Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
May 12, 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:

Clayton English, PharmD	Margot Kagan, PharmD	Patricia King, MD
Zail Berry, MD	Bill Breen, RPh	Renee Mosier, PharmD
Louise Rosales, NP	Claudia Berger, MD	Joseph Nasca, MD
Marc Pasanen, MD	Doug Franzoni, PharmD	

Absent:

Staff:

Laurie Brady, RPh, Change HealthCare	Mike Ouellette, RPh, Change Healthcare	Jacquelyn Hedlund, MD, Change Healthcare
Stacey Baker, DVHA	Lisa Hurteau, PharmD, DVHA	Scott Strenio, MD, DVHA
Nancy Hogue, Pharm D, DVHA	Jason Pope, DVHA	

Guests:

Adam Denman	Linda Burns	Jai Persico
Bryan Dillion	Tammy Kell	Dr. Matthew Gilbert
Donna Burkett, MD	Paul Isikwe	Morgan Bron
Joe Miller	Richard Angelli	

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 April meeting minutes were accepted as printed.

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

- No updates at this time.

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

- Vermont is working diligently to get TeleHealth and TeleMedicine up and running.

5. Follow-up Items from Previous Meetings: Laurie Brady, RPh, Change Healthcare

- None at this time.

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

Introduction of RetroDUR: PrEP Therapy to Prevent HIV in At-risk Populations

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 (an NSTI) and emtricitabine (an integrase inhibitor), or Descovy (tenofovir alafenamide and emtricitabine), if the patient has renal insufficiency. Change Healthcare will use 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 will identify members getting either Truvada or Descovy, in the absence of another antiretroviral medication, and examine 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 will see if HIV testing, Creatinine and pregnancy testing was done at 3 months intervals, as recommended in guidelines. Adherence rates will also be monitored, with over 80% days covered considered adequate adherence.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None needed.

Data presentation: Concurrent Use of Opioids and Benzodiazepines

Change Healthcare used paid, non-reversed Medicaid pharmacy and medical claims from calendar year 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified members, excluding those with a cancer diagnosis, who were prescribed an opioid for at least 90 days (within a 180-day span), and examined how many were given an overlapping prescription for a benzodiazepine along with continued use of the opioid. They also examined whether the member had any hospital admissions or ED visits due to respiratory depression, over-sedation, accidents or death, and whether the provider of the opioid and benzodiazepine was the same or different.

There were 1,689 members prescribed at least 90 days of an opiate. 551 (33%) had an overlapping Benzodiazepine script, and 1,137 (67%) had no overlapping Benzodiazepine script. Of the 551 members with an overlapping Benzodiazepine script, 425 (77%) had an overlap of more than 30 days.

In 2017 and 2018 combined, the total inpatient hospital/ED visits were 1204, compared with 412 for the year 2019. The distinct member count was 444 in the combined years, compared with 177 in 2019. In the combined years, 40% of the members on overlapping opioids and benzos had ER visits and/or admissions, compared with 32% in the year 2019.

Recommendation: While it is encouraging that the number of members on opiates for more than 90 days was lower in 2019 than in combined 2017 and 2018, and the percentages of those on overlapping benzodiazepines was also lower, there was still a significant number of members on more than 30 days of a benzodiazepine while also on chronic opioids. Additionally, there are some members with a high number of hospital admissions and/or ED visits. Targeted chart reviews of these members and outreach to prescribers will likely be the most effective intervention to examine the cause of the visits, whether the overlap of the medications was appropriate and worth the risk.

Public Comment: No public comment.

Board Decision: The Board approved the recommendation to outreach prescribers of patients exceeding 10 ER/hospital visits in 2019. They also were interested in the members' total daily dose for both the opiate and the benzodiazepine and asked for DVHA to explore whether these members could be added to the Vermont Chronic Care Initiative (VCCI).

Data presentation: Blood Pressure Medication Adherence and Long-term NSAID Use in Chronic Kidney Disease

Chronic kidney disease (CKD) is epidemic in the United States with an estimated 15% of the adult population (37 million) affected, per the CDC as of July 2019. CKD is an independent risk factor for cardiovascular disease, including stroke, CAD and death. There are many causes of kidney disease, including diabetes, hypertension (HTN), hyperlipidemia, inflammatory conditions and drug toxicities, and it is estimated that 80-95% of those with CKD have

concurrent hypertension. Many of those with CKD will have multiple risk factors. Additionally, early CKD often goes undetected until the estimated glomerular filtration rate falls below 60mL/min per 1.73m2 (stage 3a), when there has been mild to moderate loss of kidney function, minimally 40%. The degree of albuminuria is also a key factor in staging CKD and is a marker of damage to the nephrons. It is recognized that controlling hypertension can slow the progression of disease and decrease albuminuria, and there are guidelines for treatment that take into account the baseline blood pressure, stage of disease, presence or absence of albuminuria. Kidney Disease Improving Global Outcomes (KDIGO) 2012 guidelines used eGFR, presence or absence of DM and degree of albuminuria to determine both BP goals and recommended drug therapy to treat HTN. In general, first line therapies for treating HTN in CKD are ACE inhibitors and ARBs, regardless of whether there is albuminuria. If edema is present, loop diuretics are recommended and calcium channel blockers are recommended as second- or third- line therapy when additional therapy is needed to reach the target blood pressure (in most cases SBP <130, DBP<80). Change Healthcare used paid, non-reversed Medicaid pharmacy and medical claims from SFY 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified members with Stage 3 or later CKD, including members on dialysis, and stratified each stage into those with and without hypertension. In each group, they identified those on antihypertensive medications, including ACE, ARB, loop diuretics and CCB medications, and medication possession ratio (MPR) was evaluated to assess compliance.

Recommendation: More than 70% of members with CKD and hypertension had an MPR of 80% or greater. There were a few members with CKD without hypertension on medication, but those on an antihypertensive were generally compliant. There are significant numbers of members with hypertension and stage 3 CKD and unclassified stage who are not taking antihypertensive medications, which is concerning as hypertension left untreated will accelerate the decline in renal function. A random chart review might help define a group of providers who would benefit from targeted education or reveal reasons for lack of antihypertensive medications.

Public Comment: No public comment.

Board Decision: The Board unanimously approved sending a general education letter. They added that if the data is shared, it is important to mention that it reflects only a subset of a prescriber's population.

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

Biosimilar Drug Reviews:

- Ziextenzo® (pegfilgrastim-bmez)

Defer until Colony Stimulating Factors Therapeutic Class Review.

Full New Drug Reviews:

- Annovera® (segesterone acetate & ethinyl estradiol vaginal system)

Defer until Contraceptive Products Therapeutic Class Review.

- Gloperba® (colchicine)

Colchicine, the active ingredient of Gloperba®, is an alkaloid obtained from various species of Colchicum. It is postulated that colchicine works due to its ability to block neutrophil-mediated inflammatory responses induced by monosodium urate crystals in synovial fluid. Colchicine disrupts the polymerization of β-tubulin into microtubules, thus preventing the activation, degranulation, and migration of neutrophils to sites of inflammation. Colchicine also interferes with the inflammasome complex found in neutrophils and monocytes that mediates interleukin-1β (IL-1β) activation. It is indicated for prophylaxis of gout flares in adults. The safety and effectiveness of Gloperba® for acute treatment of gout flares during prophylaxis has not been studied. Gloperba® is not an analgesic medication and should not be used to treat pain from other causes. The evidence for the efficacy of colchicine in patients with chronic gout is derived from published literature. There are 2 studies that assessed the efficacy of colchicine 0.6mg BID for the prophylaxis of gout flares in patients with gout starting treatment with urate-lowering therapy. In both studies, colchicine treatment decreased the frequency of gout flares. Gloperba® is the first liquid formation FDA approved for this indication. This dosage form allows for dose reductions if needed for drug interactions or renal or hepatic impairment.

<u>Recommendation:</u>

- Add Gloperba® (colchicine) oral solution QTY LIMIT: 10 ml/day to non-preferred.
  - Clinical criteria
    - Add Gloperba: Medical necessity for a specialty dosage form has been provided.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Rybelsus® (semaglutide)

Semaglutide, the active ingredient of Rybelsus®, is a glucagon-like peptide-1 (GLP-1) receptor agonist. It is a GLP-1 analogue with 94% sequence homology to human GLP-1 that selectively binds to and activates the GLP-1 receptor, the target for native GLP-1. Semaglutide has a long half-life (elimination half-life of 1 week) and the main mechanism of protraction resulting in the long half-life of semaglutide is albumin binding, which results in decreased renal clearance and protection from metabolic degradation. In addition, semaglutide is stabilized against degradation by the DPP-4 enzyme. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM). The safety and efficacy of Rybelsus® have been studied as monotherapy and in combination with metformin, sulfonylureas, sodium-glucose co-transporter-2 (SGLT-2) inhibitors, insulins, and TZDs in

patients with type 2 DM. The efficacy of Rybelsus® was compared with placebo, empagliflozin, sitagliptin, and liraglutide. In addition, Rybelsus® has been studied in patients with type 2 DM with mild and moderate renal impairment. In clinical trials, Rybelsus® resulted in clinically significant reductions from baseline in HbA1c as compared with placebo. In a clinical trial compared with subcutaneous liraglutide, an injectable GLP-1 receptor agonist, treatment with Rybelsus® resulted in non-inferior reductions in HbA1c. However, in clinical trials compared with other orally active drugs, such as sitagliptin 100mg and empagliflozin 25mg, Rybelsus® 14mg resulted in a statistically significantly greater reduction in HbA1c.

Recommendation:

- Add Rybelsus® (semaglutide) QTY LIMIT: 1 tablet/day to non-preferred.
- Move TRULICITY® (dulaglutide) QTY LIMIT: 6ml/84 days to preferred.
    - Clinical criteria
        - Add Ryblesus: patient has a diagnosis of type 2 diabetes AND patient is at least 18 years of age AND patient has had a documented side effect, allergy, contraindication or treatment failure with metformin AND patient has a documented side effect, allergy, contraindication, or treatment failure with at least one preferred GLP-1 Receptor Agonist and one preferred SGLT2 inhibitor.
        - Remove Trulicity from clinical criteria.

Public Comment: Tammy Kell, PharmD Medical Account Associate Director from Novo Nordisk: Highlighted the attributes of Rybelsus.
Dr. Matthew Gilbert, DO Endocrinologist from UVMMC: Noted that Rybelsus removes the barrier of injection which can be a concern in patients with sight or dexterity issues. He also noted that it can be difficult to teach patients how to properly use on injectable product via telephonic/video consultations.

Board Decision: The Board unanimously approved the above recommendation with the addition to clinical criteria that a preferred GLP-1 receptor agonist trial will not be required if there is a clinically valid reason patient is unable to administer an injection (e.g. visual impairment or impaired dexterity).

- Slynd® (drospirenone)

Defer until Contraceptive Products Therapeutic Class Review.

- Tovet® foam (clobetasol propionate/emoll)

Clobetasol propionate, the active ingredient of Tovet® Foam, is a synthetic corticosteroid for topical use. Clobetasol, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action in corticosteroid-responsive dermatoses is not known. It is indicated for the treatment

of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 12 years and older. A randomized trial included subjects 12 years of age and older with moderate to severe atopic dermatitis who were randomized to clobetasol propionate foam, 0.05% (emulsion; N=251) or vehicle foam (N=126) twice daily for 2 weeks. At the end of treatment, 52% treated with clobetasol propionate foam, 0.05% (emulsion) achieved treatment success as compared with 14% treated with vehicle foam. Treatment success was defined by an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear (1) with at least 2 grades improvement from baseline, and scores of absent or minimal (0 or 1) for erythema and induration/papulation. Clobetasol propionate foam, 0.05% (emulsion) was found in clinical trials to be more effective as compared with vehicle for treatment success. Olux®-E, another clobetasol propionate foam (emollient), has the same indication as Tovet® Foam and has an available generic.

Recommendation:

- Add Tovet® (clobetasol propionate aerosol) 0.05% F to non-preferred.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- Vumerity® (diroximel fumarate)

The mechanism by which diroximel fumarate, the active ingredient of Vumerity®, exerts its therapeutic effect in multiple sclerosis is not known. Monomethyl fumarate (MMF) is the active metabolite of diroximel fumarate, and it has been shown to activate the nuclear factor (erythroid-derived 2)- like 2 (Nrf2) pathway. The Nrf2 pathway is involved in the cellular response to oxidative stress. After oral administration of Vumerity®, diroximel fumarate undergoes rapid pre-systemic hydrolysis by esterases and is converted to its active metabolite, monomethyl fumarate (MMF). Diroximel fumarate is not quantifiable in plasma after oral administration of Vumerity®. 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 efficacy of Vumerity® is based upon bioavailability studies in patients with relapsing forms of MS and healthy subjects comparing oral dimethyl fumarate delayed-release capsules to Vumerity® delayed-release capsules.

Recommendation:

- Add Vumerity® (diroximel fumarate) capsule QTY LIMIT: 4 capsules/day to non-preferred.
  - Clinical criteria
    - Add Vumerity: Patient is ≥ 18 years AND has a diagnosis of relapsing forms of Multiple Sclerosis AND the patient has a documented side effect, allergy, treatment failure, or contraindication to at least two preferred drugs and Tecfidera.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review:

- **Alpha- 1 Protease inhibitors**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- No changes at this time.

Public Comments: No public comment

Board Decision: No action needed.

- **Antibiotics: GI &Related**
  - No new drugs.
  - Metronidazole indicated only for initial mild-moderate cases of C. Difficile associated diarrhea (CDAD).

Recommendation:

Vancomycin

- Clinical criteria:
  - Revise Criteria for Approval: patient's diagnosis or indication is Clostridium Clostridium difficile associated diarrhea (CDAD) AND For approval of brand Vancocin, the patient must meet the above criteria and have a documented intolerance to the generic.

Rifamycins:

- Clinical criteria:
  - Revise Small Intestinal Bacterial Overgrowth (Xifaxan 550 mg or 200 mg Tablets): patient has a diagnosis of SIBO AND Quantity limit is 1,200 mg/day.1,200mg to 1,650mg/day, maximum of 14 days.
  - Remove Inflammatory Bowel Disease: Ulcerative Colitis (Xifaxan 200 mg Tablets) clinical criteria.
  - Revise Clostridium difficile Diarrhea (Xifaxan 200 mg Tablets): patient has a diagnosis of C. difficile diarrhea. AND Patient has had a

documented side effect, allergy, treatment failure or contraindication to vancomycin AND Quantity limit is 1200mg/day.

Macrolides:

- Clinical criteria:
- Revise Dificid: patient's diagnosis or indication is Clostridium difficile associated diarrhea (CDAD) AND patient has had a side-effect, allergy, treatment failure or contraindication to oral vancomycin.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Antibiotics: Topical**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- No changes at this time.

Public Comments: No public comment

Board Decision: No action needed.

- **Anti- Parasitics**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move Albenza® (albendazole) to non-preferred. Add Albendazole (compare to Albenza®) to preferred.
  - Clinical criteria:
    - Add Albenza to the Stromectol criteria.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Benign Prostatic Hyperplasia (BPH) Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move Dutasteride (compare to Avodart®) QTY LIMIT: 1 capsule/day to preferred.
- Add Silodosin (compare to Rapaflo®) QTY LIMIT: 1 tablet/day to non-preferred.

- Remove Uroxatral® (alfuzosin) from the PDL.
  - Clinical criteria:
    - Revise Rapaflo, Silodosin: The patient has had a documented side effect, allergy or treatment failure with two preferred alpha blockers.
    - Revise Avodart, Proscar: The patient has a documented intolerance to the generic equivalent.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Contraceptive Products**
  - New drug Annovera: Annovera® is a vaginal system that contains a progestin (segesterone acetate) and an estrogen (ethinyl estradiol). Combination hormonal contraceptives (CHCs) lower the risk of becoming pregnant mainly by suppressing ovulation. It is indicated for the use by females of reproductive potential to prevent pregnancy. Annovera® has not been adequately studied in females with a BMI >29kg/m2. (The study that supported approval removed women with BMI >29Kg/m2 after 2 women experienced VTEs.) The efficacy of Annovera® was assessed in two 1-year multicenter studies (N=2265) that included females aged 18-40 years, who were healthy and sexually active with regular menstrual cycles. Two multicenter studies found Annovera® to be effective, with a pregnancy rate assessed by the Pearl Index of 2.98 per 100 woman-years of Annovera® use.
  - New drug Slynd: Drospirenone, the active ingredient of Slynd®, is for use as an oral contraceptive. Drospirenone is a spironolactone analogue with anti-mineralocorticoid activity. Slynd® is a progestin-only oral contraceptive that lowers the risk of becoming pregnant primarily by suppressing ovulation. It is indicated for use by females of reproductive potential to prevent pregnancy. The efficacy of Slynd® was assessed in a single-arm, multicenter clinical trial conducted in the US that included females (N=953) who were ≤35 years of age with 5,547 evaluable cycles. Combined oral contraceptives containing drospirenone and ethinyl estradiol may be associated with a higher risk of venous thromboembolism (VTE) than those containing some other progestins in combination with ethinyl estradiol. It is not known whether the risk of VTE is increased with drospirenone alone. However, if there is a risk, it is expected to be lower than that of drospirenone in combination with ethinyl estradiol. When assessed for efficacy in 953 females, 1.8% reported pregnancy.
  - No new significant clinical changes.

Recommendation:

Monophasic Agents:

- Remove Brevicon 28 (norethindrone/ethinyl estradiol), Gildesse FE (norethindrone/ ethinyl estradiol/FE) , Junel FE 24 (norethindrone/ethinyl estradiol/FE) , LoMedia FE (norethindrone/ ethinyl estradiol/FE), Microgestin FE (norethindrone/ethinyl estradiol/FE), Norinyl 1/35(norethindrone/ethinyl estradiol) , Ovcon 35/28(norethindrone/ethinyl estradiol) , Rajani(drospirenone/ethinyl estradiol/levomefol) , Zenchent FE (norethindrone/ethinyl estradiol/FE), Zovia 1-50 (ethynodiol D/ ethinyl estradiol from the PDL.
- Add Beyaz(drospirenone/ethinyl estradiol/levomefol), Kaitlib (norethindrone/ethinyl estradiol/FE), Layolis FE (norethindrone/ethinyl estradiol/FE), Melodetta FE (drospirenone/ethinyl estradiol/levomefol), Mibelis FE (norethindrone/ethinyl estradiol/FE), Sayfral (drospirenone/ethinyl estradiol/levomefol), and Wymza FE (norethindrone/ethinyl estradiol/FE) to non-preferred.

Biphasic Agents:

- Move Azurette (desogestrel/ethinyl estradiol) to preferred.
- Remove Necon 10/11-28 (norethindrone/ ethinyl estradiol) from the PDL.
- Add Simliya (desogestrel/ ethinyl estradiol) and Volnea (desogestrel/ ethinyl estradiol) to preferred.

Triphasic Agents:

- Add Tri-Femynor (norgestimate/ ethinyl estradiol), TRI-VYLIBRA (norgestimate/ ethinyl estradiol), TRI-VYLIBRA LO (norgestimate/ ethinyl estradiol) to preferred.
- Move Tilia FE (norethindrone/ethinyl estradiol/FE), Tri-Legest FE (norethindrone/ethinyl estradiol/FE) to non-preferred.
- Add Estrostep FE (norethindrone/ethinyl estradiol/FE) to non-preferred.
- Remove Cyclessa (desogestrel/ ethinyl estradiol), MYZILRA (levonorgestrel/ ethinyl estradiol), NECON 7/7/7 (norethindrone/ethinyl estradiol), TRINESSA (norgestimate/ ethinyl estradiol), TRINESSA LO (norgestimate/ethinyl estradiol) from the PDL.

Extended Cycle:

- Move Amethia (levonorgestrel/ ethinyl estradiol) and Daysee (levonorgestrel/ ethinyl estradiol) to preferred.

- Add Jaimiess (levonorgestrel/ ethinyl estradiol), Simpesse (levonorgestrel/ ethinyl estradiol) and Setlakin (levonorgestrel/ethinyl estradiol) to preferred.
- Remove Quasense (levonorgestrel/ ethinyl estradiol 3MTH) from the PDL.

Progestin Only Contraceptives:

- Add Incassia (norethindrone), Norlynda (norethindrone) and Tulana (norethindrone) to preferred.
- Add Ortho Micronor (norethindrone) and Slynd (drospirenone) to non-preferred.
    - Clinical criteria:
        - Add Non-preferred agents: Trial with at least three preferred contraceptive products including the preferred formulation of the requested non-preferred agent.

Injectable Contraceptives:

- Clinical criteria:
    - Add Depo-Provera IM: Patient must have a documented intolerance to medroxyprogesterone acetate 150mg.

Vaginal Ring:

- Add Annovera (segesterone acetate/ethinyl estradiol vaginal ring) QTY LIMIT = 1 ring/year to non-preferred.
    - Clinical criteria:
        - Add Non-preferred agents: Trial with at least three preferred contraceptive products including the preferred formulation of the requested non-preferred agent.

Emergency Contraceptives:

- Add My Choice (levonorgestrel) and New Day (levonorgestrel) to preferred.
- Remove Fallback Solo (levonorgestrel), Next Choice (levonorgestrel), Ella (ulipristal) and React (levonorgestrel) from the PDL.

Public Comments: Donna Burkett, MD Medical Director for Planned Parenthood of Northern New England: Highlighted the attributes of Annovera, specifically that it gives women the ability to have 12-months of contraception on-hand, thereby eliminating trips to

the pharmacy. DVHA and Change Healthcare staff noted that all contraceptives can be dispensed for 12 months if the prescription is written accordingly, and no overrides are needed.

Board Decision: The Board unanimously approved the above recommendation.

- **Colony Stimulating Factor Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move Neulasta® (pegfilgrastim) Syringe to preferred.
- Add Neulasta® Onpro® (pegfilgrastim) kit to preferred.
- Move Granix® (tbo-filgrastim) Syringe to non-preferred.
- Add Ziextenzo® (pegfilgrastim-bmez) to non-prefered.
  - Clinical criteria:
    - Add Granix Syringe and Ziextenzo to the clinical criteria.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

Public Comments: No public comment

- **Erythropoietic Stimulating Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation: No changes at this time.

Public Comments: No public comment

Board Decision: No action needed.

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

Recommendation:

- Remove Condylox® solution (podofilox solution) from the PDL.
- Add Imiquimod (compare to Zyclara®) 3.75% Cream Pump QTY LIMIT: 2 pumps/ 8 weeks and Zyclara® 2.5% to non-preferred.
  - Clinical criteria:

- Add Imiquimod pump, Zyclara pump: The patient has had a documented intolerance to generic imiquimod cream and Zyclara cream.
- Add Zyclara cream to Aldara criteria.
- Remove the Condylox Solution criteria.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Idiopathic Pulmonary Fibrosis**
  - No new drugs.
  - Nintedanib (Ofev®) is also indicated to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Recommendation:

- Clinical criteria:
  - Revise Esbriet, Ofev: Age ≥ 18, Diagnosis of idiopathic pulmonary fibrosis (Esbriet and Ofev) OR chronic fibrosing interstitial lung disease or systemic sclerosis-associated interstitial lung disease (Ofev only), May not be used in combination with Ofev® or Esbriet® respectively, The prescriber is a pulmonologist, Clinical documentation that the member is a non-smoker or has not smoked in 6 weeks, FVC≥ 50% of predicted.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

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

Recommendation:

- Move Zortress® (everolimus) tablet to non-preferred with existing patients grandfathered.
- Add Everolimus (compare to Zortress®) tablet to non-preferred.
- Add Prograf® (tacrolimus) granules for suspension to non-preferred.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Movement Disorders**
    - No new drugs.
    - American Academy of Neurology (AAN), updated recommendation in 2018. Recommendations include that deutetrabenazine and valbenazine are effective treatments and "...must be recommended as treatment for tardive dyskinesia." In addition, clonazepam and Ginkgo biloba probably improve tardive dyskinesia and should be considered.

Recommendation:

- Move Tetrabenzaine (compare to Xenazine®) QTY LIMIT: 50 mg/day at initial approval (12.5 mg tablets ONLY), up to 100 mg/day at subsequent approvals (12.5 mg or 25 mg tablets) Maximum 1-month supply per fill to preferred after clinical criteria are met.
- Move Xenazine® tablets (tetrabenazine) QTY LIMIT: 50 mg/day at initial approval (12.5 mg tablets ONLY), up to100 mg/day at subsequent approvals (12.5 mg or 25 mg tablets) Maximum 1-month supply per fill to non-preferred.
    - Clinical criteria:
        - Revise Austedo: The patient is ≥ 18 years of age AND The diagnosis or indication for the requested medication is Huntington's Disease (HD) with chorea or Tardive Dyskinesia (TD) AND the results of an Abnormal Involuntary Movement Scale (AIMS) exam have been submitted AND the patient has a documented side effect, allergy, contraindication or treatment failure with tetrabenazine. For re-approval, a 30% improvement from baseline in the AIMS score must be documented.
        - Revise Ingrezza: The patient is ≥ 18 years of age AND the diagnosis or indication for the requested medication is Tardive Dyskinesia (TD) AND the results of an Abnormal Involuntary Movement Scale (AIMS) exam have been submitted AND the patient has a documented side effect, allergy, contraindication or treatment failure with tetrabenazine. For re-approval, a 30% improvement from baseline in the AIMS score must be documented.
        - Add Tetrabenazine, Xenazine: The diagnosis or indication for use is Tourette Syndrome OR the diagnosis or indication for use is Huntington's Disease (HD) with Chorea or Tardive Dyskinesia (TD) AND the patient is ≥18 years of age AND for approval of Xenazine, the patient must have a documented intolerance to tetrabenazine.

Public Comments: Paul Isikwe, PharmD Medical Outcomes Liaison from Teva Pharmaceuticals: Highlighted the attributes of Austedo.
Morgan Bron, PharmD Senior Managed Care Liaison from Neurocrine Biosciences: Highlighted the attributes of Ingrezza.

Board Decision: The Board unanimously approved the above recommendation.

- **Urinary Antispasmodics**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Gelnique 3%® (oxybutynin topical gel) from the PDL.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

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

Recommendation:

- Remove Metrogel Vaginal® (metronidazole vaginal gel 0.75%) from the PDL.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

10. Review of Newly Developed/Revised Criteria

- None at this time.

Recommendation:

- No changes at this time.

Public Comment: No public comment

Board Decision: None needed.

11. General Announcements: Michael Ouellette, RPh, Change Healthcare

- None at this time.

Public Comment: No public comment.

Board Decision: No action needed.

12. Adjourn: Meeting adjourned at 8:30 p.m.