Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
September 8, 2020

NOTE: The Meeting was held via Skype due to the Governor's "Stay Home Stay Safe" order related to the COVID-19 Emergency Declaration, and as authorized by recent modifications to Vermont's Public Meeting Law.

Board Members Present:

Zail Berry, MD
Andy Miller, RPh
Marc Pasanen, MD
Doug Franzoni, PharmD
Margot Kagan, PharmD
Bill Breen, RPh
Claudia Berger, MD
Patricia King, MD
Renee Mosier, PharmD
Joseph Nasca, MD

Absent:

Staff:

Laurie Brady, RPh, Change HealthCare
Carrie Germaine, DVHA
Lisa Hurteau, PharmD, DVHA
Nancy Hogue, Pharm D, DVHA
Stacey Baker, DVHA
Jeffrey Barkin, MD, Change Healthcare
Scott Strenio, MD, DVHA

Guests:

Adam Denman, Global Blood Therapeutics
Angela Hathaway
Brad Loo, Intra-Cellular Therapies
Brian Dillon, Otsuka
Brian Hall
Douglas Kenyon
Elizabeth Lubelczyk, Eli Lilly and Company
Franco Casagrande, Abbvie
Gene Muise, Amgen
Heather Mooney, Intra-Cellular Therapies
Jane Guo
Kristin Kollecas
Lisa Dunn, Amgen
Megan Walsh, Abbvie
Michelle Stantz, RedHill BioPharma Inc
Nicholas Boyer
Thomas Algozzine, Novartis Pharmaceuticals
Tyson Tompson, Pfizer

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:40 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. DVHA Pharmacy Administration Update: Nancy Hogue, Pharm.D., DVHA:

- DVHA welcomed new board member Andy Miller (pharmacist), Owner and manager of Brattleboro Pharmacy.
- New state legislation S220 (pending). Professional regulation bill which includes pharmacist clinical prescribing (includes ability to prescribe OTC medications, accessory devices such as spacers, short term Rx extension, and therapeutic exchange).
- Federal legislation related to MAT. SUPPORT act requires all states to cover MAT therapy. Will be part of MANDATORY Medicaid benefit (different from pharmacy which is optional). On 10/1/20 meds would not be eligible for federal or state rebates. Corrective legislation has been drafted, but technical correction of this is not likely prior to October. DVHA has been looking at ways to mitigate the fiscal impact to the state in the interim as it represents millions of dollars for the state.

4. Medical Director Update: Scott Strenio, MD, DVHA

- DVHA is looking at ways for MAT providers in HUBs to provide HEP C therapy. Goal is to enhance compliance.
- Medical Director, Scott Strenio, is also helping out the Department of Corrections which has a new vendor Vital Corp. The state is looking for a permanent employee for this position. Medicaid and DOC are attempting to align formularies. Protocol for testing and treatment of HCV is being evaluated.

5. Follow-up Items from Previous Meetings:

- None at this time.

6. RetroDUR/ProDUR: Laurie Brady, RPh, Change Healthcare and Jeffrey Barkin, MD, Change Healthcare

- Introduction of RetroDUR: Discussion Topics for 2021 RetroDUR Initiatives

HYDROXYCHLOROQUINE USE PRE AND POST COVID

Evaluate dispensing of Hydroxychoroquine 9/1/19-2/29/20 compared with 3/1/20-8/31/20 (6-month interval pre and post COVID-19 State of Emergency Declaration) to determine if there was an increase in off-label utilization.

INFLUENZA VACCINATION RATES

Evaluate what percent of patients treated for influenza with medications such as Tamiflu during last year or this year's flu season, received the flu vaccine in this flu season. We would need to look at immunization rates in both the medical and pharmacy benefit.

CODEINE USE IN THE PEDIATRIC POPULATION

FDA safety alert issued 4/20/17 included the addition of FDA's strongest warning, called a Contraindication, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years. A new Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems. VT has age restrictions in place for Tramadol (preferred only for ages 16 and older) but not for Codeine. The goal of this initiative would be to evaluate prescribing to see if restrictions or PA requirements are warranted.

USE OF ACUTE MIGRAINE TREATMENTS AFTER CGRP INITIATION

Evaluate use of acute migraine treatments (triptans, ergots, NSAIDs, and/or opiates) prior to and after initiation of preventative CGRP inhibitors (e.g. Aimovig, Ajovy, or Emgality).

IMMUNOLOGIC TREATMENTS FOR ASTHMA

Evaluate compliance with controllers and use of oral corticosteroids while on Cinquair, Dupixent, Fasenra, Nucala. These medications are indicated for add-on maintenance treatment, so continued use of a controller is important for efficacy. Use medical data to determine frequency of ER visits or hospitalizations for asthma exarcerbations while on therapy.

HERPES ZOSTER VACCINATION RATES

Evaluate use of Zostavax if Shingrix also administered.

Assess how many patients received both doses of Shingrix.

LONG-ACTING INJECTABLE ANTIPSYCHOTICS

Look at the overall rate and associated cost of prescriptions filled in the pharmacy benefit that are never administered in the provider's office as intended, therefore resulting in wasted medication.

Determine if forcing a buy and bill option is warranted with these types of drugs.

USE OF CHANTIX (varenicline) FOR SMOKING CESSATION

Examine the pattern of use of Chantix for tobacco cessation. Is there an opportunity to improve quit rates by increasing use of Chantix based on ATS guidelines?

Recent guidelines from the American Thoracic Society guidelines suggest that Chantix helps more patients quit smoking at 6 months than other agents alone. Additionally, Chantix no longer has a boxed warning about psychiatric events. Evidence also suggest considering combining Chantix plus NRT as an option if patients don't succeed with either agent alone.

Recommendation: None needed.

Public Comment: No public comment.

Board Decision: DVHA felt strongly about long-acting antipsychotic injectables, use of Chantix, and influenza vaccination rates because they coordinate with ongoing projects. After board discussion, hydroxychloroquine use pre and post COVID-19 and herpes zoster vaccination rates were eliminated from the list. The board also asked that we highlight alternatives for prescribers when presenting Codeine Use in Pediatrics.

- Data presentation: PREP HIV Therapy Prescribing Rates in those who had Post-Exposure Prophylaxis

Pre-exposure prophylaxis (PrEP) with antiretroviral drugs has become standard of care for those at high risk of contracting HIV. People considered at high risk include those who have sex with HIV-infected partners, those who have recent histories of STDs and/or high numbers of sex partners, those who are commercial sex workers and IV drug users, especially those whose injecting partners are HIV positive. Eligible patients should have a documented negative HIV test prior to starting PrEP and have no symptoms of acute HIV infection. Additionally, they should be tested for hepatitis B and appropriately vaccinated, as PrEP treatment can worsen hepatitis B infections. Renal function should be tested and be normal, and there should be documentation of other drugs taken, as there are significant drug/drug interactions with antiretroviral medications. Once the decision is made to start PrEP therapy, it is necessary to educate the patient about the monitoring that will need to be adhered to in order to continue therapy. This includes an HIV test every 3 months, medication adherence counseling, side effect assessment and STD symptom assessment. Renal function should be assessed at 3 months, and if stable, every 6 months thereafter. Women should have a pregnancy test every 3 months. The recommended treatment for PrEP therapy is Truvada, a combination of tenofovir disoproxil fumarate and emtracibine, or Descovy (tenofovir alafenamide and emtricitabine), if the patient has renal insufficiency.

Change Healthcare used paid, non-reversed Medicaid pharmacy claims from Calendar Year 2019 and medical claims from October 2018 through calendar year 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified members getting either Truvada or Descovy, in the absence of another antiretroviral medication, and examined medical claims to see if the guidelines for monitoring have been followed, including pre-prescribing HIV and Hep B testing, documentation of recent creatinine or BMP, as well as pregnancy test in women. Additionally, they looked to see if HIV testing, Creatinine and pregnancy testing was done at 3 months intervals, as recommended in guidelines. Results show that there were 43 members with a Truvada or Descovy prescription with no other HIV prescriptions. The next four measures only look for HIV and Hepatitis B procedures that happened prior to the first Truvada or Descovy claim in 2019: 18 members had both an HIV and HepB test, 5 members had just a HepB test, 14 members had just an HIV Test, and 6 members did not have either test.

The counts below show the number of times that each member had each procedure completed between 10/1/2018 - 12/31/2019. These counts are different than the counts that looked only at procedures completed before the first Truvada or Descovy claim in 2019.

Procedure Type	Procedure Count	Member Count
Creatinine or Metabolic Panel	0	11
Creatinine or Metabolic Panel	1	12
Creatinine or Metabolic Panel	2	6
Creatinine or Metabolic Panel	3	4
Creatinine or Metabolic Panel	4	5
Creatinine or Metabolic Panel	5	1
Creatinine or Metabolic Panel	6	1
Creatinine or Metabolic Panel	7	3

Procedure Type	Procedure Count	Member Count
HIV	0	18
HIV	1	8
HIV	2	10
HIV	3	3
HIV	4	1
HIV	5	1
HIV	7	1
HIV	8	1

Procedure Type	Gender	Procedure Count	Member Count
Pregnancy	F	0	2
Pregnancy	F	1	1
Pregnancy	F	3	1
Pregnancy	F	7	1
Pregnancy	M	0	37
Pregnancy	M	1	1

Members with Truvada or Descovy and no other HIV prescription by Gender

GENDER	MEMBER_COUNT
F	5
M	38

Recommendation: There was generally poor adherence to monitoring members on PrEP therapy. It might be helpful to reach out to the providers of members who had no laboratory monitoring to see what the barriers to compliance with guidelines was and determine plan of action based on those findings. Possible interventions could be to remind prescribers of PreP

therapy in real time of the need for monitoring, mailing a general reminder to all prescribers of PreP therapy of the monitoring guidelines or adding PreP members to the PCM program for adherence to medication/monitoring compliance.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the recommendation of sending out an educational letter to the prescribers of the 43 members on PrEP therapy.

7. Clinical Update: Drug Reviews: Jeffrey Barkin, MD, Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Caplyta® (lumateperone)

Lumateperone, the active ingredient of Caplyta®, is an atypical antipsychotic. While the exact mechanism of action is not known, the efficacy of lumateperone could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors. It is indicated for the treatment of schizophrenia in adults. The efficacy of Caplyta® was assessed in two placebo-controlled trials. Study 1 was a randomized, double-blind, multicenter, placebo-controlled 4-week trial that included adult patients with a diagnosis of schizophrenia per DSM-IV-TR criteria. In safety studies, the frequency of extrapyramidal symptoms (EPS) was similar to placebo (6.7% Caplyta® vs 6.3% for placebo). In addition, the mean change in body weight after 175 days of treatment with Caplyta® was -2kg. Studies with active comparators were not found.

Recommendation:

- Add Caplyta® (lumateperone) QTY LIMIT: 1 capsule/day FDA maximum recommended dose = 42 mg/day to non-preferred.
    - Clinical criteria:
        - Caplyta: The indication for use is the treatment of schizophrenia AND The patient has had a documented side effect, allergy or treatment failure with at least three preferred products (typical or atypical antipsychotics).

- *Public Comment:* Brad Loo from Intra-Cellular Therapies: Highlighted the attributes of Caplyta.

Board Decision: The Board unanimously approved the above recommendation.

- Esperoct® (antihemophilic factor (recombinant), glycopegylated-exei)

Esperoct®, a glycopegylated form of recombinant anti-hemophilic factor, temporarily replaces the missing coagulation Factor VIII needed for effective hemostasis. The Factor VIII in Esperoct® is conjugated to a 40-kDa polyethylene glycol molecule which increases the half-life and decreases the clearance compared to the non-pegylated molecule. This product is preservative free. It is indicated for use in adults and children with hemophilia A for: On-demand treatment and control of bleeding episodes, Perioperative management of bleeding, and Routine prophylaxis to reduce the frequency of bleeding episodes. Esperoct® is not indicated for the treatment of von Willebrand disease. The safety and efficacy of Esperoct® were assessed in 5 multinational, open-label trials that included male subjects with severe hemophilia A (<1% endogenous Factor VIII activity). All subjects were previously treated. The efficacy evaluation included 254 subjects who received at least one dose of Esperoct® in the following trials:

- Adolescent/Adult trial: Included 161 adults and 25 adolescents (12 to <18 years), consists of a Main Phase and optional Extension Phase. During the Main Phase, 175 subjects received the prophylaxis regimen which consisted of 50IU/kg Q4D, while 12 chose to be treated on-demand. A total of 165 subjects (91%) completed the Main Phase of the trial. There was also an extension trial that was open to subjects who experienced 2 or fewer bleeds during the last 6 months in the Main Phase.
- Pediatric trial: Included 68 subjects who were evenly divided with 34 in each age group (0 to <6 and 6 to <12 years of age). All subjects received the same prophylaxis regimen, and 63 completed the Main Phase.
- Surgery trial: Included 33 previously treated adolescents/adults who underwent 45 major surgeries. The dose level was chosen so that Factor VIII activity recommended by World Federation of Hemophilia (WFH) guidelines was targeted. In a clinical trial that included adults and adolescent patients with hemophilia A, 88.4% of bleeds were treated successfully with a single dose in the on-demand arm. There is no evidence at this time to support that Esperoct® is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add Esperoct® to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Jatenzo® (testosterone undecanoate)

Testosterone, the active ingredient of Jatenzo®, is a fatty-acid ester of the androgen testosterone. Endogenous androgens, including testosterone, are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. It is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. The safety and efficacy of Jatenzo® in males less than 18 years of age have not been established. The safety and efficacy of Jatenzo® were assessed in a 4-month open-label study that included adult

hypogonadal males (N=166). The study included a screening phase, a treatment titration phase, and a treatment maintenance phase. The primary endpoint was the percentage of patients with mean plasma total testosterone concentration (Cavg) over 24 hours within the normal eugonadal range on the final visit of the study. The safety and efficacy of use have not been established in males less than 18 years of age. Use is contraindicated in men with hypogonadal conditions, such as 'age-related hypogonadism', that are not associated with structural or genetic etiologies. In clinical studies, Jatenzo® use resulted in 87% of men having a mean total testosterone concentration within the normal eugonadal range at the end of treatment. Jatenzo® is the first and only oral softgel testosterone undecanoate and the first oral testosterone approved in the US in over 60 years. There is no evidence at this time to support that Jatenzo® is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add Jatenzo (testosterone undecanoate) capsule to non-preferred.
- Remove Striant® Sr (testosterone) 30 mg from the PDL.
    - Clinical criteria
        - Update Oral non-preferred agents: The patient has had a documented side effect, allergy, or treatment failure to TWO preferred testosterone products (topical and/or injectable formulations) AND if the request is for Methitest or methyltestosterone, the patient has had a documented side effect, allergy, or treatment failure with Jatenzo.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Secuado® (asenapine)

Asenapine, the active ingredient of Secuado®, is an atypical antipsychotic. While the mechanism of action for its approved indication is not clear, it is thought its efficacy could be mediated through a combination of antagonist activity at D2 and 5-HT2A receptors. It is indicated for the treatment of adults with schizophrenia. The efficacy of Secuado® was established, in part, on the basis of efficacy data from trials with the sublingual formulation of asenapine, available as brand name Saphris®. In addition, a 6-week, fixed-dose, randomized, double-blind and placebo-controlled trial assessed the safety and efficacy of Secuado® that included adult patients who met DSM-IV criteria for schizophrenia (N=607). The primary outcome in this study was the change from baseline in Positive and Negative Syndrome Scale (PANSS) total score to week 6 with Secuado® compared with placebo. The Clinical Global Impressions-Severity (CGI-S) rating scale was used as a secondary outcome. Results suggested that Secuado® 3.8mg/24 hours and 7.6mg/24 hours were statistically superior to placebo for both PANSS total score and CGI-S. In a short-term clinical trial compared with placebo, Secuado® was statistically significantly superior to placebo for improvement in PANSS total

score and CGI-S. Secuado® is the first and only FDA-approved transdermal system for schizophrenia, thus providing a new dosage formulation option for treating physicians.

Recommendation:

- Add a new sub-category of Transdermal Products to the PDL with a note that all products require PA.
- Add Secuado (asenapine) transdermal patch QTY LIMIT: 1 patch/day FDA maximum recommended dose = 7.6 mg/day to non-preferred.
    - Clinical criteria
        - Add Secuado: The indication for use is the treatment of schizophrenia/schizoaffective disorder AND The patient has had a documented side effect, allergy or treatment failure with at least three preferred products (typical or atypical antipsychotics) and Saphris OR The indication for use is the treatment of schizophrenia/schizoaffective disorder AND the patient is unable to take oral medications AND the patient has had a documented side effect, allergy or treatment failure with a preferred long-acting injectable.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- Talicia® (omeprazole magnesium, amoxicillin, and rifabutin)

Talicia® delayed-release capsules contain omeprazole magnesium (a proton pump inhibitor), amoxicillin (a semisynthetic antibacterial agent), and rifabutin (an antibacterial agent). Omeprazole is included in the delayed-release component of the capsule, while amoxicillin and rifabutin are included in the immediate-release component of the capsule. It is indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults. The safety and efficacy of Talicia® were assessed in a randomized, double-blind, controlled study that included treatment-naïve H. pylori-positive adult patients complaining of epigastric pain/discomfort. There is some evidence to suggest from a phase 3 study that Talicia® is more effective than a control of high dose amoxicillin and omeprazole; however, there is no evidence at this time to support that Talicia® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Talicia® (omeprazole, amoxicillin, rifabutin) delayed release capsules QTY LIMIT: 168 caps/14 days to non-preferred.
- Move Pylera® (bismuth subcitrate, metronidazole, tetracycline) capsules QTY LIMIT: 120 caps/10 days to preferred.
    - Clinical Criteria:

- Update non-preferred agents: The patient has a documented treatment failure with Lansoprazole, amoxicillin, clarithromycin combo package or Pylera used in combination with a PPI.

Public Comment: Michelle Stantz from RedHill BioPharma Inc.: Highlighted the attributes of Talicia.

Board Decision: The Board unanimously approved the above recommendations.

- Xepi® (ozenoxacin cream)

Ozenoxacin, the active ingredient of Xepi®, is a quinolone antimicrobial agent. It's mechanism of action involves the inhibition of bacterial DNA replication enzymes, DNA gyrase A, and topoisomerase IV. It is indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older. The safety and efficacy of Xepi® were assessed in two multicenter, randomized, double-blind, placebo-controlled trials. Subjects (N=723) two months of age and older with an affected body surface area of up to 100cm^2 and not exceeding 2% for subjects aged 2 months to 11 years were randomized to Xepi® or placebo for 5 days. In 2 clinical trials, Xepi® had significantly higher clinical success as compared with placebo. There is no evidence at this time to support that Xepi® cream is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add Xepi cream (ozenoxacin) to non-preferred.
  - Clinical criteria:
    - Add Xepi cream to the Mupirocin cream and Centany Ointment criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Zerviate Drops® (cetirizine)

Cetirizine, the active ingredient of Zerviate®, is a histamine-1 (H1) receptor antagonist. It is indicated for the treatment of ocular itching associated with allergic conjunctivitis. The efficacy of Zerviate® was established in 3 randomized, double-masked, placebo-controlled, conjunctival allergen challenge (CAC) clinical trials that included patients with a history of allergic conjunctivitis. In 2 clinical trials, patients treated with Zerviate® demonstrated statistically and clinically significantly less ocular itching as compared to vehicle at both 15 minutes and 8 hours after treatment. There is no evidence at this time to support that Zerviate® is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add Zerviate® (cetirizine 0.24%) QTY LIMIT:60 vials/30 days to non-preferred.
  - Clinical criteria
    - Add Zerviate: The patient has had a documented side effect, allergy, or treatment failure to TWO preferred ophthalmic antihistamines.

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:

- Allergen Immunotherapy (New Drug Review Palforzia (arachis hypogaea) will be included)
  - Palforzia® (peanut [Arachis hypogaea) allergen powder-dnfp) is a powder for oral administration manufactured from defatted peanut flour. It is an oral immunotherapy but the exact mechanism of action has not been established. It is indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia® is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older. The efficacy of Palforzia® for the mitigation of allergic reactions was assessed in a phase 3, randomized, double-blind, multicenter, placebo-controlled trial that included patients with peanut allergy aged 4 through 55 years. Palforzia® is not indicated for the emergency treatment of allergic reactions, including analphylaxis. There is a box warning listed with Palforzia®, warning of the risk of anaphylaxis, which can be life-threatening and can occur at any time during Palforzia® therapy.

Recommendation:

- Add Palforzia® (peanut allergen powder-dnfp) to non-preferred.
  - Clinical criteria:
    - Add Palforzia:
      - Patient age ≥ 4 years and ≤ 17 years for initial dose escalation or ≥ 4 years for up-dosing and maintenance
      - The prescriber is an allergist or immunologist

- Prescriber must provide the testing to show that the patient is allergic to peanuts
- Patient must not have a recent history of uncontrolled asthma, eosinophilic esophagitis, or other eosinophilic GI disease.
- Prescriber, pharmacy, and patient must be registered with the REMS program.
- Patient must have an auto-injectable epinephrine on-hand
- Initial approval will be granted for 6 months and includes approval for initial dose escalation and Up Dosing. Approval for Up Dosing may be extended if the patient was unable to tolerate all the dose levels at 2-week intervals.
- For approval of Maintenance Dosing (300mg daily), pharmacy records will be evaluated to assess compliance with once daily therapy and ensure no level was missed during Up Dosing. Documentation must be provided attesting that the patient has not experienced any treatment restricting adverse events (e.g. systemic allergic reactions, severe anaphylaxis).

- Revise current clinical criteria to apply exclusively to Oralair.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- Cytokine and CAM antagonists
  - No new drugs.
  - Additional indications approved for many drugs within this class.
  - FDA safety announcement issued 7/26/19: "The U.S. Food and Drug Administration has approved new warnings about an increased risk of blood clots and of death with the 10 mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR), which is used in patients with ulcerative colitis. In addition, the approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines. We approved these changes, including adding our most prominent Boxed Warning, after reviewing interim data from an ongoing safety clinical trial of tofacitinib in patients with rheumatoid arthritis (RA) that examined a lower and this higher dose of the medicine. The 10 mg twice daily dose of tofacitinib is not approved for RA or psoriatic arthritis (PsA). This dose is only approved for ulcerative colitis for initial treatment and for long-term use in limited situations. While the increased risks of blood clots and of

death were seen in patients taking this dose for RA, these risks may also apply to those taking tofacitinib for ulcerative colitis."

Recommendation:

Ankylosing Spondylitis: Injectables, changes will be effective 1/1/21

- Move Cosentyx® (secukinumab) Subcutaneous to non-preferred.
- Add TALTZ® (ixekizumab) QTY LIMIT: 80 mg prefilled syringe or autoinjector = 2/28 days for the first month and 1/28 days subsequently to preferred after clinical criteria are met.
    - Clinical criteria:
        - Remove current Cosentyx criteria.
        - Replace Enbrel/Humira with Clinical Criteria For all drugs: patient has a diagnosis of ankylosing spondylitis (AS) and has already been stabilized on the medication being requested. OR patient has a confirmed diagnosis of AS, and conventional NSAID treatment and DMARD therapy (e.g. methotrexate therapy) resulted in an adverse effect, allergic reaction, inadequate response, or treatment failure. If methotrexate is contraindicated, another DMARD should be tried.
        - Update Additional criteria for Taltz: the patient has a trial and failure or contraindication to Humira.
        - Update Additional criteria for Cimzia, Remicade, Simponi: the prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used. Note: Patient must be ≥ 18 years of age for Simponi approval as safety and efficacy has not been established in pediatric patients.
        - Add Additional criteria for Inflectra, Renflexis: the prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used, and the patient must be unable to use Remicade
        - Revise Statement: Patients with documented diagnosis of active axial involvement should have a trial with two NSAIDs, but a trial with DMARD is not required. If no active axial skeletal involvement, then NSAID trial and a DMARD trial are required (unless otherwise contraindicated).

Gastrointestinal, changes will be effective 1/1/21

- Rename category INFLAMMATORY BOWEL DISEASE BIOLOGICS: Initial approval is 3 months; renewals are 1 year
- Add Oral products with a note that all products will require a PA.
- Add Xeljanz® (tofacitinib) tablet QTY LIMIT: 2 tablets/day and Xeljanz® XR (tofacitinib) tablet QTY LIMIT: 1 tablet/day to non-preferred.
- Remove the Note from the Humira, Remicade, Cimzia, Tysabri, Entyvio, Inflectra, Renflexis, Stelara criteria.

- Add Tysabri to the additional criteria of Inflectra and Renflexis.
- Revise Cimzia additional criteria: Patient age >18 years AND the prescriber must provide a clinically valid reason why BOTH Remicade and Humira cannot be used.
- Add Entyvio, Inflectra, Renflexis, Simponi, and Stelara to the clinical criteria (Ulcerative Colitis) Humira and Remicade.
- Add Inflectra, Renflexis: the prescriber must provide a clinically valid reason why Humira and Remicade cannot be used.
- Add Entyvio, Simponi, Stelara additional criteria: Age > 18 years AND the prescriber must provide a clinically valid reason why Humira and Remicade cannot be used.
- Add Xeljanz, Xeljanz XR additional criteria: Age > 18 years AND the prescriber must provide a clinically valid reason why Humira and Remicade cannot be used. Note: Induction of Xeljanz 10mg twice daily or XR 22mg once daily will be limited to 16 weeks. Treatment should be discontinued after 16 weeks if adequate therapeutic response is not achieved. For patients with loss of response during maintenance treatment with 5mg twice daily or XR 11mg once daily, approval of 10mg twice daily or XR 22mg once daily will be considered and limited to the shortest duration possible.

Interleukin (IL)- 1 Receptor Blockers, changes will be effective 1/1/21

- Update category name to CRYOPYRIN ASSOCIATED PERIODIC SYNDROMES (CAPS) AND PERIODIC FEVER SYNDROME (PFS)
- Move Ilaris® (canakinumab) to non-preferred.
    - Clinical criteria:
        - Revise Ilaris: The diagnosis is Cryopyrin-Associated Periodic Syndrome (CAPS) OR The diagnosis is Familial Cold Autoinflammatory Syndrome (FCAS), Familial Mediterranean Fever (FMF), Hyper-IgD periodic fever syndrome (HIDS), Muckle-Wells Syndrome (MWS), or Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) AND The patient is > 4 years old.
        - Revise Arcalyst: The diagnosis is Cryopyrin-Associated Periodic Syndrome (CAPS) OR The diagnosis is Familial Cold Autoinflammatory Syndrome (FCAS) OR The diagnosis is Muckle-Wells Syndrome (MWS) AND The patient is > 12 years old

Psoriasis, changes will be effective 1/1/21

- Rename the subcategory from Injectables to Biologics
- Move Cosentyx® (secukinumab) to non-preferred.

- Move TALTZ® (ixekizumab) QTY LIMIT: 3 syringes/28 days for the first month, 2 syringes/28 days months 2 and 3 and 1 syringe/28 days subsequently to preferred after clinical criteria are met.
- Add Cimzia® (certolizumab pegol) QTY LIMIT: 1 kit/28 days (starter X 1, then regular) and Otezla® tablet (apremilast) QTY LIMIT: Starter Pack = 55 tablets/28 days, 30 mg = 2 tablets/day to non-preferred.
    - Clinical criteria:
        - Revise Additional Criteria for Taltz: The prescriber must provide evidence of a trial and failure or contraindication to Humira®.
        - Revise Additional Criteria for Cimzia, Cosentyx, Ilumya, Otezla, Remicade, Siliq, Skyrizi, Stelara, Tremfya: The prescriber must provide a clinically valid reason why both Humira® and Taltz® cannot be used. Note: Cosentyx approvals for 300mg dose(s) must use "300DOSE" package (containing 2 x 150mg pens or syringes). Approval will not be granted for 2 separate 150mg packages.

Rheumatoid, Juvenile & Psoriatic Arthritis: Immunomodulators, changes will be effective 1/1/21

- Move Cosentyx® (secukinumab) to non-preferred.
- Add TALTZ® (ixekizumab) QTY LIMIT: 80 mg prefilled syringe or autoinjector = 2/28 days for the first month and 1/28 days subsequently to preferred after clinical criteria are met.
- Add Ilaris® (canakinumab) and Otezla® tablet (apremilast) QTY LIMIT: Starter Pack = 55 tablets/28 days, 30 mg = 2 tablets/day to non-preferred.
- Add XELJANZ® (tofacitinib) 5 mg tablet QTY LIMIT: 2 tablets/day, Maximum 30 days supply to preferred after clinical criteria are met. Add Note: Xeljanz 10mg BID and XR 22mg are NOT recommended for Rheumatoid Arthritis or Psoriatic Arthritis. Please refer to Gastrointestinal: Inflammatory Bowel Disease Biologics for Ulcerative Colitis criteria.
    - Clinical criteria:
        - Remove the additional note for Humira.
        - Revise Taltz additional criteria: patient must be ≥ 18 years of age AND the prescriber must provide evidence of a trial and failure or contraindication to Humira
        - Add Otezla to the updated Actemra, Cimzia, Kevzara, Remicade, Simponi (subcutaneous), and Stelara additional criteria: The prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used.
        - Add Ilaris: The diagnosis is systemic juvenile idiopathic arthritis (sJIA) with active systemic features and varying degrees of synovitis with continued disease activity after initial therapy (Initial therapy defined as 1 month of anakinra (Kineret), 2 weeks of glucocorticoid monotherapy (oral or IV) or one month of NSAIDs). AND patient is > 2 years of age.

- Revise Inflectra, Renflexis additional criteria: the prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used and the patient must be unable to use Remicade.
- Revise Simponi Aria additional criteria: The patient has not responded adequately to Simponi subcutaneous. AND The prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used.
- Revise Kineret, Orencia additional criteria: The prescriber must provide a clinically valid reason why at least 2 preferred agents cannot be used.
- Revise Xeljanz XR additional criteria: Patient has not been able to tolerate or adhere to twice daily dosing of immediate release Xeljanz, resulting in significant clinical impact.
- Update Note: Patients with systemic juvenile arthritis (SJRA/SJIA) and fever are not required to have a trial of a DMARD, including methotrexate. Patients with systemic juvenile arthritis without fever should have a trial of methotrexate, but a trial of another DMARD in the case of a contraindication to methotrexate is not required.
- Update statement: Patients with psoriatic arthritis with a documented diagnosis of active axial involvement should have a trial of NSAID therapy, but a trial with DMARD is not required before a TNF-blocker is approved. If no active axial skeletal involvement, then an NSAID trial and a DMARD trial are required (unless otherwise contraindicated).

Public Comments: Gene Muse from Amgen: Highlighted the attributes of Otezla and Enbrel.
Elizabeth Lubelczyk from Eli Lilly: Highlighted the attributes of Taltz and Olumiant.
Franco Casagrande from Abbvie: Highlighted the attributes of Rinvoq.
Tyson Thompson from Pfizer: Highlighted the attributes of Xeljanz and Xeljanz XR.

Board Decision: The Board unanimously approved the above recommendations.

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

Recommendation:

- Move Ferripirox® (deferiprone) to non-preferred.
  - Clinical criteria:
    - Revise Deferasirox, Jadenu, Ferripirox: patient has had a documented side effect allergy or treatment failure to Exjade®; AND for approval of Jadenu, the patient must have a documented intolerance to generic deferasirox tablets.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Analgesics: NSAIDs**
  - Nabumetone, the active ingredient of Relafen® DS, is a non-steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic properties in studies. As with other NSAID agents, its mode of action is not known; however, the ability to inhibit prostaglandin synthesis may be involved in the anti-inflammatory effect. It is indicated for the relief of signs and symptoms of osteoarthritis and rheumatoid arthritis. The clinical studies included in the Relafen® DS prescribing information are the same as with the generically available nabumetone 500mg and 750mg tablets. Nabumetone 1000mg/day was found to be comparable to naproxen 500mg/day and to aspirin 3600mg/day in relieving the signs and symptoms of osteoarthritis and in relieving the signs and symptoms of rheumatoid arthritis. Nabumetone tablets, available in 500mg and 750mg, have been available for numerous years and have the same indications as Relafen® DS 1000mg tablets. here is no evidence at this time to support that Relafen® DS is safer or more effective than the currently preferred, more cost-effective medications, including the currently available nabumetone tablets.
  - On 2/14/20, The FDA approved Voltaren Arthritis Pain (diclofenac sodium topical gel, 1%) for over-the-counter (OTC) use. This product, previously referred to as Voltaren Gel 1%, was first approved by the FDA in 2007 as a prescription drug and was indicated for the relief of the pain of osteoarthritis of joints responsive to topical treatment, in particular, the joints of the hands, knees and feet. It has not been shown to work for strains, sprains, bruises or sports injuries.

Recommendation:

- Remove Naprosyn® (naproxen sodium) and Ponstel® (mefenamic acid) from the PDL.
- Move Celecoxib to preferred (no longer requiring clinical criteria).
- Add Relafen® DS (nabumetone) and Diclofenac (compare to Flector®) 1.3% Patch QTY LIMIT: 2 patches/day to non-preferred.
  - Clinical criteria:
    - Revise Celebrex: patient has had a documented trial of generic celecoxib.
    - Revise Diclofenac Patch, Flector Patch, Pennsaid: patient has had a documented side effect or inadequate response to Diclofenac gel or topical solution.

- Add Relafen DS: patient has had a documented side effect, allergy, or treatment failure to 4 or more preferred generic NSAIDs, including generic nabumetone.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Opiate Dependence and Overdose Treatments**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move BUPRENORPHINE/NALOXONE (formerly Suboxone®) sublingual TABLET QTY LIMIT: 8 mg = 2 tablets/day (Maximum Daily Dose = 16 mg/day, PA required for over 16 mg) to preferred.
- Revise Maximum days supply for Suboxone Films, Buprenorphine/naloxone tablets/films, and Buprenorphine tablets to 30 days
  - Clinical criteria:
    - Remove Buprenorphine/naloxone criteria.
    - Revise Bunavail/Zubsolv: Clinical documentation is submitted detailing a provider-observed reaction to both Suboxone films and buprenorphine/naloxone tablets severe enough to require discontinuation (documentation of measures tried to mitigate/manage symptoms is required).

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Otic Antibiotics**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Floxin® (ofloxacin) otic solution, Coly-Mycin S® (neomycin/colistin/thonzium/hydrocortisone), and Acetasol HC (acetic acid 2%/hydrocortisone 1% otic solution)
- Move Neomycin/Polymixin B Sulfate/Hydrocortisone Suspension to preferred.
- Add Cortisporin-TC® (neomycin/colistin/thonzium/hydrocortisone) to non-preferred.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

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

Recommendation:

Renal Disease: Phosphate Binders

- Remove Eliphos® (calcium acetate) tablet from the PDL.
  - Clinical criteria:
    - Remove Eliphos clinical criteria.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Topical Analgesics**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Lidocaine 4% solution from the PDL.
- Add Lidocaine 4% cream to preferred.
- Move Lidoderm Patch (lidocaine 5%) QTY LIMIT 3 patches/day to preferred.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **UC and Crohn's Agents**
  - No new drugs.
  - In 2019, the American Gastroenterological Association (AGA) published clinical practice guidelines on the management of mild-to-moderate ulcerative colitis. In patients with extensive mild-to-moderate UC, it is recommended to use either standard-dose mesalamine (2-3g/d) or diazo-bonded 5-ASA rather than low-dose mesalamine, sulfasalazine or no treatment (Those already on sulfasalazine in remission may reasonably choose sulfasalazine 2-4g/day if alternatives are cost-prohibitive, albeit with higher rate of intolerance). The AGA suggests in patients with extensive or

left-sided mild-to-moderate UC to add rectal mesalamine to oral 5-ASA. In patients with mild-moderate UC with suboptimal response to standard-dose mesalamine or diazo-bonded 5-ASA or with moderate disease activity, it is suggested to use high-dose mesalamine (>3g/day) with rectal mesalamine. If being treated with oral mesalamine, the AGA suggests using once-daily dosing rather than multiple times per day dosing. In addition, it is suggested to use standard-dose oral mesalamine or diazo-bonded 5-ASA rather than budesonide-MMX or controlled ileal release budesonide for induction of remission. It is also suggested to use mesalamine enemas (or suppositories) rather than oral mesalamine in patients with left-sided mild-moderate ulcerative proctosigmoiditis or proctitis. If in this population who choose rectal therapy over oral therapy, the AGA suggests using mesalamine enemas rather than rectal corticosteroids. In patients with mild-moderate UC refractory to optimized oral and rectal 5-ASA, the AGA suggests adding either oral prednisone or budesonide MMX.

Recommendation:

- Add Mesalamine tablet delayed extended release 1.2 g (compare to Lialda®) to non-preferred.
- Add Budesonide ER 9 mg tablet (compare to Uceris®) QTY LIMIT: 1 tablet/day and to non-preferred.
- Move Uceris® Rectal Foam (budesonide) to non-preferred.
- Remove Giazo® (balsalazide disodium) tablet from the PDL.
    - Clinical criteria:
        - Add Budesonide ER 9mg, Uceris: The diagnosis is ulcerative colitis AND induction therapy with mesalamine (≥2 gram/day), balsalazide, or olsalazine has failed or is not tolerated AND for approval of Uceris, The patient must have a documented intolerance to the generic budesonide ER 9mg tablets.
        - Revise Canasa, sfRowasa, Uceris Rectal Foam: The patient has had a documented intolerance to mesalamine enema or suppositories.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

11. Review of Newly Developed/Revised Criteria

- 2020/2021 Influenza Vaccine

- Remove AFLURIA® TRIVALENT (IIV3 AND FLUAD TRIVALENT(IIV3) from the PDL.
- Add FLUAD™ QUADRIVALENT (IIV4) to non-preferred.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

12. General Announcements:

- None at this time.

Public Comment: No public comment.

Board Decision: No action needed.

13. Adjourn: Meeting adjourned at 8:55 p.m.