

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS
August 2022**

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on August 3rd and 4th, 2022.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of May 2022 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the May 2022 DoD P&T Committee meeting on July 27, 2022.

B. Clarification of Previous Minutes:

- 1. February 2022 Meeting—MHS GENESIS OTC Test List—products removed from the list:** The implementation date is 180 days after signing on Oct 26, 2022, not 120 days, due to the need to send 17 different letters to patients notifying them of the changes.
- 2. May 2022-Restasis Brand Over Generic authorization**—The brand over generic requirement for cyclosporine 0.05% ophthalmic emulsion single-dose (brand Restasis) at the Mail Order and Military Treatment Facilities (MTFs) points of service will be removed, due to inability to operationalize. However, the Tier 1 copay for brand Restasis at Mail Order and Retail Network pharmacies will remain in place. Implementation will now occur 30 days after signing.

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. Antidepressants and Non-Opioid Pain: Subclasses for the following – Selective Serotonin Reuptake Inhibitors (SSRIs); Selective Serotonin/Norepinephrine Reuptake Inhibitors (SNRIs); Norepinephrine/Dopamine Reuptake Inhibitors (NDRIs); and Gamma-Aminobutyric Acid Analogs (GABAs)

Background—The P&T Committee evaluated the relative clinical effectiveness of 4 subclasses in the Antidepressants and Non-Opioid Pain Drug Class. The full drug class was first reviewed for formulary placement in November 2011, with several new entrants to the class individually reviewed as new drugs. There are currently 30 products from 8 different subclasses on the uniform formulary. The drugs in the class are now largely available as generic formulations, however, 9 branded products remain. The clinical and cost effectiveness review focused on these 9 branded products.

The drugs in the class are approved for a variety of indications, including major depressive disorder (MDD), generalized anxiety disorder, (GAD), obsessive compulsive disorder (OCD), panic disorder (PD), seasonal affective disorder (SAD), diabetic peripheral neuropathic pain (DPNP), fibromyalgia (FM), and restless leg syndrome (RLS).

The clinical review focused on an extensive review of professional treatment guidelines for the various indications, provider feedback from the pertinent subspecialties, meta-analyses evaluating efficacy and safety, and other factors, including dosing frequency, dosage titration and tapering, and issues in special populations, including pregnancy and adolescents. The major clinical attributes of the drugs are discussed below.

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

Selective Serotonin Reuptake Inhibitors (SSRIs)

- *vortioxetine (Trintellix) (note that the previous brand name was Brintellix)*
 - Trintellix has been designated NF since it was first reviewed in February 2014. Trintellix carries a single indication for MDD, in contrast to the other generic SSRIs (including citalopram, fluoxetine, paroxetine and sertraline) that are indicated for multiple conditions.
 - The 2022 Department of Defense/Veterans Affairs (DoD/VA) Clinical Practice Guideline for MDD lists Trintellix as an initial pharmacotherapy option, along with other SSRIs, SNRIs, bupropion, mirtazapine, trazadone, and vilazodone, although this is based on an overall weak recommendation.
 - A 2018 Lancet network meta-analysis concluded Trintellix did not demonstrate significantly improved efficacy or tolerability when compared to other SSRIs for MDD.

- Limited data suggests Trintellix carries less risk for sexual dysfunction and cognitive impairment compared to other antidepressants. Trintellix also has the unique advantage among SSRIs for allowing abrupt discontinuation of treatment, if needed.
- *vilazodone (Viibryd)*
 - Viibryd has been designated as NF since the original review in November 2011. Viibryd carries a single indication for MDD. It is also listed in the 2022 VA/DoD Clinical Practice Guideline for MDD as an initial pharmacotherapy option along with numerous other options, as previously stated with Trintellix.
 - A 2018 Lancet network meta-analysis concluded Viibryd did not demonstrate significantly improved efficacy or tolerability compared to other SSRIs for MDD. When compared to other SSRIs, Viibryd has a higher incidence of gastrointestinal adverse effects including diarrhea and nausea.
- *paroxetine mesylate (Pexeva)*
 - Pexeva is indicated for major depressive disorder (MDD), generalized anxiety disorder, obsessive compulsive disorder (OCD), and panic disorder. Unlike its competitor, paroxetine hydrochloride (Paxil), Pexeva lacks additional approval for post-traumatic stress disorder and seasonal affective disorder. Several clinical practice guidelines for each of Pexeva's indications recommends SSRIs overall for first-line treatment, with no recommendation for a superiority of a specific formulation or brand product.
 - There is limited clinical data available with Pexeva, as FDA-approval was based on the information using data from paroxetine hydrochloride (Paxil). There is no data to show that Pexeva confers any clinically relevant advantages over Paxil.

Selective Serotonin/Norepinephrine Reuptake Inhibitors (SNRIs)

- *levomilnacipran (Fetzima)*
 - Fetzima is an enantiomer of milnacipran (Savella). It is only indicated to treat MDD. Among the wide array of other treatment options for MDD, several generic SNRIs are available on the formulary, including duloxetine, venlafaxine, and desvenlafaxine.
 - A 2018 Lancet network meta-analysis concluded Fetzima did not confer significantly improved efficacy or tolerability compared to other SNRIs for MDD. Among the SNRIs, Fetzima carries a lower risk for gastrointestinal adverse effects.

- *milnacipran (Savella)*
 - Savella is only approved for treating fibromyalgia. The 2016 European Alliance of Associations for Rheumatology guideline supports treatment of fibromyalgia with Savella, however, this is in addition to a variety of other treatment options, including duloxetine, amitriptyline, and pregabalin.
 - A 2016 Rheumatology International network meta-analysis concluded that Savella did not demonstrate greater efficacy or tolerability when compared to duloxetine or pregabalin.
- *duloxetine delayed release (Drizalma Sprinkle)*
 - Duloxetine delayed-release capsules are a sprinkle formulation of duloxetine that was originally designated NF in November 2019. No clinical trials were used to gain FDA approval, as the efficacy and safety relied on the data from duloxetine (Cymbalta). Drizalma has the same FDA indications as duloxetine.
 - Although Drizalma Sprinkle provides a formulation for patients with swallowing difficulties, it provides no compelling advantages compared to existing formulary agents, including generic duloxetine.
 - DoD specialists (child and adult psychiatrists, and neurologists) also supported that Drizalma Sprinkle is not needed on the formulary.

Norepinephrine/Dopamine Reuptake Inhibitors (NDRIs)

- *bupropion hydrobromide (Aplenzin)*
 - Aplenzin is an extended release hydrobromide formulation of bupropion; its generic counterpart is bupropion hydrochloride extended release (Wellbutrin XL). Both agents are bioequivalent and approved for the same indications (MDD and SAD).
 - Guidelines from the 2010 American Psychiatric Association and 2019 National Institute for Health Care and Excellence recommend the same array of medication options for MDD and SAD. As previously stated, the most recent clinical guideline for MDD (2022 DoD/VA CPG) lists bupropion, but does not endorse a specific formulation (e.g., hydrochloride vs. hydrobromide). Several other subclasses are also listed as initial pharmacotherapy options for MDD.
 - There are no compelling benefits of Aplenzin compared to generic bupropion formulations.

Gamma-Aminobutyric Acid Analogs (GABAs)

- *gabapentin ER 24 hour tablets (Gralise)*

- Gralise is an extended release formulation of gabapentin indicated for Post Herpetic Neuralgia (PHN). The 2004 American Academy of Neurology PHN guidelines recommend multiple first line treatment options, including gabapentin, pregabalin, tricyclic antidepressants, opioid, and the lidocaine patch.
- A 2015 Lancet Neurology network meta-analysis concluded Gralise did not result in significantly greater efficacy for pain relief for PHN when compared to gabapentin and gabapentin enacarbil.
- Notably, Gralise carries a possible lower risk for dizziness and somnolence when compared to other gabapentin formulations. However it also requires a large tablet burden to reach recommended dosing.
- *gabapentin enacarbil (Horizant)*
 - Horizant is another extended release gabapentin formulation due to its prodrug characteristics. Horizant is indicated for PHN and Restless Leg Syndrome. The 2016 American Academy of Neurology guideline lists Horizant as a first-line treatment option, along with multiple other drugs from other classes, as mentioned previously.
 - Network meta-analyses evaluating fibromyalgia (2015 Lancet Neurology) and RLS (2013 JAMA Internal Medicine) both concluded that Horizant did not confer additional efficacy when compared to other gabapentin formulations and pregabalin, respectively.
 - Although Horizant is unique among the GABAs for allowing abrupt discontinuation if administered at doses lower than 600 mg per day, it carries a possible high risk of dizziness and somnolence when compared to other agents in the subclass.

Overall Conclusions

- The 2011 P&T efficacy conclusions remain largely unchanged; the brand-only agents reviewed do not offer significantly improved efficacy when compared to other generic agents across similar indications and subclass.
 - A comprehensive clinical efficacy evaluation for mood disorders is not possible at this time, as some agents were approved based on bioequivalence to a generic competitor, and did not have new clinical data for review.
- The 2011 P&T safety conclusions remain largely unchanged; the brand only agents do not offer significantly improved tolerability when compared to other generic competitors across like indications.

- Of note, Trintellix offers limited data supporting a lower risk of sexual dysfunction and cognitive impairment compared to other antidepressants.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and also conducted a budget impact analysis (BIA). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- Cost minimization analysis (CMA) results showed the following: All 9 branded products, Trintellix, Viibryd, Pexeva, Fetzima, Savella, Drizalma Sprinkles, Gralise, Horizant, and most notably, Aplenzin, were not cost effective relative to the generic formulations in the 4 respective subclasses.
- Budget Impact Analysis (BIA) and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating vortioxetine (Trintellix), vilazodone (Viibryd), and all generically-available agents as UF, with bupropion hydrobromide (Aplenzin), duloxetine delayed release (Drizalma Sprinkle), gabapentin (Gralise), gabapentin enacarbil (Horizant), levomilnacipran (Fetzima), milnacipran (Savella), and paroxetine mesylate (Pexeva) as NF demonstrated significant cost avoidance for the MHS.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - vortioxetine (Trintellix) *moves from NF to UF*
 - vilazodone (Viibryd) *moves from NF to UF*
 - Note that the antidepressants in the class that are currently available in generic formulations will remain UF.
- NF
 - paroxetine mesylate (Pexeva) *moves from UF to NF*
 - duloxetine DR (Drizalma sprinkle)
 - levomilnacipran (Fetzima)
 - milnacipran (Savella)
 - bupropion hydrobromide XR (Aplenzin)
 - gabapentin ER 24 hr tablets (Gralise)
 - gabapentin enacarbil (Horizant)
- Tier 4 (Not covered) – None

2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained) the following with regard to PA criteria for all 9 branded agents. There was no change to the current PA criteria for Drizalma Sprinkles, which requires the provider to justify why this formulation is needed (write-in). New manual PA criteria were recommended for paroxetine mesylate (Pexeva) and vilazodone (Viibryd), in new users.

For the remaining products where PA criteria are already in place (Trintellix, Fetzima, Savella, Gralise, Horizant, and Aplenzin), updates were recommended in new users. Automation that is currently in place for Trintellix, Fetzima, Savella, Gralise, and Horizant was removed. For all the PAs, the provider should consider non-pharmacologic options along with drug therapy. Additionally, a trial of two to three alternate formulary agents is recommended first for all the branded drugs. See Appendix C for the full criteria.

3. **COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained) new MN criteria for Pexeva and Aplenzin, and maintaining the current MN criteria for Drizalma Sprinkle, Fetzima, Savella, Gralise, and Horizant that is currently in place. See Appendix B for the full criteria.
4. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining the current exclusion for the 9 NF agents from the EMMPI program.
5. **COMMITTEE ACTION: UF, MN, PA, EMMPI and IMPLEMENTATION PERIOD**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the NF recommendation for Pexeva. (See Appendix G for the actual implementation dates.)

B. Overactive Bladder Agents (OAB) – Beta3 (β-3) Adrenergic Agonists Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the OAB β-3 adrenergic agonists. The subclass is comprised of mirabegron (Myrbetriq), vibegron (Gemtesa) and mirabegron extended-release (ER) granules for oral suspension (Myrbetriq Granules); the products were previously reviewed as new drugs in May 2014, May 2021, and November 2021, respectively. PA currently applies to all three drugs.

The previous OAB formulary review in November 2012 included the older antimuscarinic drugs [e.g. oxybutynin (Ditropan), tolterodine (Detrol), and solifenacin (Vesicare), etc.], however, they were not part of this current review.

Mirabegron (Myrbetriq) and vibegron (Gemtesa) are both approved for the treatment of OAB, while Myrbetriq Granules are only approved for neurogenic detrusor overactivity (NDO).

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

Professional Treatment Guidelines

- The 2019 OAB guidelines from the American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (AUA/SUFU) state the following:
 - Clinicians should offer behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, and fluid management) as first-line therapy to all patients with OAB. (*Standard, Evidence strength: Grade B*)
 - Clinicians should offer oral anti-muscarinics or oral β -3-adrenoceptor agonists as second-line therapy (*Standard, Evidence Strength Grade B*)
 - If a patient experiences inadequate symptom control and/or unacceptable adverse drug events with one antimuscarinic medication, then a dose modification or a different anti-muscarinic medication or a β -3-adrenoceptor agonist may be tried. (*Clinical Principle*)

Antimuscarinics vs. β -3-adrenergic agonists

- The antimuscarinics and β -3-agonists show similar efficacy for treating OAB, however the β -3-agonists have fewer side effects, such as dry mouth. One retrospective, matched cohort study found a higher risk of dementia with the antimuscarinics compared to the β -3 agonists. Limitations to this analysis include the observational study design, and that overall the difference in dementia rates between the groups was relatively small. (*BJU Intl 2020*)

Mirabegron vs. Vibegron

- For mirabegron, there was no new data that would support changes to the previous clinical conclusions from 2014; compared to placebo, mirabegron produced statistically significant reductions in incontinence episodes, but the clinical effect is small and there is a high placebo response rate.
- Vibegron has not been directly compared against mirabegron in a head-to-head trial, but indirect comparisons suggest similar efficacy.

Mirabegron

- Advantages of mirabegron include its long marketing history (it was FDA-approved in 2012), and existing high utilization in the Military Health System

(MHS). It is also indicated for use in combination with the antimuscarinic solifenacin (Vesicare). Disadvantages include that mirabegron is formulated as an ER tablet that cannot be crushed.

- The Myrbetriq granules are solely indicated for NDO, and currently have very low MHS utilization.

Vibegron

- Benefits of vibegron compared to mirabegron include fewer drug interactions, lack of clinically significant effects on blood pressure, and that the tablets can be crushed.

Overall Conclusions

- Overall, there is a high degree of therapeutic interchangeability between mirabegron and vibegron based on efficacy data. For safety, although there are subtle differences that favor vibegron over mirabegron, most patients could use either drug.
- In order to meet the needs of MHS beneficiaries, at least one β -3 agonist is required on the formulary.

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

- (CMA) results showed that mirabegron (Myrbetriq) was more cost effective than vibegron (Gemtesa).
 - BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating mirabegron (Myrbetriq) and vibegron (Gemtesa) both as UF demonstrated significant cost avoidance for the MHS.
1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:
 - UF
 - mirabegron tablets (Myrbetriq)
 - mirabegron ER granules for oral suspension (Myrbetriq granules) *moves from NF to UF*
 - vibegron (Gemtesa)
 - NF – None
 - Tier 4 (Not covered) – None
 2. **COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA**— PA criteria have been in place for Myrbetriq, Gemtesa and the Myrbetriq Granules since they were originally reviewed as new drugs. The PA criteria requires a trial of an antimuscarinic first. Additionally, at the May 2021 review of Gemtesa, the Myrbetriq PA was revised to require a trial of Gemtesa

in new users, based on cost-effectiveness. However due to the delay of the Beneficiary Advisory Panel meeting (due to the zero-based review), implementation did not occur until March 2022.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) minor updates to the current manual PA criteria for Myrbetriq and Gemtesa in new users. The current requirements for a trial of an antimuscarinic first before use of a β -3 agonist will be maintained, as the AUA/SUFU guidelines place the antimuscarinics and β -3 agonists on equal footing, and do not prefer the β -3 agonists over the antimuscarinics. Practices from commercial healthcare plans also require an antimuscarinic before a β -3 agonist. A trial of only one antimuscarinic will be required, instead of the current requirement for two prior drugs.

Minor updates were made to the dosage modifications based on renal function. Additionally, the current requirement for a trial of Gemtesa prior to Myrbetriq will be removed. There were no changes made to the existing Myrbetriq Granules PA criteria. (See Appendix C)

3. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) removing mirabegron tabs (Myrbetriq) and mirabegron ER granules for oral suspension (Myrbetriq Granules) from the program. Vibegron (Gemtesa) is not on the program.
4. ***COMMITTEE ACTION: UF, PA, EMMPI IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 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. (See Appendix G for the actual implementation date.)

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 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 August 2022 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.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:
 - UF

- alpelisib (Vijoice) – Oncological agent for PIK3CA-related overgrowth spectrum (PROS)
- daridorexant (Quviviq) – Sleep Disorders: dual orexin receptor antagonist (DORA) for treating insomnia
- edaravone oral suspension (Radicava ORS) – Miscellaneous Neurological Agent for amyotrophic lateral sclerosis (ALS) and a new oral version of an IV medication
- ganaxolone oral suspension (Ztalmy) – Anticonvulsant for treating seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency
- insulin glargine solostar unbranded authorized biologic (from Winthrop labs) – Basal insulin; note that as part of this recommendation, this product will be designated as non-step-preferred.
- mavacamten (Camzyos) – Miscellaneous Cardiovascular Agent for symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (oHCM)
- NF:
 - amlodipine oral solution (Norliqva) – Dihydropyridine Calcium Channel Blocker (CCB) alternate dosage form for hypertension
 - cyclosporine 0.1% ophthalmic emulsion (Verkazia) – Ophthalmic for vernal keratoconjunctivitis
 - donepezil patch (Adlarity) – Alzheimer’s agent for mild, moderate, to severe dementia and a patch version of an available oral agent
 - leuprolide SC injection (Camcevi Kit) – Leuprolide-hormone-release hormone (LHRH) agent for treatment of advanced prostate cancer
 - tapinarof 1% cream (Vtama) – Psoriasis Agent
 - tirzepatide SC injection (Mounjaro) – Glucagon-like peptide-1 (GLP-1) receptor agonist for type 2 diabetes
 - testosterone undecanoate 112.5 mg capsule (Tlando) – Oral Testosterone Replacement Therapy; note that as part of this recommendation, this product will be designated as non-step-preferred.
 - vonoprazan/amoxicillin (Voquezna Dual Pak) – Miscellaneous Anti-infective for *Helicobacter pylori* (*H. pylori*) infection
 - vonoprazan/amoxicillin/clarithromycin; (Voquezna Triple Pak) – Miscellaneous Anti-infective for *Helicobacter pylori* (*H. pylori*) infection

- Tier 4 (Not covered): The drugs listed below were recommended for Tier 4 status, as they provide little to no additional clinical effectiveness relative to similar agents in their respective drug classes, and the needs of TRICARE beneficiaries are met by available alternative agents. See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
 - baclofen oral granules (Lyvispah) – Skeletal Muscle Relaxant; another alternative formulation of baclofen for multiple sclerosis spasticity
 - Alternatives include baclofen tablets, baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy)
 - benzoyl peroxide 5% cream (Epsolay) – keratolytic for rosacea
 - Alternatives include other legend and OTC benzoyl peroxide formulations; metronidazole 1% gel (MetroGel, generics), azelaic acid 15% gel (Finacea) and NF products, including minocycline 1.5% topical foam (Zilxi) minocycline 50 mg capsule; minocycline 4% foam (Amzeeq); brimonidine tartrate 0.33% gel (Mirvaso); and ivermectin 1% cream (Soolantra)
2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for criteria for Adlarity, Camcevi Kit, Mounjaro, Norliqva, Tlando, Verkazia, Voquezna Double Pak, Voquezna Triple Pak, and Vtama (see Appendix B for the full criteria.)
3. **COMMITTEE ACTION: PA CRITERIA**— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):
- Applying manual PA criteria to new users of tirzepatide (Mounjaro) consistent with the other NF GLP1-RA, Ozempic. A trial of metformin will be required before Mounjaro.
 - Applying manual PA criteria to new users of Quviviq, similar to the criteria in place for the other DORAs, Belsomra and Dayvigo. A trial of zolpidem extended-release or eszopiclone is required first before a DORA.
 - Applying manual PA criteria to new users of the insulin glargine solostar unbranded authorized biologic, consistent with the criteria for the other non-preferred basal insulins. A trial of Lantus is required first.
 - Applying manual PA criteria to new users of Tlando, consistent with the criteria already in place for the oral testosterone products (Jatenzo) and the other topical testosterone replacement products. A trial of the step-preferred product Fortesta is required first.

- Applying manual PA criteria to new users of Verkazia, consistent with the existing PA criteria for other ophthalmic cyclosporine products. Patients who are younger than age 21 years and who have a history of cyclosporine 0.05% ophthalmic emulsion (Restasis) in the past 180 days do not require a manual PA for Verkazia (age edit and auto-look back). The Restasis PA was also updated to allow use in patients younger than 18 years. *(See the Utilization Management section on page 18 for updates to the Restasis PA criteria).*
 - Applying PA criteria to new users of Vtama, consistent with what is already in place for other topical Psoriasis Drugs.
 - Applying PA criteria to new users of Vjioice, Radicava ORS, Ztalmy, Camzyos, Voquezna Double Pak, Voquezna Triple Pak, Adlarity, and Camcevi Kit
4. **COMMITTEE ACTION: EMMPI**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 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. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.
5. **COMMITTEE ACTION: UF, TIER 4, MN, AND PA IMPLEMENTATION PERIOD**—The P&T Committee recommended for (16 for, 0 opposed, 0 abstained, 0 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.
 - **New Drugs Recommended for Tier 4 Status:** 1) An effective date of the first Wednesday 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.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

- a) **Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMAs)—tiotropium dry powder inhaler (Spiriva HandiHaler)**—Spiriva HandiHaler was reviewed in February 2013 and added to the BCF. In November 2016, a follow-on product, tiotropium soft mist inhaler (Spiriva Respimat), was reviewed as a new drug and also added to the BCF. Both formulations are indicated for maintenance treatment of chronic obstructive pulmonary disease (COPD), and to reduce the risk of COPD exacerbations. They produce similar improvements in forced expiratory

volume in one second (FEV1), and have safety profiles that reflect the other LAMAs.

The Spiriva HandiHaler requires insertion of the dry powder capsules into the device, and also requires a minimum inspiratory flow rate of 30 mL/min to activate the inhaler. Generics are not expected for at least two years. For Spiriva Respimat, patients with dexterity issue may have difficulty assembling and priming the device. However, advantages of the Respimat device include that more drug is deposited in the lungs, rather than the oral cavity; it is a passive inhalation device which does not rely on the patient's inspiratory effort; and it has an additional indication for maintenance treatment of asthma in patients 6 years of age and older. Spiriva Respimat is more cost-effective than Spiriva HandiHaler.

COMMITTEE ACTION: SPIRIVA HANDIHALER NEW PA CRITERIA AND IMPLEMENTATION PLAN—

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria in new and current users of Spiriva HandiHaler, in order to encourage use of Spiriva Respimat, due to compelling advantages of the delivery mechanism. The new PA will become effective the first Wednesday 120 days after the signing of the minutes, and DHA will send letters to affected patients prior to and following implementation. Additionally, Spiriva HandiHaler will be added to the rapid response (“safety net”) program, which is included in the new TPharm5 contract. See Appendix C for the full criteria.

2. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for two recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. These products are usually produced by a single manufacturer. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. These drugs all have numerous cost-effective formulary alternatives available that do not require prior authorization. For the products listed below, PA criteria is recommended in new and current users, requiring a trial of cost effective generic formulary medications first.

- a) Renin-Angiotensin Anti-hypertensives (RAAs)—valsartan 20 mg/5 mL oral solution**—Valsartan is an angiotensin receptor blocker (ARB) that is available in cost-effective generic formulations, along with several other ARBs (e.g., losartan, candesartan, telmisartan, etc). Valsartan oral solution is not cost effective compared to the other ARBs.
- b) Non-Insulin Diabetes Drugs: Biguanides Subclass—metformin immediate release (IR) 625 mg tablets**—Numerous other metformin IR (500 mg and 850 mg) and ER (750 mg and 1000 mg) formulations are more cost-effective than this 625 mg IR formulation made by a sole manufacturer.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN—

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for valsartan 20 mg/5 mL oral solution and metformin 625 mg IR tablets in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee evaluated updates to the PA criteria for several drugs, due to new FDA-approved indications. The updated PA criteria outlined below will apply to new users. See Appendix C for the full criteria.

- a) Atopy Agents (now incorporates the previously titled Respiratory Interleukins)—dupilumab injection (Dupixent)
 - i. **Eosinophilic Esophagitis (EoE):** Dupixent recently gained a new indication for treating EoE. A trial of both a proton pump inhibitor (PPI) and topical glucocorticoid is required prior to using Dupixent in new users, based on the current EoE clinical practice guidelines from the American Academy of Allergy, Asthma and Immunology (AAAI) and MHS provider feedback. Note that topical glucocorticoids in this case refers to spraying a high potency inhaled corticosteroid in the mouth and then swallowing the dose (due to extensive first pass metabolism), or making a slurry out of budesonide respules.
 - ii. **Atopic Dermatitis in young children:** The Dupixent manual PA criteria were also updated to allow for expanded use as add-on maintenance treatment of atopic dermatitis in children aged 6 months to 5 years whose disease is not adequately controlled with topical prescription treatments.
- b) **Targeted Immunomodulatory Biologics (TIBs): oral Janus Kinase (JAK) inhibitors—upadacitinib (Rinvoq)**—The manual PA criteria were updated for Rinvoq to expand use for treating ankylosing spondylitis (AS) in new users. There are currently no head-to-head trials comparing the efficacy of one biologic over another for AS. Based on current clinical practice guidelines for AS, availability of other TIBs with indications for AS [including the TNF-inhibitor adalimumab (Humira) and the anti-IL-17 product secukinumab (Cosentyx)], and due to safety issues with the oral JAK inhibitors as a class, a trial of two non-steroidal anti-inflammatory drugs (NSAIDs), Humira and Cosentyx is required prior to using Rinvoq.
- c) **TIBs: apremilast (Otezla)**—PA criteria for Otezla have applied since August 2014 for the original indications of psoriatic arthritis and moderate-to-severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy. Step-therapy applies to the TIBs, requiring a trial of Humira first for

these indications. Otezla's package labeling has recently been expanded to include adults with mild cases of plaque psoriasis.

Based on clinical practice guidelines for treating psoriasis and feedback from MHS dermatologists, a trial of Humira will not be required for patients with mild plaque psoriasis. However, other standard therapies, including phototherapy and a moderate-to-high potency topical corticosteroid, steroid sparing agent and other topical agents, will be required first.

- d) Attention Deficit Hyperactivity Disorder (ADHD): Non-Stimulants—viloxazine extended release (Qelbree)**—PA criteria have been in place for Qelbree since it was reviewed as a new drug at the August 2021 DoD P&T Committee meeting. At the time Qelbree was approved for treating ADHD only in children between the ages of 6 and 17 years. Qelbree has recently received an indication for treating adults.

For adults with ADHD, the PA criteria will be more stringent than in children, as a trial of methylphenidate (e.g., Concerta), mixed amphetamine salts (e.g., Adderall XR), atomoxetine (Strattera), and another non-stimulant [guanfacine ER (Intuniv) or clonidine ER (Kapvay)] will be required before Qelbree in new users. This requirement is due to the limited number of patients included in the trials used to gain FDA-approval (only 175 adults were studied for six weeks); the safety concerns with Qelbree in adults (including increases in heart rate and blood pressure); and the availability of numerous other cost-effective stimulants and non-stimulants for treating ADHD.

For children, updates were made to allow pediatric patients with swallowing difficulties to bypass the requirement for a trial of a different non-stimulant first, since Qelbree capsules can be opened up and mixed with applesauce. The other non-stimulants cannot be crushed or chewed.

- e) Miscellaneous Metabolic Agents—setmelanotide injection (Imcivree)**—The PA was updated for the new indication of chronic weight management in adults and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Bardet-Beidl syndrome was added to the PA.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PLAN—

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Dupixent, Rinvoq, Otezla, Qelbree and Imcivree in new users.

Implementation will be effective the first Wednesday 60 days after signing of the minutes.

4. Removal of PA

- a) Topical Acne and Rosacea Agents: azelaic acid 15% (Finacea, generics)**—The P&T Committee evaluated an MTF request to remove the PA criteria for Finacea and add it to the Basic Core Formulary (BCF). Azelaic acid 15% gel is approved for treating rosacea, but is commonly used for acne. Step therapy

requires a trial of topical metronidazole first for rosacea. Finacea is now available in cost-effective generic formulations.

There is high quality evidence that topical azelaic acid decreases inflammatory lesions and erythema in rosacea. Additionally, for acne the 2016 American Academy of Dermatology guidelines give azelaic acid a class A recommendation with level 1 evidence. Azelaic acid is also rated as pregnancy category B.

The P&T Committee recommended removing the PA criteria for azelaic acid 15% gel; it remains on the UF, but will not be added to the BCF. Note that the current PA criteria for azelaic acid 20% cream (Azelex), which is approved for acne, will remain in place.

- b) Respiratory Agents Miscellaneous: epinephrine Auto-Injector (Auvi-Q)**—PA criteria for the Auvi-Q talking epinephrine auto-injector device were reinstated in February 2020, due to the resolution of the national shortage of EpiPen. Since 2020, the price of Auvi-Q has dropped significantly, and the nationwide supply of epinephrine autoinjectors appears stable. The P&T Committee recommended removing the Auvi-Q PA.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) removing the PA criteria for azelaic acid 15% gel and Auvi-Q auto-injector. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

5. Updated PA Criteria for Reasons other than new Indications

- a) Ophthalmic Dry Eye Class: cyclosporine 0.05% ophthalmic emulsion single dose (Restasis)**—PA criteria for Restasis currently allow use in patients older than 18 years of age. The PA criteria will now have an age edit to allow patients younger than 18 to bypass the PA criteria. The change in age will enable Restasis to be used in patients with vernal keratoconjunctivitis, rather than Verkazia, if the provider chooses. There were no other changes made; adults who do not have a claim for Restasis in the past 120 days are required to go through the PA. See Appendix C.
- b) Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs)**—The GLP-1RAs were reviewed for formulary placement in May 2022, with implementation set to occur on September 28, 2022. Trulicity was designated BCF, with a trial of metformin required. For Trulicity an automated look back was added; if a patient has received any diabetic drug in the past 720 days coverage will be allowed.

6. Updated PA Criteria for Removal of Indication

Over the past several months, the FDA has removed certain indications from some oncology drugs due to safety issues. The P&T Committee recommended updates to the PAs below, based on recent FDA action.

Oncologic Agents - Poly Adenosine Diphosphate Ribose Polymerase- (PARP) Inhibitor: rucaparib (Rubraca)—The indication for BRCA-mutated ovarian cancer after at least two prior chemotherapies has been removed, due to increased risk of death compared to chemotherapy in the third-line ovarian cancer treatment setting. The indications remain for ovarian cancer as second-line maintenance treatment in chemotherapy responders and also for previously treated BRCA-mutant metastatic castration-resistant prostate cancer.

Oncologic Agents - Non-Bruton Tyrosine Kinase Inhibitors for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (non-BTKIs for CLL/SLL): duvelisib (Copiktra)—A recent clinical trial reported a possible increased risk of death with Copiktra compared to another medication for leukemia and lymphoma. Additionally there was a higher risk of serious side effects with Copiktra, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and elevated liver enzyme levels. Although the FDA has not yet formally removed the indications for CLL/SLL, the P&T Committee will continue to monitor FDA actions and respond accordingly with updating the PA if needed.

COMMITTEE ACTION: RUBRACA UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) to remove the Rubraca indication for BRCA-mutated ovarian cancer after at least two prior chemotherapies. If any updates are made to the Copiktra label, the corresponding PA criteria will be updated accordingly. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

B. Quantity Limits

- 1. Newly approved drugs:** QLs were reviewed for the newly approved drugs where there are existing QLs for the class, or due to recommended treatment course durations.

COMMITTEE ACTION: NEW DRUGS QLs AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLs for Vioice, Voquezna Dual PAK, and Voquezna Triple PAK. See Appendix D for the QLs.

- 2. Specialty Drugs QLs:** An extensive review of quantity limits for specialty medications was presented. Quantity limits for Specialty medications were systematized based on the principles listed below. Additionally administrative authority for the Formulary Management Branch to establish and make changes to days

supply and quantity limits for specialty medications as needed was also presented (see Appendix J for the Table of Administrative Authorities).

- Starting with current Mail Order days supply limits (e.g., up to 56 days supply per fill) or “quantity per days supply” (e.g., up to 120 tablets per 60 day supply), simplify requirements by changing to a days supply limit wherever possible
- Keep limits consistent across points of service
- Whenever possible, maintain consistency among similar drugs
- In general, do not set limits lower than the current limits at Mail Order, unless the product is not available at or not currently dispensed from the Mail Order pharmacy
- For products with a current Mail Order days supply limit between 31 and 60 days (e.g., 45 days supply), allow up to a 60 day supply (depending on product packaging)
- Allow the current benefit limits for non-specialty drugs (typically 30 days supply at Retail pharmacies, but up to 90 days supply with multiple copays; up to 90 days supply at MTFs and Mail) to apply to Specialty medications in selected classes (e.g., leuprolides, octreotide, growth hormone, and multiple sclerosis agents)
- In general, limit to no more than 30 days supply for products with current limits of 21-30 days supply and limited distribution medications not currently filled at Mail Order
- In general, limit starter packs to one pack per fill, with no refills
- While days supply limits are preferable logistically, keep current quantity per days supply limits in special cases where days supply limits may allow overuse
- Do not exceed REMS requirements
- Consider recommendations from providers and specialty pharmacists

COMMITTEE ACTION: SPECIALTY DRUGS QLs AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the QLs for the specialty drugs as discussed above, with implementation occurring 30 days after signing of the minutes.

C. Line Extensions

The P&T Committee clarified the formulary status for three 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) Antiretrovirals: Combinations—designating abacavir /dolutegravir/lamivudine tablets for oral suspension (Triumeq PD) as UF, with the same formulary status as the parent Triumeq
- b) Pulmonary Arterial Hypertension (PAH)—designating treprostinil dry powder inhaler (Tyvaso DPI) as UF with the same PA as Tyvaso solution for inhalation

COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS AND IMPLEMENTATION—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) the formulary status for the line extension products as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE PROPIONATE HYDROFLUOROALKANE (FLOVENT HFA) AND TIER 1 COPAY

The Inhaled Corticosteroids (ICS) subclass was reviewed in May 2014, and Flovent dry powder inhaler (DPI) and hydrofluoroalkane (HFA) inhalers were designated as BCF and step-preferred. A generic fluticasone propionate HFA formulation has entered the market, however this product is less cost-effective compared to brand Flovent HFA. Therefore, the branded Flovent HFA/Flovent DPI product will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy).

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT FOR FLUTICASONE PROPIONATE HFA INHALER, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) requiring brand Flovent HFA or Flovent DPI in all new and current users at all three points of service, based on cost effectiveness. The prescriber will provide patient-specific justification as to why brand Flovent HFA or Flovent DPI cannot be used. The Tier 1 (generic) copayment will apply to both brand Flovent HFA and DPI. The effective date will be 2 weeks after signing of the minutes. The “brand over generic” requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

The authority for the Tier 1 copayment is codified in 32 CFR 199.21(j)(3): When a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

VIII. BRAND OVER GENERIC AUTHORIZATION FOR MESALAMINE 1.2 gm (LIALDA)

Brand over generic PA requirements originally applied to mesalamine 1.2 gram tablets (Lialda) in September 2017, due to cost effectiveness. In April 2020, cost-effective generic mesalamine formulations were available at the Mail Order and MTFs, however, generic prices at Retail pharmacies were not cost effective. On May 20, 2020, the brand over generic requirements were administratively removed at the Mail Order and MTF points of service, but remained at Retail pharmacies. The cost of generic mesalamine 1.2 gram tablets has now fallen at the Retail POS.

COMMITTEE ACTION: REMOVAL OF LIALDA BRAND OVER GENERIC REQUIREMENT TIER 2 COPAYMENT AND IMPLEMENTATION PERIOD—
The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent), to remove the brand Lialda over generic PA requirement at the Retail Network. The copay for brand Lialda at Retail pharmacies will increase back to the Tier 2 copay. The effective date will be 2 weeks after signing of the minutes.

IX. RE-EVALUATION OF NF GENERICS/EMMPI REQUIREMENTS: BETA BLOCKERS—NEBIVOLOL (BYSTOLIC)

The P&T Committee reviewed the current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per unit, for generic nebivolol (Bystolic). The P&T Committee agreed that, while the unit cost of generic nebivolol has dropped significantly from the previous generic and brand cost, it is still substantially higher than generic beta blocker formulations of metoprolol tartrate, metoprolol succinate, and atenolol, which are on the Uniform Formulary. The P&T Committee also noted that generic nebivolol is most competitively priced at retail compared to mail and MTF. There are 4 generic manufacturers available, suggesting stable generic prices and likely a continued decrease in the cost of nebivolol.

COMMITTEE ACTION: NEBIVOLOL FORMULARY STATUS AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) that nebivolol (Bystolic, generics) remain NF but be exempted from the mail order requirement on the basis of comparable decreasing and competitive pricing at retail, effective the first Wednesday two weeks after the signing of the minutes. See Appendix F.

X. NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) 2017 PILOT PROGRAM: INCORPORATION OF VALUE-BASED HEALTH CARE IN PURCHASED CARE COMPONENT OF TRICARE AND MEDICATION ADHERENCE

*Background—*A pilot program outlined in the NDAA 2017 required identification of high-value medications where copayments or cost shares would be reduced for targeted populations of covered beneficiaries. The DoD P&T Committee identified rosuvastatin (Crestor generics) and insulin glargine pens (Lantus pens) as candidates for inclusion in the pilot, which was intended to assess the effects of copayment reduction or elimination on medication adherence

rates. Additionally, the amount of any reduced or eliminated copay would be credited towards the patient's deductible/catastrophic cap. Implementation occurred on January 1, 2018, to align with recommended regulatory language. (*See the November 2017 and August 2017 DoD P&T Committee minutes*)

Pilot results showed there was no meaningful change in adherence, positive or negative, for patients receiving Lantus pens or rosuvastatin following a reduction in copay.

As required by NDAA 2017 termination of the pilot will occur on December 31, 2022, therefore the following changes will occur:

- Because Rosuvastatin is a generic, the copay will increase from the current \$0 co-pay back to the Tier 1 copay at the Mail Order and Retail network pharmacies, as generic co-pays are statutorily required and absent statutory authority to exclude a specific item or service from otherwise required co-pays, they cannot be waived. Patients will be notified of the copay change via letter.
- The catastrophic cap credit for the reduced/eliminated copays will end.
- These changes will occur on January 1, 2023.

The Committee also discussed the copays for Lantus, a branded drug. At the August 2017 Basal Insulin drug class review, the Lantus pens and vials were both designated as BCF, based on provider opinion, clinical and cost effectiveness, and MHS utilization patterns. The conclusion at the time was that the majority of MHS patients could be treated with Lantus, as there was a lack of compelling advantages of the newer basal insulin analogs.

COMMITTEE ACTION: LANTUS PENS AND VIALS TIER 1 COPAY AND IMPLEMENTATION PLAN—The P&T Committee recommended (15 for, 0 against, 0 abstained, 1 absent) the following:

- Insulin glargine pens (Lantus pens): Maintaining the Tier 1 copay at the Mail Order and Retail Network
- Insulin glargine vials (Lantus vials): Applying the Tier 1 copay at the Mail Order and Retail Network
- Implementation will occur on January 1, 2023.

The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states “in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes.” Lowering the cost-share for Lantus pens and vials will provide a greater incentive for beneficiaries to use the most cost-effective basal insulin product in the purchased care points of service.

XI. OVER-THE-COUNTER MEDICATIONS—MHS GENESIS OTC TEST LIST

A. Purpose of the MHS GENESIS OTC List

Background—At retail pharmacies and the Mail Order pharmacy, OTC medications are limited to those explicitly included in the TRICARE pharmacy benefit (e.g., diabetic supplies, tobacco cessation agents), as well as medications added to the Uniform Formulary and covered by TRICARE under provisions of 32 CFR 199.21(h)(5) as being cost-effective and clinically effective compared with other drugs in the same therapeutic class (e.g., loratadine, cetirizine, fexofenadine, levonorgestrel 1.5 mg [Plan B One-Step and its generics], and doxylamine 25 mg).

Historically, MTFs have dispensed a wide variety of OTC medications, as determined by the local MTF. A transition to a more uniform list of OTC products available across MTFs was recommended. Additionally, standardization was necessary due to the implementation of MHS GENESIS, the new electronic health record system. The MHS GENESIS OTC list was implemented on March 29, 2018; it is a list of NDCs for OTC products that will successfully adjudicate through the outpatient pharmacy system at MHS GENESIS sites. The P&T Committee has been systematically reviewing OTCs on the MHS GENESIS list since 2018 in order to finalize the list, with the last two categories reviewed in May 2022. *(Please refer to P&T Committee meeting minutes for May 2019, August 2019 and February 2022 for more background information.)*

Clarification—Although the goal of the MHS GENESIS OTC list is to provide a streamlined, standardized list of drugs that will adjudicate through the Pharmacy Data Transaction Service (PDTS), MTFs are not required to include every item on the list locally. Inclusion of an OTC product on the MHS GENESIS OTC list only allows for adjudication of a product at a MHS GENESIS site, and does not mandate inclusion on MTF formularies (i.e.; “may” have, not “must” have locally).

In addition, the MHS GENESIS OTC list does not affect purchasing of OTC medications through the prime vendor for either inpatient or out-patient use. It is also not intended to provide guidance for MTF self-care programs. However, since Service policies require products dispensed through such programs to be added to patient profiles, OTC products dispensed as part of MTF self-care programs do need to be on the MHS GENESIS OTC list in order to adjudicate through PDTS and show up on patient profiles.

B. Changes to the List: Vitamin D products update

Background—The DoD P&T Committee reviewed a request from the TRICARE nutritional community for addition of two additional vitamin D products to the MHS GENESIS OTC list to support an MTF standard: vitamin D3 (cholecalciferol) 2000 unit caps/tabs and 50,000 caps. Currently the list contains the following products: vitamin D3 (cholecalciferol) 400 u/mL drops and 400-, 1000-, and 5000-unit tablets, and vitamin D2 (ergocalciferol) 8000 u/mL drops. In addition, vitamin D2 (ergocalciferol) 50,000 unit caps are legend products and widely dispensed at all three points of service.

The request for vitamin D3 50,000 was based on evidence of slightly higher vitamin D concentrations compared to vitamin D2; however the clinical significance of this is unclear.

With respect to the 2000 unit strength, CHCS MTFs currently dispense similar quantities of the capsule and tablet products.

COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC

LIST/IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding vitamin D3 2000 unit tabs and caps and 50,000 unit caps to the MHS GENESIS OTC list. See Appendix I which outlines specific products retained or added to the MHS GENESIS OTC List.

C. Maintenance of the MHS GENESIS OTC Test List—General Process and MTF Requests

The MHS GENESIS OTC list is generally controlled at drug/strength/dosage form level, with the pharmacy contractor, Express-Scripts (ESI) periodically refreshing the list to account for the introduction of new NDCs. MTFs proposing additions or deletions from the list (at drug/strength/dosage form level) may fill out the MTF Drug Review Request Form (DHA Form 111), which may be found on the Formulary Management Branch (FMB) Sharepoint page: <https://info.health.mil/hco/pharmacy/FMB/SitePages/Home.aspx>).

This form requires the rationale for the proposed change, as well as sign-off by a local MTF P&T Committee before it will be presented to the DoD P&T Committee. If MTFs are encountering difficulties due to the lack of a specific NDC for products already represented on the list, or shortages arise for products already on the list, they may contact the FMB without going through the MTF Request Form process.

COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC

LIST/IMPLEMENTATION—In order to facilitate ongoing maintenance of the list, the P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) on the following:

- Changes to be managed administratively by FMB:
 - Requests for addition of products to the list where a similar agent is on the list
 - Changes requested as a result of a shortage or other availability issue (e.g., OTC status changes), where similar agents are already on the list
 - Changes for administrative reasons that don't affect adjudication through PDTS (e.g., management of formulary lists)
- Changes to be handled administratively, but brought to the P&T Committee afterward for review
 - Changes requested as a result of a shortage or other availability issue, where similar agents aren't already on the list
- Changes requiring P&T Committee review

- Addition of products where similar agents are not already on the list (e.g., adding new category of products)
- Deletion of products that result in no agents on the list in a given category

XII. PHARMACY AND THERAPEUTICS COMMITTEE ADMINISTRATIVE FUNCTIONS—NEW MEDICAL DEVICES

Management of the TRICARE pharmacy benefit requires a wide variety of actions, with various levels of involvement of the DoD P&T Committee, the Beneficiary Advisory Panel (BAP), and the Director, DHA. In May 2005 when the UF Rule was implemented, the P&T Committee developed a comprehensive list of the functions associated with formulary management and categorized each into one of three decision pathways, depending on the level of involvement required. Periodic updates have been made (*Refer to the May 2017, May 2019, August 2020, and August 2021 meeting minutes.*)

Medical devices are not part of the TRICARE Pharmacy benefit, with limited exceptions (e.g., certain diabetic supplies [continuous glucose monitoring systems, self-monitoring blood glucose test strips] and spacers for inhalers, [Aerochamber]). Medical devices are primarily covered by the TRICARE Health Plan and any additions to the pharmacy benefit are not meant to replace this pathway for procuring medical devices. A process for identifying how and when to review new versions of medical devices currently covered under the TRICARE pharmacy benefit is needed. There is currently no statutory or regulatory requirement mandating that the DoD P&T Committee review new FDA-approved medical devices or that the TRICARE Pharmacy benefit cover such devices.

The Committee discussed and approved a process of reviewing medical devices for inclusion on the DoD Uniform Formulary. Any new version/model of a currently covered device is not automatically included on the UF; new versions/models must first be reviewed by the DoD P&T Committee for clinical and cost effectiveness before being added to the TRICARE pharmacy benefit. Issues such as Trade Agreement Act noncompliance or other regulatory factors may preclude addition to the UF. See Appendix J for details on the device review pathway in the updated Administrative Authorities document.

COMMITTEE ACTION: MEDICAL DEVICE REVIEW PROCESS—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the process for considering and reviewing new versions/models of medical devices currently covered under the TRICARE pharmacy benefit for UF status.

VIII. SPECIALTY MEDICATION DEFINITION

The P&T Committee revised the definition of Specialty medications established by the P&T Committee in Aug 2014 to the following: Specialty medications will be based on one or more of the following characteristics:

1. One or more of the following clinical factors:
 - Difficult to administer
 - Special handling or storage
 - Intense monitoring
 - High risk of adverse drug events
 - Frequent dose adjustments
 - REMS programs in place
 - Benefits of ongoing training for patients
 - Not widely used in practice
 - Other drugs in the class are designated as specialty
2. The cost of the medication to DoD exceeds a cost factor based on that used by CMS to identify Specialty medications (top 1% of spend within DoD per 30 day-supply)
3. Upon future evaluation, the Specialty Pharmacy Program continues to provide value to the patient and/or DoD

COMMITTEE ACTION: SPECIALTY MEDICATION DEFINITION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the factors mentioned above as defining a specialty medication for the MHS.

VIV. ITEMS FOR INFORMATION

A. Post-Implementation Review: Pancreatic Enzyme Replacement Products: The Committee reviewed utilization and cost trends for the Pancreatic Enzyme Replacement (PERT) Products, which were reviewed for formulary placement in November 2018. The formulary actions of using Tier 1 and implementing step preference for the class resulted in significant and sustained cost avoidance for the MHS.

XV. ADJOURNMENT

The meeting adjourned at 1715 hours on August 4, 2022. The next meeting will be in November, 2022.

Appendix A—Attendance: August 4-5, 2022 DoD P&T Committee Meeting:

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

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

**Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary
during the May 2022 DoD P&T Committee Meeting**

Appendix G—Implementation Dates

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

Appendix I—MHS GENESIS OTC Text List

Appendix J—Table of Administrative Authorities

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



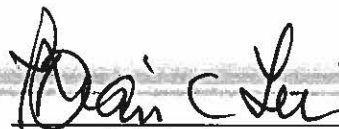
John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

concurs with all recommendations.

concurs with the recommendations, with the following modifications:

concurs with the recommendations, except for the following:



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

26 OCT 2022

Date

Appendix A—Attendance

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Mr. Edward Norton	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
MAJ Megan Donahue, MC	Army, Physician at Large
LTC Joseph Taylor, MSC	Army, Pharmacy Consultant
LTC Rosco Gore, MC	Army, Internal Medicine Physician
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Capt Jamie Geringer, MC for Lt Col Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
LTC Jason Burris, MC	Army, Oncology Physician
Walter Downs, MD	Physician at Large, DHA
Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
LCDR Samuel Mendoza	Defense Logistics Agency

Appendix A—Attendance

Guests	
CDR Daniel True, USPHS	Bureau of Prisons
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Mr. Ralph Bowie	DHA Contracting
Others Present	
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
David Folmar, RPh	DHA Formulary Management Branch Contractor
Kirk Stocker, RPh	DHA Formulary Management Branch Contractor
Michael Lee, RPh	DHA Formulary Management Branch Contractor
Dean Valibhai, PharmD	DHA Purchased Care Branch
LT Vivian Le, MSC	Navy Pharmacy Resident, San Diego

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
<ul style="list-style-type: none"> paroxetine mesylate (Pexeva) <p>Anti-Depressants & Non-Opioid Pain</p>	<ul style="list-style-type: none"> Formulary agents have resulted in therapeutic failure <p>Formulary alternatives: SSRI: citalopram, escitalopram, fluoxetine, sertraline, fluvoxamine, paroxetine hydrochloride IR; SNRI: venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER</p>
<ul style="list-style-type: none"> bupropion hydrobromide XR (Aplenzin) <p>Anti-Depressants & Non-Opioid Pain</p>	<ul style="list-style-type: none"> Formulary agents have resulted in therapeutic failure <p>Formulary alternatives: bupropion HCl (IR, SR, ER)</p>
<ul style="list-style-type: none"> duloxetine DR sprinkle (Drizalma Sprinkle) <p>Anti-Depressants & Non-Opioid Pain</p>	<ul style="list-style-type: none"> No alternative formulary agent: Patient requires duloxetine but cannot swallow duloxetine capsules <p>Formulary alternatives: duloxetine capsules, fluoxetine oral syrup/oral solution, citalopram solution, sertraline solution, venlafaxine sprinkle</p>
<ul style="list-style-type: none"> levomilnacipran XR (Fetzima) <p>Anti-Depressants & Non-Opioid Pain</p>	<ul style="list-style-type: none"> Use of formulary alternatives is contraindicated Patient has experienced or is likely to experience significant adverse effects from formulary agents that are not expected to occur with Fetzima Formulary alternatives have resulted in therapeutic failure Patient previously responded to nonformulary agent and changing would incur unacceptable risk No alternative formulary agent <p>Formulary alternatives: selective serotonin reuptake inhibitors, serotonin/norepinephrine reuptake inhibitor (except milnacipran), tricyclic antidepressants, mirtazapine, bupropion, serotonin antagonist reuptake inhibitors, monamine oxidase inhibitors</p>
<ul style="list-style-type: none"> milnacipran (Savella) <p>Anti-Depressants & Non-Opioid Pain</p>	<ul style="list-style-type: none"> Use of formulary alternatives is contraindicated Patient has experienced or is likely to experience significant adverse effects from formulary alternatives that are not expected to occur Formulary alternatives have resulted in therapeutic failure Patient previously responded to nonformulary agent and changing would incur unacceptable risk <p>Formulary alternatives: reuptake inhibitor (except levomilnacipran), tricyclic antidepressants, mirtazapine, bupropion, serotonin antagonist reuptake inhibitors, monamine oxidase inhibitors</p>

Appendix B—Table of Medical Necessity Criteria

<ul style="list-style-type: none"> gabapentin ER 24 hr tablets (Gralise) gabapentin enacarbil (Horizant) <p>Anti-Depressants & Non-Opioid Pain</p>	<ul style="list-style-type: none"> Use of formulary alternatives is contraindicated Patient has experienced or is likely to experience significant adverse effects from formulary alternatives <p>Formulary alternatives: gabapentin or the formulary non-opioid pain syndrome agents.</p>
<p>Newly Approved Drugs MN Criteria</p>	
<ul style="list-style-type: none"> amlodipine oral solution (Norliqva) <p>Calcium Channel Blockers</p>	<ul style="list-style-type: none"> No alternative formulary agent – patient has swallowing difficulties and can't take amlodipine tabs <p>Formulary alternatives: amlodipine (generic), or other DHP CCBs (felodipine, isradipine)</p>
<ul style="list-style-type: none"> cyclosporine 0.1% ophthalmic emulsion (Verkazia) <p>Ophthalmic Dry Eye</p>	<ul style="list-style-type: none"> Formulary agents result or are likely to result in therapeutic failure <p>Formulary alternatives: cyclosporine 0.05% (Restasis) or cyclosporine 0.09% (Cequa)</p>
<ul style="list-style-type: none"> donepezil patch (Adlarity) <p>Alzheimer's Agents</p>	<ul style="list-style-type: none"> Formulary agents result or are likely to result in therapeutic failure <p>Formulary alternatives: donepezil tablets, rivastigmine patch (Exelon), galantamine</p>
<ul style="list-style-type: none"> leuprolide SC injection (Camcevi Kit) <p>LHRH Agonists – Antagonists</p>	<ul style="list-style-type: none"> Patient has experienced or is likely to experience significant adverse effects from formulary agents <p>Formulary alternatives: Lupron-Depot; Eligard</p>
<ul style="list-style-type: none"> tapinarof 1% cream (Vtama) <p>Psoriasis Agents</p>	<ul style="list-style-type: none"> Use of formulary agents is contraindicated Patient has experienced or is likely to experience significant adverse effects from formulary agents Formulary agents resulted in therapeutic failure <p>Formulary alternatives: moderate to high potency topical corticosteroids (e.g., betamethasone, clobetasol, fluocinonide), topical calcineurin inhibitors (i.e., pimecrolimus, tacrolimus)</p>

Appendix B—Table of Medical Necessity Criteria

<ul style="list-style-type: none"> testosterone undecanoate 112.5 mg capsule (Tlando) <p>Androgens-Anabolic Steroids: Testosterone Replacement Therapies</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from ALL listed formulary agents ALL listed formulary agents resulted in therapeutic failure <p>Formulary alternatives: Androderm patch, testosterone 2% gel (Fortesta), testosterone 1% gel (generic to Androgel), and Testim 1% gel</p>
<ul style="list-style-type: none"> tirzepatide SC injection (Mounjaro) <p>Diabetes Non Insulin: Glucagon-Like Peptide-1 (GLP1_ Receptor Agonists</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from Trulicity which is not expected to occur with Mounjaro <p>Formulary alternatives: Trulicity</p>
<ul style="list-style-type: none"> amoxicillin; vonoprazan (Voquezna Dual Pak) amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak) <p>Anti-Infectives: Miscellaneous</p>	<ul style="list-style-type: none"> A trial of two formulary treatment courses/combinations resulted in therapeutic failure <p>Formulary alternatives: omeprazole, lansoprazole, amoxicillin, rifabutin, clarithromycin, bismuth subsalicylate, metronidazole, tetracycline, other PPIs or H2 blockers</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
<ul style="list-style-type: none"> paroxetine mesylate (Pexeva) <p>Anti-Depressants & Non-Opioid Pain - SSRI</p>	<p>PA criteria apply to all new users of Pexeva. (New PA criteria)</p> <p><u>Manual PA criteria:</u> Pexeva is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older. Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication. Patient has a diagnosis of depression, anxiety, obsessive compulsive disorder, or panic disorder Patient has tried and failed generic paroxetine at maximally tolerated dose AND The patient has a contraindication to, intolerance to, or has failed a trial of TWO other formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> vilazodone (Viibryd) <p>Anti-Depressants & Non-Opioid Pain - SSRI</p>	<p>PA criteria apply to all new users of Viibryd. (New PA criteria)</p> <p><u>Manual PA criteria:</u> Viibryd is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older. Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication. Patient is being treated for depression The patient has a contraindication to, intolerance to, or has failed a trial of THREE formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> vortioxetine (Trintellix) <p>Anti-Depressants & Non-Opioid Pain - SSRI</p>	<p>Updates to the Feb 2014 meeting are in bold and strikethrough Note that previous automation has been removed</p> <p>PA criteria apply to all new users of Trintellix.</p> <p><u>Manual PA criteria:</u> Trintellix is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older. Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication. Patient is being treated for depression The patient has a contraindication to, intolerance to, or has failed a trial of TWO formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). Patients are required to try a generic SSRI, duloxetine, SNRI (except milnacipran), tricyclic antidepressant, mirtazapine > bupropion, serotonin antagonist reuptake inhibitor (trazodone, ornefazodone), or monoamine oxidase inhibitor first <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> duloxetine DR (Drizalma Sprinkle) <p>Anti-Depressants & Non-Opioid Pain - SNRI</p>	<p>Note – There were no changes made at the August 2022 meeting.</p> <p>PA does not apply to patients 12 years of age and younger (age edit). PA criteria apply to all new users of Drizalma Sprinkle older than 12 years of age.</p> <p><u>Manual PA Criteria:</u> Drizalma Sprinkle is approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider must explain why the patient requires Drizalma sprinkle capsules and cannot take alternatives. <p>Non-FDA-approved uses are not approved. PA expires in one year.</p> <p><u>Renewal PA criteria:</u> No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.</p>
<ul style="list-style-type: none"> levomilnacipran XR (Fetzima) <p>Anti-Depressants & Non-Opioid Pain - SNRI</p>	<p>Updates to the Feb 2014 meeting are in bold and strikethrough Note that previous automation has been removed</p> <p>PA criteria apply to all new users of Fetzima</p> <p><u>Manual PA criteria:</u> Fetzima is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older. Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication. Patients are required to try a generic SSRI, duloxetine, SNRI (except milnacipran), tricyclic antidepressant, mirtazapine > bupropion, serotonin antagonist reuptake inhibitor (trazodone, ornefazodone), or monamine oxidase inhibitor first Patient is being treated for depression The patient has a contraindication to, intolerability to, or has failed a trial of THREE formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> milnacipran (Savella) <p>Anti-Depressants & Non-Opioid Pain - SNRI</p>	<p>Updates to the Nov 2011 meeting are in bold and strikethrough Note that previous automation has been removed</p> <p>PA criteria apply to all new users of Savella</p> <p><u>Manual PA criteria:</u> Savella is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older. All new users of Savella are required to try a non-opioid pain syndrome agent including SNRI including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin Patient is being treated for fibromyalgia Patient has tried and failed duloxetine at maximally tolerated dose AND The patient has a contraindication to, intolerability to, or has failed a trial of ONE other formulary medication at maximally tolerated dose (examples of formulary agents include pregabalin, amitriptyline, cyclobenzaprine). <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> bupropion hydrobromide XR (Aplenzin) <p>Anti-Depressants & Non-Opioid Pain - NDRI</p>	<p>Updates to the Nov 2017 meeting are in bold and strikethrough Note that previous automation has been removed</p> <p>PA criteria apply to all new users of Aplenzin</p> <p><u>Manual PA criteria:</u> Aplenzin is approved if all criteria are met:</p> <ul style="list-style-type: none"> The patient is 18 years or older. The patient does not have a history of seizure disorder or conditions that increase the risk of seizure (e.g. bulimia, anorexia nervosa, severe head injury). Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication. New and current users of Aplenzin are required to try generic bupropion ER and a second antidepressant first. The patient has being treated for depression or seasonal affective disorder Patient has tried and failed bupropion extended release at maximally tolerated dose AND The patient has a contraindication to, intolerability to, or has failed a trial of TWO other formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> gabapentin ER 24 hr tablets (Gralise) <p>Anti-Depressants & Non-Opioid Pain - GABA</p>	<p>Updates to the May 2012 meeting are in bold and strikethrough Note that previous automation has been removed</p> <p>PA criteria apply to all new users of Gralise</p> <p><u>Manual PA criteria:</u> Gralise is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older. The patient has a contraindication to or experienced adverse events with gabapentin or the formulary non-opioid pain syndrome agents which is not expected to occur with Horizant or Gralise. Patient is being treated for post herpetic neuralgia and: Patient has tried and failed gabapentin or pregabalin at maximally tolerated dose AND Patient has a contraindication to, intolerability to or has tried and failed a TCA at maximally tolerated dose. <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> gabapentin enacarbil (Horizant) <p>Anti-Depressants & Non-Opioid Pain - GABA</p>	<p>Updates to the May 2012 meeting are in bold and strikethrough Note that previous automation has been removed</p> <p>PA criteria apply to all new users of Horizant</p> <p><u>Manual PA criteria:</u> Horizant is approved if all criteria are met:</p> <ul style="list-style-type: none"> The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise. The patient has experienced adverse events (AEs) with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise. <p><u>For post herpetic neuralgia:</u></p> <ul style="list-style-type: none"> Patient is 18 years of age or older

Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none"> • Patient has tried and failed gabapentin or pregabalin at maximally tolerated dose AND • Patient has a contraindication to, intolerability to or has tried and failed a TCA at maximally tolerated dose. <p><u>For restless leg syndrome:</u></p> <ul style="list-style-type: none"> • Patient is 18 years of age or older. • Patient has tried and failed gabapentin or pregabalin at maximally tolerated dose AND • Patient has contraindication to, intolerability to or has tried and failed pramipexole or rotigotine at maximally tolerated dose. <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> • mirabegron tablets (Myrbetriq) <p>Overactive Bladder Agents – β-3 Agonists</p>	<p>Updates from the August 2022 meeting are in bold and strikethrough</p> <p>Manual PA criteria apply to all new users of mirabegron (Myrbetriq). <u>Manual PA criteria:</u> Myrbetriq is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Overactive Bladder <ul style="list-style-type: none"> • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency AND • 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 one two formulary stop preferred products generic antimuscarinic medication (oxybutynin IR, oxybutynin ER, tolterodine ER, trospium, solifenacin, darifenacin or fesoterodine) 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, advanced age or other medications • Patient has tried and failed or has a contraindication to vibegron (Gemtesa) • The patient's does not have a CrCl <15 mL/min estimated creatinine clearance (CrCl)/glomerular filtration rate (eGFR) is ≥ 15 mL/min/1.73m² and the provider is aware that the dose should not exceed 25 mg a day in patients with a CrCl/eGFR between 15 – 29 mL/min/1.73m² • If the CrCl is between 15-29 mL/min, the dosage does not exceed 25 mg QD <p>OR</p> <ul style="list-style-type: none"> • Neurogenic Detrusor Overactivity (NDO) <ul style="list-style-type: none"> • The patient has a confirmed diagnosis of neurogenic detrusor overactivity (NDO) secondary to detrusor overactivity and/or myelomeningocele • The drug is prescribed by or in consultation with a urologist or nephrologist • The provider acknowledges that the granules are not bioequivalent and cannot be substituted on a mg to mg basis with the tablets and will not combine dosage forms to achieve a specific dose • Provider acknowledge that there are detailed renal and hepatic dose adjustments in the package labeling and agrees to consult this before prescribing in this special population • Provider acknowledge that oxybutynin is available for patients with neurogenic detrusor overactivity and does not require prior authorization • Patient has tried and failed or has a contraindication to oxybutynin • The patient weighs greater than or equal to 35 kg <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> mirabegron extended release granules for oral suspension (Myrbetriq Granules) <p>Overactive Bladder Agents – β-3 Agonists</p>	<p>No changes made at the August 2022 meeting</p> <p>Note that the previous automation for Myrbetriq granules and tablets has been removed</p> <p>Manual PA criteria: Myrbetriq Granules are approved if all criteria are met:</p> <ul style="list-style-type: none"> Myrbetriq granules for oral suspension are prescribed by or in consultation with a urologist or nephrologist The prescription is written for neurogenic bladder secondary to detrusor overactivity and/or myelomeningocele, and not for overactive bladder Provider acknowledges that oxybutynin oral syrup is available for patients with neurogenic detrusor overactivity and does not require prior authorization Patient has tried and failed or has a contraindication to oxybutynin Patient requires Myrbetriq granules for oral suspension for one of the following reasons: <ul style="list-style-type: none"> The patient cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, etc) and not convenience. OR The patient weighs less than 35 kg Provider acknowledges that Myrbetriq granules for suspension are not bioequivalent to and cannot be substituted on a mg to mg basis to the Myrbetriq tablets Provider acknowledges that Myrbetriq granules for suspension and the Myrbetriq tablets will not be combined to achieve a specific dose Provider acknowledges the detailed renal and hepatic dosing adjustments in the package labeling and agrees to consult this before prescribing the granules in these special populations <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> vibegron (Gemtesa) <p>Overactive Bladder Agents – β-3 Agonists</p>	<p>Updates from the August 2022 meeting are in bold and strikethrough</p> <p>Manual PA criteria apply to all new users of Gemtesa.</p> <p><u>Manual PA criteria:</u> Gemtesa is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> 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 one two formulary step-preferred products generic antimuscarinic (oxybutynin IR, oxybutynin ER, tolterodine ER, trospium, solifenacin, darifenacin or fesoterodine) 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, advanced age or other medications, The patient's creatinine clearance (CrCl) is greater than 15 mL/min /glomerular filtration rate (eGFR) is ≥ 15 mL/min/1.73m² <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Newly Approved Drug PAs	
<ul style="list-style-type: none"> • alpelisib (Vijoice) <p>Oncological Agents</p>	<p>PA criteria apply to all new users of alpelisib (Vijoice).</p> <p><u>Manual PA criteria:</u> Vijoice is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescription is written by or in consultation with a medical geneticist or vascular surgeon • Patient has a documented diagnosis of PIK3CA Related Overgrowth Spectrum (PROS) which the provider determines to be severe and requiring systemic therapy • Patient has documented evidence of a mutation in the PIK3CA gene <p>Non-FDA-approved uses are not approved PA expires in one year</p> <p><u>Renewal Criteria:</u> (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if</p> <ul style="list-style-type: none"> • The patient has a documented positive clinical response to therapy
<ul style="list-style-type: none"> • amlodipine oral solution (Norliqva) <p>Calcium Channel Blockers</p>	<p>PA does not apply to patients less than 12 years of age (age edit).</p> <p>PA criteria apply to all new users of Norliqva.</p> <p><u>Manual PA criteria:</u> Norliqva is approved if all criteria are met</p> <ul style="list-style-type: none"> • Provider must explain why the patient requires amlodipine oral solution and cannot take amlodipine tablets or amlodipine suspension <p>Non-FDA-approved uses are not approved PA does not expire</p>
<ul style="list-style-type: none"> • cyclosporine 0.1% ophthalmic emulsion (Verkazia) <p>Ophthalmic Dry Eye</p>	<p>Note that an age edit and automated look back apply.</p> <ul style="list-style-type: none"> • Patients who are younger than age 21 years who have a history of Restasis do not require a PA; Verkazia is approved • Patients younger than age 21 who do not have a history of Restasis require manual PA • Manual PA is required in all new patients 21 years of age and older <p><u>Automated PA criteria:</u> The patient is younger than age 21 years AND has filled a prescription for cyclosporine 0.05% ophthalmic solution (Restasis) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days.</p> <p><u>Manual PA Criteria:</u> If automated criteria are not met, coverage is approved for Verkazia if all criteria are met:</p> <ul style="list-style-type: none"> • Verkazia is prescribed by or in consultation with an optometrist or ophthalmologist • Patient has moderate to severe vernal keratoconjunctivitis (VKC) • Patient has tried and failed an adequate course of at least one mast cell stabilizer/antihistamine (i.e., olopatadine, azelastine, epinastine, lodoxamide, cromolyn) • Patient has tried and failed, or has a contraindication to an adequate course of cyclosporine 0.05% ophthalmic emulsion (Restasis) <p>Non-FDA-approved uses are NOT approved including dry eye disease, graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) and LASIK associated dry eye</p> <p>PA does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • daridorexant (Quviviq) <p>Sleep Disorders: Insomnia Agents</p>	<p>Manual PA criteria apply to all new users of Quviviq, Belsomra, and Dayvigo.</p> <p><u>Manual PA Criteria:</u> Quviviq, Belsomra, Dayvigo is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges 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 has no current or previous history of narcolepsy • Patient has no current or previous history of drug abuse <p>Non FDA-approved uses are not approved Prior authorization expires in 1 year</p> <p><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:</p> <ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • donepezil patch (Adlarity) <p>Alzheimer's Agents</p>	<p>Manual PA criteria apply to all new users of donepezil transdermal system (Adlarity).</p> <p><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • The medication is being prescribed in consultation with a neurologist, psychiatrist, or specialist in geriatric medicine. • The patient is being treated for mild, moderate, or severe dementia of the Alzheimer's type. • The patient must have tried and failed, have a contraindication to, or have had an adverse reaction to both of the following:: <ul style="list-style-type: none"> • One oral donepezil formulation (e.g., donepezil 5 mg or, 10 mg tab or orally dissolving tablets [ODT]) AND • One topical agent: rivastigmine transdermal system (Exelon patch). <p>Non-FDA approved uses are NOT approved. PA does not expire.</p>
<ul style="list-style-type: none"> • edaravone oral suspension (Radicava ORS) <p>Neurological Agents Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Radicava ORS.</p> <p><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • The medication is prescribed by a neurologist. • The patient has a diagnosis of amyotrophic lateral sclerosis (ALS). • The disease duration is two years or less • The patient has a score of ≥ 2 points for each item of ALS Functional Rating Scale–Revised (ALSFRS-R). • The patient has preserved respiratory function (forced vital capacity $\geq 80\%$) <p>Non-FDA approved uses are NOT approved. PA does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> ganaxolone oral suspension (Ztalmey) <p>Anticonvulsants- Antimania Agents</p>	<p>Manual PA criteria apply to all new users of ganaxolone (Ztalmey)</p> <p><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> Drug is prescribed by or in consultation with pediatric neurologist Patient has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed with a genetic test <p>Non-FDA approved uses are NOT approved. PA does not expire.</p>
<ul style="list-style-type: none"> insulin glargine solostar authorized biologic <p>Basal Insulins</p>	<p>Manual PA criteria apply to all new users of insulin glargine solostar</p> <p><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider acknowledges that Lantus is the DoD's preferred basal insulin and preferred insulin glargine. Prescriptions written for Lantus do not require prior authorization and are available at the lowest Tier 1 copay. Patient must have tried and failed insulin glargine (Lantus) <p>Non-FDA approved uses are NOT approved. PA does not expire.</p>
<ul style="list-style-type: none"> leuprolide SC injection (Camcevi Kit) <p>LHRH Agonists- Antagonists</p>	<p>Manual PA criteria apply to all new users of Camcevi.</p> <p><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older Drug is prescribed by or in consultation with an oncologist or urologist Patient has a diagnosis of advanced prostate cancer Patient has intolerability to, or has failed alternative formulary leuprolide injections (i.e. Lupron Depot, Eligard) <p>Non-FDA approved uses are NOT approved. PA does not expire.</p>
<ul style="list-style-type: none"> mavacamten (Camzyos) <p>Cardiovascular Agents Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Camzyos.</p> <p><u>Manual PA criteria:</u> Camzyos is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> The patient is 18 years of age and older Drug is prescribed by a cardiologist The patient has documented evidence of obstructive hypertrophic cardiomyopathy (HCM) Left ventricular outflow tract (LVOT) pressure gradient is greater than or equal to 50 mmHg The patient has NYHA Class II to III obstructive HCM that is symptomatic (e.g., dyspnea, chest pain, light headedness, syncope, fatigue, reduced exercise capacity) The patient's left ventricular ejection fraction (LVEF) is greater than or equal to 55% Patient has failed therapy with at least one agent from both of the following classes: <ul style="list-style-type: none"> Beta blocker (non-vasodilating) – propranolol, metoprolol AND Calcium channel blockers (non-dihydropyridine) – verapamil, diltiazem Patient must not be on dual calcium channel blocker and beta blocker therapy concurrently Patient must not be receiving ranolazine or disopyramide concurrently Patient and provider must be aware of the risks of systolic dysfunction as outlined by REMS

Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none"> • Provider and patient must agree to comply to all requirements of the REMS program, including echocardiogram at 0, 4, 8, 12 weeks follow by every 12 weeks and drug interaction monitoring requirements • If the patient is of child-bearing age, the patient must not be pregnant and will receive counseling for effective contraception during therapy and for 4 months after the last dose <p>Non-FDA-approved uses are not approved PA expires in 1 year,</p> <ul style="list-style-type: none"> • <u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. PA will be renewed indefinitely if the patient has responded to therapy, as evidenced by improvement in obstructive hypertrophic cardiomyopathy symptoms
<ul style="list-style-type: none"> • tapinarof 1% cream (Vtama) <p>Psoriasis Agents</p>	<p>Manual PA criteria apply to all new users of tapinarof (Vtama).</p> <p><u>Manual PA criteria:</u> Vtama is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older. • The patient has a diagnosis of plaque psoriasis. • The medication is being prescribed in consultation with a dermatologist. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following: <ul style="list-style-type: none"> • at least one moderate to high potency topical corticosteroid (e.g., clobetasol propionate 0.05% ointment, cream, solution and gel; fluocinonide 0.05% ointment, cream, solution) AND • at least one topical calcineurin inhibitor (e.g. tacrolimus, pimecrolimus) <p>Non-FDA approved uses are not approved. PA does not expire.</p>
<ul style="list-style-type: none"> • testosterone undecanoate 112.5 mg capsules (TLando) <p>Androgens-Anabolic Steroids: Testosterone Replacement Therapies</p>	<p>Manual PA criteria applies to new users of users of Jatenzo and TLando</p> <p><u>Manual PA Criteria:</u> Jatenzo or TLando is <u>approved</u> if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions • Patient is a male age 18 years of age or older • The patient has a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL. • Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed (From Feb 2022 meeting PA update for the testosterone replacement therapy drug class) • Patient is experiencing signs and symptoms usually associated with hypogonadism • Patient has tried testosterone 2% gel (Fortesta) OR testosterone 1% gel (Androgel generic) for a minimum of 90 days AND failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after use of the agent) AND without improvement in symptoms <p>OR</p> <ul style="list-style-type: none"> • Patient has a contraindication to or has experienced a clinically significant adverse reaction to Fortesta OR generic testosterone 1% gel, that is not expected to occur with Jatenzo or TLando • The patient requires a testosterone replacement therapy (TRT) that has a low risk of skin-to-skin transfer between family members <p>OR</p> <ul style="list-style-type: none"> • Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:

Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none"> • Patient has diagnosis of gender dysphoria made by a TRICARE authorized mental health provider according to most current edition of the DSM • Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2 AND • Patient has no signs of breast cancer AND • For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g. unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) AND • Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria (deleted May 2022) • Patient does not have any of the following: <ul style="list-style-type: none"> • Hypogonadism conditions not associated with structural or genetic etiologies (e.g. “age-related” hypogonadism), carcinoma of the breast or suspected carcinoma of the prostate • Uncontrolled hypertension or is at risk for cardiovascular events (e.g., myocardial infarction or stroke) prior to start of Jatenzo or Tlando therapy or during treatment (based on the product’s boxed warning of increased risk of major adverse cardiovascular events and hypertension) <p>Non-FDA-approved uses are NOT approved. Not approved for concomitant use with other testosterone products. Prior Authorization does not expire</p>
<ul style="list-style-type: none"> • tirzepatide (Mounjaro) <p>Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)</p>	<p>Manual PA criteria apply to all new users of Mounjaro.</p> <p>All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.</p> <p><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that Trulicity is available on the UF and has an indication to reduce the risk of major adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors, Mounjaro does not have this indication • The patient has a confirmed diagnosis of Type 2 diabetes mellitus • The patient has experienced any of the following issues on metformin: <ul style="list-style-type: none"> • impaired renal function precluding treatment with metformin OR • history of lactic acidosis • The patient has had inadequate response to metformin OR • The patient has a contraindication to metformin <p>Non-FDA approved uses are NOT approved, including for weight loss in patients who do not have diabetes PA does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • vonoprazan, amoxicillin (Voquezna Dual Pak) • vonoprazan, amoxicillin, clarithromycin (Voquezna Triple Pak) <p>Anti-Infectives Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Voquezna Dual & Triple Pak</p> <p><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that other medications to treat <i>H. pylori</i> including lansoprazole, amoxicillin, and clarithromycin are on the TRICARE formulary and are available without a PA • Patient is 18 years of age or older • Prescription is written by or in consultation with a gastroenterologist or infectious disease specialist • Patient has tried and failed two 14-day trials of therapy with guideline-recommended first-line therapies (Appropriate treatment combinations of: omeprazole, lansoprazole, amoxicillin, rifabutin, clarithromycin, bismuth subsalicylate, metronidazole, tetracycline, and PPI or H2 blockers) for <i>H. pylori</i> <ul style="list-style-type: none"> • Note: Failure is defined as failure to eradicate <i>H. pylori</i> infection after a 14-day course of therapy <p>Non-FDA approved uses are NOT approved PA renewal is not allowed; A new PA is required for each course of therapy</p>
<p>Utilization Management New PAs</p>	
<ul style="list-style-type: none"> • tiotropium dry powder inhaler (Spiriva HandiHaler) <p>Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMAs)</p>	<p>Manual PA criteria apply to all new and current users of Spiriva HandiHaler.</p> <p><u>Manual PA criteria:</u> Spiriva HandiHaler is approved if all the following criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that Spiriva Respimat is the Department of Defense's preferred long-acting muscarinic antagonist and does not require prior authorization. • The provider must document a patient-specific reason as to why the patient requires Spiriva Handihaler and cannot use the Spiriva Respimat device. (blank write-in) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • metformin 625 mg IR tablets <p>Non-Insulin Diabetes Drugs: Biguanides</p>	<p>Manual PA criteria apply to all new and current users of metformin IR 625 mg tablets.</p> <p><u>Manual PA criteria:</u> Metformin IR 625 mg tablets are approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges other metformin formulations, including the 500 mg and 850 mg immediate release tablets, and 750 mg and 1000 mg extended release tablets are available without requiring prior authorization. • The provider must explain why the patient can't take a different metformin formulation. (blank write-in) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> valsartan 20 mg/5mL oral solution <p>Renin Angiotensin Antihypertensives (RAAs): Angiotensin Receptor Blockers (ARBs)</p>	<p>Manual PA criteria apply to all new and current users of valsartan 20 mg/5mL oral solution.</p> <p><u>Manual PA criteria:</u> Valsartan 20 mg/5mL oral solution is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> Provider acknowledges other angiotensin receptor blockers (ARBs) including valsartan, telmisartan and losartan are available without requiring prior authorization. The provider must explain why the patient can't take a tablet formulation of an (ARB) (blank write-in) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<p>Utilization Management Updated PAs</p>	
<ul style="list-style-type: none"> dupilumab (Dupixent) <p>Atopy Agents (Formerly Respiratory Interleukins)</p>	<p><u>Updates from the August 2022 meeting for EoE and atopic dermatitis are in bold and strikethrough. Note that no changes were made for the asthma or nasal polyps indications.</u></p> <p>Manual PA is required for all new users of dupilumab (Dupixent).</p> <p><u>Manual PA Criteria:</u> Dupixent coverage will be approved for initial therapy for 12 months if all criteria are met:</p> <p><i>For Eosinophilic Esophagitis:</i></p> <ul style="list-style-type: none"> The patient is 12 years of age or older and weighs at least 40 kilograms (~88 lbs) The drug is prescribed by or in consultation with a gastroenterologist or allergy/immunology specialist Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy For EoE, the patient has tried and failed an adequate course of both the following: <ul style="list-style-type: none"> Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND Topical glucocorticoids [e.g. fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, clinically significant adverse effects are experienced, or in children maximal doses can not be reached due to concerns for growth suppression or adrenal insufficiency <p>Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> Eosinophilic Esophagitis (EoE): <ul style="list-style-type: none"> For <u>maintenance</u>: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e): <ol style="list-style-type: none"> Reduced intraepithelial eosinophil count; OR Decreased dysphagia/pain upon swallowing; OR Reduced frequency/severity of food impaction; OR Reduced vomiting/regurgitation; OR Improvement in oral aversion/failure to thrive For <u>relapse</u>: prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval

	<p><i>For Atopic Dermatitis:</i></p> <ul style="list-style-type: none"> • The patient is at least 6 months years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe or uncontrolled atopic dermatitis • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: <ul style="list-style-type: none"> ▪ Topical Corticosteroids: <ul style="list-style-type: none"> ○ For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) ○ For patients 6 to 17 year of age: any topical corticosteroid <p>AND</p> <ul style="list-style-type: none"> ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) <ul style="list-style-type: none"> • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy <p><i>For Asthma:</i></p> <ul style="list-style-type: none"> • The patient is 6 years of age or older • The drug is prescribed by an allergist, immunologist, pulmonologist, or asthma specialist, • The patient has one of the following <ul style="list-style-type: none"> ▪ Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils ≥ 150 cells/mcL OR ▪ Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months • For eosinophilic asthma, the patient’s asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following; <ul style="list-style-type: none"> ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR ▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • For eosinophilic asthma, the patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: <ul style="list-style-type: none"> ▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi), ▪ Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) <p><i>For Chronic rhinosinusitis with nasal polyposis:</i></p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: <ul style="list-style-type: none"> ▪ Presence of nasal polyposis is confirmed by imaging or direct visualization AND ▪ At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain
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Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none"> • Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments <ul style="list-style-type: none"> ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND ▪ The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery • Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength <p>AND</p> <ul style="list-style-type: none"> • For all indications the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) <p>Non-FDA-approved uses are not approved Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely</p> <p>Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • Eosinophilic Esophagitis (EoE): <ul style="list-style-type: none"> ▪ For <u>maintenance</u>: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e): <ul style="list-style-type: none"> f) Reduced intraepithelial eosinophil count; OR g) Decreased dysphagia/pain upon swallowing; OR h) Reduced frequency/severity of food impaction; OR i) Reduced vomiting/regurgitation; OR j) Improvement in oral aversion/failure to thrive ▪ For <u>relapse</u>: prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval • Asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use • Atopic Dermatitis: The patient's disease severity has improved and stabilized to warrant continued therapy • Chronic rhinosinusitis with nasal polyposis : There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score.
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<ul style="list-style-type: none"> • upadacitinib (Rinvoq) <p>Targeted Immunomodulatory Biologics (TIBs): Miscellaneous</p>	<p>Updates from the Aug 2022 meeting are in bold. Note that there were not changes to the criteria for the other indications (RA, PsA, AD, Ulcerative Colitis)</p> <p>Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq ER).</p> <p><u>Manual PA Criteria:</u> Rinvoq is approved if all criteria are met:</p> <p><i>For Ankylosing Spondylitis</i></p> <ul style="list-style-type: none"> • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ankylosing spondylitis • The patient is 18 years of age or older • The patient has ankylosing spondylitis • Patient has had an inadequate response to Humira and Cosentyx OR • Patient has experienced an adverse reaction to Humira and Cosentyx that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira and Cosentyx AND • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months <p><i>For all indications</i></p> <ul style="list-style-type: none"> • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) <p>Non-FDA-approved uses are not approved. PA does not expire for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, or ankylosing spondylitis</p> <p><i>For Rheumatoid Arthritis</i></p> <ul style="list-style-type: none"> • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis • The provider also acknowledges that for rheumatoid arthritis a trial of Xeljanz or Olumiant is required before Rinvoq. • The patient is 18 years of age or older • The patient has a diagnosis of active rheumatoid arthritis (RA) • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz or Olumiant OR • Patient has experienced an adverse reaction to Xeljanz or Olumiant that is not expected to occur with Rinvoq OR • Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq <p><i>For Psoriatic Arthritis</i></p>
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	<ul style="list-style-type: none"> • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for psoriatic arthritis. • The provider also acknowledges that for psoriatic arthritis a trial of Xeljanz is required before Rinvoq. • The patient has a diagnosis of active psoriatic arthritis (PsA) • The patient is 18 years of age or older • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz OR • Patient has experienced an adverse reaction to Xeljanz or OR • Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq <p><i>For Atopic Dermatitis</i></p> <ul style="list-style-type: none"> • The patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient's disease is not adequately controlled with other systemic drug products, including biologics (for example, Dupixent) • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: <ul style="list-style-type: none"> ▪ Topical Corticosteroids: <ul style="list-style-type: none"> ○ For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) ○ For patients 12 to 17 year of age: any topical corticosteroid AND ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy <p><i>For Ulcerative Colitis</i></p> <ul style="list-style-type: none"> • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis • The patient is 18 years of age or older • The patient has moderately to severely active ulcerative colitis • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira • The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.) <p><i>For all indications</i></p> <ul style="list-style-type: none"> • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease
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Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none">• Provider is aware of the FDA safety alerts AND Boxed Warnings• Patient has no evidence of neutropenia (ANC < 1000)• Patient has no evidence of lymphocytopenia (ALC < 500)• Patient has no evidence of anemia (Hgb < 8)• Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) <p>Non-FDA-approved uses are not approved. PA does not expire for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, or ankylosing spondylitis; For atopic dermatitis, PA expires in 1 year</p> <p><u>Renewal criteria</u>: initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if the following apply: Atopic Dermatitis - The patient's disease severity has improved and stabilized to warrant continued therapy</p>
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<p>• apremilast (Otezla)</p> <p>TIBs</p>	<p>Updates from the August 2022 meeting are in bold and strikethrough. Note that there were no changes made to the existing criteria for treating oral ulcers associated with Behçet’s disease or active psoriatic arthritis (PsA).</p> <p>Manual PA criteria applies to new users of Otezla</p> <p><i>For Mild Plaque Psoriasis</i></p> <p><u>Manual PA Criteria:</u> Coverage approved for patients ≥ 18 years with mild plaque psoriasis who are candidates for systemic therapy or phototherapy if the following criteria are met:</p> <ul style="list-style-type: none"> • The patient has a contraindication to, intolerability to, or has failed treatment with medications from at least TWO of these THREE categories: <ul style="list-style-type: none"> ▪ Moderate to High Potency Topical Corticosteroids (class 1 – class 5) e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream, betamethasone dipropionate 0.05% cream/lotion/ointment, etc. ▪ Steroid Sparing Agents: Vitamin D analogs (e.g. calcipotriene and calcitriol), tazarotene, or topical calcineurin inhibitors (e.g. tacrolimus and pimecrolimus) ▪ Other Topicals: emollients, salicylic acid, anthralin, or coal tar AND • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy <p><i>For Psoriatic Arthritis and Moderate to Severe Plaque Psoriasis</i></p> <p>Step therapy and manual PA criteria apply to all new users of Otezla.</p> <p><u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND</p> <p><u>Manual PA Criteria:</u> If automated criteria are not met, coverage is approved for Otezla if:</p> <ul style="list-style-type: none"> • Contraindications exist to Humira. • Inadequate response to Humira. • Adverse reactions to Humira not expected with requested non-step-preferred TIB. <p>AND</p> <p>Coverage approved for patients ≥ 18 years with:</p> <ul style="list-style-type: none"> • Oral ulcers associated with Behçet’s disease (Please note: A trial of Humira first is not required for Behçet’s disease.) • Active psoriatic arthritis (PsA). • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. <p>Will Otezla be prescribed in combination with Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orenzia, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, or Xeljanz/Xeljanz XR?</p> <ul style="list-style-type: none"> • If yes: Fill in the blank write-in referencing literature to support combination, and patient will be monitored closely for adverse effects. <p>Has the patient had an inadequate response to non-biologic systemic therapy? (For example: methotrexate, aminosaliclates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])?</p> <p>Patient has negative TB test result in past 12 months (or TB is adequately managed).</p> <p>Non-FDA-approved uses are not approved.</p> <p>PA does not expire.</p>
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Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • viloxazine (Qelbree) <p>ADHD Agents: Non-Stimulants</p>	<p>Updates from the August 2022 meeting are in bold Manual PA criteria apply to all new users of Qelbree.</p> <p><u>Manual PA criteria:</u> Qelbree is approved if all criteria are met: For Adults:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient has tried and failed, had an inadequate response, OR contraindication to amphetamine salts XR (Adderall XR, generic) or other long acting amphetamine or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to methylphenidate OROS and other (Concerta, generic) or other long acting methylphenidate or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to atomoxetine (generic Strattera) • Patient has tried and failed, had an inadequate response, OR contraindication to at least one other non-stimulant ADHD medication (generic formulations of Kapvay or Intuniv) <p>For children and adolescents:</p> <ul style="list-style-type: none"> • Patient is 6 to 17 years of age • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient has tried and failed, had an inadequate response, OR contraindication to amphetamine salts XR (Adderall XR, generic) or other long acting amphetamine or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to methylphenidate OROS and other (Concerta, generic) or other long acting methylphenidate or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to at least one non-stimulant ADHD medication (generic formulations of Strattera, Kapvay, or Intuniv) • OR if patient is under the age of 18 and cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, autism spectrum disorder, etc.) and not convenience, then a trial of one non-stimulant ADHD medication (generic formulations of Strattera, Kapvay, or Intuniv) is not required <p>Non-FDA-approved uses are not approved (to include depression and anxiety). Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • setmelanotide (Imcivree) <p>Miscellaneous Metabolic Agents</p>	<p><u>Updates from the August 2022 meeting are in bold and strikethrough</u> Manual PA criteria apply to all new users of Imcivree.</p> <p><u>Manual PA criteria:</u> Imcivree is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 6 years of age or older • Patient has a confirmed diagnosis (via genetic testing) of POMC-, PCSK1-, or LEPR-deficiency that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) OR • The patient has monogenic or syndromic obesity due to Bardet-Beidl syndrome (BBS) • Patient and provider agree to evaluate weight loss after 12-16 weeks of treatment. Imcivree should be discontinued if a patient has not lost at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential

Appendix C—Table of Prior Authorization (PA) Criteria

	<p>Initial prior authorization expires in 4 months.</p> <p><u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Imcivree is approved for 1 year for continuation of therapy for POMC-, PCSK1-, or LEPR-deficiency or BBS if all criteria are met:</p> <ul style="list-style-type: none"> The patient has a documented improvement (a decrease from baseline) in at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential. <p>Non-FDA approved uses are NOT approved including Alström Syndrome, Bardet-Biedl Syndrome (BBS), POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity</p>
<ul style="list-style-type: none"> cyclosporine 0.05% ophthalmic emulsion single dose (Restasis) <p>Ophthalmic Dry Eye</p>	<p>Updates from the August 2022 meeting are in Bold</p> <p>Patients younger than 18 years of age do not require a PA</p> <p>Automated PA: If there is no Restasis, Cequa, or Xiidra prescription in the past 120 days, a manual PA is required.</p> <p><u>Manual PA criteria:</u> Coverage is approved if all the criteria are met:</p> <ul style="list-style-type: none"> The drug is prescribed by an ophthalmologist or optometrist The patient is 18 years of age or older A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: Positive symptomology screening for moderate to severe dry eye disease from an appropriate measure At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) <ul style="list-style-type: none"> Patient must try and fail the following: <ul style="list-style-type: none"> At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systame, Lacrilube]) Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) Concomitant use of Restasis, Cequa, or Xiidra is NOT allowed. Restasis is also approved for the following conditions: graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) / vernal keratoconjunctivitis (VKC), and LASIK associated dry eye (limited to 3 months of therapy) <p>Non-FDA-approved uses are not approved. PA expires in one year.</p> <p><u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all criteria are met:</p> <ul style="list-style-type: none"> The drug is prescribed by an ophthalmologist or optometrist. The patient must have documented improvement in ocular discomfort. The patient must have documented improvement in signs of dry eye disease.

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • alpelisib (Vijoice) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 28-days supply
<ul style="list-style-type: none"> • amoxicillin; vonoprazan (Voquezna Dual Pak) <p>Anti-Infective Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 1 pack/14 days
<ul style="list-style-type: none"> • amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak) <p>Anti-Infective Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 1 pack/14 days

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
alpelisib (Vioice) ONCOLOGICAL AGENTS	<ul style="list-style-type: none"> alpelisib (Piqray) 	<ul style="list-style-type: none"> 50, 125, & 200 mg film-coated tablets in blister packs for 28 day supply Dosing: Pediatrics (age 2 -1yr8): 50 mg QD with food; consider titrating to 125 mg after 24 weeks if patient ≥ 6 years old; Adults: 250 mg QD with food 	treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA Related Overgrowth Spectrum (PROS) who require systemic therapy	<ul style="list-style-type: none"> ≥ 5%: Diarrhea, stomatitis, hyperglycemia, eczema, dry skin, alopecia, headache, cellulitis 	<ul style="list-style-type: none"> 1st approved drug for PIK3CA-related overgrowth spectrum (PROS) Alpelisib (Piqray) previously approved for breast cancer Accelerated approval based on a small, single-arm study Response observed in 27% of patients Diarrhea, stomatitis, and hyperglycemia were the most common ADRs Offers a new treatment option in a serious, rare disease with limited treatment options 	<ul style="list-style-type: none"> UF
amlodipine oral solution (Norliqva) CALCIUM CHANNEL BLOCKING AGENT	<ul style="list-style-type: none"> amlodipine (Norvasc) amlodipine susp (Katerzia) isradipine (Dynacirc) lisinopril solution (Qbrelis) 	<ul style="list-style-type: none"> Solution; Oral adults: 5 mg QD; max of 10 mg QD pediatrics: 2.5 mg QD; max of 5 mg QD 	HTN down to age 6	<ul style="list-style-type: none"> peripheral edema 10% 	<ul style="list-style-type: none"> 2nd DHP calcium channel blocker (CCB) available in a liquid formulation and the 1st oral solution amlodipine oral suspension Katerzia is NF from Nov 2019 – no PA required Approved via 5050b2 application using data from Norvasc tablets No clinical data available Provides no compelling clinical advantage over existing CCBs or other antihypertensives 	<ul style="list-style-type: none"> NF Add to EMMI List

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

<p>amoxicillin; vonoprazan (Voquezna Dual Pak)</p> <p>amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak)</p> <p>ANTIINFECTIV ES: MISCELANEOU S</p>	<ul style="list-style-type: none"> omeprazole, amox, clarith omeprazole, amox, rifabutin (Talicia) 	<p>Dual</p> <ul style="list-style-type: none"> Capsule, Tablet vonoprazan 20 mg BID + amoxicillin 1000 mg TID ± food x 14 days <p>Triple:</p> <ul style="list-style-type: none"> Capsule, Tablet, Tablet vonoprazan 20 mg + amoxicillin 1000 mg + clarithromycin 500 mg BID (12 hours apart) ± food x 14 days 	<p>Treatment of <i>Helicobacter pylori</i> (<i>H. pylori</i>) infection in adults</p>	<ul style="list-style-type: none"> ADRs (≥ 2%): diarrhea, abdominal pain, vulvovaginal candidiasis (VVC) and nasopharyngitis 	<ul style="list-style-type: none"> Voquezna is a new combination of acid suppression and antibacterials approved for treatment of <i>H. pylori</i> infection in adults, co-packaged for a 14-day treatment course Vonoprazan is a new molecular entity that suppresses gastric acid secretion by inhibiting the H⁺, K⁺-ATPase enzyme system in a potassium competitive manner Available as a dual product (Voquezna Dual Pak) containing vonoprazan and amoxicillin or Available as a triple combination product (Voquezna Triple Pak) containing vonoprazan, amoxicillin, and clarithromycin Evaluated in 1 trial compared to traditional <i>H. pylori</i> treatment including lansoprazole, amoxicillin, and clarithromycin (LAC) Among all randomized patients with <i>H. pylori</i>, Voquezna Dual Pak had a cure rate of 77.2% compared to a cure rate of 68.5% with LAC Voquezna Dual Pak and Triple Pak's place in therapy is yet to be determined, but it is likely to be used as a later-line agent for refractory cases 	<ul style="list-style-type: none"> NF Do not add to EMMI list
<p>baclofen oral granules (Lyvispah)</p> <p>SKELETAL MUSCLE RELAXANTS & COMBINATION S</p>	<ul style="list-style-type: none"> baclofen tablets baclofen soln (Ozobax) baclofen susp (Fleqsuvy) 	<ul style="list-style-type: none"> Granules; Oral in 5 mg, 10 mg, and 20 mg packets Increase dose slowly in divided doses until clinical response; max dose 80 mg daily (20 mg QID); can be emptied into the mouth, mixed with liquids or soft foods, or be given via feeding tube 	<p>For the treatment of spasticity from MS, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity; may also be used in patients with spinal cord injuries/disease</p> <p>Limitations of Use: Not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders</p>	<ul style="list-style-type: none"> ADRs≥ 15%: drowsiness, dizziness, and weakness 	<ul style="list-style-type: none"> Lyvispah is the third oral alternate dosage formulation of baclofen, available as an oral granule Approved based on bioequivalence to baclofen oral tablets Lyvispah does not require refrigeration and can be emptied into the mouth, mixed with liquids or soft foods, or be given via feeding tube Received provider feedback that states there is not a need for this drug Provides little compelling clinical advantage over existing agents 	<ul style="list-style-type: none"> Tier 4/Not Covered

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

<p>benzoyl peroxide 5% cream (Epsolay)</p> <p>ACNE AGENTS: TOPICAL ACNE & ROSACEA</p>	<ul style="list-style-type: none"> • benzoyl peroxide gel • azaleic acid (Finacea gel) • metronidazole gel 	<ul style="list-style-type: none"> • Cream; Topical • Available as a 30 g pump • Apply to the affected areas once daily 	<p>For the treatment of inflammatory lesions of rosacea in adults</p>	<ul style="list-style-type: none"> • ADRs ≥1%: application site reactions: pain, erythema, pruritis and edema 	<ul style="list-style-type: none"> • Epsolay is a new benzoyl peroxide cream for the treatment of inflammatory lesions of rosacea • Differs from other benzoyl peroxides in its microencapsulation technology and controlled-release formulation, but no head-to-head clinical trials compare Epsolay to other benzoyl peroxides or rosacea drugs to determine if there is any added benefit • A little less than half of Epsolay treated patients achieved IGA success and the drug was well tolerated • Inflammatory lesions of rosacea are typically treated with: metronidazole, azelaic acid, ivermectin, doxycycline or isotretinoin; benzoyl peroxide is not a 1st-line treatment option for rosacea • Provides little compelling clinical advantage over existing agents in the treatment of rosacea 	<ul style="list-style-type: none"> • Tier 4/Not Covered
<p>cyclosporine 0.1% ophthalmic emulsion (Verkazia)</p> <p>OPHTHALMIC: DRY EYE</p>	<ul style="list-style-type: none"> • cyclosporine 0.09% (Cequa) • cyclosporine 0.05% (Restasis) • Cromolyn 4% • Lodoxamide 0.1% (Alomide) 	<ul style="list-style-type: none"> • Ophthalmic emulsion 0.1% (0.3 mL vial) • 5 vials are packaged in an aluminum pouch; 6, 12, or 24 pouches are packaged in a box • Each box contains either 30, 60 or 120 vials • 1 gtt QID 	<p>treatment of Helicobacter pylori (H. pylori) infection in adults</p>	<ul style="list-style-type: none"> • ≥ 1%: pain, erythema, pruritis, edema/swelling 	<ul style="list-style-type: none"> • Mast cell stabilizer/antihistamine are recommended for first line treatment of VKC • Verkazia is the first cyclosporine ophthalmic emulsion FDA approved for VKC – however other forms of cyclosporine ophthalmic are recommended for treatment • Providers would like to have the higher concentration available • Verkazia provides little to no compelling clinical advantage over existing agents to treat VKC 	<ul style="list-style-type: none"> • NF • Add to EMMI list

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

<p>daridorexant (Quviviq)</p> <p>SLEEP DISORDERS: INSOMNIA AGENTS</p>	<ul style="list-style-type: none"> • zolpidem 12.5mg (Ambien CR) • eszopiclone (Lunesta) • suvorexant (Belsomra) • lemborexant (Dayvigo) 	<ul style="list-style-type: none"> • Tablet; Oral • Tablets: 25 mg, 50 mg; each comes in a 30 count bottle 	<p>Multiple Sclerosis associated spasticity</p>	<ul style="list-style-type: none"> • Eye pain (12%) 	<ul style="list-style-type: none"> • Quviviq is the third DORA approved for insomnia (sleep onset and maintenance) • Quviviq has the same contraindications, drug interactions, and warnings compared to the other DORAs (Dayvigo and Belsomra) • All the DORAs carry a risk of somnolence; Quviviq has the additional slightly higher incidence of headache compared to the other DORAs • Quviviq does not have Alzheimer’s insomnia and driving performance data, unlike its competitors • Quviviq has not been studied in any head to head trials with any other insomnia agents • In its clinical trial results, a dose dependent response was observed, with the higher 50 mg strength reaching improved efficacy for all primary endpoints relative to the 25 mg strength and placebo • Quviviq provides no significant clinical advantages compared to other existing insomnia agents 	<ul style="list-style-type: none"> • UF Before Branded Agents Step • Add to EMMI list
<p>donepezil patch (Adlarity)</p> <p>ALZHEIMER’S AGENTS</p>	<ul style="list-style-type: none"> • donepezil (Aricept, Aricept ODT) • rivastigmine patch (Exelon patch) • galantamine 	<ul style="list-style-type: none"> • System; Transdermal • Transdermal System, • 5 mg/day and 10 mg/day 	<ul style="list-style-type: none"> • Rosacea 	<ul style="list-style-type: none"> • Eye pruritus (8%) 	<ul style="list-style-type: none"> • Adlarity is a topical formulation of donepezil indicated for mild, moderate, and severe Alzheimer’s dementia • It is the second topical AChEI for treatment of AD dementia • No new clinical studies were completed, only demonstrated bioequivalence to donepezil tablets • Offers once weekly treatment frequency, the longest of comparative agents for AD dementia • Provides another option for treatment of Alzheimer’s associated dementia 	<ul style="list-style-type: none"> • NF • Do not add to EMMI list

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

<p>edaravone oral suspension (Radicava ORS)</p> <p>NEUROLOGICAL AGENTS MISCELLANEOUS</p>	<ul style="list-style-type: none"> riluzole (Rilutek) riluzole film (Exservan) edaravone IV (Radicava IV) 	<ul style="list-style-type: none"> Suspension; Oral 105 mg (5 mL) orally or feeding tube (NG, PEG) in the morning after overnight fasting. Food should not be consumed for 1 hour after administration except water. Initial course: daily dosing for 14 days followed by 14 days drug-free Subsequent: daily dosing for 10 days out of 14-day period, followed by 14 days drug-free 	<ul style="list-style-type: none"> vernal keratoconjunctivitis 	<ul style="list-style-type: none"> ≥ 5%: headache, somnolence 	<ul style="list-style-type: none"> Radicava ORS is another formulation of edaravone No new clinical studies were published for FDA approval, the oral solution demonstrated bioequivalence to IV edaravone ICER Review 2022, for a narrow subset of ALS patients, IV edaravone demonstrated a clinically meaningful change in ALSFRS-R scores; and as a result deems oral edaravone to be comparable or incremental compared to riluzole JAMA Neurology 2022, long term cohort study concludes that addition of IV edaravone to standard treatment (riluzole) did not cause a significant change to disease progression rates, time to noninvasive ventilation, and survival probability Provides another treatment option for ALS patients 	<ul style="list-style-type: none"> UF Do not add to EMMI list
<p>ganaxolone oral suspension (Ztalmy)</p> <p>ANTICONVULSANTS-ANTIMANIA AGENTS</p>	<ul style="list-style-type: none"> levetiracetam oral soln valproic acid oral soln vigabatrin powder packet 	<ul style="list-style-type: none"> Suspension; Oral Oral suspension (50mg/mL) 110 mL per bottle 	<ul style="list-style-type: none"> treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance 	<ul style="list-style-type: none"> 505(b)(2) to oral donepezil 	<ul style="list-style-type: none"> Ztalmy is indicated for seizures associated with CDD CDD is a rare pediatric neurodevelopmental disorder with early onset and severe, refractory, multiple, evolving seizure types Ztalmy's clinical trial demonstrated a 27% median reduction of motor seizure frequency in CDD patients relative to placebo No head to head trials with other AEDs are available at this time Ztalmy is another anti-epileptic option for refractory seizures in CDD 	<ul style="list-style-type: none"> UF Do not add to EMMI list

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

<p>insulin glargine solostar authorized biologic</p> <p>INSULINS: BASAL</p>	<ul style="list-style-type: none"> insulin glargine (Lantus, Semglee, -yfgn, Basaglar) 	<ul style="list-style-type: none"> Injectable; Injection 100 units/mL 10 mL MDV 3 mL single-patient-use prefilled pen 	<p>mild, moderate, and severe dementia of the Alzheimer's type</p>	<ul style="list-style-type: none"> Headache, pruritus, insomnia, cramps, abd pain, const/diar 	<ul style="list-style-type: none"> Current condition set is only one product step preferred (Lantus) and all others NF and non-step preferred Insulin glargine by Winthrop is another insulin glargine formulation approved for Type 1 and Type 2 diabetes mellitus in adults and pediatrics 7th long acting basal insulin analog Utilize clinical trials from the original Lantus NDA application No differences in efficacy or safety compared to another insulin glargine Provides no compelling clinical advantage over existing formulary agents 	<ul style="list-style-type: none"> UF and Non-Step Preferred Add to EMMI list
<p>leuprolide SC injection (Camcevi Kit)</p> <p>LHRH AGONISTS-ANTAGONISTS</p>	<ul style="list-style-type: none"> leuprolide (Eligard) leuprolide (Lupron Depot) leuprolide (Fensolvi) 	<ul style="list-style-type: none"> Emulsion; Subcutaneous 42 mg administered subcutaneously once every 6 months Injectable emulsion: 48 mg leuprolide mesylate = 42 mg leuprolide 	<p>treatment of amyotrophic lateral sclerosis</p>	<p>(≥10%) contusion, gait disturbance, headache</p>	<ul style="list-style-type: none"> Camcevi is the 3rd leuprolide formulation approved for the treatment of advanced prostate cancer Approval was based on the results from an open-label, single-arm study, where 98% of eligible patients achieved castrate levels (serum testosterone suppression to ≤ 50 ng/dL) at 28 days, and 97% maintained this endpoint through 336 days No head-to-head studies have been completed with other leuprolide formulations Camcevi provides no compelling clinical advantage compared to existing formulary agents 	<ul style="list-style-type: none"> NF

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

<p>mavacamten (Camzyos)</p> <p>CARDIOVASCULAR AGENTS MISCELLANEOUS</p>	<ul style="list-style-type: none"> diltiazem (Cardizem) metoprolol (Toprol XL) propranolol (Inderal LA) verapamil (Calan SR) disopyramide (Norpace) 	<ul style="list-style-type: none"> Capsule; Oral 2.5, 5, 7.5 or 10 mg caps Complicated dosage titration/adjustment based on LV outflow track gradient ad 	<p>Seizures associated with CDKL5 deficiency (CDD); DEA schedule pending</p>	<p>somnolence</p>	<ul style="list-style-type: none"> 1st cardiac myosin inhibitor for treatment of NYHA class II-III obstructive hypertrophic cardiomyopathy (oHCM) Guidelines recommend non-vasodilating beta blockers, non-DHB CCB, and disopyramide or surgery for severe cases Limited evidence suggests potential benefit in cardiac remodeling, rather than just treating symptoms (BB, CCB, disopyramide treat symptoms) REMS program implemented for risk of heart failure with treatment ICER rated as promising but inconclusive compared to disopyramide or usual care due to lack of mortality data, lack of active comparator data and risk of heart failure 	<ul style="list-style-type: none"> UF Do not add to EMMI list
<p>tapinarof 1% cream (Vtama)</p> <p>PSORIASIS AGENTS</p>	<ul style="list-style-type: none"> calcipotriene/betamethasone (Taclonex) calcipotriene 0.005% (Dovonex) pimecrolimus 1% (Elidel) ruxolitinib 1.5% (Opzelura) 	<ul style="list-style-type: none"> Cream; Topical Cream (1%); 1 gram= 10 mg of tapinarof 60 g tube 	<p>T1DM and T2DM</p>	<p>pyrexia</p>	<ul style="list-style-type: none"> Aryl hydrocarbon receptor agonist for treatment of psoriasis in adults Vtama 1% cream was evaluated in two clinical trials and achieved significant reduction in PGA scores relative to placebo No head-to-head studies with other topical agents Most common adverse events include folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza Vtama offers an additional option for treating psoriasis, however numerous alternative formulary agents are available, its use is limited to a single indication, there is no direct comparative efficacy data available at this time, and its place in therapy is unclear 	<ul style="list-style-type: none"> NF Add to EMMI list

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

<p>testosterone undecanoate 112.5 mg capsule (Tlando)</p> <p>ANDROGENS-ANABOLIC STEROIDS: TESTOSTERONE REPLACEMENT THERAPIES</p>	<ul style="list-style-type: none"> • Fortesta Gel • Testim Gel • Androgel • Jatenzo Cap • Androderm Patch 	<ul style="list-style-type: none"> • Capsule; Oral • Dose: 225 mg PO BID w/ food • Available as 112.5 mg capsules • Bottles of #120 	<p>For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone; Limitations of Use: safety and efficacy in males < 18 years old have not been established</p>	<p>ADRs ≥ 2%: increased blood prolactin, hypertension, increased hematocrit, upper respiratory tract infection, weight increased, headache, and musculoskeletal pain</p>	<ul style="list-style-type: none"> • Tlando is the 2nd oral capsule testosterone undecanoate and the 14th available testosterone • Unlike Jatenzo, Tlando does not require dose titration • In an open-label, single-arm study, 80% of patients taking Tlando met the primary outcome specified testosterone concentration • Tlando was well tolerated • There are numerous alternative testosterone formulations available; Tlando’s place in therapy remains unclear, and there is no compelling clinical advantage over existing formulary agents 	<ul style="list-style-type: none"> • NF and Non-Step Preferred • Add to EMMI list
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Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

<p>tirzepatide SC injection (Mounjaro)</p> <p>DIABETES NON-INSULIN; GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONISTS INJECTABLE</p>	<ul style="list-style-type: none"> • dulaglutide (Tuclicity) • semaglutide (Ozempic) • exenatide (Bydureon BCise) 	<ul style="list-style-type: none"> • Injectable; Injection • 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, or 15mg SQ once weekly in pre-filled single dose auto-injector pens 	<p>treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.</p>	<p>seasonal allergy</p>	<ul style="list-style-type: none"> • Mounjaro is the first dual acting GLP-1 and GIP agonist approved for use in adults with T2DM as an adjunct to diet and exercise administered SubQ once weekly • Tirzepatide was studied for T2DM in the SURPASS clinical trial program and was evaluated against other GLP1RAs (semaglutide and dulaglutide), rapid-acting and basal insulins, oral agents, and as monotherapy in treatment naïve patients • The primary end point (HbA1c reduction) was statistically significant in comparison to baseline, with average A1c reductions between 1.8-2.1% for 5 mg and between 1.7-2.4% for both 10 mg and 15 mg strengths • Patients lost between 12 lb. (5 mg strength) and 25 lb. (15 mg strength) on average • Most common ADRs are GI-related including nausea, diarrhea, decreased appetite, vomiting, constipation, indigestion (dyspepsia), and stomach (abdominal) pain • Warnings and contraindications are similar to the GLP1RA class • Ongoing studies for Mounjaro are numerous and include use for weight loss in those without diabetes, NASH, and heart failure with preserved ejection fraction • Mounjaro is the first dual-acting GLP1/GIP agonist approved for adults with T2DM and has shown a clinically significant improvement in glycemic control as well as weight loss with similar ADRs to the GLP1RAs • Given that other GLP1RAs have an additional indication for CV risk reduction, true utility of Mounjaro remains unclear until the CVOT (SURPASS-CVOT) is completed 	<ul style="list-style-type: none"> • NF • Add to EMMI list
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Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary

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 2022	<p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF <i>Similar agents are already on list</i></p> <ul style="list-style-type: none"> daridorexant (Quviviq) <p>Designated NF: <i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:</i></p> <ul style="list-style-type: none"> amlodipine oral solution (Norliqva) cyclosporine 0.1% ophth emulsion (Verkazia) insulin glargine solostar authorized biologic tapinarof 1% cream (Vtama) testosterone undecanoate 112.5 mg caps (TLando) tirzepatide (Mounjaro) 	<p>Beta Blockers <i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> nebivolol (Bystolic; generics) <p>Drug Class Reviews Designated UF:</p> <p>OABs <i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> mirabegron (Myrbetriq) mirabegron (Myrbetriq Granules) vibegron (Gemtesa) <p>Antidepressants/Non-Opioid Pain Drugs <i>Comparable pricing at mail order vs MTFs or retail</i></p> <ul style="list-style-type: none"> vortioxetine (Trintellix) vilazodone (Viibryd) <p>Designated NF:</p> <p>Antidepressants/Non-Opioid Pain Drugs <i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> paroxetine mesylate (Pexeva) duloxetine DR (Drizalma sprinkle) levomilnacipran (Fetzima) milnacipran (Savella) bupropion hydrobromide XR (Aplenzin) gabapentin ER 24 hr tablets (Gralise) gabapentin enacarbil (Horizant) <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Not yet clear if feasible to provide through mail:</i></p> <ul style="list-style-type: none"> alpelisib (Vijoice) edaravone ORS (Radicava) mavacamten (Camzyos) <p><i>Acute use exception applies</i></p> <ul style="list-style-type: none"> amoxicillin; vonoprazan (Voquezna Dual Pak) amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak) <p><i>Drugs in class not currently represented on EMMPI List</i></p> <ul style="list-style-type: none"> ganaxolone oral suspension (Ztalmy) <p>Designated NF: <i>Not yet clear if feasible to provide through mail:</i></p> <ul style="list-style-type: none"> leuprolide SC injection (Camcevi) <p><i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> donepezil patch (Adlarity)

Appendix G—Implementation Dates*

Upon signing: October 26, 2022

Two weeks after signing: November 9, 2022

30 Days after Signing: November 30, 2022

60 days after signing: December 28, 2022

90 days after signing: January 5, 2023

Termination of NDAA 2018 Medication Adherence Pilot: December 31, 2022 (as per statute)

120 Days after signing: March 1, 2023

*** Note that implementation occurs the first Wednesday following “X” days after signing of the minutes in all points of service.**

Appendix H—Not Covered Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
August 2022	Skeletal Muscle Relaxants	<ul style="list-style-type: none"> • baclofen oral solution (Lyvispah) 	<ul style="list-style-type: none"> • baclofen oral solution (Ozobax) • baclofen oral suspension (Fleqsuvy) • baclofen tablets 	<ul style="list-style-type: none"> • 120 days
August 2022	Acne Agents: Topical Acne & Rosacea	<ul style="list-style-type: none"> • benzoyl peroxide 5% cream (Epsolay) 	<ul style="list-style-type: none"> • benzoyl peroxide gel OTC and Rx versions • azaleic acid 15% gel (Finacea gel) • metronidazole 1% gel • brimonidine 0.33% gel (Mirvaso) • ivermectin 1% cream (Soolantra) • minocycline 1.5% topical foam (Zilxi) • minocycline 4% foam (Amzeeq) • minocycline 50 mg tablets 	<ul style="list-style-type: none"> • 120 days
May 2022	Nephrology Agents Miscellaneous	<ul style="list-style-type: none"> • budesonide (Tarpeyo) 	<ul style="list-style-type: none"> • prednisone • methylprednisolone • budesonide delayed release capsules (Entocort EC, generics) 	<ul style="list-style-type: none"> • November 30, 2022 (120 days)
May 2022	Narcotic Analgesics and Combinations	<ul style="list-style-type: none"> • celecoxib/tramadol (Seglentis) 	<ul style="list-style-type: none"> • tramadol • celecoxib 	<ul style="list-style-type: none"> • November 30, 2022 (120 days)
May 2022	Anticholinergics-Antispasmodics	<ul style="list-style-type: none"> • glycopyrrolate (Dartisla ODT) 	<ul style="list-style-type: none"> • glycopyrrolate tablets • glycopyrrolate oral solution (Cuvposa) • omeprazole • famotidine 	<ul style="list-style-type: none"> • November 30, 2022 (120 days)
May 2022	Endocrine Agents Miscellaneous	<ul style="list-style-type: none"> • levoketoconazole (Recorlev) 	<ul style="list-style-type: none"> • ketoconazole • metyrapone (Metopirone) • osilodrostat (Isturisa) • pasireotide (Signifor LAR -medical benefit) 	<ul style="list-style-type: none"> • November 30, 2022 (120 days)
May 2022	Diuretics	<ul style="list-style-type: none"> • torsemide 20 mg and 60 mg tablets (Soanz) 	<ul style="list-style-type: none"> • torsemide • furosemide • bumetanide • ethacrynic acid 	<ul style="list-style-type: none"> • November 30, 2022 (120 days)
May 2022	Acne Agents: Topical Acne & Rosacea	<ul style="list-style-type: none"> • tretinoin 0.1%/ benzoyl peroxide 3% topical cream (Twyneo) 	<ul style="list-style-type: none"> • tretinoin cream • benzoyl peroxide cream 	<ul style="list-style-type: none"> • November 30, 2022 (120 days)

Appendix H—Not Covered Drugs and Therapeutic Alternatives

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
February 2022	Pain Agents: NSAIDs	<ul style="list-style-type: none"> celecoxib oral solution (Elyxyb) 	<ul style="list-style-type: none"> celecoxib tablets ibuprofen naproxen diclofenac numerous other NSAIDs or combos 	<ul style="list-style-type: none"> August 24, 2022 (120 days)
Nov 2021	Antianxiety Agents: Benzodiazepines	<ul style="list-style-type: none"> lorazepam ER capsule (Loreev XR) 	<ul style="list-style-type: none"> lorazepam IR tablets alprazolam IR and XR tablets 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Nov 2021	Migraine Agents	<ul style="list-style-type: none"> dihydroergotamine mesylate nasal spray (Trudhesa) 	<ul style="list-style-type: none"> DHE nasal spray sumatriptan nasal and oral rizatriptan zolmitriptan eletriptan 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Aug 2021	Antilipidemic-1s	<ul style="list-style-type: none"> rosuvastatin/ezetimibe (Roszet) 	<ul style="list-style-type: none"> rosuvastatin with ezetimibe atorvastatin with ezetimibe simvastatin/ezetimibe (Vytorin) evolocumab (Repatha) alirocumab (Praluent) 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
May 2021	Anticonvulsants-Antimania Agents	<ul style="list-style-type: none"> levetiracetam (Elepsia XR) 	<ul style="list-style-type: none"> levetiracetam ER lamotrigine XR topiramate ER 	<ul style="list-style-type: none"> June 15, 2022 (120 days)

*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. 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>.

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.

The first Tier 4 products were designated at the February 2019 P&T Committee meeting, with implementation occurring on August 28, 2019. For a cumulative listing of all Tier 4 drugs to date, refer to previous versions of the DoD P&T Committee quarterly meeting minutes, found on the health.mil website.

Appendix I—MHS GENESIS OTC Text List

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

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Vitamins Fat Soluble		
May 2022	<p>Add these GCNs</p> <ul style="list-style-type: none"> • 99882 vitamin D3 (cholecalciferol) 2000 unit caps • 12309 vitamin D3 (cholecalciferol) 2000 unit tabs • 98425 vitamin D3 (cholecalciferol) 50,000 unit caps <p>Retain these GCNs</p> <ul style="list-style-type: none"> • 53740 vitamin D3 (cholecalciferol) 400 unit tabs • 00223 vitamin D3 (cholecalciferol) 1000 unit tabs • 93242 vitamin D3 (cholecalciferol) 5000 unit caps • 26416 vitamin D3 (cholecalciferol) 400 unit/mL drops • 94411 vitamin D3 (cholecalciferol) 8000 unit/mL drops <p>Note: Vitamin D2 (ergocalciferol) 50,000 unit caps are legend and available at all 3 points of service.</p>	

DoD P&T Committee Updates to Approval Authorities

Note that updates are in **bold** font.

Table 1. Processes and Recommendation/Approval Authorities For August 2022 DoD P&T Committee Meeting

Process	Function
<p>Administrative (not part of DoD P&T Committee process; Beneficiary Advisory Panel (BAP) comments not required; Director, DHA, approval not required)</p> <p>Responsible parties include: TPharm4 (Mail Order Pharmacy and Retail Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; P&T Committee Chair and others as needed</p>	<ul style="list-style-type: none"> ▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting. ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDS] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing prior authorization (PA) requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non step preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to prior authorization forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as “innovator” drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation

	<p>with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes.</p> <ul style="list-style-type: none"> ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be “grandfathered” when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the Expanded MTF/Mail Order Pharmacy Initiative. ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the Expanded MTF/Mail Order Pharmacy Initiative from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing “brand over generic” authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. The branded product will adjudicate at the Tier 1 co-pay at the Retail Pharmacy Network and Mail Order Pharmacy. The “brand over generic” authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating “line extension” products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug, and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes.
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	<ul style="list-style-type: none"> ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA “health.mil” website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends, and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. ▪ Adding or deleting drugs or drug classes from the Clinical Services Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies. Addition or deletion of drugs or drug classes from the Clinical Services Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying manual PA criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs and/or QLs implemented in these situations will be removed when the situation has resolved. ▪ FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA approved devices or supplies and determination as to whether a new FDA approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination made to consider for coverage, timeline for review by DoD P&T Committee. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit. ▪ Designating “line extension” devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the
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Appendix J—Table of Administrative Authorities

	<p>DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.</p>
<p>Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments</p>	<ul style="list-style-type: none"> ▪ Classification of a medication as non-formulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication as Tier 4 (not covered) on the Uniform Formulary, for products selected for complete exclusion that provide very little or no clinical effectiveness relative to similar agents, and implementation plan (including effective date). ▪ Establishment of prior authorization requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing prior authorization (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of prior authorization requirements for a drug. ▪ Clarification of a medication as non-formulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as non-formulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as non-formulary (Tier 3 co-pay). ▪ The Director may approve devices or supplies as recommended by the P&T Committee and the BAP; however approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. ▪ Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with prior authorization criteria and implementation plans as recommended by the DoD P&T Committee and BAP.
<p>Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to BAP for comments)</p>	<ul style="list-style-type: none"> ▪ Establishment of quantity limits for a medication, device or supply or class of medications, devices or supplies; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for non-formulary drugs, devices or supplies. ▪ Addition or deletion of medications, devices or supplies listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes, devices or supplies on the Expanded MFT/Mail Order Pharmacy Initiative Program. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes, devices or supplies from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications, devices or supplies from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs,

Appendix J—Table of Administrative Authorities

	<p>antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order).</p> <ul style="list-style-type: none">▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.
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