Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
May 11, 2021

NOTE: The Meeting was held via Microsoft Teams 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	Margot Kagan, PharmD	Renee Mosier, PharmD
Doug Franzoni, PharmD	Bill Breen, RPh	
Joseph Nasca, MD	Mark Pasanen, MD	

Absent: Patricia King, MD, Claudia Berger, MD, Andy Miller, RPh

Staff:

Laurie Brady, RPh, Change HealthCare	Mike Ouellette, RPh, Change Healthcare	Laureen Biczak, DO, Change Healthcare
Carrie Germaine, DVHA	Lisa Hurteau, PharmD, DVHA	Scott Strenio, MD, DVHA
Nancy Hogue, Pharm D, DVHA	Jason Pope, DVHA	

Guests:

Tom Yelle (Xcenda)	Eric Hyde (Aveo Oncology)	Erin Booth
Beth D'Ambrosio (Novartis)	Kristen Chopas	Lisa Libera
Brian Dillon (Otsuka)	Lindsey Walter	Kristen Kollecas
Mattew Burke (Genetech)	Margaret Glassman	Tawney Mahesh
Nickhil Kacker (Genetech)	Rick Dabner	Michaela Hedberg
Patty Arcese (Amgen)	Rob Houk	Terry Geldart
		Kathryn Bemis

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 May meeting minutes were accepted as printed.

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

- DVHA is in the process of working on a legislative report focused on pricing transparency. Both gross and net cost are evaluated. If the price of a

medication increased by >50% over 5 years or >15% over 1 year, this is reported to the Attorney General and the Green Mountain Care Board. The AG then works directly with the manufacturers.
- The FDA just expanded the Emergency Use Authorization for the Pfizer COVID-19 vaccine to include adolescents ages 12-15. The point of sale coding is being modified and will be retroactive to 5/10/21.
- One 7/1/21, codes will be opened for pharmacists to bill for tobacco cessation counseling. A communication will be sent.

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

- DVHA continues to work with the Department of Corrections to align their formularies wherever possible. One of the DOC's goal is to start as many patients on Hepatitis C therapies as possible, and they are using the same criteria as DVHA.
- The commissioner of DVHA, Cory Gustafson, is resigning at the end of May.

6. Follow-up Items from Previous Meetings:

- **Chantix (Varenicline) Use**

DHVA intern attempted to reach out to those members identified in SFY2020 that completed a full course of Chantix (defined as 12 weeks). Out of the 70 patients identified, she reached24 members, however, only 12 of those 24 were willing to participated in the survey. Of those 12, six were currently not smoking.

Public Comment: No public comment

Board Decision: None needed.

7. RetroDUR/ProDUR: Mike Ouellette, RPh, Change Healthcare

- Introduction of RetroDUR: Long-Acting Injectable Antipsychotics

One of the challenges of treating people with schizophrenia is compliance with daily oral medication regimens. It is estimated that the adherence rate is less than 60%. Contributing to low adherence is the side effect profile with antipsychotics, both short and long term. Additionally, patients may still have hallucinations or delusions that convince them to stop taking medications, even when they were being taken appropriately. In patients who struggle with medication adherence, there is the option of every 2 week or once monthly injectable long-acting antipyschotics (LAIs), either given IM or SC. This strategy can be employed in those who have a history of adequate response to oral treatment, but relapse due to non-adherence. Using long-acting antipsychotics can prevent hospitalizations and are a way to deal with issues that complicate compliance, such as drug abuse, lack of stable housing or social structure, and unstable disease. Using LAIs can identify patients whose disease refractoriness is due to compliance alone, vs those who have less than optimal response to oral treatment. Additionally, some patients may have a better response to a constant blood level of drug, rather than the peaks and troughs that come with oral formulations. Some may find side-effects less bothersome. However, there are still potential issues with compliance since

patients need to stay on a schedule and appear at the provider's office to receive the injections. Concern is that there may be excessive waste in the system if patients miss appointments or refuse the injection. Prescriptions filled and labeled for an individual patient are not able to be reused for another patient. Additionally, injectable antipsychotic medications are substantially more costly than oral formulations.

Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from calendar year 2019 (pre-COVID), excluding members with Part D, TPL, VMAP and Healthy Vermonters coverage. They will look at all pharmacy claims for monthly LAIs in calendar year 2019 and determine if the monthly prescriptions filled at the pharmacy level were administered by looking to see if the appropriate CPT code was billed within 7 days of pharmacy billing. The analysis will look at 5 antipsychotics that are administered on an every 4 week schedule: Invega Sustenna®, Aristada® (except 882mg), Abilify Maintena®, Perseris®, and Haloperidol Decanoate. Zyprexa® Relprevv™ can be included in the analysis, but we will need to consider that it may be given every 2 or 4 weeks.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: After discussion it was decided that the data pull with look at 1 year time frames before COVID-19 (3/1/19-2/28/20) and after COVID-19 (3/1/20-2/28/21).

- Data presentation: Codeine Use in the Pediatric Population

Codeine use in children has come under scrutiny within the last few years due to the recent attention paid to complications of opiate use, including death. Codeine has been historically considered safe for treating pain in children and is often used to treat acute pain after surgical procedures and to suppress cough associated with respiratory infections. In 2013, the FDA restricted use in children younger than 18 to those who have acute pain after tonsillectomy/adenoidectomy. In a 2015 Drug Safety Communication, the public was warned about children who were ultra-rapid metabolizers of codeine, leading to high concentrations of the active metabolite too quickly, resulting in breathing difficulties. From 1969 – 2015, 64 cases of serious breathing problems, including 24 deaths in children under 18 were reported to the FDA Adverse Event Reporting System. This is likely is an underreporting of the incidence of these complications. An FDA safety alert was issued in April 2017 stating the use of codeine was contraindicated in the pediatric population younger than 12 years old and issued a warning about use in those ages 12-18 who are obese or have conditions such as obstructive sleep apnea or severe lung disease. The same safety alert also included the concern about using tramadol in the pediatric population and Vermont has placed age restrictions on the use of tramadol, but not codeine. In February 2018, codeine was removed from over the counter pain and cough medications. The purpose of this retrospective DUR was to investigate the practice

patterns of use of codeine in children, including as a cough suppressant as well as pain management among providers who care for pediatric patients.

Change Healthcare used paid, non-reversed Medicaid pharmacy and medical claims from calendar years 2019 and 2020, excluding members with Part D, VMAP and Healthy Vermonters coverage was used. They identified members, stratified by age cohort (less than 12, 12-18) with at least one prescription for a codeine containing product. They identified the total number of members with prescriptions from both medical and dental providers. They also looked at the average days prescribed and speculated if codeine was being used for acute or chronic pain management based on the classification of the drug. Overall, prescribing of codeine in children decreased from 2019 to 2020, with 137 claims among 127 members in 2019 and 79 claims among 76 members in 2020. There were very few prescription refills. Pain management was the primary indication, and it was used infrequently for cough suppression. As such, the highest number of prescriptions came from dentists, oral maxillofacial surgeons, and family practitioners. Pediatricians rarely prescribed codeine, which may be due to better education about the risks. Because there were also claims from ED providers and surgical subspecialists, it appears that most codeine use is for acute pain associated with trauma or procedures. Fortunately, the days supplied were very low, with the lengthiest days' supply being for cough suppressants that contained codeine. There were 70 individual prescribers in 2019 and 43 in 2020.

Recommendation: It appears that overall, use of codeine in children is being done judiciously. We recommend the implementation of an age limit edit for ages 12 and under. After much discussion, education should be done regarding the contraindication of codeine as well as the alternatives. An academic detailing module will be pursued to see if they can incorporate pain management in pediatrics. Change healthcare will bring back to the committee additional data regarding the use of morphine products in the same population.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendation

8. Clinical Update: Drug Reviews: Laureen Biczak, DO, Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Recommendation:

Public Comment: No public comment.

Board Decision: None needed.

Full New Drug Reviews:

- Cystadrops® (cysteamine- ophthalmic solution)

Cysteamine, the active ingredient of Cystadrops®, acts as a cystine-depleting agent by converting cystine to cysteine and cysteine-cysteamine mixed disulfides, and it reduces corneal cystine crystal accumulation. It is indicated for the treatment of corneal cystine crystal deposits in adults and children with cystinosis. The safety and efficacy of Cystadrops® were assessed in 2 studies, including a single-arm study conducted for 5 years (OCT-1 study) and a randomized controlled study conducted for 90 days (CHOC study). In a small clinical trial, Cystadrops® was associated with a greater reduction from baseline at 90 days in the IVCM total score across all corneal layers compared with control. It is the only eye drop FDA approved for this indication used four times per day. Cystaran®, by comparison, is to be used every hour during waking hours. At the end of 7 days, patients should discard the bottle even though there may be medication left in the bottle.

Recommendation:

- Rename subcategory Cysteamine.
- Add Cystadrops® (cysteamine) 0.37% ophthalmic solution with QTY LIMIT: 4 bottles (20 ml)/28 days and Maximum day supply/Rx = 28 days to non-preferred.
    - Clinical criteria:
        - Add Cystadrops to the Cystaran criteria: The indication for use is corneal cystine accumulation in patients with cystinosis.

Public Comment: Tom Yelle from Xcenda: Highlighted the attributes at Cystadrops®.

Board Decision: The Board unanimously approved the above recommendations.

- Lampit® (nifurtimox tablets)

Nifurtimox, the active ingredient of Lampit®, is an antiprotozoal. While the mechanism of action is not fully understood, studies suggest that nifurtimox is metabolized/activated by Type I (oxygen insensitive) and Type II (oxygen sensitive) nitro reductases (NTR) leading to production of toxic intermediate metabolites and/or reactive oxygen species that induce DNA damage and cell death of both intracellular and extracellular forms of T. cruzi. It is indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5kg) for the treatment of Chagas disease (American Trypanosomiasis) caused by Trypanosoma cruzi. This indication was approved under accelerated approval based on the number of treated patients who became immunoglobulin G (IgG) antibody negative or who showed an at least 20% decrease in optical density on two different IgG antibody tests against antigens of T. cruzi. The safety and efficacy of Lampit® for the treatment of Chagas disease in pediatric patients' birth to less than 18 years of age and weighing at least 2.5kg were demonstrated in one prospective, randomized, double-blind study conducted in Argentina, Bolivia, and Columbia. Continued approval for this indication may be contingent upon verification and description of clinical benefits in a

confirmatory trial. Lampit® tablets should not be split mechanically with a table splitting device, but rather should be split at the scored lines by hand. In a randomized, double-blind trial, serologic response was superior in the 60-day arm compared with the 30-day arm treatment groups. Note that the 30-day regimen is not an approved dosing regimen.

Recommendation:

- Add Lampit (nifurtimox) to preferred after clinical criteria are met.
  - Clinical criteria:
    - Update Benznidazole, Lampit: patient must be between 2-12 years of age (Benznidazole) or ≤ 18 years (Lampit) AND patient has a diagnosis of Chagas Disease (American trypanosomiasis) AND length of therapy does not exceed 60 days.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Oxlumo® (lumasiren)

Lumasiran, the active ingredient of Oxlumo®, is an HAO1-directed double-stranded small interfering ribonucleic acid (siRNA), covalently linked to a ligand containing N-acetyl galactosamine (GalNAc). Lumasiran reduces levels of glycolate oxidase (GO) enzyme by targeting the hydroxy acid oxidase 1 (HAO1) messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference. Decreased GO enzyme levels reduce the amount of available glyoxylate, a substrate for oxalate production. As the GO enzyme is upstream of the deficient alanine-glyoxylate aminotransferase (AGT) enzyme that causes PH1, the mechanism of action of lumasiran is independent of the underlying AGXT gene mutation. It is indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients. Oxlumo® is not expected to be effective in primary hyperoxaluria type 2 (PH2) or type 3 (PH3) because its mechanism of action does not affect the metabolic pathways causing hyperoxaluria in PH2 and PH3. The safety and efficacy of Oxlumo® were assessed in a randomized, double-blind study comparing lumasiran and placebo in patients 6 years of age and older (N=39) with PH1 and an eGFR ≥30ml/min/1.73m2 (ILLUMINATE-A). In a small study that included 39 patients with ages ranging from 6 to 61 years, the least square mean % change from baseline in 24-hour urinary oxalate was -65% with Oxlumo® as compared with -12% with placebo, which was statistically significantly different ($p<0.0001$).

Recommendation:

- Add Oxlumo™ (lumasiran) to non-preferred.
  - Clinical criteria:
    - Add Oxlumo: The patient has a diagnosis of Primary Hyperoxaluria Type I (PH1) confirmed via genetic testing (identification of alanine: glyoxylate aminotransferase gene (AGXT) mutation) AND urinary oxalate excretion > 0.5mmol/1.73 m^2 or urinary oxalate: creatinine ratio is above the upper limit of normal for age AND medication is being

prescribed by, or in consultation, with a nephrologist or urologist AND patient has not previously received a liver transplant.

Public Comment: Ali Toumadj from Alnylam: Highlighted the attributes of Oxlumo.

Board Decision: The Board unanimously approved the above recommendations.

- Reditrex® (methotrexate)

Methotrexate, the active ingredient of RediTrex®, is a folate analog metabolic inhibitor that inhibits dihydrofolic acid reductase. Dihydrofolates must be reduced to tetrahydrofolates by this enzyme before they can be utilized as carriers of one-carbon groups in the synthesis of purine nucleotides and thymidylate. Thus, methotrexate interferes with DNA synthesis, repair, and cellular replication. Actively proliferating tissues such as malignant cells, bone marrow, fetal cells, buccal and intestinal mucosa, and cells of the urinary bladder are in general more sensitive to this effect of methotrexate. The mechanism of action in rheumatoid arthritis is not known, but it may affect immune function. It is indicated for Rheumatoid arthritis (RA) including polyarticular juvenile idiopathic arthritis, in the management of selected adults with severe, active RA (ACR criteria), or children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs). RediTrex® is not indicated for the treatment of neoplastic diseases. Clinical trials in patients with rheumatoid arthritis and polyarticular juvenile idiopathic arthritis were performed using other formations of methotrexate. Most studies of methotrexate in patients with RA were relatively short. Methotrexate has been available for several decades and has been found to be a relatively safe and effective product. Numerous dosage forms, including oral and injectable are available. RediTrex® is a new methotrexate delivery system of pre-filled syringes intended for ease of handling and dosing in patients with RA/pJIA and psoriasis. There is no evidence at this time to support that RediTrex® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add METHOTREXATE 25 MG/ML solution for injection to preferred.
- Add RediTrex® (methotrexate) Prefilled syringe for subcutaneous use) with QTY LIMIT: 4 syringes/28 days to non-preferred.
    - Clinical criteria:
        - Add Reditrex to the Otrexup and Rasuvo criteria: the patient has a diagnosis of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA) or psoriasis AND The patient has been intolerant to oral methotrexate AND The patient has been unable to be compliant with a preferred form of injectable methotrexate (includes difficulty with manual dexterity).

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Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Sevenfact® (coagulation factor VIIa [recombinant]-jncw)

Sevenfact® contains coagulation Factor VIIa (recombinant)-jncw as the active ingredient. It is produced by recombinant DNA technology using genetically engineered rabbits into which the DNA coding sequence for human Factor VII has been introduced. Human Factor VII is expressed in the rabbit mammary gland and secreted into the milk. The manufacturing process of Sevenfact® includes specific steps to reduce impurities. Sevenfact® may contain trace amounts of rabbit proteins. It is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors. A limitation of use is that Sevenfact® is not indicated for the treatment of patients with congenital Factor VII deficiency. The safety and efficacy of Sevenfact® for the treatment of bleeding episodes were assessed in Study 1, a multicenter, randomized, open-label crossover of two initial dose regimens that included subjects with hemophilia A or B with inhibitors who were treated for 468 bleeding events, of which 465 were mild or moderate and 3 were severe bleeding events. In a clinical study, the proportion of mild or moderate bleeds with hemostatic efficacy at 12 hours was 82% with the 75mcg/kg dosing regimen and 91% in the 225mcg/kg dosing regimen. The median number of infusions needed to achieve bleeding control in the first 12 hours per mild or moderate bleeding episodes was 1 for the 225mcg/kg dosing regimen and 2 in the 75mcg/kg dosing regimen.

Recommendation:

- Add Sevenfact® to non-preferred.
  - Clinical criteria:
    - Add Sevenfact: Medication is being used for the treatment of acute bleeding episodes in a patient with Hemophilia A or B with inhibitors AND there is a clinically compelling reason why Novoseven RT cannot be used.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Sutab® (sodium sulfate, magnesium sulfate, and potassium chloride)

The primary mode of action of Sutab® is osmotic action of sodium sulfate and magnesium sulfate, which induce a laxative effect. The physiological consequence is increased water retention in the lumen of the colon, resulting in loose stools. It is indicated for the cleansing of the colon as a preparation for colonoscopy in adults. The safety and efficacy of Sutab® for colon cleansing were assessed in 2 randomized, single-blind, active-controlled multicenter studies that included adult subjects undergoing colonoscopy for colorectal cancer screening and surveillance, or diagnostic colonoscopy, including subjects with abdominal pain, diarrhea, constipation, and non-severe inflammatory bowel disease. In two studies to assess the efficacy

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of Sutab® with active comparators that included adults undergoing colonoscopy for colorectal cancer screening and surveillance, or diagnostic colonoscopy, Sutab® was non-inferior to the active comparator for the primary endpoint of the proportion of patients with successful colon cleansing.

Recommendation:

- Add BOWEL PREP AGENTS to the subcategory GASTROINTESTINAL AGENTS: CONSTIPATION/DIARRHEA, IRRITABLE BOWEL SYNDROME-CONSTRIPATION (IBS-C), IRRITABLE BOWEL SYNDROME-DIARRHEA (IBS-D), SHORT BOWEL SYNDROME, OPIOID INDUCED CONSTIPATION.
- Add GAVILTYE-G, GAVILYTE-H, GAVILYTE-N, MOVIPREP, PEG-3350, and SUPREP® to preferred.
- Add Clenpiq®, Gavilyte-C, Golytely, Nulytely, Plenvu®, and Sutab® to non-preferred.
    - Clinical criteria:
        - Add Non-preferred agents: The patient has a documented intolerance or treatment failure of at least one preferred agent (defined by failure to complete cleansing of the colon as a preparation for colonoscopy) AND if the product has an AB rated generic, there must have been a trial with the generic formulation.

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:

- **Analgesics, Narcotics- Long Acting**
    - No new drugs.
    - No new significant clinical changes.

Recommendation:

- Remove Dolophine® (methadone) tablets, Kadian® (morphine sulfate XR), Arymo® ER (morphine sulfate, extended release) and Morphabond® ER (morphine sulfate, extended release) from the PDL.
- Update XTAMPZA ER® (oxycodone ER) QTY LIMIT: 60 caps/strength/30day instead of tablets.

Public Comments: No public comment.

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Board Decision: The Board unanimously approved the above recommendations. Change Healthcare will update the naming of the Therapeutic Drug Class to use Opioids rather then Narcotics.

- **Analgesics, Narcotics- Short Acting**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Tylenol® #3 and #4 (acetaminophen w/codeine), Roxybond™ (oxycodone), Roxanol® (morphine sulfate), Opana® (oxymorphone), Ibudone® (hydrocodone w/ ibuprofen), Lazanda® (fentanyl) Nasal Spray, Lortab® (hydrocodone w/ acetaminophen), DIHYDROCODEINE COMPOUND, ASPIRIN W/CODEINE, Abstral® (fentanyl) Sublingual Tablets, and Subsys® (fentanyl) sublingual spray from the PDL.
- Remove quantity limits for HYDROMORPHONE tablets, Dilaudid®(hydromorphone) tablets, OXYCODONE (plain) tablets, and Oxycodone (plain) capsules.
- Move Meperidine with QTY LIMIT: 30 tablets/5-day supply per 30 days to non-preferred.
- Update quantity limits on Oxycodone w/ acetaminophen and hydrocodone w/ acetaminophen to 12 tablets/day (combination tablets with acetaminophen are no longer available with an acetaminophen dose above 325mg).

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Epinephrine, Self-Injectable**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove concentrations for both preferred and non-preferred products (only the mg strength will be listed). Move Epi-Pen® 2-pack Inj 0.3mg to non-preferred. DVHA was temporarily preferring it due to product shortages which have now resolved.

Public Comments: No public comment.

Board Decision: No action needed.

- **Hepatitis B**

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

Recommendation:

- No change.

Public Comments: No public comment.

Board Decision: None needed at this time.

- **Multiple Sclerosis Agents (new drug Kesimpta® (ofatumumab) included)**
  - Ofatumumab, the active ingredient of Kesimpta®, is a recombinant human monoclonal immunoglobulin G1 (IgG1) antibody that binds to human CD20 expressed on B-cells. The exact mechanism of action by which ofatumumab exerts its therapeutic effects for its approved indication is not known, but is presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, ofatumumab results in antibody-dependent cellular cytolysis and complement-mediated lysis. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. The safety and efficacy of Kesimpta® were assessed in 2 randomized, double-blind, double-dummy, active comparator-controlled trials of identical design that included patients with relapsing forms of MS. Both studies enrolled patients with at least one relapse in the previous year, 2 relapses in the previous 2 years, or the presence of a T1 gadolinium-enhancing (GdE) lesion in the previous year, in addition to an Expanded Disability Status Scale (EDSS) score from 0 to 5.5. In two phase 3 clinical trials, Kesimpta® was found to be significantly more effective than teriflunomide for the primary endpoint of ARR, with Kesimpta® being associated with lower annualized relapse rates than teriflunomide. Kesimpta® was significantly more effective than teriflunomide for other secondary endpoints assessed.

Recommendation:

- Add Kesimpta® (ofatumumab) non-preferred.
- Move all Dimethyl fumarate generics to preferred.
- Move Tysabri® (natalizumab) to preferred after clinical criteria are met.
  - Clinical criteria:
    - Kesimpta, Lemtrada, Ocrevus: Patient is ≥ 18 years AND has a diagnosis of relapsing multiple sclerosis AND has a documented side effect, allergy, treatment failure or contraindication to at least two preferred drugs, one of which must be Gilenya or

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Tysabri, unless contraindicated OR Patient is ≥18 years AND has a diagnosis of primary progressive multiple sclerosis (Ocrevus only).
- Revise Copaxone 40 mg Syringe: The patient is unable to tolerate or be compliant with Copaxone 20 mg daily dosing.
- Add Tecfidera to the Ampyra criteria: patient must have a documented intolerance to the generic equivalent.
- Revise Tysabri: Patient is ≥ 18 years AND has a diagnosis of relapsing multiple sclerosis (including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease)

Public Comments: Beth D'Ambrosio from Novartis: Highlighted the attributes of Kesimpta.

Board Decision: The Board unanimously approved the above recommendations.

- **Neuropathic Pain/Fibromyalgia Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:
- Add Pregabalin (compare to Lyrica®) solution to non-preferred.
- Add quantity limits of 2 capsules/day to Cymbalta® (duloxetine).
  - Clinical criteria:
    - Update Pregabalin solution, Lyrica solution: the patient is unable to use Lyrica capsules (e.g. Swallowing disorder) AND For approval of brand Lyrica oral solution, the patient must have a documented intolerance to the generic equivalent

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Pseudobulbar Affect Agents**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:
- No change.

Public Comments: No public comment.

Board Decision: None needed at this time.

- **Topical Steroids**

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

Recommendation:

- Remove DesOwen® (desonide) 0.05% cream and lotion, Cordran® (all products), and Elocon® (all products) from the PDL.
- Move Hydrocortisone valerate 0.2% cream and ointment and clobetasol propionate 0.05% lotion and spray to preferred. Add Halcinonide 0.1% cream and halobetasol 0.05% foam to non-preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

12. Review of Newly-Developed/Revised Criteria:

- **Acne Agents: Topical Retinoids**
  - There was a change in manufacturer for Tazorac®, and they do not participate in the Medicaid Drug Rebate Program.

Recommendation:

- Remove TAZORAC® (tazarotene) from the PDL.
- Add Adapalene/Benzoyl Peroxide (compare to Epiduo) 0.1-2.5% Gel and Epiduo Forte (adapalene/benzoyl peroxide) 0.3-2.5% Gel to non-preferred.
  - Clinical criteria:
    - Aklief, Arazlo, Fabior, Tazarotene: patient has had a documented side effect or treatment failure with a preferred topical tretinoin product and Differin.
    - Clindamycin/tretinoin gel, Epiduo Forte: patient has had a documented side effect or treatment failure on combination therapy with the separate ingredients of the combination product.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Hyperkalemia Agents**
  - No new drugs
  - Cation exchange resins, such as SPS®, can cause fatal intestinal necrosis. Guidelines now indicate that they should not be used in chronic mild or moderate hyperkalemia in patients that do not have a hyperkalemic emergency.

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- Lokelma (sodium zirconium cyclosilicate or Veltassa (patiromer sorbitex calcium) are considered first line agents.

Recommendation:

- Move Lokelma™ (sodium zirconium cyclosilicate) to preferred.
  - Clinical criteria:
    - Update Veltassa: The patient requires therapy for the treatment of non-emergent hyperkalemia AND where clinically appropriate, medications known to cause hyperkalemia (e.g. ACE inhibitors, ARBs, aldosterone antagonists, NSAIDs) have been discontinued or reduced to the lowest effective dose AND where clinically appropriate, a loop or thiazide diuretic has failed for potassium removal, AND the patient has been counseled to follow a low potassium diet (≤ 3 grams/day)

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

13. General Announcements:

- None at this time.

Public Comment: No public comment.

Board Decision: No action needed.

14. Adjourn: Meeting adjourned at 8:40 p.m.

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