DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2021

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on May 5 and 6, 2021. Due to the COVID-19 pandemic, the meeting was held via teleconference.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Status of February 2021 Minutes—**The February 2021 meeting minutes have not been signed yet, due to the zero based review of the TRICARE Beneficiary Advisory Panel by the Secretary of Defense.

2. **Clarification of Previous Minutes**

   a) **May 2019 Meeting—MHS GENESIS OTC Test List**: Due to a shortage of acetaminophen 325mg tablets, acetaminophen 500mg tablets (GCN 16965) were added to the MHS GENESIS OTC list until the shortage resolves.

3. **Formulary Status of immunoglobulin gamma subcutaneous injection human-klhw solution (Xembify):** Xembify is a subcutaneous immunoglobulin (SCIG) product that was FDA-approved in 2019 and was designated UF on May 13, 2020.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. All uniform formulary (UF), basic core formulary (BCF), and TRICARE Tier 4/Not Covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018. Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF 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. UF DRUG CLASS REVIEWS

A. Menopausal Hormone Therapy: Single Agents, Combination Agents, and Vaginal Agents Subclasses

Background—The Menopausal Hormone Therapy (MHT) class has not previously been reviewed for formulary placement, however several products have been designated as Basic Core Formulary (BCF) dating back to 1999 (prior to the implementation of the UF Final Rule in 2005). Estradiol vaginal insert (Imvexxy) and estradiol/micronized progesterone (Bijuva) were reviewed as innovators in 2018 and 2019, respectively, and both were designated nonformulary with Imvexxy also requiring prior authorization (PA) criteria. Three MHT subclasses, Oral Single Agents, Oral Combination Agents, and Vaginal Agents, are the subject of this review.

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

Oral Single Agents Subclass

- The subclass is made up of three drugs, estradiol (Estrace and generics), conjugated equine estrogens (Premarin), and esterified estrogens (Menest).
- Estradiol and esterified estrogens are plant-derived. The conjugated equine estrogens (CEE) found in Premarin products are derived from pregnant mares' urine. While potency and doses differ among the drugs in this subclass, there is little difference in efficacy for treating vasomotor symptoms of menopause (hot flashes). (North American Menopause Society (NAMS) 2017 Position Statement)
- Data from one randomized controlled trial included in the 2016 Cochrane Review does not suggest a safety difference between estradiol and CEE; however, small observational trials suggest cardiovascular and cognitive benefits with estradiol over CEE.
- Estradiol is preferred over CEE in transgender patients due to ease of monitoring.

Oral Combination Agent Subclass

- The oral combination subclass is primarily used to treat vasomotor symptoms of menopause. The class is comprised of estrogen/progestogen combinations and estrogen/testosterone combinations.

- The purpose of adding a progestin to an estrogen for the combination products is to prevent endometrial hyperplasia and cancer in women who have a uterus. Uterine cancer can develop in as little as 6 months with use of unopposed estrogen therapy in women who have not had a hysterectomy.
- There is conflicting data regarding the relative endometrial protection provided with different progestogens (i.e., norethindrone acetate, medroxyprogesterone acetate, progesterone). (American Association of Clinical Endocrinologists and American College of Endocrinology [AACE/ACE] 2017)
- The 2017 AACE/ACE guidelines state that micronized progesterone is considered the safer alternative when progesterone is necessary.
- Compared to medroxyprogesterone acetate, micronized progesterone appears to have better outcomes for cardiovascular effects, blood pressure, venous thromboembolism, stroke, and breast cancer. However, safety risks with medroxyprogesterone acetate are diminished if used for 5 years or less.
- Bijuva is the only combination product that contains estradiol and micronized progesterone.
- Estradiol/drospirenone (Angeliq) has additional contraindications (renal impairment and adrenal insufficiency) and drug interactions (NSAIDs, ACEIs, ARBs) compared to the other oral combination agents. However, it is the only product that contains the progestin drospirenone, which has anti-mineralocorticoid activity, and may cause small reductions in blood pressure.
- Combination products containing methyltestosterone (i.e., Covaryx, generics) may be used in menopausal women with sexual interest/arousal disorder.

Vaginal Agents Subclass

- The subclass is further divided into vaginal creams, inserts, and rings. With the exception of Femring, which is a systemically acting hormone therapy, all other drugs in this subclass are locally acting.
- The Vaginal Agents are almost exclusively used to treat the genitourinary syndrome of menopause (GSM). There are no significant differences in efficacy between the various estrogen creams, inserts, and rings for the treatment of GSM, including urogenital atrophy (Cochrane 2016).
- Overall, there are little to no differences in safety between the various vaginal estrogens when used at typical doses and dosing frequencies.

- Estradiol acetate vaginal ring (Femring) bypasses the GI tract and thus has a less anticipated impact on lipids and blood clotting and is not associated with an increased risk of venous thromboembolism compared to oral products.
- Vaginal rings (Estring, Femring) are convenient as they last for three months, but they can become dislodged and may not initially be used in patients with significant vaginal stenosis.
- Vaginal creams (Premarin, Estrace) allow for dose titration and for application directly to external tissues, but are messier than the other vaginal dosage forms.
- Vaginal inserts (Yuvafem vaginal tablets and Imvexxy vaginal capsules) are less messy than the creams, but cannot be titrated. Imvexxy capsules are available in a lower estradiol strength of 4 mcg in addition to 10 mcg.
- Some patients may prefer the vaginal rings and tablets over the vaginal creams, as they may be easier to administer, are less messy, and some patients consider these formulations more comfortable.

Overall Clinical Conclusions

In order to meet the needs of Military Health System (MHS) beneficiaries, a variety of menopausal hormone therapy products are needed on the formulary. The formulation, dose, and route of administration should be determined individually and reassessed periodically. Inclusion of multiple agents in each subclass on the uniform formulary is beneficial in supporting differences in patient and provider preferences.

Relative Cost-Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic formulations in each subclass were the most cost-effective, followed by the branded products, which are ranked from least to most costly, as outlined below:
    - **For the oral single agents**, generic estradiol tablets were the most cost-effective agent followed by conjugated equine estrogens tablets (Premarin), and esterified estrogens (Menest).
    - **For the oral combination agents,** the generics (e.g., generic Femhrt, Activella, Femt) were most cost effective, followed by conjugated equine estrogens/medroxyprogesterone acetate tablet (Prempro), conjugated equine estrogens plus medroxyprogesterone acetate tablets (Premphase), estradiol/progesterone caps (Bijuva), estradiol/norgestimate (Prefest) and estradiol/drospirenone (Angeliq).

- **For the vaginal agents**: Generic estradiol vaginal cream and vaginal tablets were the most cost effective products, followed by estradiol vaginal ring (Estring), estradiol vaginal insert (Imvexxy), conjugated equine estrogens vaginal cream (Premarin cream), and estradiol acetate vaginal ring (Femring).

- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating all oral single, oral combination and vaginal agents as UF and none as NF or Tier 4 demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Oral Single Agents Subclass

- UF
    - conjugated equine estrogens tablets (Premarin)
    - estradiol tablets (Estrace, generics)
    - esterified estrogens tablets (Menest)
- NF – None
- Tier 4/Not Covered – None

Oral Combination Agents Subclass

- UF
    - conjugated equine estrogens/medroxyprogesterone acetate tablets (Prempro)
    - conjugated equine estrogens plus medroxyprogesterone acetate tablets (Premphase)
    - ethinyl estradiol/norethindrone acetate tablets (Femhrt, and generics Jinteli, Fyavolv)
    - estradiol/norethindrone acetate tablets (Activella, and generics Amabelz, Jinteli, Mimvey, Mimvey Lo)
    - esterified estrogens/methyltestosterone (Covaryx, Covaryx HS, Eemt, Eemt HS, generics)
    - estradiol/drospirenone (Angeliq)
    - estradiol/norgestimate (Prefest)
    - estradiol/progesterone capsules (Bijuva) *(moves from NF to UF)*
- NF – None

- Tier 4/Not Covered – None

Vaginal Agents Subclass

- UF
    - conjugated equine estrogens vaginal cream (Premarin)
    - estradiol vaginal cream (Estrace, generics)
    - estradiol vaginal ring (Estring)
    - estradiol acetate vaginal ring (Femring)
    - estradiol vaginal tablet (Yuvafem, Vagifem generics)
    - estradiol vaginal insert (Imvexxy) *(moves from NF to UF)*
- NF – None
- Tier 4/Not Covered – None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following for the BCF:

   Oral Single Agents Subclass

   - Adding estradiol oral tablet (generic)
   - Removing conjugated equine estrogens tablet (Premarin)

   Oral Combination Agents Subclass

   - Removing conjugated equine estrogens/medroxyprogesterone acetate tablet (Prempro)

   Vaginal Agents Subclass

   - Estradiol vaginal cream (generic) is added to the BCF (*previous BCF recommendation allowed for the MTFs to select the estrogenic vaginal cream of their choice*)

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***Existing PA criteria currently apply to estradiol vaginal insert (Imvexxy). The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing the PA for Imvexxy. As a result, there are no PA requirements in any of the three MHT subclasses reviewed.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—***The P&T Committee recommended (18 for, 0

opposed, 0 abstained, 0 absent), removing Premarin, Menest, Prempro, Premphase, Estring, and Prefest from the EMMPI program, as they have comparable pricing across all three points of service. The Committee also recommended maintaining Bijuva, Imvexxy, Femring, Vagifem, Estrace tablet, Activella, Femhrt, and Angeliq on the EMMPI program. Premarin vaginal cream and Estrace vaginal cream remain not subject to the EMMPI program requirements, due to package size and day supply issues.

5. ***COMMITTEE ACTION: UF, BCF, PA REMOVAL, EMMPI PROGRAM AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30-days after signing of the minutes in all points of service. Based on the P&T Committee's recommendation, the effective date is March 30, 2022.

B. Sleep Disorders: Insomnia Agents Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the drugs used to treat insomnia. This class was last reviewed in May 2012. Drugs in the class include numerous formulations of zolpidem (immediate-release, extended-release, oral spray, and sublingual), eszopiclone, zaleplon, and doxepin, melatonin agonists (ramelteon and tasimelteon), and the newer dual orexin receptor antagonists (DORAs) suvorexant (Belsomra) and lemborexant (Dayvigo). The DORAs were previously reviewed as individual new drugs in May 2015 and August 2020, respectively.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

Guidelines and Therapies

- Non-pharmacological therapies including sleep hygiene, relaxation, and cognitive behavioral therapy for insomnia (CBT-I) are recommended as first-line treatment of chronic insomnia.
- Pharmacologic treatment can be used in addition to non-pharmacologic therapies for patients who continue to have insomnia.
- Guidelines recommend treating insomnia with pharmacologic therapies for the shortest possible treatment course.
- Options for sleep onset insomnia include zolpidem IR (Ambien, generics), zaleplon (Sonata, generics), and the melatonin agonist ramelteon (Rozerem, generics). Agents approved for both sleep onset and sleep maintenance include zolpidem ER (Ambien CR, generics), eszopiclone (Lunesta, generics), and the DORAs suvorexant (Belsomra) and lemborexant (Dayvigo).

Older Agents

- All the older agents improve sleep latency (the time to fall asleep) by approximately 10 to 15 minutes, compared to placebo.
- For the older insomnia drugs, there was no new data to change the conclusions from the May 2012 meeting which stated that there are no clinically relevant differences between the drugs.
- Doxepin tablets (Silenor, generics) improve insomnia due to sleep maintenance problems; no comparative data exists with doxepin and the other drugs in the class. One advantage is that doxepin is not a controlled substance.
- Other than providing an alternative dosage formulation for patients with swallowing difficulties, zolpidem oral spray (Zolpimist), and zolpidem sublingual (Edluar and Intermezzo) do not offer clinically compelling advantages over other insomnia drugs.

DORAs

- Suvorexant (Belsomra) and lemborexant (Dayvigo) competitively inhibit the wakefulness-promoting neuropeptides orexin A and B.
- No direct comparative data are available between Belsomra and Dayvigo, and indirect comparisons are confounded due to the different endpoints used. An indirect comparison showed both DORAs decrease the time to fall asleep by approximately 15 minutes and increase the total time asleep by about 30 minutes.
- Both agents have efficacy and safety data in older adults and in patients with dementia related to Alzheimer's disease who have insomnia. There is currently no evidence to support that one DORA is better than another when treating elderly patients.
- More data is needed to determine comparative effectiveness in patients experiencing middle of the night awakenings.
- Both DORAs have drug-drug interactions that should be considered when treating patients. Lemborexant has a longer half-life (17-19 hours) compared to suvorexant (12 hours). Adverse events with lemborexant and suvorexant are generally similar and dose-related.
- Warnings and precautions for the DORAs include daytime somnolence (patients using higher doses are cautioned against driving the next day); sleep paralysis, hallucinations, and cataplexy-like symptoms; and complex sleep behaviors. The DORAs should be used with caution in patients with compromised respiratory function; and worsening of depression.

Melatonin Agonists

- Ramelteon (Rozerem, generics) is a melatonin agonist that improves sleep onset and is not a controlled substance.
- Tasimelteon (Hetlioz) is another prescription melatonin agonist, and has been designated as NF with PA criteria since February 2015. It was originally indicated for blind patients with non-24 hour sleep-wake disorder.
- The prescription products ramelteon (Rozerem generics) and tasimelteon (Hetlioz) have similar chemical compositions to the dietary supplement melatonin.
- Since the last formulary review, tasimelteon is now indicated for use in Smith-Magenis Syndrome (SMS), a rare condition. A liquid formulation (Hetlioz LQ) specifically approved for children aged 3 to 15 years with SMS was recently marketed. Use of tasimelteon in SMS is based on one unpublished study with poor efficacy results and numerous limitations.
- Other than its unique indications, tasimelteon offers no compelling clinical advantages over other melatonin agonists.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that doxepin tablets (Silenor, generics), eszopiclone (Lunesta, generics), ramelteon (Rozerem, generics), zaleplon (Sonata, generics), and zolpidem IR and ER tablets (Ambien, Ambien CR, and generics) are more cost-effective than lemborexant (Dayvigo) and suvorexant (Belsomra). Intermezzo, Zolpimist, Edluar, Hetlioz and Hetlioz LQ are not cost-effective relative to the other insomnia drugs.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating generic doxepin, eszopiclone, ramelteon, zaleplon, and zolpidem IR/ER as UF, with lemborexant (Dayvigo) and suvorexant (Belsomra) as UF and step-preferred branded products, and branded tasimelteon (Hetlioz, Hetlioz LQ), zolpidem spray (Zolpimist), and zolpidem tablets (Edluar, Intermezzo, and generics) as NF and non-step-preferred demonstrated significant cost avoidance for the MHS.

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

    - UF generics

- eszopiclone (Lunesta, generics)
- zaleplon (Sonata, generics)
- zolpidem IR (Ambien, generics)
- zolpidem ER (Ambien CR, generics)
- doxepin 3 mg, 6 mg (Silenor, generics)
- ramelteon (Rozerem, generics) *(moves from NF to UF)*

- UF and step-preferred brands
  - lemborexant (Dayvigo)
  - suvorexant (Belsomra) *(moves from NF to UF)*
  - Note that as part of the formulary recommendation for Belsomra and Dayvigo, a trial of zolpidem ER or eszopiclone is required

- NF and non-step-preferred brands
  - zolpidem oral spray (Zolpimist)
  - zolpidem 5 mg, 10 mg sublingual tabs (Edluar)
  - zolpidem 1.75 mg, 3.5 mg sublingual tabs (Intermezzo)
  - tasimelteon capsules (Hetlioz)
  - tasimelteon oral suspension (Hetlioz LQ)
  - Note that as part of this formulary recommendation for Zolpimist, Edluar, and Intermezzo, a trial of zolpidem IR or zaleplon and Belsomra or Dayvigo are required in new and current users
  - Note that as part of this formulary recommendation for Hetlioz and Hetlioz LQ, a trial of ramelteon and melatonin are required in new users

- Tier 4/Not Covered: None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining zolpidem IR on the BCF, and adding zolpidem ER to the BCF.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***PA has applied to the older insomnia drugs since 2010, the DORA Belsomra since 2015, the DORA Dayvigo since 2020, and to Hetlioz since 2014. The P&T Committee

recommended (16 for, 1 opposed, 0 abstained, 1 absent) updates to the manual PA criteria as outlined below. See Appendix C for the full criteria.

- Ramelteon (Rozerem generics) and doxepin 3 mg, 6 mg (Silenor generics): The existing PA criteria will be removed. Use of these two agents will be monitored for inappropriate use and consideration will be given to reinstating PA criteria if necessary.
- Edluar, Intermezzo and Zolpimist: The updated PA criteria in new and current users will include a trial of cognitive behavioral therapy for insomnia (CBT-I) as part of the non-pharmacologic therapy options. In addition to a trial of a generic zolpidem IR or zaleplon first, the PA will also require a trial of a DORA (Belsomra or Dayvigo). The current automated setup will be removed and replaced with manual criteria. Renewal criteria will now be required.
- Dayvigo and Belsomra: The updated PA criteria in new users will include a trial of CBT-I as a non-pharmacologic therapy option and require renewal criteria.
- Hetlioz and Hetlioz LQ: The updated PA criteria in new users will include a trial of ramelteon in addition to OTC melatonin. Note that melatonin 3 mg and 5 mg were added to the MHS GENESIS OTC test list, in order to standardize dispensing of melatonin at MTFs. See p 21-22 for more detail.

4. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated MN criteria for Edluar, Intermezzo, Zolpimist to allow in cases of swallowing difficulties, and updated MN criteria for Hetlioz, and Hetlioz LQ, requiring a trial of ramelteon and OTC melatonin first. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) applying a 30 day supply quantity limit (QL) at all points of service for Hetlioz and Hetlioz LQ. See Appendix D.

6. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) AND NF TO MAIL REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining Dayvigo on the program, and adding Edluar, Intermezzo and Zolpimist to the EMMPI program. Belsomra, Hetlioz, and Hetlioz LQ are not subject to the EMMPI requirements.

7. ***COMMITTEE ACTION: UF, BCF, PA, MN, QL, EMMPI PROGRAM AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service; 2) DHA send letters to beneficiaries who are affected by the updated PA requirements for Edluar, Intermezzo and Zolpimist. Based on the P&T Committee's recommendation, the effective date is April 20, 2022.

V. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 2021 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

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

- UF:
  - cabotegravir (Vocabria) – Integrase strand transfer inhibitor antiretroviral for HIV
  - ponesimod (Ponvory) – Oral miscellaneous multiple sclerosis (MS) agent for relapsing forms of MS
  - tepotinib (Tepmetko) – Oral oncologic agent for non-small cell lung cancer (NSCLC)
  - tivozanib (Fotivda) – Oral oncologic agent for renal cell carcinoma (RCC)
  - umbralisib (Ukoniq) – Oral oncologic agent for marginal zone lymphoma (MZL) and follicular lymphoma (FL)
  - vericiguat (Verquvo) – Miscellaneous cardiovascular agent for reducing risk of cardiovascular death in adults with chronic heart failure
  - vibegron (Gemtesa) – Overactive Bladder (OAB) drug

- NF:
    - ethinyl estradiol (EE) 20 mcg/ levonorgestrel 0.1 mg chewable tablet (Tyblume) – Monophasic combination oral contraceptive with 20 mcg estrogen
    - levothyroxine sodium 100 mcg/5 mL oral solution (Thyquidity) – Thyroid Agent
    - mannitol inhalation powder (Bronchitol) – Miscellaneous Respiratory Agent for Cystic Fibrosis
    - methotrexate injection (Reditrex) – Antirheumatic
    - solifenacin oral suspension (Vesicare LS) – Antimuscarinic Overactive Bladder Agent for pediatric neurogenic detrusor overactivity (NDO)
    - tirbanibulin 1% ointment (Klisyri) – Antineoplastic for actinic keratosis
    - voclosporin (Lupkynis) – Calcineurin inhibitor immunosuppressive for active lupus nephritis (LN)

- Tier 4/Not Covered: See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
    - levetiracetam 1,000 mg and 1,500 mg extended-release tablets (Elepsia XR) – Anticonvulsant Agent
        - Elepsia XR was recommended for Tier 4 status as it has little to no additional clinical effectiveness relative to other levetiracetam products and similar agents in the class, and the needs of TRICARE beneficiaries are met by available alternative anticonvulsant agents. Alternatives include levetiracetam 500 mg and 750 mg ER tablets (Keppra generics), lamotrigine XR, and topiramate ER.

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Bronchitol, Klisyri, Lupkynis, Reditrex, Thyquidity, Tyblume, and Vesicare LS. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following (see Appendix C for the full criteria):

- OAB Drugs: Applying manual criteria to new users of vibegron (Gemtesa), requiring a trial of two formulary generic OAB drugs first. [See the Utilization Management (UM) Section on pages 16 and 38 for updates to the PA for the branded OAB drug mirabegron (Myrbetriq)].

- Antirheumatics: Applying manual criteria to new users of Reditrex, requiring a trial of oral methotrexate first. [See the UM section on pages 16 for updated PAs for the Otrexup and Rasuvo injectable MTX products].
- Oncologic drugs: Applying manual PA criteria to new users of Fotivda, Tepmetko, and Ukoniq.
- Applying manual PA criteria to new users of Bronchitol, Klisyri, Lupkynis, Ponvory, Thyquidity, Tyblume, and Verquvo.
- Applying manual PA criteria to new users of Vesicare LS.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the following:

- **New Drugs Recommended for UF or NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service, on March 2, 2022.

- **New Drugs Recommended for Tier 4/Not Covered Status:** 1) An effective date 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation, on June 15, 2022.

VI. BCF CLARIFICATION: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR ANTAGONISTS (GLP1 RAs)

The Diabetes Non-Insulin: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) subclass was last reviewed at the February 2018 DoD P&T Committee meeting. At that time, the recommendation was to maintain exenatide once weekly (Bydureon) and add exenatide once weekly autoinjector (Bydureon BCise) to the BCF. These two products, along with dulaglutide (Trulicity) are the UF and step-preferred products in the subclass.

Early in 2021, the manufacturer of Bydureon informed DoD that Bydureon would be discontinued, but noted that production of the Bydureon BCise formulation would continue.

A. COMMITTEE ACTION: EXENATIDE ONCE WEEKLY (BYDUREON) ON THE BCF—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing exenatide once weekly (Bydureon) from the BCF upon signing of the minutes. Bydureon will be removed from the manual PA criteria of the non step-preferred GLP1RA drugs. As a result, the exenatide once weekly autoinjector (Bydureon BCise) will be the sole GLP1RA remaining on the BCF.

VII. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

a) **Attention Deficit/Hyperactivity Disorder (ADHD) Stimulants – Methylphenidate Extended Release 72 mg tablets (Relexxii, generics)—**Relexxii 72 mg ER tablets use the same technology as found in Concerta, which is available in 18 mg, 27 mg, 36 mg, and 54 mg tablets. FDA approval for Relexxii was based on the data for Concerta. Several cost-effective extended release methylphenidate formulations are available on the UF without PA. Relexxii and its generics are not cost effective relative to other formulary long-acting methylphenidate formulations including generic Concerta and methylphenidate ER/CD/LA, Quillivant XR, and Aptensio XR.

> ***COMMITTEE ACTION: NEW PA CRITERIA FOR RELEXXII 72 mg—*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for methylphenidate 72 mg extended release tablets in new and current users, to ensure that more cost-effective methylphenidate ER products are tried first. See Appendix C for the full criteria.

b) **Targeted Immunomodulatory Biologics (TIBs) – Rilonacept injection (Arcalyst)—**The targeted immunomodulatory biologic rilonacept (Arcalyst) was originally approved in 2008 for the treatment of cryopyrin-associated periodic syndrome (CAPS), and for maintenance of remission of deficiency of interleukin-1 receptor antagonist (DIRA), which are rare conditions. In March 2021, Arcalyst received a new indication for treatment of recurrent pericarditis.

The 2015 European Society of Cardiology treatment guidelines for pericardial disease recommend aspirin or NSAIDs plus colchicine for six months as first-line therapy to improve remission rates and prevent recurrences of pericarditis. Corticosteroids may be added if there is an incomplete response to first-line therapies. MHS provider input supported PA to require a trial of conventional therapies for recurrent pericarditis.

> ***COMMITTEE ACTION: TARGETED IMMUNOMODULATORY BIOLOGICS – RILONACEPT (ARCALYST)—***The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for rilonacept (Arcalyst) in new users, to ensure that guideline recommended therapies for recurrent pericarditis are tried first. See Appendix C for the full criteria.

2. Updated PA Criteria and Step Therapy

Updates to the manual PA criteria and step therapy were recommended due to availability of cost-effective alternative treatments, clinical trial data, clinical practice

guideline updates, or provider recommendation. The updated PAs and step therapy outlined below will apply to new users. See Appendix C for full criteria.

a) **Gastrointestinal-2 Agents: Chronic Idiopathic Constipation/Irritable Bowel Syndrome Constipation predominant (CIC/IBS-C) — lubiprostone (Amitiza)**—The CIC/IBS-C class was reviewed in November 2018. Amitiza, linaclotide (Linzess), and plecanatide (Trulance) were made uniform formulary, with prucalopride (Motegrity) designated non-formulary and tegaserod (Zelnorm) designated as Tier 4/Not covered. As of November 2018, the drugs in the class all require PA, with a trial of standard laxatives required first. A generic to Amitiza has recently entered the market; however, it is markedly more expensive than Linzess. The manual PA criteria for Amitiza was updated to require a trial of linaclotide (Linzess) prior to use of Amitiza for all new users.

   COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Amitiza.

b) **Antirheumatics: Injectable methotrexate—Otrexup and Rasuvo**—The injectable methotrexate agents were reviewed in November 2015. Generic methotrexate injectable solution is uniform formulary while both methotrexate autoinjector formulations (Otrexup and Rasuvo) are NF. Oral methotrexate tablets are BCF. The manual PA criteria for Otrexup and Rasuvo were updated to require oral methotrexate in addition to generic injectable methotrexate prior to use of these less cost-effective autoinjector formulations for all new users. The updated PA criteria are similar to the PA criteria recommended for the new drug Reditrex (See p 12).

   COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Otrexup and Rasuvo.

c) **OAB Drugs – mirabegron (Myrbetriq)—**Manual PA criteria for Myrbetriq have been in place since 2014. Vibegron (Gemtesa) is a new beta-3 adrenergic receptor agonist also approved for OAB, which was recommended for UF status (see p 12 in the new drug section). Vibegron is a therapeutic alternative to mirabegron, and is more cost effective. New users of Myrbetriq will now be required to try Gemtesa first, in addition to the existing PA requirements. *Note that Myrbetriq tablets received an additional indication for neurogenic detrusor overactivity (NDO) at the August 2021 P&T meeting; refer to the August 2021 meeting for the full updates.).*

   COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Myrbetriq.

d) **Renin-Angiotensin Antihypertensives: Combinations – sacubitril/valsartan (Entresto)—**Sacubitril/valsartan is an angiotensin receptor-neprilysin inhibitor

(ARNI) approved for treating patients with chronic heart failure (HF). Entresto was reviewed and recommended for UF status with a manual PA in May 2016. Current PA criteria requires the patient to have been stabilized on an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) first, and to have a left ventricular ejection fraction (LVEF) ≤ 35%, based on the inclusion criteria of the PARADIGM clinical trial, which was used to gain FDA approval.

The Committee reviewed the February 2021 American College of Cardiology (ACC) Expert Consensus Decision Pathway for Optimization of HF, which now recommends ARNI therapy as preferred for first line treatment of chronic HF. Earlier this year, the FDA expanded the Entresto package insert, which now states the drug is indicated to decrease the risk of cardiovascular death and HF hospitalization in adults with chronic heart failure, with the benefits most evident in patients with LVEF below normal. The PARAGON trial results in patients with heart failure and preserved ejection fraction (HFpEF) were also reviewed. MHS cardiology providers have requested expanded access to Entresto.

COMMITTEE ACTION: ***UPDATED MANUAL PA CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the current PA criteria for sacubitril/valsartan, recognizing that guideline directed medical therapies (GDMT) for chronic HF, including Entresto are underutilized, and also acknowledging the 2021 ACC consensus pathway recommendations and updated FDA package labeling. Follow-up monitoring for Entresto utilization will be ongoing to evaluate usage patterns.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

- **Oncological Agents**
  - **Lung Cancer – crizotinib (Xalkori)**—The manual PA criteria were updated to allow for the new indication for treatment of relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase-positive (ALK+) in pediatric patients one year of age and older, and young adults. There is a limitation of use in older adults for this new indication as safety and efficacy of Xalkori is not established in older adults with relapsed or refractory, systemic ALK+ ALCL.
  - **Lung Cancer – lorlatinib (Lorbrena)**—Manual PA criteria now allow use as first-line treatment of adults with ALK+ metastatic non-small cell lung cancer (NSCLC) when tumors are ALK+ as detected by an FDA-approved test.
- **Targeted Immunomodulatory Biologics (TIBs)**

- **adalimumab (Humira)**—Manual PA criteria now allow use in pediatric patients 5 years of age and older as well as adults for moderately to severely active ulcerative colitis (UC).
- **tocilizumab subcutaneous (Actemra SQ)**—Includes the new FDA-approved indication for slowing the rate of decline in pulmonary function in systemic sclerosis-associated interstitial lung disease (SSc-ILD) in adults.

- **Parkinson's Disease Agents – amantadine (Gocovri)**—Includes the new indication for use as adjunctive treatment to levodopa/carbidopa for add-on therapy for "off" episodes of Parkinson's Disease (PD).
- **Pulmonary Arterial Hypertensions: prostacyclin nebulized – treprostinil (Tyvaso) —** Includes the new FDA-approved indication for treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Xalkori, Lorbrena, Humira, Actemra SQ, Gocovri, and Tyvaso. See Appendix C for the full PA criteria.

B. Quantity Limits

General QLs: QLs were reviewed for 7 drugs from drug classes where there are existing QLs, and for some of the new drugs, including the TIBs, methotrexate, antineoplastic and premalignant lesion agents, OAB drugs and oncological agents.

COMMITTEE ACTION: QLs—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for Arcalyst, Reditrex, Klisyri, Vesicare LS, Fotivda, Tepmetko, and Ukoniq. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

COMMITTEE ACTION: PA AND QLs IMPLEMENTATION PERIOD—The P&T Committee recommended the following implementation periods:

- (17 for, 0 opposed, 0 abstained, 1 absent) The new PA for methylphenidate 72 mg extended release tablets (Relexxii) will become effective in new and current users the first Wednesday 90 days after the signing of the minutes and DHA will send letters to affected patients (May 18, 2022).

- (16 for, 0 opposed, 1 abstained, 1 absent) The new PA for Arcalyst will become effective in new users the first Wednesday 30 days after the signing of the minutes (March 16, 2022).
- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria in new users for the oncology drugs Xalkori and Lorbrena; the TIBs Humira and Actemra SQ; the Parkinson's Disease Agent Gocovri; the pulmonary arterial hypertension drug Tyvaso will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2022)
- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria in new users for Amitiza, the updates to the Rasuvo and Otrexup PA criteria in new users, updates to the PA for Myrbetriq in new users, and the removal of the Entresto PA criteria will become effective the first Wednesday 30 days after the signing of the minutes (March 16, 2022).
- (17 for, 0 opposed, 0 abstained, 1 absent) the QLs listed in Appendix D will become effective the first Wednesday 2 weeks after the signing of the minutes in all POS (March 2, 2022).

VIII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for several product line extensions ("follow-on products") by the original manufacturer. Line extensions have the same FDA indications as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION*—**The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMPI List status, and specialty status for the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes (March 2, 2022).

- **Oncological Agents: 2nd-Gen Antiandrogens—**designating **enzalutamide (Xtandi) 40 mg and 80 mg tablets** as UF, with the same Tier 1 co-pay, same manual PA criteria requirements, QL, and same specialty status as Xtandi 40 mg capsule. (Note that neither the Xtandi caps or tabs will be on the specialty program.)
- **Targeted Immunomodulatory Biologics: Miscellaneous—**designating **tofacitinib oral solution (Xeljanz)** as UF, with the same step therapy and PA criteria, QL, specialty status, and EMMPI List status, similar to Xeljanz 5 mg and 10 mg tablets. (Note that Xeljanz XR tablets are on the specialty program).

- **Diabetes Non-Insulin: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—**designating **semaglutide (Ozempic) 1 mg/0.75 mL injection** as NF and Non-step-preferred, with the same MN criteria, same PA criteria, and EMMPI List status, similar to the existing Ozempic injection strengths.
- **Parkinson's Disease Agents—**designating **opicapone (Ongentys) 25 mg capsules** as UF, similar to Ongentys 50 mg capsules.

IX. RE-EVALUATION OF NF GENERICS: CALCIUM CHANNEL BLOCKERS (CCBs)

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The P&T Committee's process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, of the then TRICARE Management Agency (now DHA), on July 24, 2007. A summary of the criteria is available in Appendix E of the November 2012 P&T Committee minutes available online at https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/DoD-Pharmacy-and-Therapeutics-Committee-2021/Meeting-Minutes.

CCBs: The P&T Committee re-evaluated the UF status of the six NF CCBs, all of which are now available in generic formulations: verapamil capsule 24 hr (Verelan PM); verapamil capsule (Verelan); diltiazem tablet ER 24h (Cardizem LA); isradipine capsule (generic only); nicardipine (generic only); and nisoldipine tablet ER 24h (Sular).

Verelan PM has been designated as NF since the CCB drug class review in August 2005. The P&T Committee re-evaluated the formulary status of Verelan PM due to price reductions in generic verapamil capsule 24 hour formulations available across all three points of service (POS). There was no new clinical data to change the conclusion that the CCBs are highly therapeutically interchangeable.

Current utilization trends, numbers of generic products on the market from different manufacturers, and relative cost-effectiveness, including the weighted average cost per unit for generic verapamil capsule 24 hour were also reviewed. The unit cost of generic verapamil capsule 24 hour formulations has dropped significantly from the previous generic and brand cost, and the generic supply appears stable. The other NF CCB products have not shown a significant decline in cost.

COMMITTEE ACTION: FORMULARY STATUS, AND EMMPI RECOMMENDATION AND IMPLEMENTATION —The P&T Committee recommended (17 for, 0 opposed, 0 abstained, and 1 absent) the following, effective the first Wednesday 30 days after signing of the minutes:

- Returning generic verapamil capsule 24 hour (Verelan PM) to formulary status

- Removing generic verapamil capsule 24 hour from the EMMPI program

- The remaining NF CCBs, Verelan, Cardizem LA, isradipine, nicardipine, and nisoldipine will remain NF, and remain subject to the requirement that they be generally available only at mail order, regardless of generic status.

X. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE MAIL ORDER PROGRAM

Newly Approved Drugs per 32 CFR 199.21(g)(5)
See Appendix F for the mail order status of medications designated UF or NF during the May 2021 P&T Committee meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement. The implementation date for all of the recommendations from the May 2021 meeting listed in Appendices E and F, including those for newly approved drugs, will be effective upon the first Wednesday two weeks after the signing of the minutes.

COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent), adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. See Appendix F.

XI. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFs: MELATONIN

Background—The DoD P&T Committee continued reviewing the OTC drugs on the MHS GENESIS OTC list. For a full description of the background and process details, refer to the May 2019 and August 2019 DoD P&T Committee meeting minutes, found at http://health.mil/PandT.

Factors influencing whether a particular OTC product is retained or removed from the MHS GENESIS OTC List include volume and utilization across multiple MTFs; feedback from MTF stakeholders to include primary care providers, pediatricians, and other providers, DHA Clinical Community advisory groups, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

- **Melatonin—**The FDA classifies melatonin as a dietary supplement, therefore it is not FDA-approved for any indication. Melatonin is commonly used as a sleep aid or for treating circadian rhythm disorders. There is little risk of harm and few adverse effects associated with its use.

  The most utilized strengths of melatonin currently dispensed at MTFs include the 3 mg and 5 mg tablets. The average cost per month is less than $1 per prescription, and 39% of all MTFs have dispensed at least one melatonin prescription in the last quarter. Providers consistently reported wanting the option to prescribe melatonin at MTFs.

  1. ***COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—***The P&T Committee recommended (15 for, 1 opposed, 0 abstained, 2 absent) the following:

     - Retaining melatonin 3 mg (GCN 68738) and 5 mg (GCN 99671) tablets on the MHS GENESIS OTC list.
     - Removing melatonin 1mg tablet (GC 94035), melatonin 5 mg SL tablet (GCN 13448) and the 10 mg mphase tablet (GCN 31649) from the MHS GENESIS OTC list.
     - An implementation of 120 days following signing of the minutes for the products removed from the list. No patient letters are required due to the typically intermittent use of the products. Appendix I outlines specific products retained or added to the MHS GENESIS OTC List.

XII. ITEMS FOR INFORMATION

A. Veterans Affairs Continuity of Care List

The P&T Committee was briefed on the updated DoD/VA Continuity of Care Drug List, a joint list of medications for pain, sleep disorders, psychiatric, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by FY16 NDAA, Section 715. Additions, deletions, and clarifications to the list were based on discussions between DoD and VA subject matter experts. The updated list will now go to the VA for review and will be posted on www.health.mil when finalized.

B. MHS and Commercial Pharmacy Trends

The Committee was briefed on various aspects of MHS prescribing, including overall trends and spends, the effect of co-pay changes on utilization patterns, the top 25 drug classes, and the continued increases in use and cost of specialty drugs. Comparisons between the MHS and commercial health plans in these trends was discussed.

C. Post-Implementation Review: Utilization Management Actions

A retrospective review of several UM actions was presented to the Committee, including chlorzoxazone, doxycycline IR/DR, droxidopa (Northera), epinephrine injector (Auvi-Q), lidocaine-tetracaine 7%-7%, prenatal vitamins (Azesco, Trinaz, Zalvit), rotigotine (Neupro Patch), topical sulfacetamide, and venlafaxine ER 24 hour tablets. Overall trends in utilization and expenditures were reviewed since implementation.

XIII. ADJOURNMENT

The meeting adjourned at 1630 hours on May 6, 2021. The next meeting will be in August 2021.

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

Brian C. Lein, MD
Assistant Director,
Healthcare Administration
for Ronald J. Place
LTG, MC, USA
Director

11 Feb 2022
Date

Appendix A—Attendance: May 2021 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Col Markus Gmehlin BSC	Chief, DHA Pharmacy Operations Division (POD)
CDR Scott Raisor	DHA Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
MAJ Wendra Galfand, MC	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Christopher Janik for CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Matthew Kemm for Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Col Corey Munro, BSC	Air Force, Pharmacy Officer
Ms. Beth Days	Oncology Pharmacist
LCDR Joseph An, MSC	Navy, Oncologist
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
Fakhrudin Valibhai, PharmD	COR TRICARE Pharmacy Program
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
LCDR William Agbo	DLA Troop Support
Janet Dailey, PharmD (May 5th) Kelly Echevarria, PharmD (May 6th)	Department of Veterans Affairs

Appendix A—Attendance: May 2021 P&T Committee Meeting

Guests	
CPT Jennifer Weeks, MC	Army, Physician at Large alternate
Maj Angelina Escano, MC	Air Force physician
Mr. Jason Wray	DLA Troop Support
Ms. Pat Legra	DHA Contracting
Ms. Viktoria Reed	DHA Contracting
Mr. Dwight Bonham	DHA Contracting
Mr. Hudson Tompkins	DHA Contracting
Ms. Grace Steier	DHA Contracting
Mr. Monroe Porter	DHA Contracting
Others Present	
CDR Heather Rovey, MSC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
MAJ Triet Nguyen, MSC	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
Mr. David Folmar	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Ebony Moore	DHA Formulary Management Branch Contractor
CPT Julian Rodriguez, MSC	BAMC Pharmacy Resident

Drug / Drug Class	Medical Necessity Criteria
Class Review MN Criteria	
• zolpidem sublingual (Intermezzo) • zolpidem sublingual (Edluar) • zolpidem oral spray (Zolpimist) **Sleep Disorders: Insomnia**	• No alternative formulary agent: patient has documented swallowing difficulties **Formulary alternatives:** zolpidem IR tab, zaleplon
• tasimelteon (Hetlioz/Hetlioz LQ) **Sleep Disorders: Insomnia**	• Two agents (OTC melatonin and ramelteon) have resulted in therapeutic failure **Formulary alternatives:** melatonin OTC, ramelteon
Newly Approved Drugs MN Criteria	
• ethinyl estradiol (EE) 20 mcg/levonorgestrel 0.1 mg chewable tablet (Tyblume) **Contraceptive Agents: Monophasics with 20 mcg estrogen**	• No alternative formulary agent: patient requires Tyblume chewable tablets due to established swallowing difficulties. **Formulary alternatives:** levonorgestrel/EE tablets (generic Lutera, Sronyx, or equivalent)
• levothyroxine sodium 100 mcg/ 5 mL oral solution (Thyquidity) **Thyroid Agents**	• No alternative formulary agent: patient is not able to swallow capsules or sprinkle capsules on food or chew a tablet **Formulary alternatives:** Tirosint-SOL, Tirosint capsule, levothyroxine tabs (various)
• mannitol inhalation powder (Bronchitol) **Respiratory Agents Miscellaneous**	• Use of two formulary agents (Pulmozyme, hypertonic saline 7% inhalation) are contraindicated • Two formulary agents (Pulmozyme, hypertonic saline 7% inhalation) resulted in therapeutic failure/inadequate response **Formulary alternatives:** dornase alfa (Pulmozyme), hypertonic saline 7% inhalation (sodium chloride)

Drug / Drug Class	Medical Necessity Criteria
• methotrexate injection (Reditrex) **Antirheumatics: Injectable Methotrexate**	• No alternative formulary agent: The patient requires a prefilled syringe due to decreased finger dexterity, or limited vision or impaired cognition **Formulary alternatives:** generic methotrexate vials, generic methotrexate tablets
• solifenacin oral suspension (Vesicare LS) **Overactive Bladder Agents**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result in therapeutic failure **Formulary alternatives:** oxybutynin
• tirbanibulin 1% ointment (Klisyri) **Antineoplastic and Premalignant Lesion Agents**	• Use of formulary agents is contraindicated • Formulary agents result in therapeutic failure **Formulary alternatives:** fluorouracil, imiquimod
• voclosporin (Lupkynis) **Immunosuppressives**	• Patient has experienced significant adverse effects from formulary agents • Formulary agents result in therapeutic failure • Patient previously responded to the non-formulary agents and changing to a formulary agent would incur unacceptable risk **Formulary alternatives:** tacrolimus, mycophenolate, corticosteroids, cyclophosphamide, Benlysta

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• suvorexant (Belsomra) • lemborexant (Dayvigo) **Sleep Disorders: Insomnia**	**<u>Updates from the May 2021 meeting are in bold.</u>** Manual PA criteria apply to all new users of Belsomra and Dayvigo. <u>Manual PA criteria</u>: Belsomra and Dayvigo are approved if <u>all</u> criteria are met: • **The provider acknowledges that the following agents are available without prior authorization: zolpidem IR and ER, zaleplon, eszopiclone** • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, **cognitive behavioral therapy for insomnia (CBT-I),** sleep hygiene, **and the patient will continue with non-pharmacologic therapies throughout treatment** • Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release OR eszopiclone • Patient does not have a current or previous history of narcolepsy • Patient does not have a current or previous history of drug abuse Non-FDA-approved uses are not approved. **Prior authorization expires in 1 year.** **<u>Renewal criteria</u> Note that initial TRICARE PA approval is required for renewal. PA will be renewed for an additional 1 year if the renewal criteria are met.** • **Patient has not adequately responded to non-pharmacologic therapies** • **Patient agrees to continue with non-pharmacologic therapies including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), and/or sleep hygiene** • **Patient continues to respond to the drug**

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• tasimelteon (Hetlioz/Hetlioz LQ) **Sleep Disorders: Insomnia**	**<u>Updates from the May 2021 meeting are in bold. (Note that changes recommended at the Feb 2021 meeting in the UM section have been updated)</u>** Manual PA criteria apply to all new users of Hetlioz/Hetlioz LQ. <u>Manual PA criteria</u>: Hetlioz or Hetlioz LQ is approved if <u>all</u> of the following criteria are met: • The provider acknowledges that Hetlioz capsules are not approved for pediatrics or adolescents and are not approved for treating SMS; and that Hetlioz LQ liquid is only approved for pediatrics with SMS and is not approved for Non-24 sleep wake disorder or for use in adults. • For the Hetlioz capsule formulation, the patient is 18 years of age or older and is totally blind and has a documented diagnosis of non-24 sleep wake disorder OR • For the Hetlioz LQ liquid formulation, the patient is 3 years of age up to 15 years of age and has a documented diagnosis of Smith-Magenis Syndrome (SMS) • The patient has had a trial of melatonin and either failed or had an adverse event • **The patient has tried and failed ramelteon** • The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers) Non-FDA-approved uses are not approved including insomnia, jet lag disorder, or other circadian rhythm disorders. PA Criteria will expire after 6 months (if patient has not responded after 6 months, they will be deemed a non-responder) **<u>Renewal criteria</u>: Note that initial TRICARE PA approval is required for renewal** • **The patient has been receiving Hetlioz/Hetlioz LQ for 6 months and has had a documented response to therapy. Renewal approved for 6 months.**

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• zolpidem sublingual (Intermezzo • zolpidem sublingual (Edluar) • zolpidem oral spray (Zolpimist) **Sleep Disorders: Insomnia**	**Updates from the May 2021 meeting are in bold.** Note that the current automation will be removed. **Manual PA criteria apply to all new and current users of Intermezzo, Edluar, and Zolpimist.** Manual PA criteria: Intermezzo, Edluar, and Zolpimist are approved if all criteria are met: • **The provider acknowledges that the following agents are available without prior authorization: zolpidem IR, zolpidem ER, zaleplon, eszopiclone** • Patient has documented diagnosis of insomnia characterized by difficulties with **sleep onset** • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, **cognitive behavioral therapy for insomnia (CBT-I),** sleep hygiene **and the patient will continue with non-pharmacologic therapies throughout treatment** • Patient has tried and failed or had clinically significant adverse effects to **zolpidem immediate-release or zaleplon** • **Patient has tried and failed or had clinically significant adverse effects with an orexin antagonist (i.e., Belsomra or Dayvigo)** • Patient has documented swallowing difficulties Non-FDA-approved uses are not approved. **Prior authorization expires after 1 year.** **Renewal criteria Note that initial TRICARE PA approval is required for renewal. PA will be renewed for an additional 1 year if the renewal criteria are met.** • **Patient has not adequately responded to non-pharmacologic therapies** • **Patient agrees to continue with non-pharmacologic therapies including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), and/or sleep hygiene** • **Patient continues to respond to the drug**
Newly Approved Drug PAs	
• ethinyl estradiol (EE) 20 mcg/levonorgestrel 0.1 mg chewable tablets (Tyblume) **Contraceptive Agents: Monophasics with 20 mcg estrogen**	Manual PA criteria apply to all new users of Tyblume. **PA does not apply to patients younger than 12 years of age (age edit)** Manual PA criteria: Tyblume is approved if all criteria are met: • Provider acknowledges that other formulations of EE 20 mcg/levonorgestrel 0.1 mg (e.g., Sronyx, Lutera, or equivalent) do not require prior authorization. • Patient has been counseled that this medication needs to be taken on an empty stomach with a full glass of water • Patient requires chewable tablets and cannot swallow due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, developmental disability, etc. and not due to convenience Non-FDA approved uses are not approved, including migraine headache Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• levothyroxine sodium 100 mcg/5 mL oral solution (Thyquidity) **Thyroid Agents**	Manual PA criteria apply to all new users of Thyquidity. **PA does not apply to patients younger than 6 years of age (age edit)** Manual PA criteria: Thyquidity is approved if all criteria are met: • The patient is not able to chew a levothyroxine tablet • The patient is not able to swallow a levothyroxine capsule or tablet • Thyquidity is prescribed by or in consultation with an endocrinologist Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. No renewal allowed; must fill out a new PA.
• mannitol inhalation powder (Bronchitol) **Respiratory Agents Miscellaneous**	Manual PA criteria apply to all new users of Bronchitol. Manual PA criteria: Bronchitol is approved if all criteria are met: • The provider is aware and acknowledges that dornase alfa (Pulmozyme) and hypertonic saline 7% inhalation (sodium chloride) are formulary alternatives available to DoD beneficiaries without the need of PA. Providers are encouraged to consider changing the prescription to Pulmozyme or hypertonic saline 7% inhalation • The patient is 18 years of age or older • The patient has a diagnosis of cystic fibrosis (CF) • Bronchitol is prescribed by or in consultation with a pulmonologist • The provider has performed a Bronchitol Tolerance Test (BTT) AND the patient did not have a severe reaction • The patient has been counseled on how to appropriately use Bronchitol • The patient has or will be prescribed a short-acting bronchodilator (i.e., ProAir is TRICARE's formulary short-acting beta agonists [SABA]) to use before treatment with Bronchitol • The patient has tried and had an inadequate response to dornase alfa (Pulmozyme) and hypertonic saline OR has a contraindication to both products • The patient will not use Bronchitol in combination with hypertonic saline Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• methotrexate subcutaneous injection (Reditrex) • methotrexate subcutaneous injection (Otrexup, Rasuvo) **Antirheumatics: Injectable Methotrexate**	Manual PA criteria apply to all new users of Reditrex, Otrexup and Rasuvo **Updates to Rasuvo and Otrexup from the May 2021 meeting are in bold** Manual PA criteria: Reditrex, Otrexup, or Rasuvo is approved if all criteria are met: • **The patient has a diagnosis of active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis or severe, recalcitrant, disabling psoriasis in adults** • **The patient has tried and failed ORAL methotrexate. AND** • The patient has experienced intolerance or significant adverse effects from generic injectable methotrexate OR • Patient has decreased finger dexterity, limited vision or impaired cognition resulting in the inability to utilize generic injectable methotrexate. Non-FDA-approved uses are not approved including neoplastic diseases. Prior authorization does not expire.
• ponesimod (Ponvory) **Multiple Sclerosis Agents: Oral Miscellaneous**	Manual PA is required for all new users of Ponvory. Manual PA Criteria: Ponvory is approved if all criteria are met: • Prescribed by a neurologist • Patient has a documented diagnosis of relapsing forms of multiple sclerosis (MS) • Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroximel fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunamide [Aubagio]) • Patient has not previously failed a treatment course of fingolimod (Gilenya) • Patient has not previously failed a treatment course of siponimod (Mayzent) • Patient has not previously failed a treatment course of ozanimod (Zeposia) • Provider acknowledges that all recommended Ponvory monitoring has been completed and the patient will be monitored throughout treatment as recommended in the package insert. Monitoring includes complete blood count (CBC); liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), pulmonary function tests (PFTs), blood pressure, skin assessments and macular edema screening as indicated. • Ponvory will not be used in patients with significant cardiac history, including: o Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization o Patients with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• solifenacin oral suspension (Vesicare LS) **Over Active Bladder Agents**	Manual PA criteria apply to all new users of solifenacin oral suspension (Vesicare LS). Automated PA Criteria**:** PA does not apply to patients younger than 12 years of age (age edit) AND if the patient has filled a prescription for oxybutynin tablets or oral syrup at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. If automated criteria are not met: Manual PA criteria: Vesicare LS is approved if all criteria are met: • The provider acknowledges that oxybutynin oral syrup is available for patients with neurogenic detrusor overactivity and does not require prior authorization • Prescribed by or in consultation with a urologist or nephrologist • Patient has a diagnosis of neurogenic bladder secondary to detrusor overactivity and/or myelomeningocele • Patient cannot swallow due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience OR • Patient requires a dose that cannot be achieved without splitting a solifenacin tablet • Patient has tried and failed or has a contraindication to oxybutynin Non-FDA-approved uses are not approved including for overactive bladder. Prior authorization does not expire.
• tepotinib (Tepmetko) **Oncological Agents: Lung Cancer**	Manual PA criteria apply to all new users of Tepmetko. Manual PA criteria: Tepmetko is approved if all criteria are met: • The patient is 18 years of age or older • Tepmetko is prescribed by or in consultation with a hematologist/oncologist • The patient has metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to laboratory-confirmed mesenchymal-epithelial transition (MET) exon 14 skipping. • The provider will monitor for interstitial lung disease (ILD)/pneumonitis and hepatotoxicity • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• tirbanibulin 1% ointment (Klisyri) **Antineoplastic and Premalignant Lesion Agents**	Manual PA criteria apply to all new users of Klisyri. Manual PA criteria: Klisyri is approved if all criteria are met: • Klisyri is prescribed by or in consultation with a dermatologist • The patient is 18 years of age or older • The patient has a diagnosis of actinic keratosis of the face or scalp • The patient has tried and failed or has a contraindication to fluorouracil and imiquimod Non-FDA-approved uses are not approved. Prior authorization does not expire.
• tivozanib (Fotivda) **Oncological Agents: Renal Cell Carcinoma**	Manual PA criteria apply to all new users of Fotivda. Manual PA criteria: Fotivda is approved if all criteria are met: • The patient is 18 years of age or older • The patient has laboratory evidence of relapsed or refractory advanced renal cell carcinoma with clear cell histology following two or more prior systemic therapies including at least one VEGFR kinase inhibitor other than sorafenib (Nexavar) (e.g., Sutent, Votrient, Cabometyx, or Lenvima). • The patient will be monitored for hypertensive crisis, cardiac ischemia, arterial and venous thromboembolism, hemorrhage, proteinuria, thyroid dysfunction, and reversible posterior leukoencephalopathy syndrome • Fotivda is prescribed by or in consultation with a hematologist/oncologist • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 month after cessation of therapy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• umbralisib (Ukoniq) **Oncological Agents**	Manual PA criteria apply to all new users of Ukoniq. Manual PA criteria: Ukoniq is approved if all criteria are met: • The patient is 18 years of age or older • Ukoniq is prescribed by a hematologist/oncologist • The patient has a diagnosis of: o Relapsed or refractory marginal zone lymphoma (MZL) AND has received at least one prior anti-CD20-based regimen [e.g,. rituximab (Rituxan) obinutuzumab (Gazyva)] OR o Relapsed or refractory follicular lymphoma (FL) AND has received at least three prior lines of systemic therapy including an anti-CD20 based regimen and an alkylating agent • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Female patients of childbearing potential and male patients with female partners of childbearing potential agree to use contraception during treatment and for at least 1 month after the cessation of treatment • Male patients are aware that Ukoniq may cause male infertility • The diagnosis is NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Non-FDA-approved uses are NOT approved, except as noted above Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• vericiguat (Verquvo) **Cardiovascular Agents Miscellaneous**	Manual PA criteria apply to all new users of Verquvo. Manual PA criteria: Verquvo is approved if all criteria are met: • Patient is 18 years of age or older • Initial prescription is written by or in consultation with a cardiologist • Patient has a documented diagnosis of chronic HF (NYHA II-IV) • Patient has a left ventricular ejection fraction (LVEF) < 45% • Patient has worsening heart failure symptoms defined as one of the following: o History of previous heart failure hospitalization within the past 6 months OR o Outpatient IV diuretics for heart failure (without hospitalization) within the past 3 months • Patient's systolic blood pressure is at least 100 mmHg • Patient is receiving appropriate guideline-directed medical therapy (GDMT), including the following: ACE/ARB/ARNI, BB, MRA, SGLT2 inhibitor, hydralazine plus nitrate, Corlanor, and/or diuretic o Unless contraindicated or unable to tolerate due to adverse effects • Patient is not receiving concomitant treatment with long-acting nitrates, other sGC stimulators (riociguat [Adempas], or PDE5 inhibitors (sildenafil [Viagra, Revatio], tadalafil [Cialis, Adcirca]) • For women of childbearing age: o Patient is not pregnant AND o Provider is aware and the patient has been counseled on the teratogenicity risks with Verquvo and will comply with the contraceptive requirements listed in the package insert. Non-FDA-approved uses are not approved including HFpEF, acute decompensated HF, PAH. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• vibegron (Gemtesa) **Overactive Bladder Agents**	Manual PA criteria apply to all new users of Gemtesa. Manual PA criteria: Gemtesa is approved if all criteria are met: • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with 2 formulary step-preferred products (oxybutynin IR, oxybutynin ER, tolterodine ER) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with at least one oral OAB medication OR is at increased risk for such central nervous system effects due to comorbid conditions or other medications, • The patient's creatinine clearance (CrCl) is greater than 15 mL/min Non-FDA-approved uses are not approved. Prior authorization does not expire.
• voclosporin (Lupkynis) **Immunosuppressives**	Manual PA criteria apply to all new users of Lupkynis. Manual PA criteria: Lupkynis is approved if all criteria are met: • The patient is 18 years of age or older • Lupkynis is prescribed by or in consultation with a nephrologist • The patient has a documented diagnosis of active lupus nephritis (LN) • The patient has tried and failed previous therapy with mycophenolate • The patient has tried and failed previous therapy with either tacrolimus or cyclosporine • Lupkynis will not be used concomitantly with cyclophosphamide, as evidence for this combination has not been established • Due to drug interactions, the patient agrees to avoid eating grapefruit or drinking grapefruit juice while taking Lupkynis • The patient will not receive live vaccines • The provider agrees to monitor renal function, blood pressure, ECG, electrolytes, and monitor for neurotoxicity including risk of posterior reversible encephalopathy syndrome (PRES) • The provider is aware and patient is informed of the increased risk for developing malignancies and serious infections with Lupkynis or other immunosuppressants that may lead to hospitalization or death • For women of childbearing age: the provider is aware and patient is informed of the risk of fetal harm Non-FDA-approved uses are not approved including kidney transplantation. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
New PAs	
• methylphenidate extended release 72 mg tablets (Relexxii) **Attention Deficit/Hyperactivity Disorder: Stimulant**	Manual PA criteria apply to all new and current users of methylphenidate extended release 72 mg tablets (Relexxii). Manual PA criteria: Relexxii is approved if all criteria are met: • Provider is aware and acknowledges that several other long-acting methylphenidate ER formulations, including generic Concerta, generic Metadate CD, generic Methylin ER, generic Aptensio XR, generic Ritalin, and Quillivant XR are available to DoD beneficiaries without requiring prior authorization • The provider must explain why the patient requires Relexxii 72 mg ER tablets and cannot take the available alternatives. Non-FDA-approved uses are not approved. Prior authorization does not expire.
• rilonacept injection (Arcalyst) **Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitor**	Manual PA criteria apply to all new users of rilonacept (Arcalyst). Manual PA criteria: Arcalyst is approved if all criteria are met: • Patient has one of the following diagnoses: o Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) • Patient is 12 years of age of older o Recurrent pericarditis • Patient is 12 years of age of older • Prescription is written by or in consultation with a cardiologist • Patient has a contraindication to colchicine and at least ONE of the following drug classes: aspirin, NSAIDs OR • Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes: aspirin, NSAIDs, corticosteroids o Deficiency of Interluekin-1 Receptor Antagonist (DIRA) • The patient weighs at least 10 kg (22 pounds) • The patient is not concurrently receiving a TNF-inhibitor (e.g., Humira, Enbrel, Cimzia, and Simponi) due to the increased risk of serious infections. Non-FDA-approved uses are not approved, including rheumatoid arthritis, neonatal-onset multisystemic inflammatory disease (NOMID), cardiovascular disease other than pericarditis (MI, acute coronary syndrome, atherosclerosis, heart failure, and Kawasaki disease), and gout. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Updated PAs	
• lubiprostone (Amitiza) **Gastrointestinal-2 Agents: CIC/IBS-C**	**Updates from the May 2021 meeting are in bold.** Manual PA criteria apply to all new users of Amitiza. Manual PA Criteria: Coverage is approved if all criteria are met: • The patient is 18 years of age or older OR is prescribed in consultation with a pediatric gastroenterologist for pediatric patients • Patient has documented symptoms for ≥ 3 months • Patient has diagnosis of constipation predominant irritable bowel syndrome (IBS-C) or chronic idiopathic constipation (CIC) or opioid induced constipation (OIC) in adults with chronic, non-cancer pain o Patient is currently taking an opioid if used for OIC o Patient is female if used for IBS-C • Patient has documentation of failure of an increase in dietary fiber/dietary modification to relieve symptoms • Patient has absence of GI obstruction • Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as o osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories) o bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids; o stool softener (e.g., docusate); o stimulant laxative (e.g., bisacodyl, sennosides) • **Patient has tried and failed linaclotide (Linzess)** • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik) Non-FDA-approved uses are NOT approved Prior authorization expires after 1 year. Renewal PA Criteria: Note that initial TRICARE PA approval is required for renewal. PA will be approved for 1 year for continuation of therapy if: • Patient has had improvement in constipation symptoms and • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• mirabegron (Myrbetriq) **Overactive Bladder Agents**	**Updates from the May 2021 meeting are in bold.** Manual PA criteria apply to all new users of mirabegron (Myrbetriq). Manual PA criteria: Myrbetriq is approved if all criteria are met: • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with 2 formulary step-preferred products (oxybutynin IR, oxybutynin ER, tolterodine ER) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such central nervous system effects due to comorbid conditions or other medications, • **Patient has tried and failed or has a contraindication to vibegron (Gemtesa)** • The patient does not have a CrCl < 15 mL/min • If the CrCl is between 15-29 mL/min, the dosage does not exceed 25 mg QD Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors**	**Changes from the May 2021 meeting are in bold.** Manual PA criteria applies to all new users of adalimumab (Humira). Manual PA Criteria: Humira is approved if all criteria are met: Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication: • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS) • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy • Moderate to severely active Crohn's disease (CD) • **Moderate to severely active ulcerative colitis (UC)** • Moderate to severe hidradenitis suppurativa (HS) • Non-infectious intermediate, posterior, and panuveitis • Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation • Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids OR Coverage approved for pediatric patients 12-17 years of age with diagnosis of: • Moderate to severe hidradenitis suppurativa (HS) OR Coverage approved for pediatric patients 6-17 years of age with diagnosis of: • Moderate to severely active Crohn's disease (CD) **OR** **Coverage approved for pediatric patients 5-17 years of age with diagnosis of:** • **Moderately to severely active ulcerative colitis (UC)** OR Coverage approved for pediatric patients 4-17 years of age with diagnosis of: • Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate OR Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) • Non-infectious intermediate, posterior, and panuveitis Below criteria applies to AS indication only: • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months Below criteria applies to adult patients for all indications except for fistulizing Crohn's disease**,** ankylosing spondylitis (AS)**,** hidradenitis suppurativa and pyoderma gangrenosum (PG), and applies to pediatric patients with plaque psoriasis or non-fistulizing Crohn's disease: • Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) Below criteria applies to all patients (regardless of age): • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
	Coverage for non-FDA-approved uses not listed above. Please provide a diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER).
• amantadine ER (Gocovri) **Parkinson's Disease Agents**	**Changes from the May 2021 meeting are in bold.** Manual PA criteria applies to all new users of amantadine ER (Gocovri). Manual PA Criteria: Gocovri is approved if all criteria are met: • Patient is 18 years of age or older • Patient has a diagnosis of Parkinson's Disease (PD) • Patient is using requested medication for one of the following: o Treatment of dyskinesia and receiving levodopa-based therapy, with or without concomitant dopaminergic medications AND patient experienced therapeutic failure with a trial of amantadine immediate release of at least 300 mg daily in divided doses OR o **Treatment of "off" episodes and receiving levodopa/carbidopa** Non-FDA-approved uses are not approved. Prior authorization does not expire.
• crizotinib (Xalkori) **Oncological Agents: Lung Cancer**	**Updates from the May 2021 meeting are in bold.** Manual PA criteria apply to all new users of crizotinib (Xalkori). Manual PA criteria: Xalkori is approved if all criteria are met: • Prescribed by or in consultation with a hematologist/oncologist • **Patient has one of the following diagnoses:** o Metastatic non-small cell lung cancer (NSCLC) AND • Tumors are anaplastic lymphoma kinase (ALK) positive OR ROS1-positive (as detected by an approved test) o Relapsed or refractory systemic anaplastic large cell lymphoma (ALK) positive AND • **Patient is 1 year of age and older or a young adult (Note – limitation of use: safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory systemic ALK-positive anaplastic large cell lymphoma)** • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Non-FDA-approved uses are not approved including neoplastic diseases. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• iloprost inhalation (Ventavis) • treprostinil (Tyvaso) **Pulmonary Arterial Hypertension: Prostacyclin Nebulized**	**Changes from the May 2021 meeting are in bold.** Manual PA criteria applies to all new users of iloprost inhalation (Ventavis) or treprostinil (Tyvaso). Manual PA Criteria: Ventavis or Tyvaso are approved if all criteria are met: • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has a documented diagnosis of one of the following: o WHO group 1 pulmonary arterial hypertension (PAH) AND • Patient has had a right heart catheterization (documentation required) • Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH o **Tyvaso only: Patient has a documented diagnosis of WHO group 3 pulmonary hypertension associated with interstitial lung disease (PH-ILD)** Non-FDA-approved uses are not approved. Prior authorization does not expire.
• lorlatinib (Lorbrena) **Oncological Agents: Lung Cancer**	**Updates from the May 2021 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of lorlatinib (Lorbrena). Manual PA criteria: Lorbrena is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • **Patient has metastatic non-small cell lung cancer (NSCLC) AND** • **Tumors are anaplastic lymphoma kinase (ALK) positive (as detected by an approved test)** ~~• Patient has disease progression on one of the following:~~ ~~• crizotinib (Xalkori) and at least one other ALK inhibitor~~ ~~• alectinib (Alecensa) as a first-line agent~~ ~~• ceritinib (Zykadia) as a first-line agent~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Non-FDA-approved uses are not approved including neoplastic diseases. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria

• tocilizumab subcutaneous (Actemra SQ)
 	
Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors
	Changes from the May 2021 meeting are in bold and strikethrough.
	
	Manual PA criteria applies to all new users of tocilizumab subcutaneous (Actemra SQ).
	
	Manual PA Criteria: Actemra SQ is approved if all criteria are met:
	
	• Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication:
	  • Moderate to severe active rheumatoid arthritis (RA) AND have had an inadequate response to at least 1 or more disease modifying anti-rheumatic drugs (DMARDS) non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])
	  • Giant cell arthritis (GCA) (Trial of Humira not required)
	  • **Slowing the rate of decline in pulmonary function in systemic sclerosis-associated lung disease (SSc-ILD) (Trial of Humira not required)**
	OR
	• Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication:
	  • Active polyarticular juvenile idiopathic arthritis (pJIA)
	  • Systemic juvenile idiopathic arthritis (SJIA)
	
	• Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications
	• The patient has a contraindication to Humira (adalimumab) OR
	• The patient had an inadequate response to Humira OR
	• The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent
	
	~~• Patient has been stable on an IV Actemra with continuous use in the last 3 months and needs to transition to the SQ formulation of Actemra~~
	• Patient's platelet count is greater than or equal to 100,000 per mm^3 AND ALT/AST is less than or equal to 1.5 times UNL **(for adult patients only with RA, GCA, or SSc-ILD)**
	• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) **(all patients)**
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.
	
	Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER).

Drug / Drug Class	Quantity Limits
• methotrexate subcutaneous injection (Reditrex) **Antirheumatics: Injectable Methotrexate**	▪ Retail: 4 injectors per fill ▪ MTF/Mail: 12 injectors per fill
• rilonacept injection (Arcalyst) **Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitors**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• solifenacin oral suspension (Vesicare LS) **Overactive Bladder Agents**	▪ Retail: 2 bottles/30 days ▪ MTF/Mail: 6 bottles/90 days
• tasimelteon (Hetlioz) • tasimelteon oral liquid (Hetlioz LQ) **Sleep Disorders: Insomnia**	▪ MTF/Mail/Retail: 30 day supply ▪ Note that implementation will occur 60 days after signing of the minutes
• tepotinib (Tepmetko) **Oncological Agents: Lung Cancer**	▪ Retail/MTF/Mail: 30 day supply
• tirbanibulin 1% ointment (Klisyri) **Antineoplastic and Premalignant Lesion Agents**	▪ Retail/MTF/Mail: 5 day supply
• tivozanib (Fotivda) **Oncological Agents: Renal Cell Carcinoma**	▪ Retail/MTF/Mail: 28 day supply
• tofacitinib oral solution (Xeljanz) **Targeted Immunomodulatory Biologics: Miscellaneous**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• umbralisib (Ukoniq) **Oncological Agents**	▪ Retail/MTF/Mail: 30 day supply
• enzalutamide (Xtandi) **Oncological Agents: 2nd-Gen Antiandrogens**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
cabotegravir (Vocabria) Antiretrovirals: Integrase strand transfer inhibitors (INSTI)	• dolutegravir/ rilpivirine • dolutegravir/ lamivudine	• 30mg film coated tablets	HIV	• Vocabria is the 5th INSTI for adults with HIV-1 who are on stable antiretroviral (ARV) therapy, who are virologically suppressed, and have no documented history of virologic failure • Indicated with rilpivirine (Edurant) once daily x 4 weeks as oral lead-in therapy to evaluate tolerance before initiating long-acting injectable cabotegravir/rilpivirine (Cabenuva) • Final dose of Vocabria and Edurant should be taken together on the same day as the first injection of Cabenuva • Overall, well tolerated • No compelling evidence that Vocabria offers a clinical advantage over other oral INSTIs in its class (non-inferior) • The long-acting combination injectable (Cabenuva) has the potential to increase adherence and treatment success for those with HIV-1	• UF • Do not add to EMMI list
ethinyl estradiol (EE) 20 mcg)levonorgestrel 0.1 mg chewable tablet (Tyblume) Contraceptive Agents: Monophasics with 20 mcg estrogen (Sronyx, Lutera or equivalent)	• LNG 0.1mg/EE 20mcg tablet (Sronyx) • Norethindrone 1mg/EE 20mcg + Fe chewable tablet (Minastrin)	• Chewable tablet	Low dose oral contraceptive	• levonorgestrel/EE chewable tablet contains the same doses and same hormones as BCF Sronyx, Lutera, and generics; only difference is that this product is chewable • Multiple other chewable oral contraceptive products exist in addition to other forms of contraception that bypass the oral route (IUD, patch, vaginal ring, etc.) • Among the chewable oral contraceptives, this is the only product that contains levonorgestrel • Needs to be taken on an empty stomach which is a clinical disadvantage and raises concerns for reduced efficacy if taken incorrectly • No new clinical data • Provides little to no clinical benefit over existing formulary agents	• NF • Do not add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
levetiracetam 1000 mg and 1500 mg ER tablets (Elepsia XR) AnticonvulsantAntimania Agents	• levetiracetam extended release (Keppra XR)	• 1000 mg extended release tablet • 1500 mg extended release tablet	Adjunctive therapy in the treatment of partial-onset seizures in patients 12 years and older	• Elepsia XR is a new formulation of extended release levetiracetam available in a higher strength (1000mg and 1500mg) than Keppra 500 mg and 750 mg ER tabs • Elepsia XR is indicated for adjunctive therapy in the treatment of partial-onset seizures in patients 12 years and older • No new clinical trials were conducted with Elepsia XR • Elepsia XR demonstrated bioequivalence to Keppra XR tablets • Elepsia XR is not recommended in patients with moderate to severe renal impairment • Other than a theoretical decreased pill burden, Elepsia XR offers no clinically compelling advantage relative to existing agents	• Tier 4/Not covered
levothyroxine sodium 100 mcg/5 mLoral solution (Thyquidity) Thyroid agents	• levothyroxine solution (Tirosint-SOL) • levothyroxine tabs (Synthroid, various) • levothyroxine caps (Tirosint)	• Oral solution	Hypothyroidism and TSH suppression	• Thyquidity is the second FDA-approved levothyroxine oral solution (after Tirosint – Sol) • Tirosint-SOL reviewed May 2019 and designated UF • No new clinical data • Thyquidity provides little to no clinical benefit relative to similar agents on the formulary	• NF • Add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
mannitol inhalation powder (Bronchitol) Respiratory Agents Miscellaneous	• hypertonic saline, sodium chloride 3% and 7% solution (Nebusal, Pulmosol, Hyper-Sal)	• 40 mg capsule for inhalation • 400 mg (10 capsules) twice a day by oral inhalation, in the morning and evening, with later dose take 2-3 hours before bedtime	Add-on inhalation therapy for cystic fibrosis in adults	• Bronchitol is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in adults with cystic fibrosis (CF) • Dosing can be burdensome requiring patient to inhale the contents of 10 capsules twice a day; a short-acting bronchodilator (i.e., ProAir) must be given before every dose • Patient must pass a Bronchitol Tolerance Test (BTT) under the supervision of a healthcare provider before Bronchitol can be prescribed • Offers convenience in that it doesn't require refrigeration, nebulization, or routine equipment sterilization like other therapies • Efficacy was based on three, phase 3, randomized, double-blind, controlled, 26-week pivotal studies comparing study drug, at recommended dose, to control (inhaled mannitol 50 mg BID) which is a sub therapeutic dose • Primary efficacy endpoint in all three studies was improvement of lung function as determined by the mean change from baseline in pre-dose FEV_1 (mL) • Two studies involved patients ≥ 6 years of age and one included ≥ 18 years of age • All other CF therapies were allowed to be continued during studies except hypertonic saline • Inhaled short-acting bronchodilator (albuterol or equivalent) was given 5 to 15 minutes before Bronchitol dosing to help prevent bronchospasm • Overall for efficacy, Bronchitol had a modest effect in terms of improvements in lung function; clinical significance is hard to determine • Clinical place in therapy is unclear	• NF • Add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
methotrexate SQ injection (Reditrex) Antirheumatics: Injectable methotrexate	• Generic methotrexate injectable solution • Otrexup autoinjector • Rasuvo autoinjector	• Prefilled syringe • 7.5 to 30 mg subcutaneously once weekly	• Rheumatoid arthritis (RA) • Polyarticular juvenile idiopathic arthritis (pJIA) • Psoriasis	• Reditrex is a new injectable formulation of methotrexate (MTX) in a prefilled syringe • Indications include RA, pJIA, and psoriasis however Reditrex is not approved for neoplastic diseases • No new clinical trial data • Efficacy and safety data relied on old MTX clinical trials • Generic formulations of injectable MTX are available as well as two other methotrexate autoinjector formulations (Otrexup and Rasuvo) • Reditrex has no compelling advantages over existing agents	• NF • Add to EMMPI list
ponesimod (Ponvory) Multiple sclerosis agents: oral miscellaneous	• fingolimod (Gilenya) • siponimod (Mayzent) • ozanimod (Zeposia)	• Tablets: 2, 3, 4, 5, 6, 7, 8, 9, 10, and 20 mg; Titration to 20 mg daily	For the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	• Ponvory is another option for treatment of relapsing forms of MS and is the fourth sphingosine 1-phosphate (S1P) receptor modulator • Indirect comparison to other S1PRMs shows similar efficacy • Overwhelming majority of study population with RRMS (fewer with CIS or SPMS) • Safety profile comparable to teriflunomide (Aubagio) • Dose monitoring required for arrhythmias, heart block, and/or a history of MI or CHF	• UF • Do not add to EMMPI list
solifenacin oral suspension (Vesicare LS) Overactive Bladder agents	• Oxybutynin syrup	• 5mg/mL oral suspension	Overactive bladder (OAB) in pediatric patients aged ≥ 2 years	• Vesicare LS is a new oral suspension formulation of solifenacin approved for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 2 years old • Convenient once daily dosing compared to up to three times a day dosing with oxybutynin syrup • Pivotal trials were open-label and did not directly compare Vesicare LS to other antimuscarinic agents; however, when compared indirectly, it appears to have similar efficacy to oxybutynin syrup • No new safety signals noted compared to solifenacin • Guidelines do not yet address the role of Vesicare LS, although they do strongly encourage the use of antimuscarinic medications for NDO • Vesicare LS offers a second child-friendly antimuscarinic formulation for the treatment of NDO	• NF • Add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
tepotinib (Tepmetko) Oncological Agents: Lung Cancer	• Capmatinib (Tabrecta)	• 450 mg once daily with food • 225 mg tablets	METex14 positive metastatic Non-small cell lung cancer (NSCLC)	• Second drug FDA-approved for the treatment of patients with NSCLC and a mutation that leads to MET exon 14 skipping. (capmatinib; Tabrecta was the 1st) • Tepmetko is a preferred agent for first-line and subsequent therapy in patients with NSCLC and METex14 skipping mutations according to NCCN guidelines. • Among patients with advanced NSCLC with a confirmed MET exon 14 skipping mutation, tepotinib was associated with an overall response rate in 43% of patients. • Serious adverse events occurred in 45% of patients treated with Tepmetko. Edema occurred in 70% of patients and caused a grade 3 or higher adverse reaction in 9% of patients. • MET exon 14 skipping mutations occur in 3% to 4% of patients with NSCLC and the approval of Tepmetko provides another option for treatment of patients with these tumors.	• UF • Do not add to EMMPI list
tirbanibulin 1% ointment (Klisyri) Antineoplastic and premalignant lesion agents	• Fluorouracil • Imiquimod • Diclofenac	• 1% ointment	Actinic keratosis	• Klisyri is a new, well-tolerated topical treatment for AK of the face or scalp • Several treatment options exist for the management of AK including other topical medications • Klisyri has a unique mechanism of action and a short treatment duration (5 days) • Only studied against vehicle in clinical trials • When indirectly compared to other topical treatments, Klisyri appears to have similar rates of AK clearance and higher rates of AK recurrence at 12 months • Not yet mentioned in the NCCN squamous cell skin cancer guidelines • Klisyri is an additional topical option for the treatment of AK with little to no clinical benefit over existing agents	• NF • Do not add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
tivozanib (Fotivda) Oncological Agents: Renal Cell Carcinoma	• sunitinib (Sutent) • sorafenib (Nexavar) • axitinib (Inlyta) • pazopanib (Votrient) • cabozantinib (Cabometyx) • lenvatinib (Lenvima) • bevacizumab (Avastin, Mvasi, Zirabev)	• 1.34 mg and 0.89 mg capsules: take 1.34 mg qday for 21 days on followed by 7 days off (28 day cycle)	Treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies	• Tivozanib offers a slight progression-free survival advantage over sorafenib; however, tivozanib and sorafenib offer identical overall survival rates • Tivozanib is less-well tolerated than sorafenib • Tivozanib has a significant amount of serious warnings and precautions • Tivozanib is an additional treatment option in an already crowded drug class	• UF • Add to EMMPI list
umbralisib (Ukoniq) Oncological Agents	• duvelisib (Copiktra) • idelalisib (Zydelig) Medical benefit • copanlisib (Aliqopa)	• 200 mg tablet • 800 mg orally once daily with food	Relapsed or refractory marginal zone lymphoma (MZL) if patient received at least one prior anti-CD20-based regimen and follicular lymphoma (FL) if patient has received at least three prior lines of systemic therapy	• Ukoniq is the 4th phosphatidylinositol 3-kinase (PI3K) inhibitor and has dual activity against δ and ε isoforms • Ukoniq is indicated for: • Relapsed or refractory marginal zone lymphoma (MZL) in adults who have received at least one prior anti-CD20-based regimen • First PI3K FDA-approved for relapsed or refractory MZL (NCCN guidelines recommend other PI3K but after 2 prior therapies) and relapsed or refractory follicular lymphoma (FL) in adults who have received at least three prior lines of systemic therapy • Fourth PI3K inhibitor FDA-approved for relapsed or refractory follicular lymphoma and other PI3K only require 2 prior therapies • Approval was based on limited available data (one, phase 2, open label, pivotal study with no control group for two different indications [MZL, FL]) • Provides alternative treatment for MZL and FL with no boxed warning(s) or REMS Program, however it currently has minimal studies and due to FDA accelerated approval, further adequate and well-controlled clinical trials to verify and describe the clinical benefit are required	• UF • Do not add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
vericiguat (Verquvo) Cardiovascular Agents Miscellaneous	• sacubitril/ valsartan (Entresto) • empagliflozin (Jardiance) • ACE/ARBs • Beta blockers • spironolactone • hydralazine/ isosorbide dinitrate	• 2.5 mg po QD • titrate to target dose of 10 mg QD	Reduce risk of CV death and HF hospitalization following a HF hospitalization or need for outpatient IV diuretics, in adults with symptomatic chronic HF and LVEF <45%	• New drug class for HF, soluble guanylate cyclase (sGC) stimulator, an enzyme in the nitric oxide signaling pathway • Another sGC stimulator riociguat (Adempas) is approved for PAH • Increases production of cyclic guanosine monophosphate (cGMP), leading to smooth muscle relaxation and vasodilation, which preserves myocardial function • In the VICTORIA clinical trial used to gain FDA approval it showed a 10% reduction in the composite of death from CV cause or first hospitalization for HF • Compared to other treatments, was studied in high-risk patients with recently decompensated heart failure with reduced ejection fraction (HFrEF) (40% of pts were NYHA Class III HF with mean LVEF 29%) • Drug interaction with PDE-5 inhibitors – risk of hypotension • Contraindicated in pregnancy • Potential place in therapy as an add-on option to guideline-directed medical therapy (GDMT) • Listed as an “emerging therapy” in the 2021 American College of Cardiology Consensus Pathway	• UF • Do not add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
vibegron (Gemtesa) Overactive Bladder Agents	• mirabegron (Myrbetriq)	• 75mg tablet	OAB	• 2nd β-3 adrenergic receptor agonist approved for the treatment of overactive bladder, after mirabegron (Myrbetriq) • OAB guidelines, published before the approval of vibegron, recommend either antimuscarinics or β3-adrenergic receptor agonists as 2nd-line therapy after behavioral therapies • Compared to antimuscarinics, β3-adrenergic receptor agonists avoid the side effects of constipation and dry mouth and are not associated with increased risk of dementia with long-term use • Vibegron offered statistically significant improvements in primary and secondary endpoints when compared to placebo and was well-tolerated • Not directly compared against mirabegron, but indirect comparisons suggest similar efficacy • Benefits of vibegron compared to mirabegron, include its ability to be crushed, fewer drug interactions, and lack of clinically significant effects on blood pressure • Vibegron is a therapeutic alternative to mirabegron; most patients could use either drug, and formulary tools preferring one over the other would not be inappropriate	• UF and step-preferred • Do not add to EMMPI list

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21 (g)(5)

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
voclosporin (Lupkynis) Immuno-suppressives	• tacrolimus • mycophenolate mofetil (MMF) • belimumab (Benlysta)	• 7.9 mg caps • Starting dose = 23.7 mg (3 caps) BID = 6 caps/day total • Must use in combo with MMF and corticosteroids	Active lupus nephritis (LN)	• Another oral calcineurin inhibitor approved for use in adults with active lupus nephritis (LN);must be used in combination with corticosteroids and mycophenolate (MMF; Cellcept) • Approval based on 2 placebo controlled studies • Primary endpoint of complete renal response showed a greater response with voclosporin (41%) vs placebo (23%) • Primary and secondary endpoints were statistically significant compared to placebo • Voclosporin has not been compared head-to-head to tacrolimus or Benlysta for active LN • BBW: an increased risk for developing malignancies and serious infections or other immunosuppressants that may lead to hospitalization or death • Warnings: monitor renal function, BP, ECG and electrolytes due to risk of hyperkalemia, monitor for neurologic abnormalities including risk of posterior reversible encephalopathy syndrome (PRES) • Lupkynis offers another option in the treatment of LN, however place in therapy is currently unclear	• NF • Do not add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 2021 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program if NF, Exempted from Mail Order Requirement)
May 2021	**Sleep Disorders: Insomnia UF (brand maintenance only)** *Maintain current status:* • lemborexant (Dayvigo) **Sleep Disorders: Insomnia NF** *No reason to exempt from NF-2 Mail requirement:* • zolpidem nasal (Zolpimist) • zolpidem SL (Edluar, Intermezzo) **Menopausal Hormone Therapy: Vaginal Agents UF (brand maintenance only)** *Maintain current status:* • estradiol acetate vaginal ring (Femring) • estradiol vaginal insert (Imvexxy) • estradiol vaginal insert (Vagifem) **Menopausal Hormone Therapy: Oral Single Agents UF (brand maintenance only)** *Maintain current status:* • estradiol tablet (Estrace) **Menopausal Hormone Therapy: Oral Combination Agents UF (brand maintenance only)** *Maintain current status:* • estradiol/progesterone capsule (Bijuva) • estradiol/norethindrone acetate tablet (Activella, Amabelz, Mimvey) • ethinyl estradiol/norethindrone acetate tablet (Femhrt, Jinteli, Fyavolv) • estradiol/drospirenone (Angeliq)	**Sleep Disorders: Insomnia UF (brand maintenance only)** *Maintain current status and do not add to EMMPI Program due to comparable pricing at mail order vs MTFs or retail:* • suvorexant (Belsomra) **Sleep Disorders: Insomnia NF** *Exempt from NF-2 Mail requirement due to being unavailable at mail:* • tasimelteon (Hetlioz/Hetlioz LQ) **Menopausal Hormone Therapy: Vaginal Agents UF (brand maintenance only)** *Maintain current status and do not add to EMMPI Program due to package size and day supply issues:* • conjugated equine estrogens vaginal cream (Premarin) • estradiol vaginal cream (Estrace) *Remove from EMMPI Program due to comparable pricing at mail order vs MTFs or retail:* • estradiol vaginal ring (Estring) **Menopausal Hormone Therapy: Oral Single Agents UF (brand maintenance only)** *Remove from EMMPI Program due to comparable pricing at mail order vs MTFs or retail:* • conjugated equine estrogens tablet (Premarin) • esterified estrogens (Menest) **Menopausal Hormone Therapy: Oral Combination Agents UF (brand maintenance only)** *Remove from EMMPI Program due to comparable pricing at mail order vs MTFs or retail:* • conjugated equine estrogens/medroxy-progesterone acetate tablet (Prempro) • conjugated equine estrogens/medroxy-progesterone acetate tablet (Premphase) • estradiol/norgestimate (Prefest) *Maintain current status and do not add to EMMPI Program due to not being an FDA-approved product:* • esterified estrogens/methyltestosterone (Covaryx, Covaryx HS, Eemt, Eemt HS)

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 2021 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program if NF, Exempted from Mail Order Requirement)
	Newly Approved Drugs per 32 CFR 199.21(g)(5) **Designated UF:** *Add to EMMPI List pending availability at mail:* • tivozanib (Fotivda) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending availability at mail:* • levothyroxine sodium 100 mcg/ 5 mL oral solution (Thyquidity) • mannitol inhalation powder (Bronchitol) • methotrexate SQ injection (Reditrex) • solifenacin oral suspension (Vesicare LS) **Line Extensions** **Designated UF** *Similar/parent agent already on list:* • tofacitinib oral solution (Xeljanz) **Line Extensions** **Designated NF** *No reason to exempt from NF-2-Mail requirement, similar/parent agent already on list:* semaglutide injection (Ozempic)	**Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Not yet clear if feasible to provide through mail order:* • tepotinib (Tepmetko) • umbralisib (Ukoniq) *Drugs in class not currently represented on EMMPI List:* • cabotegravir (Vocabria) • ponesimod (Ponvory) *Comparable pricing at mail order vs MTFs or retail:* • vericiguat (Verquvo) • vibegron (Gemtesa) **Designated NF:** *Contraceptive exception/existing exclusion applies:* • levonorgestrel 0.1 mg & EE 0.02 mg (Tyblume) *Not yet clear if feasible to provide through mail order:* • voclosporin (Lupkynis) *Exception due to acute use/limited duration of use and comparable pricing at mail order vs MTFs or retail:* • tirbanibulin 1% ointment (Klisyri)

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

<table>
<tr><th>Date</th><th>DoD PEC Drug Class</th><th>Type of Action</th><th>BCF/ECF Medications

MTFs must have BCF meds on formulary</th><th>UF Medications

MTFs may have on formulary</th><th>Nonformulary Medications

MTFs may not have on formulary</th><th>Decision Date / Implement Date</th><th>PA and QL Issues</th><th>Comments</th></tr>
<tr><td rowspan="2">May 2021</td><td rowspan="2">Menopausal Hormone Therapy: Single Agents, Combination Agents, and Vaginal Agents</td><td rowspan="2">UF Class Review</td><td colspan="3">Tier 4/Not Covered Medications

MTFs <u>must not</u> have on formulary
Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies
▪ None</td><td rowspan="2">Pending signing of the minutes: 30 days

The effective date is March 16, 2022</td><td rowspan="2">▪ No PAs or QLs for any agents in any of the three subclasses
▪ Current PA for Imvexxy was removed</td><td rowspan="2">▪ Premarin and Prempro removed from the BCF
▪ Estradiol vaginal cream and estradiol oral tablets added to the BCF
▪ Estradiol vaginal cream BCF addition specifies this product, as previously MTFs could choose</td></tr>
<tr><td>Vaginal Agents
▪ estradiol vaginal cream (generic)

Oral Single Agents
▪ estradiol oral tablet (generic)

Oral Combination Agents
▪ None</td><td>Vaginal Agents
▪ conjugated equine estrogens vaginal cream (Premarin)
▪ estradiol vaginal cream (Estrace, generics)
▪ estradiol vaginal ring (Estring)
▪ estradiol acetate vaginal ring (Femring)
▪ estradiol vaginal tablet (Vagifem, generics)
▪ estradiol vaginal insert (Imvexxy) moves from NF to UF

Oral Single Agents
▪ conjugated equine estrogens tablets (Premarin)
▪ estradiol tablets (Estrace, generics)
▪ esterified estrogens (Menest

Oral Combination Agents
▪ conjugated equine estrogens/medroxyprogesterone acetate tablets (Prempro)
▪ conjugated equine estrogens plus medroxyprogesterone acetate tablets (Premphase)
▪ ethinyl estradiol/norethindrone acetate tablets (Jinteli, Femhrt, Fyavolv, generics)
▪ estradiol/norethindrone acetate tablets (Activella, Amabelz, Jinteli, Mimvey, Mimvey Lo, generics)
▪ esterified estrogens/ methyltestosterone (Covaryx, Covaryx HS, Eemt, Eemt HS, generics)
▪ estradiol/drospirenone (Angeliq)
▪ estradiol/norgestimate (Prefest)
▪ estradiol/progesterone caps (Bijuva) moves from NF to UF</td><td>▪ None</td></tr>
</table>

Appendix G—Table of Implemented Status of UF Recommendations/Decision 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
May 2021	**Sleep Disorders: Insomnia**	UF Class Review Class last reviewed May 2012	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ None			Pending signing of the minutes: 60 days The effective date is April 20, 2022	▪ PA criteria were removed for doxepin tablets and ramelteon ▪ Manual PA criteria for Belsomra and Dayvigo require a generic first ▪ Updated manual PA criteria for new users of Hetlioz/Hetlioz LQ, requires a trial of ramelteon and melatonin ▪ Updated PA criteria for new and current users of Edluar, Intermezzo, Zolpimist requires a generic agent and a DORA first ▪ PAs for all brand agents expire yearly, with renewal criteria required	▪ See Appendices B and C for MN and PA criteria. ▪ Melatonin OTC 3 mg and 5 mg added to the MHS GENESIS OTC test list in order to standardize dispensing of melatonin at MTFs
			▪ zolpidem IR ▪ zolpidem ER	<u>UF step-preferred generics</u> ▪ zolpidem IR (Ambien, generics) ▪ zolpidem ER (Ambien CR, generics) ▪ eszopiclone (Lunesta, generics) ▪ zaleplon (Sonata, generics) ▪ ramelteon (Rozerem, generics) *moves from NF to UF* ▪ doxepin 3 mg, 6 mg tablets (Silenor, generics) <u>UF step-preferred brands</u> ▪ suvorexant (Belsomra) *moves from NF to UF* ▪ lemborexant (Dayvigo)	<u>NF and non-step-preferred brands</u> ▪ zolpidem IR 1.75 mg, 3.5 mg sublingual tabs (Intermezzo, generics) ▪ zolpidem IR 5 mg, 10 mg sublingual tabs (Edluar) ▪ zolpidem oral spray (Zolpimist) ▪ tasimelteon capsules (Hetlioz) ▪ tasimelteon oral suspension (Hetlioz LQ)		

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives (Last 12 months)*†

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2021	Anticonvulsants-Antimania Agents	• levetiracetam (Elepsia XR)	• levetiracetam ER • lamotrigine XR • topiramate ER	• June 15, 2022 (120 days)
Feb 2021	Corticosteroids-Immune Modulators: High Potency	• clobetasol propionate 0.05% lotion metered dose pump (Impeklo)	• betamethasone/propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % (emulsion) foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• June 15, 2022 (120 days)
Feb 2021	Psoriasis Agents	• calcipotriene/ betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora)	• vitamin D analog (calcipotriene 0.005% cream, ointment or solution) with a high potency topical corticosteroid (clobetasol propionate 0.05% ointment, cream, solution and gel • fluocinonide 0.05% cream, gel, and solution • calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary]	• June 15, 2022 (120 days)
Nov 2020	Attention-Deficit/ Hyperactivity Disorder (ADHD) Agents: Stimulants	• methylphenidate ER sprinkle capsules (Adhansia XR)	• methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties • methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties • methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) • methylphenidate long-acting (Ritalin LA, generics) • methylphenidate controlled delivery (CD) (Metadate CD, generics) • dexmethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics)	• Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	• budesonide ER 9 mg capsules (Ortikos)	• budesonide ER tablets (Entocort EC, generics) • other corticosteroids	• June 2 2021
Nov 2020	Corticosteroids	• dexamethasone 20 mg tables (Hemady)	• dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs	• June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	• fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler)	• fluticasone (Flovent Diskus) • fluticasone (Flovent HFA) • fluticasone furoate (Arnuity Ellipta) [non formulary] • beclomethasone (QVAR) [non formulary] • budesonide (Pulmicort Flexhaler) [non formulary] • ciclesonide (Alvesco) [non formulary] • flunisolide (Aerospan) [non formulary] • mometasone (Asmanex Twisthaler [non formulary]	• June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	• fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler)	• fluticasone/salmeterol (Advair Diskus) • fluticasone/salmeterol (Advair HFA) • fluticasone/vilanterol (Breo Ellipta) [non formulary] • mometasone/formoterol (Dulera) [non formulary] • budesonide/formoterol (Symbicort) [non formulary] • fluticasone/salmeterol (AirDuo Respiclick) [non formulary]	• June 2 2021
Nov 2020	Calcium Channel Blockers	• levamlodipine (Conjupri)	• amlodipine • felodipine • nifedipine • diltiazem • verapamil	• June 2 2021
Nov 2020	GI-2 Agents	• metoclopramide nasal spray (Gimoti)	• metoclopramide oral tablet (Reglan generics) • metoclopramide oral solution (Reglan, generics) • metoclopramide orally disintegrating tablet (Reglan ODT)	• June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	• calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic)	*Scalp Psoriasis:* • calcipotriene 0.005% solution • clobetasol 0.05% solution, shampoo • fluocinonide 0.05% solution • calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] *Psoriasis involving areas other than the scalp:* • calcipotriene 0.005% ointment, cream, solution • clobetasol 0.05% ointment, cream • fluocinonide 0.05% cream, ointment	• February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	• halcinonide 0.1% topical solution (Halog)	• betamethasone propylene glycol 0.05% cream • clobetasol propionate 0.05% cream and ointment • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream and ointment • fluocinonide 0.05% cream and ointment • fluocinonide/emollient base 0.05% cream • halobetasol propionate 0.05% ointment	• February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	• tazarotene 0.045% lotion (Arazlo)	• adapalene 0.1% lotion, gel, cream • adapalene 0.3% gel • clindamycin phosphate 1% gel, cream, lotion, and solution • clindamycin/ benzoyl peroxide 1.2% - 5% gel • tazarotene 0.1% cream • tretinoin 0.025%, 0.05%, and 0.1% cream • tretinoin 0.01% and 0.025% gel	• February 24, 2021

* The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents, based on an interim final rule published on December 11, 2018. https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. Drugs recommended for Tier 4/Not Covered status will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4/Not Covered drug at the Retail points of service.

† For a cumulative list of previous Tier 4 recommendations, refer to the November 2020 DoD P&T Committee minutes, found at health.mil/pandt

Appendix I—MHS GENESIS OTC Test List

DoD P&T Meeting	RETAIN or ADD the following to the OTC MHS Genesis List	REMOVE the following from the OTC MHS Genesis List
Analgesics and NSAIDs		
May 2019 (May 2021 update)	**ADD these GCNs** • 16965 –acetaminophen 500mg, due to shortage of acetaminophen 325 mg tablets (May 2019 meeting update)	
Melatonin		
May 2021	**Retain these GCNs:** • 68738 – melatonin 3 mg tablets • 99671 – melatonin 5 mg tablets	**Remove these GCNs:** • 94035 – melatonin 1 mcg tablet spray • 13448 – melatonin 5 mg SL tablet • 31649 – melatonin 10 mg mphase

*GCN Additions will be implemented the first Wednesday two weeks after signing of the minutes, with the deletions implemented at 120 days.

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
AACE/ACE	American Association of Clinical Endocrinologist and American College or Endocrinology	MHS	Military Health System
ACC	American College of Cardiology	MHT	Menopausal hormone therapy
ADR	Adverse reaction	MN	Medical Necessity
AE	Adverse event	MS	Multiple Sclerosis
AK	Actinic keratosis	MTF	Military Treatment Facility
BCF	Basic Core Formulary	MZL	Marginal zone lymphoma
BIA	Budget impact analysis	NAMS	North American Menopause Society
CCBs	Calcium channel blockers	NCCN	National Comprehensive Cancer Network
CBT-I	Cognitive behavioral therapy - Insomnia	NDAA	National Defense Authorization Act
CEE	Conjugated equine estrogens	NDC	National Drug Codes
CFR	Code of Federal Regulations	NDO	Neurogenic detrusor overactivity
CMA	Cost minimization analysis	NSCLC	Non-small cell lung cancer
CV	Cardiovascular	NYHA	New York Heart Association
DHA	Defense Health Agency	OAB	Overactive bladder
DoD	Department of Defense	ODT	Orally Disintegrating Tablet
DORA	Dual orexin receptor antagonist	OTC	Over the counter
DR	Delayed release	PA	Prior authorization
ECF	Extended Core Formulary	PAH	Pulmonary artery hypertension
EE	Ethinyl estradiol	PH-ILD	Pulmonary hypertension associated interstitial lung disease
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	POD	Pharmacy Operations Division
ER	Extended release	POS	Point of service
FDA	U.S. Food and Drug Administration	PRN	As needed
FL	Follicular lymphoma	RCC	Renal cell carcinoma
GDMT	Guideline directed medical therapy	RRMS	Relapsing remitting multiple sclerosis
GSM	Genitourinary syndrome of menopause	QL	Quantity limits
HF	Heart failure	SC	Subcutaneous
HFpEF	Heart failure with preserved ejection fraction	SMS	Smith-Magenis Syndrome
LN	Lupus nephritis	SL	Sublingual
LVEF	Left ventricular ejection fraction	TIB	Targeted Immunomodulatory Biologics