Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
February 15, 2022

Board Members Present:

Mark Pasanen, MD
Bill Breen, RPH
Douglas Franzoni, PharmD
Claudia Berger, MD,
Joseph Nasca, MD
Lucy Miller, MD
Andy Miller, RPH
Margot Kagan, PharmD
Renee Mosier, PharmD

Absent:

Staff:

Laurie Brady, RPh, Change HealthCare
Nancy Hogue, Pharm D, DVHA
Andrea De La Bruere, DVHA
Lisa Hurteau, PharmD, DVHA
Sandi Hoffman, DVHA
Jacquelyn Hedlund, MD, Change Healthcare
Mike Ouellette, RPh, Change Healthcare

Guests:

Adam Denman (Global Blood Therapeutics)
Alain Nguyen
Anna Basoff, Pharm D(Otsuka)
Christine Dube (AstraZeneca)
Eric Hyde (Aveo)
Gene Muise (Amgen)
Jessica Todd
Karen Evenson (Albireo)
Karen Szydlik (Pear Therapuetics)
Kathleen Bernstein
Kristen Chopas (Gilead Sciences)
Matt McMahon
Michael Brousseau (Indivior)
Nicole Trask (Janssen)
Nikhil Kacker (Genetech, Inc)
Russell Moyer (Argenx)
Stacy Sandate (Albireo)
Tony Okoro, PharmD, MPH (Bayer)
Tricia Mulcahy

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 December meeting minutes were accepted as printed with an abstention from Renee Mosier.

3. DVHA Pharmacy Administration Update: Nancy Hogue, Pharm.D., DVHA:

- Introduction of Andrea DeLaBruere who was appointed by Gov. Scott as the new commissioner of the Department of Vermont Health Access (DVHA), effective December 20, 2021. DeLaBruere was the Executive Director of the Agency of Human Services (AHS) and has a wide variety of experience in the pharmaceutical, medical device, and health information technology industries. Prior to AHS, she worked at VITL and was responsible for promoting VITL's health information exchange and technology products, and custom solutions to Vermont health care organizations. DeLaBruere received

her Bachelor of Science degree in Health Education from Norwich University, and her Master of Science in Health Care Administration from Southern New Hampshire University.

- There are 2 legislative bills that would have an impact on pharmacy. H353 has to do with regulation of PBM's. Part of the bill calls for the DVHA dispensing fee to be required as the dispensing fee for all PBM's in Vermont. Another aspect of the bill requires DVHA to contract with a wholesaler. The proposal is for DVHA to pay for the drug directly and just a dispensing fee would be paid to the pharmacy. S243 revisits the possibility of an unused drug repository for Vermont. The Department of Health will be developing estimates for this.
- There are ongoing openings on the DUR Board. 2 pharmacists, 1 physician, and 1 member at large will be needed in anticipation of terms that are expiring in the near future

4. Medical Director Update:

- Dr. Scholten was unable to attend the meeting.

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

- None at this time.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None at this time.

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

- Introduce: Letrozole Use for Infertility

Letrozole, an aromatase inhibitor with brand name Femara®, has indications for treatment in hormone receptor positive breast cancer, in the adjuvant, extended adjuvant, and advanced disease settings. The oral dosing in all these settings is 2.5 mg daily. In breast cancer, off-label indications include using in combination with other drugs in the advanced disease and metastatic settings, again at 2.5mg/day dosing. Other off-label indications include treatment of recurrent ovarian cancer (2.5mg/day) and infertility/ovulation stimulation in anovulatory females with polycystic ovarian syndrome. The doses in this case include 2.5 up to 7.5mg/day, starting day 3-5 of the cycle for 5 days. It is important to note, that not all anovulatory treatment is done to treat infertility. For example, causes of anovulation include polycystic ovary syndrome, hypogonadatropic hypogonadism, primary ovarian insufficiency, and hyperprolactinemia. It is established that anovulatory or oligo-ovulatory women are at higher risk of endometrial cancers and regulating the menstrual cycle is desirable. Treatment of

DRAFT

infertility is not a covered benefit in members who receive Medicaid drug coverage in Vermont, therefore it is important to monitor the use of letrozole in women of child-bearing age in this population. We will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2021 excluding members with Part D, VMAP and Healthy Vermonters coverage. We will identify women between the ages of 20 and 50 who are taking letrozole and identify the ordering provider to determine whether the medication may have been prescribed for fertility. By looking at the doses and length of treatment we may see a population that is being treated for infertility.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None at this time.

- Data Presentation: Immunologic Therapies for Asthma

Immunologic therapies for asthma have significantly improved outcomes and quality of life for patients with moderate or severe asthma who are not controlled on chronic treatment with inhaled corticosteroids and long-acting bronchodilators. One of the goals of immunotherapy is to decrease the need for intermittent treatment with oral corticosteroids, which have numerous deleterious effects when used chronically. Benralizumab (Fasenra®) and mepolizumab (Nucala®) are IL-5 receptor antagonist monoclonal antibodies that are FDA approved for use in those 12 years of age and older with severe asthma with elevated eosinophil counts. Dupilumab (Dupixent®) is an IL-4 and IL-13 dual inhibitor for those 12 years of age or older with either an eosinophilic phenotype or who are dependent on oral corticosteroids. GINA guidelines recommend adding immunologic anti - IL-4 or IL-5 therapy as step 5 in asthma management in adults and adolescents, in those who are dependent on high dose ICS-LABA inhalers rather than adding oral corticosteroids, with the appropriate phenotype. Of note, the GINA guidelines do recommend adding anti-IgE therapy (Xolair, omalizumab) in those 6 years of age and older with the appropriate phenotype, however Xolair was until recently only a physician administered drug and this RetroDUR is focusing on self-administered medications.

Change Healthcare used paid, non-reversed Medicaid pharmacy and medical claims from SFY 2021 excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified all members ages 12 and older with a diagnosis of asthma who were prescribed Nucala, Fasenra or Dupixent. They looked to see how many members were compliant with these medications and with their concurrent inhalers (ICS or ICS/LABA combinations) and the frequency at which members were prescribed oral corticosteroids. 33 members were identified that had an Immunology claim and Asthma diagnosis who were 12 years of age or older. Of these 33, 17 were at least 80% compliant with ICS after Immunotherapy added in SFY 2021 was added and 16 were less than 80% compliant.

DRAFT

18 members had an oral corticosteroid both before and after the start of immunotherapy. Of these 18 members:
9 had fewer claims after Immunotherapy than before, 5 had the same number and 4 members had an increase in the claims for oral corticosteroids after the addition of Immunotherapy. Eight members who had oral corticosteroids before Immunotherapy had no further claims after starting immunotherapy, which is notable. Seven members never had oral corticosteroids.

There is variability in the use of corticosteroids by members who were started on immunotherapy for the diagnosis of asthma. All members remained on their ICS, however compliance was not uniform among members who started immunotherapy and the use of oral corticosteroids was still required for some members. It could be that the dosage and duration of oral corticosteroids decreased among some members, or that the severity of their symptoms decreased, but we did not examine that with this analysis.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None needed.

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

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Azstarys® (serdexmethylphenidate & dexmethylphenidate)

Azstarys® contains dexmethylphenidate (a CNS stimulant) and serdexmethylphenidate (a prodrug of dexmethylphenidate). Each capsule contains a fixed molar ratio of 30% dexmethylphenidate and 70% serdexmethylphenidate. The mode of therapeutic action in ADHD is not known. It is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years of age and older. The efficacy of Azstarys® for the treatment of ADHD in pediatric patients 6 to 12 years of age was assessed in a randomized, double-blind, placebo-controlled, parallel group, analog classroom study. As with other CNS stimulants for ADHD, Azstarys® has a box warning regarding abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. In a randomized, double-blind, placebo-controlled analog classroom study that included pediatric patients 6 to 12 years of age who met DSM-5 criteria for ADHD, the mean change from baseline in the SKAMP-Combined scores, averaged across the test day (primary outcome) was statistically significantly lower (improved) with Azstarys® compared to placebo. This product offers physicians another treatment option for ADHD.

Recommendation:

- Add Azstarys™ (serdexmethylphenidate/ dexmethylphenidate) to non-preferred.
  - Clinical criteria:
    - Add Azstarys to Adhasia XR, Cotempla XR ODT, Jornay PM clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Brexafemme® (ibrexafungerp)

Ibrexafungerp citrate, the active ingredient of Brexafemme®, is a triterpenoid antifungal agent. It inhibits glucan synthase, an enzyme involved in the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall. Ibrexafungerp has concentration-dependent fungicidal activity against Candida species as measured by time kill studies and it retains in vitro antifungal activity when tested at pH 4.5 (the normal vaginal pH). It is indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC). If specimens for fungal culture are obtained prior to therapy, antifungal therapy may be instituted before the results of the cultures are known. However, once these results become available, antifungal therapy should be adjusted accordingly. The safety and efficacy of Brexafemme® were assessed in two randomized, placebo-controlled trials with a similar design that included non-pregnant, post-menarchal females with a diagnosis of VVC. A diagnosis of VVC was defined as a minimum composite vulvovaginal signs and symptoms (VSS) score of ≥4 with at least 2 signs or symptoms having a score of 2 (moderate) or greater, as well as a positive microscopic examination with 10% KOH in a vaginal sample revealing yeast forms or budding yeasts and a normal vaginal pH (≤4.5). In two placebo-controlled studies, statistically significantly greater percentages of patients experienced a complete clinical response at test of cure visit (TOC; primary endpoint), negative culture at TOC visit, and complete clinical response at follow-up visit in those treated with Brexafemme® as compared with placebo. In a phase 2, randomized dose-finding study that included patients with acute vulvovaginal candidiasis, the primary endpoint results (percentage of patients with a clinical cure at TOC visit) were 51.9% with ibrexafungerp 300mg and 58.3% with fluconazole 150mg, suggesting comparable efficacy.

Recommendation:

- Add sub-category Triterpenoids to the Antifungals PDL class.
- Add a note that all products require PA within this new sub-category.
- Add Brexafemme® (ibrexafungerp) tablets to non-preferred.
  - Clinical criteria:
    - Add Brexafemme: The patient is not pregnant and has been counseled to use effective contraception during treatment and for 4 days after the last dose (if applicable) AND the patient has recurrent yeast infections despite a treatment course of 7-14 days

DRAFT

with a preferred vaginal azole AND a longer course of oral fluconazole (e.g. one dose every 3 days for a total of 3 doses)

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Bylvay® (odevixibat)

Odevixibat, the active ingredient of Bylvay®, is a reversible inhibitor of the ileal bile acid transporter (IBAT). It decreases the reabsorption of bile acids (primarily the salt forms) from the terminal ileum. Although the complete mechanism by which odevixibat improves pruritus in progressive familial intrahepatic cholestasis (PFIC) patients is not known, it may involve inhibition of the IBAT, which results in decreased reuptake of bile salts, as observed by a decrease in serum bile acids. It is indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis. Bylvay® may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3). The safety and efficacy of Bylvay® were assessed in a randomized, double-blind, placebo-controlled trial of 24-week duration that included pediatric patients (Trial 1, N=62) aged 6 months to 17 years, with a confirmed molecular diagnosis of PFIC type 1 or type 2 and the presence of pruritus at baseline. Patients treated with Bylvay® demonstrated greater improvement in pruritus compared with placebo.

Recommendation:

- Add Bylvay® (odevicibat) to non-preferred
  - Clinical criteria:
    - Add Bylvay: The patient is experiencing moderate to severe pruritis associated with a diagnosis of progressive familial intrahepatic cholestasis (PFIC) confirmed by molecular genetic testing AND the patient does not have a ABCB11 variant resulting in non-functional or complete absence of the bile salt export pump protein (BSEP-3) AND the patient does not have a history of liver transplant or clinical evidence of decompensated cirrhosis AND baseline liver function tests and fat-soluble vitamin (A, D, E, and K) levels have been completed and will be monitored periodically during treatment AND patient has had an inadequate response or contraindication to cholestyramine and ursodiol. For re-approval, there must be documented clinical improvement (e.g. reduced serum bile acid or decreased pruritis).

Public Comment: Stacy Sandate from Albireo: Highlighted the attributes of Bylvay.

Board Decision: The Board unanimously approved the above recommendations.

DRAFT

- Kerendia® (finerenone)

Finerenone, the active ingredient of Kerendia®, is a nonsteroidal selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription. Finerenone blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g. kidney) and nonepithelial (e.g. heart and blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation. Finerenone has a high potency and selectivity for the MR and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors. It is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). The safety and efficacy of Kerendia® (finerenone) were assessed in a randomized, double-blind, placebo-controlled, multicenter study (FIDELIO-DKD) that included adults with chronic kidney disease (CKD) associated with type 2 diabetes, defined as either having an urinary albumin-to-creatinine ratio (UACR) of 30 to 300mg/g, eGFR 25 to 60ml/min/1.73m2, and diabetic retinopathy, or as having an UACR of ≥300mg/g and an eGFR of 25 to 75ml/min/1.73m2. The trial excluded patients with known significant non-diabetic kidney disease. The treatment effect reflected a reduction in a sustained decline in eGFR of ≥40% and progression to kidney failure. In addition, Kerendia® also significantly reduced the incidence of the composite endpoint of CV death, non-fatal MI, non-fatal stroke, or hospitalization for heart failure (HR 0.86, p=0.034; NNT =56) as a secondary endpoint as compared to placebo.

Recommendation:

- Add subcategory Mineralocorticoid Receptor Antagonists.
- Add Kerendia® (finerenone), Aldactone® (spironolactone) and Inspra® (eplerenone) to non-preferred.
- Add eplerenone and spironolactone to preferred.
  - Clinical criteria:
    - Add Aldactone, Inspra: The patient has a documented intolerance to the generic formulation.
    - Add Kerendia: The patient has a diagnosis of chronic kidney disease (CKD) associated with Type II Diabetes AND the estimated glomerular filtration rate at baseline is ≥ 25 mL/min/1.73m^2 AND the urine albumin-to-creatinine ratio is ≥ 30mg/g AND the patient is currently receiving, or has a contraindication to, an ACE inhibitor or angiotensin receptor blocker (ARB)

Public Comment: Tony Okoro from Bayer: Highlighted the attributes of Kerendia.

Board Decision: The Board unanimously approved the above recommendations.

- Kloxxado® (naloxone HCl)

DRAFT

Naloxone, the active ingredient of Kloxxado®, is an opioid antagonist that reverses opioid effects by competing for the same receptor sites. Administration of naloxone HCl reverses the effects of opioids, including respiratory depression, sedation, and hypotension. It can also reverse the psychotomimetic and dysphoric effects of mixed agonist-antagonists such as pentazocine. It is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients. Kloxxado® is intended for immediate administration as emergency therapy in settings where opioids may be present. Kloxxado® is not a substitute for emergency medical care. There were no clinical trials present in the prescribing information for Kloxxado®. However, in 2 pharmacokinetic studies in up to 24 healthy adult volunteers for each study, the bioavailability (BA) of a single 8mg dose (one spray) of Kloxxado® was compared to a single 0.4mg IM dose and a single 2mg IV dose of naloxone. Narcan® nasal spray, also a naloxone single dose intranasal product, has the same indication as Kloxxado® but is available as a 2mg and 4mg dose. Per the information from a press release by Hikma, "in a survey of community organizations to which Narcan® nasal spray 4mg has been distributed, 34% of attempted reversals used two or more doses. Additionally, a separate study published in 2019 found that the percent of overdose-related EMS calls in the US requiring multiple doses of naloxone during 2013-2016 had increased to 21%, representing a 43% increase over those 4 years."Kloxxado® offers prescribers a new, higher dose, treatment option.

Recommendation:

- Add Kloxxado™ (naloxone HCl) 8mg Nasal Spray with QTY LIMIT: 4 single-use sprays/28days to non-preferred.
- Add clarification of 4mg to Narcan® (naloxone HCl) 4mg Nasal Spray

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Rezurock® (belumosudil)

Belumosudil, the active ingredient of Rezurock®, is a kinase inhibitor. It is an inhibitor of rho-associated, coiled-coil containing protein kinase (ROCK) which inhibits ROCK2 and ROCK1. Belumosudil down-regulated proinflammatory responses via regulation of STAT3/STAT5 phosphorylation and shifting Th17/Treg balance in in-vitro human T cell assays. Belumosudil also inhibited aberrant pro-fibrotic signaling, in-vitro. It is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least 2 prior lines of systemic therapy. The safety and efficacy of Rezurock® were assessed in a randomized, open-label, multicenter study that included patients with chronic GVHD who had received 2 to 5 prior lines of systemic therapy and required additional treatment. The efficacy of Rezurock® was based on overall response rate (ORR) through cycle 7 day 1 where overall response included complete response or partial response per the 2014 NIH Response Criteria. In a randomized, open-label, single-arm study that included patients with chronic GVHD who had received 2 to 5 prior lines of systemic therapy and required additional treatment (N=65), results of the primary endpoint of overall response rate was 75%.

Recommendation:

- Add Rezurock™ (belumosudil) tablet to non-preferred.
  - Clinical criteria:
    - Add Rezurock: The patient is ≥ 12 years of age AND The patient has a diagnosis of Chronic Graft-versus-host disease And The patient has had a treatment failure with at least 2 prior courses of systemic immunosuppressant therapy (e.g. Corticosteroids, rituximab) AND The prescriber attests to monthly monitoring of liver function tests (total bilirubin, AST, and ALT)

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Saphnelo® (anifrolumab-fnia)

Anifrolumab-fnia, the active ingredient of Saphnelo®, is a type I interferon (IFN) receptor antagonist. It is a human IgG1k monoclonal antibody that binds to subunit 1 of the type I interferon receptor (IFNAR) with high specificity and affinity. This binding inhibits type I IFN signaling, thereby blocking the biologic activity of type I IFNs. Anifrolumab-fnia also induces the internalization of IFNAR1, thus reducing the levels of cell surface IFNAR1 available for receptor assembly. Blockade of receptor mediated type I IFN signaling inhibits IFN responsive gene expression as well as downstream inflammatory and immunological processes. Inhibition of type I IFN blocks plasma cell differentiation and normalizes peripheral T-cell subsets. It is indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy. The efficacy of Saphnelo® has not been evaluated in patients with severe active lupus nephritis or severe active CNS lupus. Use of Saphnelo® is not recommended in these situations. The safety and efficacy of Saphnelo® were assessed in three 52-week treatment period, multicenter, randomized, double-blind, placebo-controlled trials that included patients diagnosed with SLE per the American College of Rheumatology (1982 reviewed) classification criteria. Three studies assessed the safety and efficacy of Saphnelo®. While in study 2 treatment with anifrolumab-fnia did not result in statistically significant improvements over placebo for the primary endpoint of SRI-4 responder analysis, anifrolumab-fnia 300mg demonstrated statistically significant and clinically meaningful efficacy in overall disease activity compared with placebo in trial 3 for the primary endpoint of BICLA responder analysis. This is the first FDA approval for a type 1 interferon receptor antagonist, offering physicians another treatment option in SLE.

Recommendation:

- Add Saphnelo® (anifrolumab-fnia) to non-preferred.
  - Clinical criteria:
    - Add Saphnelo: The patient has a diagnosis of moderate-severe Systemic Lupus Erythematosus AND The patient is ≥ 18 years

of age AND Medication is prescribed by, or in consultation with, a nephrologist or rheumatologist AND The patient has had a documented inadequate response or intolerance to at least TWO of the following agents: hydroxychloroquine, corticosteroids, azathioprine, methotrexate, mycophenolate mofetil AND The patient has had a documented intolerance or treatment failure with Benlysta. Initial approval will be granted for 3 months. For therapy continuation, clinical documentation must be submitted documenting stable disease activity OR reduction in disease activity or corticosteroid dose. Note: The efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Saphnelo has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Saphnelo is not recommended in these situations.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

9. New Therapeutic Drug Classes

- None at this time.

10. Therapeutic Drug Classes- Periodic Review:

- **Antibiotics, Cephalosporins**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Keflex® capsules and Suprax® capsule from the PDL.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antibiotics, Fluoroquinolones**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove ciprofloxacin oral suspension.

DRAFT

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antibiotics, GI (new drug Aemcolo® (rifamycin) included)**
  - New Drug Aemcolo® (rifamycin)
    Rifamycin, the active ingredient of Aemcolo®, is an antibacterial drug that belongs to the ansamycin class of antibacterial drugs. It acts by inhibiting the beta-subunit of the bacterial DNA-dependent RNA polymerase, blocking one of the steps in DNA transcription. This results in inhibition of bacterial synthesis and consequently growth of bacteria. It is indicated for the treatment of traveler's diarrhea (TD) caused by non-invasive strains of Escherichia coli in adults. It is not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of Escherichia coli. The safety and efficacy of Aemcolo® were assessed in a multicenter, randomized, double-blind, placebo-controlled study that included adults with traveler's diarrhea. This trial was conducted at clinical sites in Guatemala and Mexico and provides the primary evidence for the efficacy of Aemcolo®. The clinical efficacy of Aemcolo® was assessed using an endpoint of time to last unformed (watery or soft) stool (TLUS) before achieving clinical cure. The median duration of diarrhea was significantly shorter in patients treated with Aemcolo® than in the placebo group. In addition, more patients treated with Aemcolo® were classified as clinical cures than were those in the placebo group. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. There is no evidence at this time to support that Aemcolo® is safer or more effective than the other currently preferred, more cost-effective medications.
  - American College of Gastroenterology (ACG) guidelines for the management of irritable bowel syndrome (IBS) were recently updated. They include recommendations against the use of antispasmodics. They also do not suggest using bile acid sequestrants to treat IBS-D symptoms. Tricyclic antidepressants and Xifaxan® (rifaximin) have strong recommendations for use.
  - In 2021, the Infectious Diseases Society of American (IDSA) and Society for Healthcare Epidemiology of American (SHEA) published clinical practice guidelines with focused update on the

DRAFT

management of Clostridioides difficile infection in adults. Recommendations include:

- "For patients with an initial Clostridioides difficile infection (CDI) episode, we suggest using fidaxomicin rather than a standard course of vancomycin (conditional recommendation, moderate certainty of evidence)."
- "In patients with recurrent CDI episodes, we suggest fidaxomicin (standard or extended-pulsed regimen) rather than a standard course of vancomycin (conditional recommendation, low certainty evidence)."
- "For patients with a recurrent CDI episode within the last 6 months, we suggest using bezlotoxumab as a co-intervention along with standard-of-care (SOC) antibiotics rather than SOC antibiotics alone (conditional recommendation, very low certainty of evidence)."
- When fidaxomicin is not available or feasible, vancomycin is a suitable alternative for the initial episode.

Recommendation:

Rifamycins

- Add Aemcolo® (rifamycin) delayed release tablets with QTY LIMIT: 12 tablets, max of 3 days to non-preferred.
  - Clinical criteria:
    - Add Aemcolo: patient has a diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. AND Patient has had a documented side effect, allergy, treatment failure or contraindication with a fluoroquinolone or azithromycin.
    - Update Traveler's Diarrhea (Xifaxan 200 mg Tablets Only): patient has a diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. AND Patient has had a documented side effect, allergy, treatment failure or contraindication with a fluoroquinolone or azithromycin. AND Quantity limit is 9 tablets/RX (200 mg tablets only).
    - Update Small Intestinal Bacterial Overgrowth (Xifaxan 550 mg or 200 mg Tablets): patient has a diagnosis of SIBO confirmed by breath test AND Quantity limit is 1,200 mg to 1,650mg/day for 14 days; maximum of 3 courses will be approved.
    - Update Irritable Bowel Syndrome (Xifaxan 550 mg or 200 mg Tablets): patient has a diagnosis of irritable bowel syndrome without constipation or with symptoms of bloating. AND Patient has attempted dietary modification and has had a documented side effect, allergy, treatment failure or contraindication to

DRAFT

loperamide and a tricyclic antidepressant. Quantity limit is 1,200 mg to 1,650 mg/day for 14 days; maximum of 3 courses will be approved.
- Update Inflammatory Bowel Disease: Crohn's Disease (Xifaxan 550 mg or 200 mg Tablets): patient has a diagnosis of Crohn's Disease. AND Patient has had a documented side effect, allergy, treatment failure or contraindication to two of the following: 6-mercaptopurine, azathioprine, corticosteroids, or methotrexate AND Quantity limit is 600 mg to 1,600 mg/day.

Vancomycin

- Add Vancomycin oral solution to non-preferred.
  - Clinical criteria:
    - Remove previous criteria for approval.
    - Add Firvanq, Vancomycin oral solution: The patient has a diagnosis or indication of Clostridium difficile associated diarrhea (CDAD) or staphylococcus enterocolitis AND for approval of Vancomycin oral solution, the patient has a documented intolerance to Firvanq.
    - Add Vancocin, Vancomycin capsules: The patient has a diagnosis or indication of Clostridium difficile associated diarrhea (CDAD) or staphylococcus enterocolitis AND for approval of Vancocin, the patient has a documented intolerance to generic vancomycin capsules.

Public Comments: No public comment.

Board Discussion: Dr. Pasanen noted that SIBO breath tests were on-hold during the COVID-19 pandemic and have not been available. He is unsure if they have resumed this testing at UVM. Dr. Nasca expressed concerns about the criteria for treating IBS with Xifaxan; requiring a TCA be used may not be applicable to the pediatric/adolescent population.

Board Decision: Deferred until the April meeting to obtain follow up information on the concerns the board raised on the above topics

- **Antibiotics, Miscellaneous**

  - No new drugs.
  - The 2021 GOLD recommendations for the treatment and prevention of COPD exacerbations are:
    - Treatment Antibiotics, when indicated, can shorten recovery time, reduce the risk of early relapse, treatment failure, and hospitalization duration. Recommended duration of therapy is 5-7 days (Evidence B)

DRAFT

- The use of antibiotics for the treatment of COPD exacerbations should occur in those who have the 3 cardinal symptoms: increased dyspnea, sputum volume, and sputum purulence.
- Antibiotic selection is based on the local resistance patterns/rates. Initial treatment usually consists of amoxicillin/clavulanate, macrolide, or tetracycline.
- Route of antibiotic administration depends on several factors, including the severity, the patient's ability to eat, and the pharmacokinetic profile.

- COPD Exacerbation Prevention:
  - Continued use for 1 year of either azithromycin 250mg/day or 500mg three times per week or erythromycin (500mg BID) may reduce exacerbation rate. There is no safety or efficacy data for long-term therapy beyond one year.

Recommendation:

Macrolides

- Clinical criteria:
  - Update Azithromycin/Zithromax packets: A clinically valid reason why the dose cannot be obtained using generic azithromycin tablets or suspension AND if the request is for brand Zithromax, the patient has a documented intolerance to the generic product.
  - Update Cystic Fibrosis: length of authorization for azithromycin is up to 12 months
  - Update Severe Bronchiectasis or COPD with frequent exacerbations: length of authorization for azithromycin is up to 1 year (There is no safety or efficacy data for long-term therapy beyond one year).

Oxazolidnones

- Clinical criteria:
  - Update Criteria for Approval: patient has been started on intravenous or oral linezolid or tedizolid in the hospital and will be finishing the course of therapy in an outpatient setting OR patient has a documented blood, tissue, sputum, or urine culture that is positive for Vancomycin-Resistant Enterococcus (VRE) species. AND patient has had a documented treatment failure with trimethoprim/sulfamethoxazole, clindamycin, doxycycline, or minocycline OR there is a clinically valid reason that the patient cannot be treated with one of those agents AND for approval of Zyvox or Sivextro the patient has an intolerance to generic linezolid

Penicillins (Oral)

- Remove Augmentin® suspension and Augmentin XR® tablets from the PDL.
- Remove note: PA will be granted for 125 mg/5 mL strength for patients < 12 weeks of age
  - Clinical criteria:

- Update Amoxicillin/Clavulanate ER: prescriber must provide a clinically valid reason for the use of the requested medication.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antibiotics, Tetracyclines**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move DOXYCYCLINE HYCLATE 20MG tablets to preferred.
- Remove Adoxa® 150 mg tab from the PDL.

Public Comments: No public comment.

Board Decision: The board unanimously approved the above recommendations.

- **Antiretrovirals**
  - Cabotegravir extended-release injectable suspension was approved in December 2021 for use in at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV. This will be reviewed at a later DUR Meeting.
  - No other significant clinical changes.

Recommendation:

- Remove Atripla®, Didanosine DR, Videx EC and Videx® from the PDL.
- Add Etravirine (compare to Intelence®) to non-preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antivirals, Oral**
  - No new drugs.
  - The FDA approved a Supplemental NDA for Xofluza® (baloxavir) as a treatment to prevent influenza in people 12 years of age or older following contact with someone with influenza (known as post-exposure prophylaxis). Xofluza® is the first single-dose influenza medicine approved for post-exposure prophylaxis. Xofluza® is now

DRAFT

available in an 80mg tablet (previously 2 x 40mg tablets were required for patients weighing more than 80kg).

Recommendation:

- Remove the quantity limit from Xofluza.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antivirals, Topical**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Move ACYCLOVIR (compare to Zovirax®) 5 % Ointment and ZOVIRAX® (acyclovir) 5% Cream to preferred.
- Move Docosanol 10% Cream to non-preferred.
- Add Acyclovir 5% cream to non-preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Skeletal Muscle Relaxants**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Remove Robaxin® tablets from the PDL.
- Remove statement "Maximum duration of therapy all musculoskeletal agents = 90 days."

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

12. Review of Newly-Developed/Revised Criteria:

- None at this time.

13. General Announcements:

- None at this time.

DRAFT

14. Adjourn: Meeting adjourned at 8:00 p.m.

DRAFT