OCUDOSE (timolol maleate) **Add SIMBRINZA (brinzolamide/brimonidine)**	Azopt (brinzolamide) ZIOPTAN (tafluprost) BETIMOL (timolol) 0.0025, ISTALOL (timolol maleate) Travatan Z (travoprost)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Q6G that are intended for chronic use to be added to EMMPI list	
Growth stimulating	Growth hormone (P1A) NORDITROPIN FLEXPRO, NUTROPIN AQ, NUTROPIN AQ NUSPIN **Add SEROSTIM, ZOMACTON, ZORBTIVE, NUTROPIN AQ NUSPIN (somatropin)**	GENOTROPIN, HUMATROPE, OMNITROPE, SAIZEN
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 P1A that are intended for chronic use to be added to EMMPI list	
Gynecological misc	Progestational agent (G2A) *Provera* (medroxyprogesterone) tablet *Aygestin* (norethindrone acetate) *Prometrium* (progesterone, micronized)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 G2A that are intended for chronic use to be added to EMMPI list	
Hepatitis C	Direct acting – various GC3s -	-
	Hep C treatment agent (W5G) PEGASYS (peginterferon alfa-2a) PEGINTRON, PEGINTRON REDIPEN (peginterferon alfa-2b) *Copegus, Rebetol* (ribavirin) INTRON A (interferon alfa-2b) **Add PEGASYS PROCLICK (peginterferon alfa-2a)**	Ribasphere RibaPak
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 W5G that are intended for chronic use to be added to EMMPI list	

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
Insulins (subclass = basal)	Insulin (C4G) LEVEMIR (insulin detemir) vial LANTUS (insulin glargine) vial LANTUS SOLOSTAR (insulin glargine) pen **Add Toujeo (insulin glargine 300 u/mL pen)**	LEVEMIR FLEXTOUCH (insulin detemir) pen
Insulins (subclass = combos)	Insulin (C4G) NOVOLOG MIX 70-30 vial, pen HUMULIN 70-30 vial, pen NOVOLIN 70-30 vial, pen HUMALOG MIX 50-50, 75-25 vial, pen	-
Insulins (subclass = intermediate-acting)	Insulin (C4G) HUMULIN N vial, pen NOVOLIN N vial, pen	-
Insulins (subclass = short-acting)	Insulin (C4G) NOVOLOG (insulin aspart) vial, pen, cartridge APIDRA (insulin glulisine) vial, pen HUMALOG (insulin lispro) vial, pen, cartridge **Add Afrezza (inhaled regular insulin)**	-
Insulins (subclass = misc)	Diabetic supplies (Y9A) -	VGO 20, 30, 40
Insulins	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 C4G that are intended for chronic use to be added to EMMPI list	
Leukotriene modifying	Z4B – Leukotriene receptor antagonist *Accolate* (zafirlukast) *Singulair* (montelukast)	ZYFLO, ZYFLO CR (zileuton)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3 Z4B that are intended for chronic use to be added to EMMPI list	
Migraine agents	H3F Antimigraine preparation -	*Axert* (almotriptan) FROVA (frovatriptan) *Amerge* (naratriptan) SUMAVEL DOSEPRO (sumatriptan needle-free injection) **Not suitable for mail; acute use exception applies**
MS agents	Agents to treat multiple sclerosis (H0E) COPAXONE, GLATOPA (glatiramer) AVONEX (interferon beta-1a) REBIF (interferon beta-1a) syringe BETASERON (interferon beta-1b) kit **Add REBIF REBIDOSE (interferon beta-1a) pen** **EXTAVIA (interferon beta-1b)**	PLEGRIDY, PLEGRIDY PEN (peginterferon beta-1a)
Mydriatics	Mydriatric (Q6J) ISOPTO ATROPINE (atropine sulfate) *Cyclogyl* (cyclopentolate) CYCLOMYDRIL (cyclopentolate/phenylephrine)	-

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	Mydriacyl (tropicamide)	
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s Q6J that are intended for chronic use to be added to EMMPI list	
Narcotic analgesics and combinations	-	NUCYNTA (tapentadol) Ultram ER (tramadol ER 24H) ABSTRAL (fentanyl SL tab) FENTORA (fentanyl buccal) LAZANDA (fentanyl nasal) SUBSYS (fentanyl SL spray) **Not suitable for mail; acute use and/or C-II exceptions apply**
Ophthalmic-1 agents	-	Prolensa (bromfenac) **Not suitable for mail; acute use exception applies**
Osteoporosis agents	Bone resorption inhibitor (P4L) & bone resorption inhibitor & Vit D combos (P4N) Fosamax (alendronate) 70mg Boniva (ibandronate) 150mg Evista (raloxifene) **Add Duavee (conjugated estrogens/bazedoxifene)**	BINOSTO (alendronate 70mg eff tab) FOSAMAX PLUS D (alendronate/vit D3) *Atelvia* (risedronate DR) 35mg
	Bone formation stim agents – parathyroid (P4B) FORTEO (teriparatide)	Miacalcin (calcitonin, salmon, synthetic) nasal
	Class Definition – **RECOMMENDATION:** Branded, legend products in GC3s P4L, P4N, P4B that are intended for chronic use to be added to EMMPI list	
Pain agents	Antimigraine preparation (H3F) -	CAMBIA (diclofenac potassium) powder pack – **Not suitable for mail; acute use exception applies**
	Nasal NSAIDs, COX non-selective (Q7K) -	SPRIX (ketorolac) - **Not suitable for mail; acute use exception applies**
	NSAID & H2 blocker (S2X) -	DUEXIS (ibuprofen/famotidine)
	NSAID & PPI (S2P) VIMOVO (naproxen/esomeprazole)	-
	NSAIDs, COX-2 selective (S2L) Celebrex (celecoxib)	-
	Salicylates (H3D) -	-
	Topical anti-inflammatory, NSAID (Q5E) Voltaren (diclofenac sodium) gel	PENNSAID (diclofenac sodium solution pump) FLECTOR (Diclofenac epolamine) **All above: Not suitable for mail; acute use exception applies** *diclofenac sodium drops* (topical)

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	NSAIDs (S2B) *Voltaren-XR* (diclofenac sodium ER 24H) *Nalfon* (fenoprofen calcium) *Mobic* (meloxicam) *EC-Naprosyn, Naprosyn* (naproxen) *Anaprox, Anaprox DS* (naproxen sodium) *Daypro* (oxaprozin) *Feldene* (piroxicam)	ZIPSOR (diclofenac potassium) ZORVOLEX (diclofenac micronized) PONSTEL (mefenamic acid) **All above: Not suitable for mail; acute use exception applies** Naprelan (naproxen sodium 24H)
Pancreatic enzyme agents	Pancreatic enzyme (D8A) - **RECOMMENDATION – add other pancreatic enzyme agents: CREON, ZENPEP, PANCREAZE, VIOKACE**	PERTYZE ULTRESA
	Class Definition – RECOMMENDATION: Branded, legend products in GC3 D8A that are intended for chronic use to be added to EMMPI list	
Parkinsons agents	C7B Decarboxylase inhibitor *Lodosyn* (carbidopa)	-
	Antiparkinsonism drugs, other (H6A) *Sinemet, Sinemet CR* (carbidopa/levodopa) *Stalevo* (carbidopa/levodopa/entacapone) *Comtan* (entacapone) *Mirapex, Mirapex ER* (pramipexole) AZILECT (rasagiline mesylate) *Requip, Requip XL* (ropinirole) NEUPRO (rotigotine) patch *Eldepryl* (selegiline) ZELAPAR (selegiline) 1.25 mg tab rapdis *Tasmar* (tolcapone)	-
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s C7B and H6A that are intended for chronic use to be added to EMMPI list	
PDE-5 inhibitors (for ED)	Drugs to treat erectile dysfunction (F2A) VIAGRA (sildenafil)	CIALIS (tadalafil) LEVITRA, STAXYN (vardenafil) STENDRA (avanafil)
	Class Definition – RECOMMENDATION: Branded, legend products in GC3 F2A and that are intended for chronic use to be added to EMMPI list	
PPIs	Proton pump inhibitor (D4J) *Nexium* (esomeprazole) *Prilosec* (omeprazole) *Protonix* (pantoprazole)	DEXILANT (dexlansoprazole) *Prevacid* (lansoprazole) *Aciphex* (rabeprazole)
	Class Definition – **RECOMMENDATION**: Branded, legend products in GC3s D4J that are intended for chronic use to be added to EMMPI list	
Pulmonary-1 agents	ICS/LABA (J5G) ADVAIR DISKUS, HFA (fluticasone/salmeterol)	SYMBICORT (budesonide/formoterol) BREO ELLIPTA (fluticasone/vilanterol) DULERA (mometasone/formoterol)
	ICS (B6M) Pulmicort (budesonide) neb FLOVENT DISKUS, HFA (fluticasone)	QVAR (beclomethasone) PULMICORT FLEXHALER (budesonide) ALVESCO (ciclesonide) AEROSPAN (flunisolide) ASMANEX (mometasone)

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	Beta-adrenergic agents (J5D) Vospire ER (albuterol 12H tab)	PROVENTIL HFA, VENTOLIN HFA (albuterol) XOPENEX HFA (levalbuterol) **Not suitable for mail; acute use exception applies**
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s J5G, B6M that are intended for chronic use to be added to EMMPI list. Note: does not include albuterol and levalbuterol inhalers (J5D).	
Pulmonary-2 agents	Xanthines (A1B) -	-
	General bronchodilator agent (A1D) *Atrovent HFA* (ipratropium) TUDORZA PRESSAIR (aclidinium) SPIRIVA (tiotropium) INCRUSE ELLIPTA (umeclidinium)	
	Beta-adrenergic & anticholinergic (J5J) ANORO ELLIPTA (umeclidinium/vilanterol)	
	PDE-4 inhibitor (Z2X) -	
	Beta-adrenergic agent (J5D) BROVANA (arformoterol) FORADIL (formoterol) SEREVENT (salmeterol)	PERFOROMIST (formoterol neb) ARCAPTA (indacaterol)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s A1B, A1D, J5J, Z2X that are intended for chronic use to be added to EMMPI list.	
RBC stimulants	Erythropoiesis-stimulating agent (N1B) ARANESP (darbepoetin alfa) EPOGEN, PROCRIT (epoetin alfa)	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 N1B that are intended for chronic use to be added to EMMPI list	
Renin-angiotensin antihypertensives	ACEI (A4D) & ACE/thiazide (A4J) *Lotensin; Lotensin HCT* (benazepril) *Vasotec; Vaseretic* (enalapril) *Prinivil; Zestril; Zestoretic* (lisinopril) *Aceon* (perindopril) *Accupril;Accuretic* (quinapril) *Altace* (ramipril) *Mavik* (trandolapril)	-
	ACEI & CCB (A4K) *Tarka* (tradolapril/verapamil)	

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	ARB (A4F) & ARB/thiazide (A4I) EDARBI; EDARBYCLOR (azilsartan) *Atacand, Atacand HCT* (candesartan) *Avapro; Avalide* (irbesartan) *Cozaar; Hyzaar* (losartan) BENICAR; BENICAR HCT (olmesartan) *Micardis; Micardis HCT* (telmisartan) *Diovan, Diovan HCT* (valsartan)	
	ARB & CCB (A4H) or ARB/CCB/thiazide (A4V) AZOR(amlodipine/olmesartan) *Exforge; Exforge HCT* (amlodipine/valsartan) *Twynsta* (amlodipine/telmisartan) *Lotrel* (amlodipine/benazepril)	TRIBENZOR (amlodipine/olmesartan/HCTZ)
	Direct renin inhibitor (A4T) or DRI/CCB (A4X) or DRI/thiazide (A4U) TEKTURNA (aliskiren) TEKTURNA HCT (aliskiren/HCTZ)	TEKAMLO (aliskiren/amlodipine)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s A4J, A4K, A4I, A4V, A4T, A4X, A4U that are intended for chronic use to be added to EMMPI list	
Sedative hypnotic agents (newer)	-	EDLUAR, INTERMEZZO (zolpidem sublingual) ZOLPIMIST (zolpidem spray ROZEREM (ramelteon) BELSOMRA (suvorexant) – May 15 **All above: Not suitable for mail; acute use exception applies**
Self-monitoring blood glucose systems	-	Numerous **Not suitable for mail; previously defined exception applies**
Skeletal muscle relaxants & combos	Skeletal muscle relaxant (H6H) *Dantrium* (dantrolene sodium) *Zanaflex* (tiazanidine)	
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 H6H that are intended for chronic use to be added to EMMPI list	
TIBs (subclass = non-TNF inhibitors)	Anti-inflammatory, PDE-4 inhibitor (S2Z) OTEZLA (apremilast) oral	-
	Janus kinase inhibitor (Z2Z) XELJANZ (tofacitinib) oral	-
	Antipsoriatic agents systemic (L1A) CONSENTYX (secukinumab)	-
	Anti-inflam IL-1 antagonists (S2M) ARCALYST (Rilonacept)	KINERET (anakinra)
	Anti-inflam T-cell inhibitor (S2Q)	ORENCIA (abatacept)

Appendix G—Table of Recommended Changes to the Expanded Maintenance Medication Program Drug List and Nonformulary Medications Excluded from Mail Order Requirements

DoD P&T Class / Subclass	EMMPI (Branded products only, by First Data Bank GC3 drug class)	Nonformulary (Tier 3)
	-	
	IL-6 inhibitor (Z2V) -	ACTEMRA (tocilizumab SQ
	IL-12/23 inhibitor (Z2U) STELARA (ustekinumab)	-
	Tx chronic inflam dz of colon (D6A) -	CIMZIA (certolizumab)
TIBs (subclass = TNF inhibitors)	TNF inhibitors (S2J) HUMIRA (adalimumab) SIMPONI (golimumab)	ENBREL (etanercept)
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3s S2Z, Z2Z, L1A, S2M, S2Q, Z2V, Z2U, D6A, S2J that are intended for chronic treatment of RA, JRA, PsA, AS, psoriasis, Crohns disease, or ulcerative colitis to be added to EMMPI list	
Thyroid & antithyroid agents	Thyroid hormone (P3A) *Synthroid,* TIROSINT, *Unithroid* (levothyroxine) *Cytomel* (liothyronine) *Armour Thyroid* (thyroid, pork) *Tapazole* (methimazole)	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 P3A that are intended for chronic use to be added to EMMPI list	
Urinary misc	Urinary pH modifier (R1S) *Urocit-K* (potassium citrate)	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 R1S that are intended for chronic use to be added to EMMPI list	
WBC stimulants	Leukocyte (WBC) stimulant (N1C) NEUPOGEN (filgrastim) NEULASTA (pegfilgrastim) LEUKINE (sargramostim) **RECOMMENDATION: Add Granix (tbo-filgrastim)**	-
	Class Definition – **RECOMMENDATION** – Branded, legend products in GC3 N1C that are intended for chronic use to be added to EMMPI list	

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2015	**Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	UF class review (previously reviewed Feb 2012)	▪ mixed amphetamine salts ER (Adderall XR; generic) ▪ methylphenidate osmotic controlled release oral delivery system (OROS) (Concerta; generic)	▪ amphetamine sulfate tabs (Evekeo) ▪ methylphenidate ER oral suspension (Quillivant XR suspension) ▪ methylphenidate ER (Aptensio XR) ▪ methamphetamine (Desoxyn, generic) ▪ dextroamphetamine (Dexedrine spansule, Dextrostat tabs, ProCentra solution, generics; Zenzedi tabs) ▪ methylphenidate CD (Metadate CD; generic) ▪ methylphenidate IR (Ritalin IR, generic) ▪ methylphenidate LA (Ritalin LA, generic) ▪ methylphenidate SR (Ritalin SR, generic) ▪ methylphenidate ER (Metadate ER, Methylin ER, generic) ▪ methylphenidate chewable tablets, solution (Methylin, generic) ▪ mixed amphetamine salts IR (Adderall, generic) ▪ dexmethylphenidate IR (Focalin; generic)	▪ lisdexamfetamine (Vyvanse) ▪ methylphenidate transdermal system (Daytrana) ▪ dexmethylphenidate ER (Focalin XR)	Pending singing of the minutes / 90 days The effective date is May 4, 2016.	▪ None	▪ Updated Medical Necessity for Vyvanse: does not include Binge Eating Disorder. (See Appendix B) ▪ Note that methylphenidate LA (Ritalin LA, generic) and methylphenidate IR (Ritalin IR, generic) are removed from the 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
Nov 2015	**Antirheumatics: Injectable Methotrexate Subclass**	UF class review	BCF: None (BCF selections from the Antirheumatics Drug Class include generic methotrexate 2.5 mg tablets)	▪ Generic methotrexate 50 mg/2 mL vials	▪ Methotrexate auto-injector (Otrexup) ▪ Methotrexate auto-injector (Rasuvo)	Pending singing of the minutes / 90 days The effective date is May 4, 2016.	▪Manual prior authorization applies to Otrexup and Rasuvo – see Appendix C ▪QLs apply – see Appendix D	
Nov 2015	**Acne Drugs: Oral Isotretinoins Subclass**	UF class review	BCF: None (BCF Acne drugs include topical acne products: tretinoin 0.025% and 0.05%, clindamycin 1% and 2%)	▪ Amnesteem ▪ Claravis ▪ Zenatane ▪ Myorisan	▪ Absorica	Pending signing of the minutes / 90 days The effective date is May 4, 2016.	▪Prior authorization applies to Absorica – see Appendix C	
Nov 2015	**GI-2 Miscellaneous Drug Subclass**	UF class review Previously reviewed Nov 2012 (GI-2 antibiotics) and Feb 2011 (GI-1)	▪ Metronidazole 250 mg and 500 mg tablets	▪ Alosetron (Lotronex) ▪ Fidaxomicin (Dificid) ▪ Linaclotide (Linzess) ▪ Lubiprostone (Amitiza) ▪ Nitazoxanide (Alinia) ▪ Rifaximin (Xifaxan) ▪ Tegaserod (Zelnorm) – discontinued ▪ Metronidazole (Flagyl, generics) ▪ Neomycin ▪ vancomycin	None	Pending signing of the minutes / 60 days The effective date is March 30, 2016.	▪Prior Authorization applies to rifaximin – see Appendix C	▪Dificid not available from the Mail Order Pharmacy

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2015	**Alzheimer's Disease Agents**	New Drug Class previously reviewed Nov 2005	• ECF: Donepezil (Aricept, generics)	• Memantine IR (Namenda, generics) • Galantamine (Razadyne, generic) • Galantamine ER (Razadyne ER) • Rivastigmine (Exelon, generic) • Rivastigmine transdermal system (Exelon Patch)	Nov 2015 • **Memantine ER (Namenda XR)** • **Memantine ER/donepezil (Namzaric)** • Donepezil 23 mg (Aricept 23 mg) – Feb 2011 • Tacrine– discontinued	Pending signing of the minutes / 90 days The effective date is May 4, 2016.	•Prior Authorization applies – see Appendix C	

TRICARE Formulary Search tool: http://tricare.mil/pharmacyformulary

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

Appendix I—Table of Abbreviations

ADHD	attention deficit hyperactivity disorder
AE	adverse event
AASLD/IDSA	American Association for the Study of Liver Diseases/Infectious Diseases Society of America
ASCVD	atherosclerotic cardiovascular disease
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
CD	controlled delivery
CDI	*Clostridium difficile* infection
CIC	chronic idiopathic constipation
CFR	Code of Federal Regulations
CK	creatinine kinase
CMA	cost minimization analysis
CV	cardiovascular
DAAs	direct acting antivirals
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DM	diabetes mellitus
DMARD	disease-modifying antirheumatic drugs
DoD	Department of Defense
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FY	fiscal year
GI-2	Gastrointestinal-2 Miscellaneous Drugs
GT3	genotype 3 hepatitis virus infection
GT4	genotype 4 hepatitis virus infection
HBV	hepatitis B virus
HCV	hepatitis C virus
HDL	high-density lipoprotein
HeFH	heterozygous familial hypercholesterolemia
HF	heart failure
HoFH	homozygous familial hypercholesterolemia
HSDD	hyposexual desire disorder
IBS	irritable bowel syndrome
IBS-C	constipation-predominant irritable bowel syndrome
IBS-D	diarrhea-predominant irritable bowel syndrome
IR	immediate release
LDL	low-density lipoprotein
LDL-C	low-density lipoprotein cholesterol
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
NMDA	N-methyl-D-aspartate
OTC	over-the-counter
ODT	orally dissolving tablet
OROS	osmotic controlled release oral delivery system
P&T	Pharmacy and Therapeutics
PA	prior authorization
PCSK9	proprotein convertase subtilisin/kexin type 9 inhibitors
POS	points of service
RA	rheumatoid arthritis
REMS	Risk Evaluation and Mitigation Strategies
QD	once daily
QLs	quantity limits
SC	subcutaneous
SGLT2	sodium-glucose co-transporter 2 inhibitor
SVR	sustained virologic response
TFL	TRICARE for Life
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary