Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
April 5, 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
Marietta Scholten, DVHA
Jason Pope, DVHA
Lisa Hurteau, PharmD, DVHA
Sandi Hoffman, DVHA
Jeffrey Barkin, MD, Change Healthcare
Mike Ouellette, RPh, Change Healthcare

Guests:

Adam Denman (Global Blood Therapeutics)
Angela Hathaway
Beth Morton
Erica Hintze
Frank Lanotte
Jai Persico
Joseph Ward
Kathleen Bernstein
Kevin Gaffney
Lisa Libera
Matt McMahon
Nicholas Primpas
Nicole Trask (Janssen)
Nikhil Kacker (Genetech)
Punit Patel (Abbvie)
Rasheed Jandali
Russell Moyer (Argenx)
Steve Angelcyk
Tim Birner (Sanus)

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 February meeting minutes were accepted as printed.

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

- Current legislation H728 has passed the House and is now with the Senate. It would expand needle exchange programs and prohibit a PA in the first 60 days for MAT therapy or medications used for acute opioid withdrawal. DVHA provided testimony and ultimately, they have decided to modify the language. DVHA was asked to research the following topics: Quantity limits, moving Buprenorphine mono formulation to preferred, how other state Medicaid programs have managed the 60-day PA deferral, feasibility of removing annual renewal, and parody between HUB and Spoke allowances.

If the legislation passes, these will be presented to the board for review and consideration.

4. Medical Director Update: Marietta Scholten, MD, DVHA

- DVHA has hired a new Chief Medical Officer, Dr. Julia Logan, who starts at the end of the month. Dr. Scholten is hopeful that she will be able to attend the next DURB meeting in May.

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

- Antibiotics/GI

Re-review of these recommendations was because 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.

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.
    - Update Small Intestinal Bacterial Overgrowth (Xifaxan 550 mg or 200 mg Tablets: patient has a diagnosis of SIBO 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. 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:
    - 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.
    - 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 Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

7. RetroDUR/ProDUR: Laurie Brady, RPH and Mike Ouellette, MD, Change Healthcare

- Introduce: Concurrent Use of GLP-1 Receptor Agonists and DPP-4 Inhibitors

Treatment for Type 2 Diabetes Mellitus (DM) has improved substantially in the last decade. Several effective newer classes of medications are now available, including glucagon-like peptide-1 receptor agonists (GLP-1 agonists), sodium-glucose co-transporter 2 inhibitors (SGLT-2 inhibitors) and dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors, also called gliptins), along with older medications, such as sulfonylureas and insulin. Recent guidelines from the American Diabetes Association and the American Society of Endocrinology incorporate these newer agents into treatment algorithms, often recommending considering these drugs before starting insulin therapy. Some of these agents have beneficial effects on other risks, such as heart failure and other cardiovascular diseases, and determining which drugs to use depends on an individual's health profile. GLP-1 receptor agonists work by stimulating insulin secretion and decreasing glucagon production. DPP-4 inhibitors prevent the degradation of GLP-1. Both have shown benefit in lowering blood glucose, however comparative trials have shown GLP-1 receptor agonists to be superior in improving glycemic control and inducing weight loss. Studies have shown that combining a GLP-1 agonist with a DPP-4 inhibitor provides minimal improvement in glycemic control and weight loss compared with either monotherapy, and combination therapy is not cost effective. Guidelines do not support combined therapy with these drugs.

Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from January 2021 – December 2021, excluding members with Part D or other insurance as primary

coverage, VMAP and Healthy Vermonters coverage. They will look at members to see if any are being prescribed both a DDP-4 inhibitor and GLP-1 agonist to determine if the practice is widespread or isolated among a few providers. This will determine if there should be adjustment to the PDL, PA process, or if provider education is warranted.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None at this time.

- Data presentation: Blood Glucose Test Strips in CGM Users

The use of continuous glucose monitors (CGMs) has become accepted standard of care for both type 1 diabetes and insulin dependent type 2 diabetes mellitus. While the value of CGM in type 2 diabetics not requiring insulin is uncertain due to rare occurrence of hypoglycemia, there are studies that show improvement in A1c levels compared with conventional blood glucose monitoring. In addition, blood glucose monitoring with finger sticks has potential errors due to poor compliance, dirty or contaminated meters, improper storage of test strips, expired test strips and poor skin preparation. Use of CGMs has improved glycemic control and over time, as technology has improved, there is less need to rely on testing to verify the CGM results. Initially when CGMs came on the market, conventional testing with finger sticks was recommended multiple times a day. As CGMs have evolved, however, the recommendation now is to corroborate results when the CGM reading seems inaccurate, either due to symptoms or unexplained fluctuations in the readings. Blood glucose monitoring is still required during CGM warm-up periods, to double check high and low values and sometimes for calibrating CGMs. For members using CGMs, it is expected that the increased expense of the monitors, sensors and supplies would be somewhat offset by decreased need to do fingerstick testing, and therefore decreased cost of glucose test strips.

Change Healthcare used paid, non-reversed Medicaid pharmacy claims from 10/1/19-3/31/20, excluding members with Part D, VMAP and Healthy Vermonters coverage. Members with a medical procedure code of A9276 (sensor), A9277 (transmitter), or A9278 (receiver) between 4/1/19 and 3/31/20 were eliminated from the analysis since they were not likely new CGM users. They were considered members who transitioned from the medical/DME channel to the pharmacy channel. Any member who did not have a medical procedure code on file during this time was classified as a new CGM User. Change Healthcare looked at all pharmacy claims for members who began Dexcom G6 or Freestyle Libre CGM between 10/1/19-3/31/20, excluding those that transferred from the medical/DME channel to the pharmacy channel. They evaluated blood glucose test strip usage in the 1-year time frame prior to the CGM period (10/1/18-9/30/19) and for 1 year after the CGM period (4/1/20-3/31/21). 211 members had a pharmacy CGM claim from 10/1/19-3/31/20.

211 members had a pharmacy CGM claim from 10/1/19-3/31/20. Of those 211 members, 68 were identified as patients transitioning from the Medical Benefit, and 143 were identified as being new users of CGM. 21 of these new users had no claims for blood glucose testing strips in the PRE and POST timeframe analyzed, whereas 122 members did. Further analysis was then

completed on these 122 members. The average total test strip use prior to the CGM period was 917, and the average total test strip use after to the CGM period was 583, a decrease of 36.41%. The average daily test strip use prior to the CGM period was 2.51, and the average daily test strip use after the CGM period was 1.6. 87 members (71%) had a decrease in daily test strip utilization while 35 members (29%) had an increase in daily test strip utilization.

Recommendation: There was a decrease in overall test strip utilization, and the majority of individual patients also had a decrease in test strip utilization, however, there were some outliers. 17 members used more than 4 blood glucose testing strips, on average, per day. DVHA could consider applying quantity limits on test strips and require a prior authorization for members using more than 200 strips per 30 days.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendation of putting a quantity limit of 200 strips per 30 days. Board chair Rene Mosier noted that this is worth re-visiting due to the % of members that had an increase in utilization.

8. Clinical Update: Drug Reviews: Jeff Barkin, MD, Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Aduhelm® (aducanumab)

Aducanumab-avwa, the active ingredient of Aduhelm®, is a recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease although it is unclear if beta amyloid is etiologically relevant in the pathogenesis of this disorder. Aduhelm® reduces amyloid beta plaques, as evaluated in Studies 1, 2, and 3. It is indicated for treatment of Alzheimer's disease. Treatment with Aduhelm® should be initiated in patients only with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aduhelm®. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). There is no data to suggest that this product enhances cognition or improves the symptoms of Alzheimer's disease. The safety and efficacy of Aduhelm® were assessed in 2 randomized, double-blind, placebo-controlled, parallel group studies that included patients with Alzheimer's disease (patients with confirmed presence of amyloid pathology and mild cognitive impairment or mild dementia stage of disease, consistent with

Stage 3 and Stage 4 Alzheimer's disease, stratified to include 80% Stage 3 patients and 20% Stage 4 patients).

Recommendation:

- Add new sub-category Immunoglobulin Gamma (IgG1) Monoclonoal Antibody with a note that all products require a PA.
- Add Aduhelm® (aducanumab-avwa) to non-preferred.
    - Clinical criteria:
        - Add Aduhelm: Patient is 50 years of age or older AND Prescriber has assessed and documented baseline disease severity utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive, Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]) AND Patient has mild cognitive impairment (MCI) due to Alzheimer's Disease or mild Alzheimer's dementia as evidenced by the following: Clinical Dementia Rating (CDR) Global Score of 0.5, Objective evidence of cognitive impairment at screening, MMSE score between 24 and 30, PET scan is positive for amyloid beta plaque OR Cerebrospinal fluid (CSF) test is positive for amyloid AND Patient has had a recent (within 1 year) brain MRI prior to initiating treatment and prescriber attests to a repeat brain MRI prior to the 7th infusion (first dose of 10mg/kg) and 12th infusion (sixth dose of 10mg/kg) AND Patient does not have any of the following within 1 year of treatment initiation: pretreatment localized superficial siderosis, 10 or more brain microhemorrhages, or brain hemorrhage >1 cm AND Patient has had a documented treatment failure with a preferred cholinesterase inhibitor, unless contraindicated. For re-approval, the patient must have responded to therapy compared to pre-treatment baseline as evidenced by improvement, stabilization, or slowing in cognitive or functional impairment AND patient has not progressed to moderate or severe disease (there is insufficient evidence in moderate or severe AD).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations with the following revision: Patient has had a documented treatment failure, as defined by significant disease progression after 1 year of therapy, with a preferred cholinesterase inhibitor, unless contraindicated.

- Invega® Hafyera (paliperidone palmitate injection, suspension, extended-release)

Paliperidone palmitate, the active ingredient of Invega® Hafyera, is hydrolyzed to paliperidone, which is the major active metabolite of risperidone. It is an atypical antipsychotic and while its mechanism of action is unclear, its efficacy in the treatment of schizophrenia may be mediated through a combination of central dopamine D2 and serotonin 5HT2A receptor antagonism. It is indicated as an every -six-month injection for the treatment of schizophrenia in adults after they have been adequately treated with: once-a-month paliperidone palmitate extended-release injectable suspension (e.g. Invega® Sustenna) for at least four months, or three-month paliperidone palmitate extended-release injectable suspension (e.g. Invega® Trinza) for at least one three-month cycle. The safety and efficacy of Invega® Hafyera were assessed in a randomized, double-blind, active-controlled, interventional, parallel-group, multicenter, non-inferiority study that included patients with schizophrenia who had previously been stably treated with either PP1M for at least 4 months or PP3M for at least one 3-month injection cycle. In a double-blind, active-controlled, multicenter, non-inferiority study, a relapse event was experienced by 7.5% of the Invega® Hafyera group as compared with 4.9% of the PP3M group, which demonstrated non-inferiority of Invega® Hafyera to PP3M.

- Lybalvi® (olanzapine and samidorphan L-malate)

Lybalvi® is a combination of olanzapine (an atypical antipsychotic) and samidorphan (as samidorphan L-malate; an opioid antagonist). The mechanism of action of olanzapine is not clear, however its efficacy in the treatment for its approved indications could be mediated through a combination of dopamine and serotonin type 2 (5HT2) antagonism. The mechanism of action of samidorphan may be mediated through opioid receptor antagonism. It is indicated for the treatment of Schizophrenia in adults and Bipolar I disorder in adults: Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate, Maintenance monotherapy treatment. The safety and efficacy of Lybalvi® for the treatment of schizophrenia in adults is based, in part, upon adequate and well-controlled studies of orally administered olanzapine. In a double-blind, placebo- and active controlled study that included adults who met DSM-5 criteria for schizophrenia, adults were randomized to Lybalvi®, olanzapine, or placebo; however, the study was designed to compare Lybalvi® with placebo, not with olanzapine. Results suggested that compared with placebo, a statistically significant improvement in the change from baseline in PANSS total score at week 4 was observed in patients treated with Lybalvi®. The inclusion of samidorphan in Lybalvi® did not appear to negatively impact the antipsychotic efficacy of olanzapine. Furthermore, in a second study that compared Lybalvi® with olanzapine in patients with schizophrenia, weight gain was assessed. Treatment with Lybalvi® was associated with statistically significantly less weight gain than with olanzapine alone and with a smaller proportion of patients who gained ≥10% body weight.

Recommendation:

- Add Invega Hafyera® (paliperidone palmitate) with FDA maximum recommended dose = 1560 mg/6 months to preferred after clinical criteria are met.

- Add Lybalvi® (olanzapine/samidorphan) with QTY LIMIT: 1 tablet/day; FDA maximum recommended dose = 20mg/10mg (per day) to non-preferred.
    - Clinical criteria:
        - Add Invega Hafyera: The patient is started and stabilized on the medication OR The patient has been adequately treated with Invega Sustenna (paliperidone palmitate 1-month) for at least four months or Invega Trinza (paliperidone palmitate 3-month) following at least one 3-month injection cycle.
        - Revise Caplyta: Indication for use is Bipolar Depression: the patient has had a documented side effect, allergy, or treatment failure with two preferred products (typical or atypical antipsychotics). If the prescriber feels that neither quetiapine or olanzapine/fluoxetine combination would be appropriate alternatives for the patient because of pre-existing conditions such as obesity or diabetes, the patient must have a documented side effect, allergy, or treatment failure with lurasidone.
        - Add Lybalvi: The patient has a documented side effect, allergy, or treatment failure with at least three antipsychotics, one of which must be aripiprazole or lurasidone.

Public Comment: Nicole Trask from Janssen yielded her time back to the committee. Timothy Birner from Alkermes: Highlighted the attributes of Lybalvi.

Board Decision: The Board unanimously approved the above recommendations with the following addition to Lybalvi criteria: There has been at least a 7-day opioid free interval from last use of short-acting opioids and at least a 14-day opioid free interval from last use of long-acting opioids.

- Loreev® XR (lorazepam capsule, extended release)

Lorazepam, the active ingredient of Loreev® XR, is a benzodiazepine that exerts its effect for the treatment of anxiety disorders through binding to the benzodiazepine site of the gamma-aminobutyric acid-A (GABA-A) receptors in the brain and enhances GABA-mediated synaptic inhibition. It is indicated for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets. There were no clinical trials in the Loreev® XR prescribing information. At steady-state, the mean area under concentration curve (AUCTau), the mean peak plasma concentration (Cmax), and the mean minimum plasma concentration (Cmin) of lorazepam following Loreev® XR 3 mg once-daily administration was 694 ng*h/mL, 35 ng/mL, and 25 ng/mL, respectively. AUCTau, Cmax, and Cmin of lorazepam from lorazepam tablets following 1 mg, three-times daily administration were 765 ng*h/mL, 41 ng/mL, and 29 ng/mL, respectively. The safety of Loreev® XR is based on studies with lorazepam tablets. Lorazepam tablets, available both generically and under the brand name Ativan®, have been available for many years and have been found to be effective in the management of anxiety disorders or for the short-term relief of the symptoms of anxiety

or anxiety associated with depressive symptoms. This formulation provides physicians a treatment option that allows for once daily dosing.

Recommendation:

- Add Loreev XR™ (lorazepam extended release) to non-preferred.
- Remove Niravam® (alprazolam ODT) from the PDL.
    - Clinical criteria:
        - Add Loreev XR: The patient is receiving a stable dose of lorazepam tablets, evenly divided, three times daily AND medical reasoning for use beyond convenience or enhanced compliance is provided.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Qulipta® (atogepant)

Atogepant, the active ingredient of Qulipta®, is a calcitonin gene-related peptide (CGRP) receptor antagonist. It is indicated for the preventive treatment of episodic migraine in adults. The safety and efficacy of Qulipta® for the preventive treatment of episodic migraine were assessed in two randomized, multicenter, double-blind, placebo-controlled studies that included adults with at least a 1-year history of migraine with or without aura, per the International Classification of Headache Disorders (ICHD-3) diagnostic criteria. In both 12 weeks studies, adults were permitted to use acute headache treatments (i.e., triptans, ergotamine derivatives, NSAIDs, acetaminophen, or opioids) as needed. The use of a concomitant medication that acts on the CGRP pathway was not permitted for either acute or preventive treatment of migraine. The studies excluded patients with myocardial infarction, stroke, or transient ischemic attacks within 6 months prior to screening. In both studies, results suggested that there was a significantly greater reduction in mean monthly migraine days across the 12-week treatment period in all three Qulipta® treatment doses as compared with placebo. Qulipta® is now the second FDA approved oral CGRP receptor antagonist indicated for the preventive treatment of episodic migraine.

Recommendation:

- Add Qulipta™ (atogepant) with QTY LIMIT: 30 tablets/30 days to non-preferred.
    - Clinical criteria:
        - Add Qulipta to the Nurtec ODT clinical criteria.
        - Add Qulipta additional criteria: The patient must have a documented side effect, allergy, or treatment failure to Emgality, Ajovy, and Nurtec ODT.

Public Comment: Punit Patel from Abbvie: Highlighted the attributes Qulipta.

Board Decision: The Board unanimously approved the above recommendations.

- Trudhesa® (dihydroergotamine mesylate spray)

Dihydroergotamine, the active ingredient of Trudhesa®, binds with high affinity to 5-HT1Dα and 5-HT1Dβ receptors. The therapeutic activity of dihydroergotamine in migraine is generally attributed to the agonist effects at 5-HT1D receptors. 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. It is not indicated for the management of hemiplegic or basilar migraine. The efficacy of Trudhesa® is based on the relative bioavailability of Trudhesa® nasal spray compared to dihydroergotamine mesylate nasal spray in healthy subjects. The clinical studies described in the prescribing information for Trudhesa® were conducted using dihydroergotamine mesylate nasal spray, which is available under the brand name Migranal®. Migranal® is also available as a generic and has the same indication as Trudhesa®. Neither treatments are approved for use in the pediatric population. However, Trudhesa® is the first and only migraine treatment to use Precision Olfactory Delivery (POD) technology and thus delivers dihydroergotamine to the upper nasal space, which is vascular rich. Per the manufacturer, this provides rapid absorption into the bloodstream, as well as consistent medication delivery. It reaches maximum plasma concentration within 30 minutes.

Recommendation:

- Add new sub-category Dihydroergotamines.
- Add Migranal (dihydroergotamine mesylate) nasal spray with QTY Limit of 8 units/30 days to preferred.
- Add Dihydroergotamine mesylate nasal spray (compare to Migranal®) with QTY LIMIT: 8 units/30 days to non-preferred.
- Add Trudhesa™ (dihydroergotamine mesylate) nasal spray QTY LIMIT: 8 units/30 days to non-preferred.
    - Clinical criteria:
        - Add Dihydroergotamine, Trudhesa: The patient has a documented intolerance to Migranal nasal spray.

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:

- **Acne Agents (new drug Winlevi® (clascoterone) included**
    - Clascoterone, the active ingredient of Winlevi®, is an androgen receptor inhibitor. The mechanism of action for its approved indication is not known. It is indicated for the topical treatment of acne vulgaris in

patients 12 years of age and older. The safety and efficacy of Winlevi® cream were assessed in two identically designed multicenter, randomized, double-blind, vehicle-controlled trials for the treatment of acne vulgaris that included subjects 12 years of age and older (N=1421) with facial acne vulgaris. More patients in the Winlevi® group obtained IGA success as compared with placebo in both studies, as well as a greater mean percent reduction in inflammatory and non-inflammatory lesions. Per the full-text study by Hebert et al, more patients achieved IGA success with Winlevi® as compared with vehicle ($p<0.001$ for both studies) at week 12. Comparator studies with other active ingredients were not identified.

Recommendation:

Oral Agents

- Move Isotretinoin capsules to non-preferred. Note that Amnesteem, Claravis, Myorisan, and Zenatane remain preferred.
  - Clinical criteria:
    - Add Isotretinoin to Absorica clinical criteria.

Topical Agents

- Remove Aczone® (dapsone 5% Gel), Azelex® (azelaic acid 20% Cream), Benzoyl Peroxide 6% Cleanser, and Cleocin-T® (clindamycin) 1% Solution, Pads, Gel from the PDL.
- Move Klaron® (sodium sulfacetamide 10% Lotion) to preferred.
  - Clinical criteria:
    - Remove combination product criteria and Azelex clinical criteria.
    - Add Benzaclin, Benzamycin: patient must have a documented intolerance to the generic equivalent.
    - Add Sodium Sulfacetamide Products: patient has had a documented side effect, allergy, or treatment failure with two preferred products, one of which must be Klaron lotion.
    - Add Onexton to Clindamycin/Benzoyl peroxide pump clinical criteria.

Topical- Androgen Receptor Inhibitors

- Add Winlevi® (clascoterone) 1% Cream to non-preferred.
  - Clinical criteria:
    - Add Winlevi: patient has had a documented side effect, allergy, or treatment failure with two preferred products

Topical- Rosacea

- Move Soolantra® (ivermectin) 1% cream to preferred.
- Add Ivermectin (compare to Soolanta®) 1% Cream to non-preferred.
  - Clinical criteria:

- Add Ivermectin cream: the patient has a documented intolerance to brand Soolantra.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Alpha-1 Proteinase Inhibitors**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- No changes.

Public Comments: No public comment.

Board Decision: None needed.

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

Recommendation:

- Remove Cortisporin® Cream, Cortisporin® Ointment from the PDL.

Public Comments: No public comment.

Board Decision: None needed.

- **Anti-infectives, Vaginal**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Move Nuvessa™ (metronidazole 1.3% Vaginal Gel) to non-preferred.
  - Clinical criteria:
    - Add Nuvessa to the Vandazole clinical criteria.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antiparasitics, Oral**

- No new drugs.
- No other significant clinical changes.

Recommendation:

- No changes.

Public Comments: No public comment.

Board Decision: None needed.

- **Scabicides and Pediculicides**
  - No new drugs.
    - In April 2021, the FDA approved Natroba™ (spinosad) topical suspension for the treatment of scabies infestations in patients 4 years of age and older. The approval was based on data from 2 multicenter, randomized, double-blind, vehicle-controlled phase 3 trials that assessed the efficacy and safety of Natroba in 533 patients from 206 households in which the youngest household member had an active scabies infestation. All household members were treated with either Natroba or vehicle, whether or not the member had an active scabies infestation. Patients applied a single application of Natroba or vehicle on day 1, then returned for evaluation on day 28. The primary endpoint was the proportion of primary patients (defined as the youngest infested household member) who achieved complete cure 28 days after treatment. Findings from Trial 1 showed that 69.8% (n=30/43) of patients treated with Natroba achieved complete cure at day 28 compared with 46.5% (n=20/43) of patients treated with vehicle. In Trial 2, 83.9% (n=52/62) of patients treated with Natroba achieved complete cure at day 28 compared with 34.5% (n=20/58) of patients treated with vehicle. Natroba is also indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

Recommendation:

- Remove Elimite™ (permethrin 5%) Cream, Eurax® (crotamiton 10 %) Cream and Lotion, Lindane Lotion and Sklice® (Ivermectin 0.5 %) Lotion.
- Add Vanalice (piperonyl butoxide/pyrethrins) Gel and Ivermectin 0.5% Lotion to non-preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Genital Warts/ Actinic Keratosis Therapies**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

Genital Wart Therapy

- Add Imiquimod (compare to Zyclara®) 3.75% Cream with QTY Limit: 56 packets/8 weeks to non-preferred.
- Remove Zyclara® 2.5% Cream from the PDL.
- Add Zyclara® 2.5% Cream Pump to the PDL.

Actinic Keratosis Therapy

- Move Efudex® (fluorouracil) 5% cream to non-preferred.
- Move Fluorouracil 5% cream to preferred.
- Remove Tolak® Cream, Picato® 0.015% gel, and Picato® 0.05 % Gel from the PDL.
  - Clinical criteria:
    - Add Efudex cream, Fluorouracil solution: The patient has a documented intolerance to fluorouracil 5% cream.
    - Add Fluorouracil 0.5% cream: The patient has a documented intolerance to brand Carac.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

12. Review of Newly-Developed/Revised Criteria:

- Spravato ® (esketamine)

Recommendation:

- Add clinical criteria for Major Depressive Disorder (MDD) with acute suicidal ideation or behavior: the patient is ≥ 18 years of age AND the medication is being used as adjunct treatment with an oral antidepressant AND the healthcare site and patient are enrolled in the Spravato® REMS program. Approval will be granted for 4 weeks.
- Allow dispensing via Pharmacy channel (had previously been restricted to medical benefit only).

Public Comments: Nicole Trask from Janssen yielded her time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

13. General Announcements:

- None at this time.

14. Adjourn: Meeting adjourned at 8:20 p.m.