Department of Vermont Health Access
Pharmacy Benefits Management Program
DUR Board Meeting
Draft Minutes

September 13, 2022: 6:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Lucy Miller, MD**		**Douglas Franzoni, PharmD**
	Joseph Nasca, MD		**Margot Kagan, Pharm D**		
	Claudia Berger, MD		**Annie Daly, PharmD**		

DVHA Staff Present:

	Carrie Germaine, DVHA		**Sandi Hoffman, DVHA**
	Lisa Hurteau, PharmD, DVHA		**Taylor Robichaud, DVHA**
	Michael Rapaport, MD, DVHA		**Ashley MacWalters, DVHA**

Change Healthcare Staff Present:

	Jacquelyn Hedlund, MD, Change Healthcare		**Laurie Brady, RPh, Change Healthcare**		**Carla Quinlivan, Change Healthcare**

Guests/Members of the Public:

Jane Guo (Novartis), Anna Loh (Calliditas Therapeutics), Andrew Seaman, MD (Better Life Partners), Kimberly Blake, MD (UVMMC), Elly Riser, MD (UVMMC), Nels Kloster MD, (Savida Healthcare), Anthony Folland (VT Dept. of Health, State Opioid Treatment Authority), Kristen Chopas (Gilead Sciences), Amy Cunningham (NZAC), Tricia Mulcahy, Sara Stolfus, Tom Seignious, Glenn Cornish, Janet Rose

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:30 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Attendance was called and introductions of DVHA and Change Healthcare staff were made.
- The June meeting minutes were accepted as printed.

3. Election of DUR Board Chair

- Douglas Franzoni, PharmD was nominated for DUR Board Chair.
- The Board unanimously approved the above nomination.

4. DVHA Pharmacy Administration Update: Lisa Hurteau, Pharm.D., DVHA:

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- Housekeeping: During voting, board members were asked to unmute to ensure their vote is heard.
- Introduction of new board member, Annie Daly, PharmD. She is currently the pharmacy manager at Rite Aid in Brattleboro.
- Introduction of several new members of the DVHA team. Taylor Robichaud, PharmD, started as the Clinical Pharmacist in July. Ashley Mac Walters is now the Health Program Administrator. She recently completed a master's in public health and is a certified pharmacy technician. Dr. Michael Rappaport just joined last week as the Chief Medical Officer. He has experience in Family Medicine, Prison Health, and Substance Use Disorder Treatment. He was most recently the director of the Central Vermont Opioid Treatment HUB in Berlin.

5. Medical Director Update: Michael Rapaport, Chief Medical Officer, DVHA

- Introduced himself to the board and is looking forward to working together with the board.
- No other updates at this time.

6. Follow-up Items from Previous Meetings: Laurie Brady, RPH Change Healthcare

- None at this time.

7. RetroDUR/ProDUR: Jacquelyn Hedlund, MD and Laurie Brady, RPh, Change Healthcare

- Introduce: Proposed RetroDUR topics for 2023

CHRONIC USE OF SEDATIVES/HYPNOTICS

Purpose: Long term use of sedative hypnotics may be necessary in patients with severe insomnia, refractory insomnia, and/or chronic comorbid psychiatric disorder, SUD, or other medical conditions. However, chronic use may be associated with memory impairment, dizziness, falls, and impairment of daytime performance.

- Evaluate of use of sedative/hypnotics for a period exceeding 6 months.
- Consider looking at concurrent use with Cognitive Behavioral Therapy, if possible to identify in data.

CONCURRENT USE OF MULTIPLE ACUTE MIGRAINE MEDICATIONS

Purpose: Agents with novel mechanisms of action have been approved for the acute management of migraines in recent years. They are more costly than triptans, however, and Prior Authorization (PA) criteria apply. For approval of Nurtec® ODT (Rimegepant), Ubrelvy® (ubrogepant), and Reyvow® (lasmiditan), the patient must either have a contraindication to triptans or treatment failure with at least 2 distinct triptans. This RetroDUR will look at continued use of triptans despite approval of a gepant or ditan.

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•Evaluate pharmacy claims for concurrent use of triptans with Nurtec® ODT (Rimegepant), Ubrelvy® (ubrogepant), or Reyvow® (lasmiditan).

ADHERENCE TO HEART FAILURE MEDICATIONS

Purpose: Poor adherence to medications is a common problem in heart failure (HF) patients. This can lead to increased HF exacerbations, increased physical limitations, and a higher risk for hospitalization or death.

- •Identify adult patients with a heart failure diagnosis using medical claims data.
- •Consider the following medication classes to evaluate compliance:
  - ACE-I (e.g. enalapril, lisinopril) or ARB (e.g. losartan, valsartan)
  - Beta Blockers (e.g. metoprolol)
  - Aldosterone Antagonists (e.g. spironolactone, eplerenone)
  - ARNI (e.g Entresto)
  - SGLT-2 Inhibitors (e.g. Farxiga)

TRIPLE THERAPY: OPIOIDS, BENZODIAZEPINES, AND SKELETAL MUSCLE RELAXANTS

Purpose: These classes of medications have overlapping side effects in terms of drowsiness, respiratory depression, confusion, tremor, and increased seizure risk. Sometimes referred to as "The Holy Trinity," use of these medications in combination can be synergistic in causing adverse effects such as respiratory depression which may result in death.

- •Evaluate pharmacy claims for overlapping use of opioids, benzodiazepines, and skeletal muscle relaxants (e.g. carisoprodol).
- •Consider system edits to require prior authorization in members using these medications in combination.

USE OF WARFARIN WITH ANTIBIOTICS (POTENTIAL DRUG-DRUG INTERACTIONS)

Purpose: Some antibiotics may interact with warfarin, increasing the risk for severe bleeding events. Antibiotics considered "High-risk" include trimethoprim/sulfamethoxazole (TMP/SMX), ciprofloxacin, levofloxacin, fluconazole, azithromycin, and clarithromycin.

- • Evaluate pharmacy claims for overlapping use of warfarin and select antibiotics/antifungals.
- • Determine if the patient had a hospitalization considered to be caused by a serious bleeding event within 30 days of the antibiotic claim.

CONCURRENT USE OF OPIOIDS AND ANTIPSYCHOTICS

Purpose: CMS mandate as part of the SUPPORT Act. Increased risk of respiratory and CNS depression with concurrent use of opioids and CNS depressants. Prospective DUR edit to alert dispensing pharmacist was implemented in January 2021.

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• Identify members, excluding those with a cancer diagnosis, who were prescribed an opioid for at least 90 days and examine how many were given an overlapping antipsychotic along with continued use of the opioid.
• Last analysis looked at Calendar Year 2019.

BUPRENORPHINE USE IN PREGNANCY

Purpose: SAMHSA and the ACOG recommend treatment with methadone or buprenorphine for pregnant women with OUD, in conjunction with behavioral therapy and other medical services. Combination buprenorphine/naloxone tablets were historically not recommended for treatment due to limited evidence. A growing body of evidence, however, now supports the use of combination buprenorphine/naloxone tablets in pregnancy over buprenorphine monotherapy. This may reduce the risk of diversion as well as anxiety associated with making a medication change in the postpartum period. When buprenorphine/naloxone is taken sublingually, naloxone is minimally absorbed orally.

- Identify members with an OUD diagnosis on file and pregnancy indicator. Determine the formulation of buprenorphine these patients are using.

Board Discussion: Dr. Rappaport indicated that most treatment centers are no longer prescribing the mono formulation of Buprenorphine. He recommends removal of the buprenorphine use in pregnancy topic. Dr. Nasca asked if we could evaluate the impact CFTR therapies have had on patients with Cystic Fibrosis. Doug Franzoni requested that we include length of time patients stay on a heart failure therapy such as Entresto.

Public Comment: No public comment.

Board Decision: After board review and discussion it was decided to remove Buprenorphine use in Pregnancy. Change Healthcare will work with DVHA to create a RetroDUR calendar for 2023.

- Data presentation: Opioid Use from Multiple Providers

Monitoring of opioid prescribing has been a focus of federal and state medical agencies for several years. Prescription monitoring systems have been instituted, and prescribers must query the database before writing an opioid prescription for a patient when such a prescription exceeds 10 pills. Per the Vermont Prescription Monitoring System (VPMS) Rule, "The intent is to promote public health through enhanced opportunities to prevent, detect and treat misuse of controlled substances, without interfering with the legitimate medical use of those substances." Pharmacies are required to report all controlled substance dispensing, and Vermont-licensed pharmacists are required to query the VPMS in the following circumstances:
1.) Prior to dispensing a prescription for a Schedule II, III, or IV opioid controlled substance to a patient who is new to the pharmacy.

2.) When an individual pays cash for a prescription for a Schedule II, III, or IV opioid controlled substance and the individual has prescription drug coverage on file.
3.) When a patient requests a refill of a prescription for a Schedule II, III, or IV opioid controlled substance substantially in advance of when a refill would ordinarily be due; and
4.) When the dispenser is aware that the patient is being prescribed Schedule II, III, or IV opioid controlled substances by more than one prescriber.
Change Healthcare used paid, non-reversed Medicaid pharmacy claims from calendar year 2021, excluding members with Part D, VMAP and Healthy Vermonters coverage. Patients with a cancer diagnosis on file and those on hospice were also excluded from the analysis. They identified all adult members receiving prescriptions for opioids from four or more different prescribers during the year. The analysis only included prescriptions billed through Vermont Medicaid. It did not include cash prescriptions. If patients had prescriptions from different prescribers that had the same physical address on file, we counted that as only 1 prescriber. There are some slight limitations to this as the analyst can only pull the primary address in the system.
There were a total of 8,090 members who received at least one opioid prescription in 2021. Of these members, 77 had between 4 and 6 prescribers sending prescriptions for opioid medications. This number represents 0.95% of all the members included in this analysis.

Recommendation: One suggestion to ensure effective care for members with multiple prescribers is to refer them to the Team Care program at DVHA. The Team will evaluate member specific issues and determine if the member should be "locked in" with specific providers for their opioid prescriptions. Overall, a small number of members receiving narcotics are getting their prescriptions from multiple providers.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

8. Clinical Update: Drug Reviews: Jacquelyn Hedlund, MD Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Dartisla® ODT (glycopyrrolate)

Glycopyrrolate, the active ingredient of Dartisla® ODT, is an anticholinergic (antimuscarinic) agent. It inhibits the action of acetylcholine on parietal cells in the stomach and decreases the volume and acidity of gastric secretions. It is indicated for use in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. It is not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established. There were no clinical trials identified in the prescribing information for Dartisla®

ODT. Glycopyrrolate tablets, available as 1mg and 2mg tablets, have been available for numerous years and have been demonstrated to be safe and effective. They have the same indication as Dartisla® OTD. Dartisla® ODT offers prescribers a different dosage form.

Recommendation:

- Add Dartisla ODT ™ (glycopyrrolate) with QTY LIMIT = 4 tabs/day, Glycopyrrolate 1mg/5ml oral solution (compare to Cuvposa), Robinul® (glycopyrrolate) 1mg, and Robinul® Forte (glycopyrrolate) 2mg to non-preferred.
    - Clinical criteria:
        - Revise Cuvposa, Glycopyrrolate oral solution: The patient has medical necessity for a non-solid oral dosage form OR the dose cannot be obtained from the tablet formulation.
        - Add Dartisla ODT: The patient has been established on the 2mg dosage strength of another form of glycopyrrolate AND the patient has a documented intolerance to glycopyrrolate tablets and solution.
        - Add Robinul, Robinul Forte: The patient has a documented intolerance to glycopyrrolate tablets.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Fleqsuvy® (baclofen oral suspension) and Lyvispah® (baclofen granules for oral suspension)

Baclofen, the active ingredient of Fleqsuvy®, is a gamma-aminobutyric acid (GABA-ergic) agonist. While the exact mechanism of action is not fully understood, baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect. Baclofen is a structural analog of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) and may exert its effects by stimulation of the GABA-B receptor subtype. Baclofen has been shown to have general CNS depressant properties, as indicated by the production of sedation with tolerance, somnolence, ataxia, and respiratory and cardiovascular depression. It is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Fleqsuvy® may also be of some value in patients with spinal cord injuries and other spinal cord diseases. It is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. There are no clinical trials in the prescribing information for Fleqsuvy®. Rather, the efficacy of Fleqsuvy® is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Fleqsuvy®. A pharmacokinetic study in healthy adult male and female subjects under fasting conditions receiving a 20mg dose level

demonstrated similar bioavailability for baclofen oral suspension and oral tablets. Baclofen oral tablets have been available for many years and have the same indication as Fleqsuvy®.

Baclofen, the active ingredient of Lyvispah®, is a gamma-aminobutyric acid (GABA-ergic) agonist. While the exact mechanism of action is not fully understood, baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect. Baclofen is a structural analog of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) and may exert its effects by stimulation of the GABA-B receptor subtype. Baclofen has been shown to have general CNS depressant properties, as indicated by the production of sedation with tolerance, somnolence, ataxia, and respiratory and cardiovascular depression. It is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Lyvispah® may also be of some value in patients with spinal cord injuries and other spinal cord diseases. It is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. There are no clinical trials in the prescribing information for Lyvispah®. The efficacy of Lyvispah® is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Lyvispah®. A pharmacokinetic study in healthy adult subjects under fasting conditions at a 20mg dose level demonstrated similar bioavailability for baclofen oral granules and oral tablets. Baclofen oral tablets have been available for many years and have the same indication as Lyvispah®. Lyvispah® offers providers a treatment option in a different dosage formulation.

Recommendation:

- Add Fleqsuvy® (baclofen oral suspension) and Lyvispah® (baclofen granules for oral suspension) to non-preferred.
  - Clinical criteria:
    - Add Lyvispah: Patient has a medical necessity for a non-solid oral dosage form.
    - Add Baclofen oral solution, Fleqsuvy: Patient has a medical necessity for a non-solid oral dosage form AND the patient has a documented intolerance to Lyvispah.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Leqvio® (inclisiran)

Inclisiran, the active ingredient of Leqvio®, is a double-stranded small interfering ribonucleic acid (siRNA), conjugated on the sense strand with triantennary N-Acetyl galactosamine (GalNAc) to facilitate uptake by hepatocytes. In hepatocytes, inclisiran utilizes the RNA interference mechanism and directs catalytic breakdown of mRNA for proprotein convertase subtilisin kexin type 9 (PCSK9). This increases LDL-C receptor recycling and expression on the

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hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation. It is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C). The effect of Leqvio® on cardiovascular morbidity and mortality has not been determined. The safety and efficacy of Leqvio® were assessed in 3 randomized, double-blind, placebo-controlled trials that included adults (N=3457) with HeFH or clinical ASCVD who were taking maximally tolerated statin therapy and required additional LDL-C lowering. The efficacy of Leqvio® in lowering LDL-C was assessed in 3 multicenter, placebo-controlled, double-blind studies that included patients with clinical ASCVD or HeFH who were taking maximally tolerated statin therapy and required additional LDL-C lowering. In all studies, the difference between the Leqvio® and placebo groups in mean percentage change in LDL-C from baseline to day 510 was statistically significant, in favor of Leqvio®.

Recommendation:

- Add Leqvio® (inclisiran) to non-preferred
- Remove labeler restrictions from preferred forms of Praluent.
  - Clinical criteria:
    - Add Leqvio to Praluent, Repatha and update clinical criteria: The patients' age is FDA approved for the given indication AND Concurrent use with statin therapy AND Documented adherence to prescribed lipid lowering medications for the previous 90 days AND Inability to reach goal LDL-C despite a trial of 2 or more maximum tolerated dose of statins (one of which must be atorvastatin or rosuvastatin). For approval of Leqvio, the patient must have a documented side effect, allergy, or treatment failure (defined as inability to get within 10% of stated LDL-C goal, not to exceed guideline recognized goals) with a minimum 12-week trial of both Praluent and Repatha.

Public Comment: Jane Guo from Novartis Highlighted the attributes of Leqvio.

Board Decision: The Board unanimously approved the above recommendations.

- Seglentis® (celecoxib and tramadol hydrochloride)

Seglentis® is a combination product containing celecoxib (a NSAID) and tramadol (an opioid agonist and inhibitor of norepinephrine and serotonin reuptake). It is indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Seglentis® for use in patients for whom alternative treatment options (e.g., non-opioid analgesics): Have not been tolerated, or are not expected to be tolerated and have not provided adequate analgesia or are not expected

to provide adequate analgesia. The safety and efficacy of Seglentis® were assessed in a randomized, double-blind, parallel group study comparing Seglentis® to tramadol, celecoxib, and placebo that included adults (N=637) that were 18 years of age or older (age ranged from 18 and 77 years) with acute post-operative pain (≥5 and ≤9 on a 0-10 Numeric Pain Rating Scale [NPRS]) following unilateral first metatarsal osteotomy with internal fixation. There is some evidence at this time to suggest that Seglentis® is more effective than each of the individual ingredients of the product (tramadol or celecoxib) for the endpoint of time-weighted summed pain intensity difference over 48 hours (SPID48); however, there is no evidence at this time to support that Seglentis® is safer or more effective than other currently preferred, more cost-effective medications, including using the combination of the individual products.

Recommendation:

- Add Seglentis® (celecoxib and tramadol hydrochloride) to non-preferred.
- Remove Qdolo® (tramadol) oral solution from the PDL.
  - Clinical criteria:
    - Add Seglentis: The patient has a documented side effect, allergy, or treatment failure with two or more preferred agents AND the patient is unable to take the individual components separately.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Tarpeyo® (budesonide)

Budesonide, the active ingredient of Tarpeyo®, is a synthetic corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. Mucosal B-cells present in the ileum, including the Peyer's patches, express glucocorticoid receptors and are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy. Through their anti-inflammatory and immunosuppressive effects at the glucocorticoid receptor, corticosteroids can modulate B-cell numbers and activity. It has not been established to what extent the efficacy of Tarpeyo® is mediated via local effects in the ileum vs systemic effects. It is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo® slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. The effect of Tarpeyo® on proteinuria was assessed in a randomized, double-blind, multicenter study that included patients with biopsy-proven IgAN, eGFR ≥35ml/min/1.73m2, and proteinuria (defined as either ≥1g/day or UPCR ≥0.8g/g) who were on a stable dose of maximally-tolerated RAS inhibitor therapy. The recommended duration of therapy is 9 months, and the safety and efficacy of treatment with subsequent

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courses of Tarpeyo® have not been established. Tarpeyo® is the first and only FDA-approved treatment to reduce levels of protein in the urine in adults with IgA nephropathy at high risk of disease progression. In a double-blind study, the Tarpeyo® group had a 34% reduction in UPCR at 9 months compared to baseline while the placebo group had a 5% reduction in UPCR. This result was statistically significant in favor of Tarpeyo®.

Recommendation:

- Add Tarpeyo® (budesonide) delayed release capsule to non-preferred.
  - Clinical criteria:
    - Add Tarpeyo: The patient has a diagnosis of Immunoglobulin A Nephropathy (IgAN) confirmed by biopsy AND eGFR ≥ is 35ml/min/1.73m2 AND The patient meets one of the following: Proteinuria ≥ 1g/day or Urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g AND The patient is on a stable dose of maximally tolerated ACE-I or ARB therapy for a minimum of 3 months AND The patient's kidney function has continued to decline despite treatment with a preferred oral corticosteroid AND Duration of therapy does not exceed 9 months

Public Comment: Anna Loh from Calliditas Therapeutics Highlighted the attributes of Tarpeyo.

Board Decision: The Board unanimously approved the above recommendations.

9. New Therapeutic Drug Classes

- None at this time.

10. Therapeutic Drug Classes- Periodic Review:

- **Allergen Extract Immunotherapy**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Add note All products will require a PA.
- Update Oralair: Patient age ≥10 years and ≤65 years AND Treatment must start 12 weeks before expected onset of pollen season and only after confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the 5 grass species contained in Oralair AND Patient must have an auto-injectable epinephrine on-hand

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

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- **Analgesics: NSAIDs (new drug Lofena® (diclofenac potassium) and Elyxyb® (celecoxib) included)**
  - Diclofenac potassium, the active ingredient of Lofena®, is a benzene-acetic acid derivative that has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action of Lofena®, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2). Diclofenac is a potent inhibitor of prostaglandin synthesis. Because diclofenac is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues. Carefully consider the potential benefits and risks of Lofena® and other treatment options before deciding to use Lofena®. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals. Lofena® is indicated for: Treatment of primary dysmenorrhea, Relief of mild to moderate pain, Relief of the signs and symptoms of osteoarthritis (OA), Relief of the signs and symptoms of rheumatoid arthritis (RA). There was no information in the prescribing information regarding clinical trials. Diclofenac potassium tablets, available as a 50mg strength, have been available for many years, have the same indication as Lofena® tablets, and have been demonstrated to be safe and effective. Lofena® is a lower 25mg dose and provides a new dosage strength.
  - Celecoxib, the active ingredient of Elyxyb®, is a nonsteroidal anti-inflammatory drug with analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action by which celecoxib exerts therapeutic effects for its approved indication is not fully understood but may involve inhibition of prostaglandin synthesis, mainly via inhibition of COX-2. It is indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventive treatment of migraine. The safety and efficacy of Elyxyb® for the acute treatment of migraine with or without aura were demonstrated in two randomized, double-blind, placebo-controlled clinical trials. In both studies, the percentage of patients achieving most bothersome symptom freedom at 2 hours post-dose was significantly greater in those patients treated with Elyxyb® as compared with placebo; however, only in study 2 was the percentage of patients achieving headache pain freedom at 2 hours post-dose significantly greater among those treated with Elyxyb® as compared with placebo. This endpoint in study 1 was not statistically significant between treatment groups. Elyxyb® allows providers another treatment option for patients needing acute treatment of migraine.
  - No other significant clinical changes.

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- Remove EC-Naprosyn® (naproxen sodium enteric coated), Indocin® (indomethacin) suppository, Mobic® (meloxicam) tablets, Qmiiz (meloxicam) ODT™, Tivorbex (indomethacin) capsules and Vivlodex® (meloxicam) capsules.
- Add Meloxicam capsule (compare to Vivlodex®), Naproxen suspension, Ibuprofen/famotidine (compare to Duexis®) with QTY LIMIT: 3 tablets/day, and Naproxen/esomeprazole (compare to Vimovo®) to non-preferred.
- Move Naproxen Sodium 275 mg and 550 mg and Mefenamic acid capsules to preferred.
- Add Elyxyb™ (celecoxib) oral solution and Lofena™ (diclofenac) tablet to non-preferred.
    - Clinical criteria:
        - Update Arthrotec, Diclofenac/Misoprostol: patient has a documented side effect or treatment failure to 2 or more preferred generic NSAIDs OR patient is not a candidate for therapy with a preferred generic NSAID mono-therapy due to one of the following: patient is 60 years of age or older, Patient has a history of GI bleed, Patient is currently taking an oral corticosteroid, Patient is currently taking methotrexate. AND for approval of diclofenac/misoprostol, the patient must have a documented intolerance to brand Arthrotec.
        - Add Duexis, Ibuprofen/famotidine, naproxen/esomeprazole, Vimovo: patient is unable to take the individual components separately AND for approval of Ibuprofen/famotidine or naproxen/esomeprazole, the patient must have a documented intolerance to the brand name equivalent.
        - Add Elyxyb: drug is being prescribed for treatment of acute migraine attacks AND patient has had a documented side effect or treatment failure to 2 or more preferred generic NSAIDs, one of which must be generic celecoxib OR drug is being prescribed for treatment of acute migraine attacks AND patient has a requirement for an oral liquid dosage form (i.e. swallowing disorder, inability to take oral medications) AND patient has had a documented side effect or treatment failure with the generic ibuprofen suspension.
        - Add Lofena, Zipsor, Zorvolex: patient has had a documented side effect, allergy, or treatment failure to 4 or more preferred generic NSAIDs, one of which must be generic diclofenac.
        - Update Meloxicam Capsule: patient has had a documented side effect, allergy, or treatment failure to 4 or more preferred generic NSAIDs, one of which must be generic meloxicam tablet.
        - Add Naproxen suspension: patient has a requirement for an oral liquid dosage form (i.e. swallowing disorder, inability to

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take oral medications) AND patient has had a documented side effect or treatment failure with the generic ibuprofen suspension.
    - Update Relafen DS: patient has had a documented side effect, allergy, or treatment failure to 4 or more preferred generic NSAIDs, one of which must be generic nabumetone.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Analgesics: Topical Anesthetics**
    - No new drugs.
    - No other significant clinical changes. Lidoderm® has been on intermittent product allocation. Overrides for the generic are being provided by the Change Healthcare helpdesk as needed.

Recommendation:

- Move Synera® (lidocaine/tetracaine) Patch to non-preferred.
    - Clinical Criteria:
        - Add Synera: patient has had a documented side effect, allergy, treatment failure or contraindication to lidocaine/prilocaine cream.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Iron Chelating Agents**
    - No new drugs.
    - No other significant clinical changes.

Recommendation:

- Add Deferasirox dispersible tablet, Deferasirox granule pack, Deferiprone tablet, Ferripirox® (deferiprone) tablet, Ferripirox® solution, Jadenu®(deferasirox) tablet, and Jadenu®(deferasirox) granule pack to non-preferred.
- Move Exjade® (defarasirox) dispersible tablet to non-preferred.
- Move Deferasirox tablet to preferred.
    - Clinical Criteria:
        - Add Deferasirox dispersible tablet, Exjade dispersible tablet: The patient has a medical necessity for a non-solid oral dosage form AND for approval of Exjade, the patient has a documented intolerance to generic deferasirox dispersible tablets.

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- Add Deferiprone tablet, Ferriprox tablet, Jadenu tablet: the patient has a documented intolerance to generic deferasirox tablets
- Add Deferasirox granule pack, Ferripirox solution, Jadenu granule pack: The patient has a medical necessity for a non-solid oral dosage form AND The patient has a documented intolerance to generic deferasirox dispersible tablets.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Opioid Dependency, Opioid withdrawal treatment, Overdose Treatment, and Alcohol Dependency (new drug Zimhi® (naloxone HCl) included)**
  - Naloxone, the active ingredient of Zimhi®, is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites. Naloxone reverses the effects of opioids, including respiratory depression, sedation, and hypotension. Also, it can reverse the psychotomimetic and dysphoric effects of agonist-antagonists such as pentazocine. It is indicated in adults and pediatric patients for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or CNS depression. Zimhi® is intended for immediate administration as emergency therapy in settings where opioids may be present. It is not a substitute for emergency medical care. There are no clinical trials in the Zimhi® prescribing information. Zimhi® was approved through the 505(b)(2) pathway, and this pathway "…may rely on the FDA's finding that a previously approved drug is safe and effective or on published literature to support the safety and/or effectiveness of the proposed product…". Zimhi® delivers 5mg of naloxone per 0.5ml injection rather than previously approved naloxone injection products in 0.4mg/1ml and 2mg/2ml doses. Zimhi® provides an additional treatment option for the treatment of opioid overdoses.
  - 5/6/21 Response Letter from the FDA to Alkermes: Because the Medication Guide (as part of the REMS) and communication plan are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Vivitrol (naltrexone). The Medication Guide will remain as part of the approved labeling for Vivitrol (naltrexone).

Recommendation:

- Rename category to Substance Use Disorder Treatments with the following sub-categories: Alcohol Use Disorder, Opioid Use Disorder, Opioid Withdrawal Treatment, and Overdose Treatment.
- Add Zimhi™ (naloxone HCl) 5mg Prefilled Syringe to non-preferred.

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- Remove Antabuse® (disulfiram) and Probuphine® (buprenorphine) subdermal implant from the PDL.
- Move Naloxone HCl (compare to Narcan® 4 mg Nasal Spray) with QTY LIMIT: 4 single-use sprays/28days to non-preferred.
- Move VIVITROL® (naltrexone for extended-release injectable suspension) with QTY LIMIT: 1 injection (380 mg) per 28 days to preferred (clinical criteria no longer required).
    - Clinical criteria:
        - Add Buprenorphine/naloxone films: The patient must have a documented intolerance to both preferred buprenorphine/naloxone combination products.
        - Add Naloxone Nasal Spray: Narcan must be on a backorder and unavailable from the manufacturer.
        - Add Zimhi: The prescriber must provide a clinically compelling reason why the preferred agents would not be suitable alternatives.
        - Update Buprenorphine: Patient is either pregnant and copy of positive pregnancy test has been submitted (duration of PA will be one 1 month post anticipated delivery date) OR Patient is breastfeeding an opiate dependent baby and history from the neonatologist or pediatrician has been submitted. Other requests will be considered after a documented trial and failure of both preferred buprenorphine/naloxone combination products.

Public Comments: Andrew Seaman, MD, VT Medical Director, Better Life Partners, requested the removal of prior authorization for preferred buprenorphine/naloxone formulations for doses up to 24mg. He also requested no limit on 2mg to assist with micro inductions. He stated that many patients return to illicit drug use if the claim at the pharmacy rejects for a dose > 16mg.
Kimberly Blake, MD, Assistant Professor, UVMMC, advocated for the removal of prior authorization for preferred buprenorphine/naloxone formulations for doses up to 24mg. She noted that 2mg micro dosing often allows for a smoother induction. She states it is difficult to obtain a prior authorization for doses > 16mg without demonstrating withdrawal symptoms.
Elly Riser, MD, UVMMC, advocated for the removal of prior authorization for preferred buprenorphine/naloxone formulations for doses up to 24mg. She stated these doses have no risk of respiratory depression or euphoria, and they reduce morbidity and mortality in this population. Higher dose prior authorization creates a barrier to care for new patients.
Nels Kloster, MD, Addiction Psychiatrist, Brattleboro HHUB Medical Director, Serenity House Medical Director, Savida Healthcare, expressed concerns over raising the dose limit based on public health (i.e. burden vs benefit of PA process). He stated that the average processing time for a PA is 30 minutes. Buprenorphine mono product carries a high risk of misuse and morbidity and mortality. Overprescribing leads to diversion which can lead to new cases of opioid use disorder. He stated that doses over 24mg are ineffective.

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Anthony Folland, VT Dept. of Health, State Opioid Treatment Authority stated that he has seen multiple people use Buprenorphine from the same prescription, and also cautioned that increasing the dose limit could lead to more new users and increased diversion.

Board Discussion:
Dr. Rappaport noted that micro inductions of buprenorphine in fentanyl users can be done in a controlled setting with comfort meds and careful monitoring of dosage. He stated that DVHA was considering a way to implement "preferred provider status" for those providers who can demonstrate the ability to appropriately monitor patients, perform pill counts, routine urinalysis, etc. They would subsequently be able to get higher doses without the need for PA.
Dr. Nasca indicated that he liked this idea. He also relayed that the amount of money spent on MAT is disproportionate to that spent on primary care and feels this is not equitable.
Doug Franzoni requested data on how frequently doses over 16mg get denied. He also asked that DVHA re-send a notice to pharmacies about the ability to use a 72-hour emergency override if/when needed.
Margot Kagan asked the physician panel how long patients stay on doses >16mg.
Dr. Seaman responded that doses up to 24mg should be considered because it protects patients from fentanyl overdose. They don't relapse as hard and can safely come back to treatment. He indicated that if they stabilize a patient on a higher dose, they often remain at that dose.

Board Decision: The Board unanimously approved the above recommendations. DHVA and Change Healthcare will work together to gather additional information on PAs and can bring this category back to the December meeting. At that time, a decision can be made on changing the maximum daily dose and/or quantity limits.

- **Otic Anti-Infectives/ Anti-Inflammatories**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Add Ciprofloxacin/Dexamethasone (compare to Ciprodex®) otic suspension, DermOtic® Oil (fluocinolone acetonide) 0.01%, Flac® Oil (fluocinolone acetonide) 0.01% and Ciprofloxacin/Fluocinolone otic solution with QTY LIMIT: 28-units dose packages/7days to non-preferred.
- Add Fluocinolone Oil 0.01% to preferred.
- Remove Otovel® (ciprofloxacin 0.3%/fluocinolone 0.025%) otic solution and Otiprio® (ciprofloxacin 6%) otic suspension from the PDL.
  - Clinical criteria:
    - Update Anti-infective single and combination agents: The patient has had a documented side effect, allergy, or treatment failure to two preferred products.

- Add DermOtic, Flac Oil: the patient has a documented intolerance to generic fluocinolone oil.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Phosphate Binders**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:
- No changes at this time.

Public Comments: No public comment.

Board Decision: None needed.

- **Ulcerative Colitis (non-biologic oral and rectal agents)**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:
- Move Uceris® (budesonide) ER Tablet with QTY LIMIT = 1 tablet/day to preferred.
- Remove Entocort EC®* (budesonide 24 hr cap) from the PDL.
  - Clinical criteria:
    - Updated Budesonide ER 9mg, Ortikos: the patient has a documented intolerance to brand-name Uceris.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

12. Review of Newly-Developed/Revised Criteria:

- 2022/23 Influenza Vaccines
  - ACIP approved the following recommendation at its June 2022 meeting:

    ACIP recommends that adults aged ≥65 years preferentially receive one of the following influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent

recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4). If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.

- There is still no preferential recommendation for people younger than 65.

Recommendation:

- Add age edit to make Fluzone High-Dose, Flublok, and Fluad preferred if the member is ≥ 65 years of age with no Medicare coverage.
  - Clinical criteria:
    - Update Flucelvax Quadrivalent: Patient must have a documented severe reaction to egg based influenza vaccine OR Prescriber provides clinical rationale why one of the preferred influenza vaccines cannot be used.
    - Update Flublok: Patient is ≥ 65 years old OR Patient must have a documented severe reaction to egg based influenza vaccine AND the patient is unable to use Flucelvax.
    - Update Fluzone High Dose, Fluad: Patient is ≥ 65 years old OR prescriber provides clinical rationale why one of the preferred influenza vaccines cannot be used.

13. General Announcements:

- None at this time.

14. Adjourn: Meeting adjourned at 8:44 p.m.

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