Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
May 7, 2019

Board Members:

Present:

Bill Breen, RPh	Jocelyn Van Opdorp, PharmD	Louise Rosales, NP
Zail Berry, MD	Margot Kagan, PharmD	Claudia Berger, MD
Patricia King, MD	Marc Pasanen, MD	Joseph Nasca, MD

Absent: Renee Mosier, PharmD, Clayton English, PharmD

Staff:

Laurie Brady, RPh, Change HealthCare	Stacy Baker, DVHA	Jeffrey Barkin, MD, Change Healthcare
Jason Pope, DVHA	Mike Ouellette, RPh, Change Healthcare	Lisa Hurteau, PharmD, DVHA
Scott Strenio, MD, DVHA	Danielle Carpenter, PharmD, Change Healthcare	Nancy Hogue, PharmD, DVHA

Guests:

Roxann Stubbs, Abbvie	Erica Hintzes, Allergan	Andrew Weis, Abbott
Joseph Miller, Novo Nordisk	Laurie Williams, Gilead	Jane Guo, Otsuka
Linda Burns, Abbott	Alex Felizendo, Otsuka	

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:

- Introductions were made around the table.
- The April meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Lisa Hurteau, PharmD DVHA

- Welcomed a new board member, Dr. Pasanen.

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

- No update at this time.

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

- None at this time.

6. RetroDUR/DUR: Laurie Brady, RPh, Change Healthcare,

- **Introduce: Use of Gabapentin**

The use gabapentin tripled between 2001 and 2015. While the labeled indications for gabapentin include control of seizures and pain associated with post-herpetic neuralgia, off-

label uses include diabetic neuropathy, fibromyalgia, essential tremor, panic disorder, hot flashes associated with menopause or breast cancer treatment, social phobia, nystagmus, orthostatic tremor and migraine prophylaxis. For each indication the recommended doses of gabapentin vary. Additionally, the adverse effect profile of gabapentin, especially in higher doses, is significant. The FDA is currently evaluating the use of gabapentinoids in patients on opioids and other CNS depressants as adverse reactions, including respiratory depression and death, are substantial. A Canadian hospital study showed that patients co-prescribed gabapentin and opioids were 49% more likely to experience an opioid-related death and Canada has required an updated package insert to include information about the risks of respiratory depression, syncope, profound sedation and death with co-prescribing of opioids and gabapentin. Doses of greater than 3,000mg daily pose the highest risk, but increased risk is noted between moderate dose (900-1799mg/day) and high dose (greater than 1800mg/day). There is no indication for doses greater than 3600mg total daily dose. Additionally, gabapentin is now recognized as a drug with abuse potential and street value. While not a controlled substance in the US now, the DEA may in the future change that, as it has pregabalin.

Change Healthcare will use paid, non-reversed Medicaid pharmacy claims from January 2018 through March 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. They will identify members on a stable dose of gabapentin for the entirety of 1 year and examine how many are refilling prescriptions early, perhaps taking a higher daily dose than prescribed, or for diversion. By starting our search in January of 2018 but evaluating use from 4/1/18-3/31/19, the intention is to minimize the effect of the dose escalation often done before the patient reaches control of symptoms so that we are only looking at consistent dosing per prescription. Searching the top diagnoses for each member will help identify members who may be getting gabapentin without an appropriate indication. They will independently search to see how many members on continual gabapentin have a substance abuse disorder or a diagnosis of depression and/or anxiety. Additionally, we will identify those on more than 3000mg/day and those who are taking concurrently an opiate or MAT medication. We will also stratify into cohorts of low (up to 899mg/day), intermediate (900-1799mg/day) and high (greater than 1800mg/day) dosages to get a sense of how prescribers are using gabapentin.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: The board requested that the dose breakdowns be 1800-2400mg, 2401-3600mg, and >3600mg. They did not feel the need to look at doses lower than 1800mg. They felt it was worthwhile to look for concomitant substance abuse disorder or a diagnosis of depression and/or anxiety, but noted there is no need to pull additional diagnoses due to the numerous off label uses for gabapentin and the inability to know for sure which diagnosis gabapentin was being used for.

- **Data presentation: Evaluation of Opioid Prescribing for Chronic Pain**

Chronic opioid use has become endemic and the societal problems of substance abuse and deaths related to opioids are devastating in the United States. Patients can become addicted to opioids very quickly, even at low doses. Although overdose may occur at any opioid dose, higher doses are associated with higher risk of overdose and death. Opioid doses ≥ 100 morphine milligram equivalents (MME) per day increase overdose risk by nine times compared with dosages between 0 and 20 MME. It has been well identified that for many types of pain, opioids are not necessary or, in some cases, particularly effective. National efforts to stem the prescriptions of opioids are underway, including better patient and physician education around pain management, prescription drug monitoring programs and quantity limits on narcotics. Problems of diversion, misuse, selling and stockpiling narcotics are well known issues that plague the use of these medications today.

Change Healthcare used paid, non-reversed Medicaid pharmacy claims from calendar year 2017 and compare them with those of calendar year 2018, excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified members on any opioid medication (short or long acting) for greater than 90 days and stratify into those on a combined daily dose of ≥ 100MME, ≥200MME and ≥ 300MME, excluding members with diagnoses of cancer or mat. They also looked at the prescribing patterns geographically.

Number of members on any opioid medication (short or long acting) for greater than 90 days within the selected year.

CALENDAR_YEAR	MEMBER_COUNT
2017	2348
2018	2070

Stratification of members above by MME

AVG_DAILY_MME	2017 MEMBER_COUNT	2018 MEMBER_COUNT	PCT Change
< 100	2,029	1,778	-12.37%
>= 100	226	214	-5.31%
>= 200	53	46	-13.21%
>= 300	38	27	-28.95%

Members with 2 different distinct short acting opioids with no long acting opioid on file. These are members that had 90-day supply or greater within the calendar year with at least 30 days overlap of both opioids.

CALENDAR_YEAR	MEMBER_COUNT
2017	202
2018	176

Members on 2 different distinct long- acting opioids. As above, these members had 90 -day supply or greater within the calendar year with at least a 30 day overlap of both opioids.

CALENDAR_YEAR	MEMBER_COUNT
2017	6
2018	3

Geographic breakdown of average MME for members on opioids for greater than 90 days

Prescriber County	2017 AVERAGE_DAILY_MME	2018 AVERAGE_DAILY_MME	PCT Change
Addison	68.27	70.33	3.03%
Bennington	55.76	57.58	3.28%
Caledonia	57.23	56.65	-1.02%
Chittenden	84.88	85.28	0.47%
Essex	99.28	101.84	2.58%
Franklin	76.50	76.26	-0.32%
Grand Isle	70.16	68.64	-2.17%
Lamoille	61.10	63.90	4.59%
Orange	40.42	40.70	0.69%
Orleans	44.84	45.63	1.77%
Rutland	63.62	64.25	0.99%
Washington	51.13	52.16	2.01%
Windham	66.56	66.65	0.14%
Windsor	43.37	43.01	-0.82%

Recommendation: Additional data will be collected. For members on 2 different short acting opioids, the medications being used in this situation will be determined. A detailed look at the member profiled should be completed for those identified as being on 2 different long acting opioids. Member count and MME count per member will be analyzed to determine if only a select few members are bringing up the averages.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

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

Biosimilar Drug Reviews:

a) Nivestym® (filgrastim-aafi)

Recommendation:

- Defer until after the Udenyca review.

Public Comment: None at this time.

Board Decision: None needed.

b) Udenyca® (pegfilgrastim-cbqv)

Recommendation:

- Add Nivestym™ (filgrastim-aafi) Vial, Syringe to non-preferred.
- Add Udenyca™ (pegfilgrastim-cbqv) to preferred.
  - Clinical criteria

- Add Nivestym to the Leukine, Neulasta, Neupogen syringe, Zarxio syringe clinical criteria.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews:

a) Abilify® Mycite (aripiprazole with sensor)

Aripiprazole, the active ingredient of Abilify® Mycite, is an atypical antipsychotic. While the mechanism is not known, it is thought to be mediated through a combination of partial agonist activity at the D2 and 5-HT1A receptors as well as antagonist activity at 5-HT2A receptors. Abilify® Mycite, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to tract drug ingestion, is indicated for the

- treatment of adults with schizophrenia
- Treatment of bipolar 1 disorder
  - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate
- Adjunctive treatment of adults with Major Depressive Disorder (MDD)

The ability of the Abilify® Mycite to improve patient compliance or modify aripiprazole dosage has not been established. In addition, the use of Abilify® Mycite to track drug ingestion in 'real-time' or during an emergency is not recommended as detection may be delayed or not occur. Aripiprazole tablets are embedded with an ingestible event marker (IEM) sensor, which upon contact with gastric fluid, magnesium and cuprous chloride within the IEM react to activate and power the device. The IEM then communicates to the Mycite patch, to track aripiprazole ingestion. A Mycite patch (wearable sensor) is designed to detect the ingestion of the Abilify® Mycite tablet, record the ingestion of the IEM and transmit ingestion data to the mobile patient application. The data on the mobile application can be shared with healthcare providers and caregivers. There is also a web-based portal for healthcare professionals and caregivers. The studies in the Abilify® Mycite clinical trials section were the same as in the clinical trials section of Abilify® tablets, with the exception of the pediatric trials, as Abilify® Mycite is not indicated for the pediatric population.

Recommendation:

- Add Abilify® Mycite (aripiprazole tablets with sensor) with Quantity limit = 1 tab/day to non-preferred.

- Clinical criteria:
    - Abilify Mycite: The patient has not been able to be adherent to aripiprazole tablets resulting in significant clinical impact (documentation of measures aimed at improving compliance is required) AND there is a clinically compelling reason why Abilify Maintena or Aristada cannot be used. Initial approval will be granted for 3 months. For renewal, documentation supporting use of the tracking software must be provided and pharmacy claims will be evaluated to assess compliance with therapy.
    - Update Rexulti criteria for adjunct treatment of Major Depressive Disorder (MDD): the patient has had a documented inadequate response to at least 3 different antidepressants from two different classes AND the patient has had a documented side effect, allergy or treatment failure with two preferred atypical antipsychotic product being used as adjunctive therapy, one of which must be aripiprazole.

Public Comment: Jane Guo from Otsuka: Highlighted the attributes of Abilify® Mycite.

Board Decision: The Board unanimously approved the above recommendation.

b) Cequa® (cyclosporine)

Cyclosporine, the active ingredient of Cequa®, is a topical ophthalmic solution. When cyclosporine is administered systemically, it is a calcineurin inhibitor immunosuppressant agent. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, topical administration of cyclosporine is thought to act as a partial immunomodulator; however, the exact mechanism of action is not known. It is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye). The efficacy of Cequa® was assessed in 2 multicenter, randomized, well-controlled studies that included adults with keratoconjunctivitis sicca (N=1048). In both studies, Cequa® was compared to vehicle. Results suggested that at day 84, there was a statistically significantly higher percentage of eyes with increases of ≥10mm from baseline in Schirmer wetting. This effect was seen in about 17% of the Cequa®-treated group as compared with 9% of the vehicle-treated group. There is no evidence found to suggest Cequa® is safer or more effective than other currently preferred, more cost-effective medications, including artificial tears.

Recommendation:

- Add Cequa® (cyclosporine ophthalmic solution) 0.09% to non-preferred.
    - Clinical criteria:
        - Add Cequa to the Xiidra clinical criteria.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation.

c) Inveltys® (loteprednol etabonate)

Loteprednol etabonate, the active ingredient of Inveltys®, is a corticosteroid. Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. It is indicated for the treatment of post-operative inflammation and pain following ocular surgery. The efficacy of Inveltys® was assessed in 2 multicenter, randomized, double-masked, placebo-controlled studies where patients with an anterior cell grade ≥2 after cataract surgery were randomized to Inveltys® or placebo after surgery. Compared with vehicle, a significant benefit was seen with Inveltys® regarding complete resolution of ocular inflammation (at days 8 and 15) and complete resolution of pain (at days 4, 8, and 15). Lotemax® products carry the same indication as Inveltys®. All Lotemax® dosage forms are to be administered 4 times daily. Inveltys® is to be administered twice daily. There is no evidence to support that Inveltys® is safer or more effective than the other preferred, more cost-effective medications, including other lower cost formulations of loteprednol.

<u>Recommendation</u>:

- Add Inveltys® (loteprednol) suspension to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Nocdurna® (desmopressin acetate)

Desmopressin acetate, the active ingredient of Nocdurna®, is a synthetic analogue of the endogenous pituitary hormone, 8-arginine vasopressin, an antidiuretic hormone (ADH). The effects of desmopressin are mediated by stimulation of vasopressin 2 (V2) receptors, thus increasing water reabsorption in the kidneys and reducing urine production. It is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. (Nocturnal polyuria was defined in the Nocdurna® clinical trials as nighttime urine production exceeding one-third of the 24-hour urine production.) Before starting treatment, evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and address other treatable causes of nocturia. Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously. The safety and efficacy of Nocdurna® were assessed in two 3-month, randomized, double-blind, placebo-controlled, multicenter studies that included adults ≥18 years of age with

nocturia due to nocturnal polyuria. Many conditions can cause nocturia; the safety and efficacy of Nocdurna® have not been established for the treatment of all causes of nocturia. Nocdurna® is indicated only for patients who have nocturia due to nocturnal polyuria. There is no evidence that Nocdurna® is safer or more effective for nocturnal polyuria than other less costly formulations of desmopressin.

Recommendation:

- Add Nocdurna® (desmopressin acetate) SL tablets with Qty limit = 1 tablet/day to non-preferred.
- Remove Minirin (desmopressin) Nasal Spray 0.01% from the PDL.
    - Clinical criteria:
        - Add Nocdurna to Noctiva criteria, noting that the Patient age requirement is ≥ 18 years of age (Noctiva remains ≥ 50 years).

Public Comment: from: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Siklos® (hydroxyurea)

Hydroxyurea, the active ingredient of Siklos®, is an antimetabolite. The mechanisms by which Siklos® produces its benefits in patients with sickle cell anemia are not certain. Known effects of Siklos® which may contribute to its beneficial effects including increasing hemoglobin F levels in red blood cells (RBCs), decreasing neutrophils, increasing the water content of RBCs, increasing deformability of sickled cells, and altering the adhesion of RBCs to endothelium. The correlation between hydroxyurea concentrations, reduction of crisis rate, and increase in hemoglobin F is not known. It is indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises. The efficacy of Siklos® was assessed in the European Sickle Cell Disease Cohort study (ESCORT HU), which was an open-label single-arm study that included pediatric patients (N=405) from 2-18 years of age with sickle cell disease, of which 141 had not been previously treated with hydroxyurea prior to enrollment. In the ESCORT HU trial, Siklos® was found to reduce the incidence of some sickle cell related clinical events in the pediatric population for 12 months of treatment compared to the previous 12 months with no treatment. There is no evidence found to suggest Siklos® is safer or more effective than other currently preferred, more cost-effective medications.

Recommendation:

- Add new PDL category Sickle Cell Disease Therapies.
- Add Siklos® (hydroxyurea) 100mg, 1000mg tablet and Hydrea® (hydroxyurea) 500mg cap to non-preferred.
- Add Droxia® (hydroxyurea) 200mg, 300mg, 400mg cap and Hydroxyurea (compare to Hydrea®) 500mg cap to preferred.

- Clinical criteria
  - Siklos: Patient has a diagnosis of Sickle Cell Anemia with recurrent moderate to severe pain crises AND the required dose is < 200mg OR Patient has a diagnosis of Sickle Cell Anemia with recurrent moderate to severe pain crises AND has a documented intolerance to a preferred hydroxyurea formulation. For re-approval, the patient must have a documented decrease in vaso-occlusive episodes, acute chest syndrome, SCD related hospitalizations, or blood transfusions.
  - Hydrea: Patient has had a documented intolerance to the generic equivalent.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Tiglutik® (riluzole)

Riluzole, the active ingredient of Tiglutik®, is a member of the benzothiazole class. The exact mechanism of action by which riluzole exerts its therapeutic effects in patients with amyotrophic lateral sclerosis (ALS) is not known. It is indicated for the treatment of amyotrophic lateral sclerosis (ALS). The efficacy of Tiglutik® is based upon bioavailability studies comparing oral riluzole tablets to Tiglutik® oral suspension. The efficacy of riluzole was assessed in 2 studies that evaluated 50mg tablets BID in patients with ALS. Both studies included patients with either familial or sporadic ALS, disease duration of less than 5 years, and baseline forced vital capacity ≥60% of normal. Both studies were randomized, double-blind, placebo-controlled studies. Tiglutik® was approved on the basis of its similar bioavailability to riluzole tablets. While this preformulated thickened suspension may be more convenient than crushing riluzole tablets, which patients have been doing for some time, Tiglutik® is prohibitively priced at more than 30X the cost of riluzole tablets.

Recommendation:

- Add Tiglutik (riluzole) suspension and Rilutek® (riluzole) to non-preferred.
  - Clinical criteria:
    - Rilutek: patient must have a documented intolerance with riluzole.
    - Tiglutik**:** patient must be unable to take whole or crushed riluzole tablets.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

g) Xelpros® (latanoprost ophthalmic emulsion)

Latanoprost, the active ingredient of Xelpros®, is a prostaglandin F2α analogue. It is thought to reduce the intraocular pressure (IOP) by increasing the outflow of aqueous humor. Studies in humans and in animals suggest that the main mechanism of action is increased uveoscleral outflow. Elevated IOP is a major risk factor for glaucomatous field loss; the higher the IOP, the greater chance of optic nerve damage and visual field loss. It is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Xelpros® is a sterile, isotonic, buffered aqueous emulsion with potassium sorbate added as a preservative. Limited information was found in the clinical trials section for Xelpros®. In randomized, controlled clinical trials including patients with open angle glaucoma or ocular hypertension with mean baseline IOP of 23-26mmHg, the mean IOP-lowering effect of Xelpros® given once daily in the evening was up to 6-8mmHg. Latanoprost ophthalmic solution has been available for some time as both a brand and generic and found to be effective for lowering IOP; however, Xelpros® is the first and only benzalkonium chloride-free (BAK-free) form of latanoprost.

Recommendation:

- Add Xelpros (latanoprost) BAK Free to non-preferred.
  - Clinical criteria:
    - Add Xelpros to the Bimatoprost, Vyzulta, Xalatan, Zioptan clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

h) Xyosted® (testosterone enanthate)

Testosterone enanthate, the active ingredient of Xyosted®, is an ester derivative of the endogenous 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 the testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-

hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

The safety and efficacy of Xyosted® in adult males with 'age-related hypogonadism' (also referred to as 'late-onset hypogonadism') have not been established. The safety and efficacy of Xyosted® in males less than 18 years of age have not been established. In clinical studies, Xyosted® was found to deliver physiologic amounts of testosterone, producing circulating testosterone levels that approximate normal concentrations (of 300-1100ng/dL) in healthy men. There is no evidence found to suggest Xyosted® is safer or more effective than other currently preferred, more cost-effective medications.

Recommendation:

- Update category name to Testosterone Replacement Therapy.
- Add new sub-category Injectable.
- Add Aveed® (testosterone undecanoate) IM, Depo®-Testosterone (testosterone cypionate) IM, TESTOPEL® (testosterone) implant pellets and Xyosted™ (testosterone enanthate) SC to non-preferred.
- Add Testosterone Cypionate IM (compare to Depo®-Testosterone) and Testosterone Enanthate IM to preferred.
    - Clinical criteria:
        - Depo-Testosterone: The patient has a documented intolerance to generic testosterone cypionate.
        - Aveed, Testopel, Xyosted: The patient has had a documented side effect, allergy, or treatment failure to TWO preferred testosterone products, of which one must be an injectable formulation.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. New Therapeutic Drug Classes

a) Continuous Glucose Monitoring Supplies

Typically, CGM is comprised of a 3-part system. Sensor—transmitter—receiver

- A small sensor is inserted under the skin (typically on the belly or arm) and measures interstitial glucose levels (interstitial fluid is the thin layer of fluid that surrounds the cells of the tissues below the skin. (Note: Blood glucose readings tend to be about 5 to 10 minutes ahead of interstitial glucose readings).
- Sensors tests glucose every few minutes. The sensor must be replaced every 7-14 days, depending on the model.
- A small, re-usable transmitter connects to the sensor and wirelessly sends the information to a receiver. The receiver may be part of an insulin pump or a separate device. Many new CGM models send the information directly to a tablet or smartphone

and do not require a separate receiver. (Note: Dexcom and Medtronic communicate continuously with the receiver. You have to scan the sensor to get a reading with the Abbott Libre, however, it will provide an 8-hour history upon scanning).

- Special features of a CGM:
    - Allows measurement of glucose levels in real-time throughout the day and night (patient can be sleeping, showering, exercising, etc). CGM can "fill the gaps" between BG fingerstick checks or replace them in many situations.
    - CGM can alert the patient to high and low glucose values (thresholds set by user). Some models can send information right away to a second person's smartphone. For example, if a child's glucose drops dangerously low overnight, the CGM could be set to alarm and wake a parent in the next room.
    - Meals, physical activity, illness, and medicines can be noted alongside glucose levels and can help assess impact.
    - Data can be downloaded to a computer or smart device to more easily see glucose trends and time in target.
- Calibration
    - Device dependent. Used to "Teach" the sensor its accuracy.
    - Dexcom G5 requires calibration at least once every 12 hours. The newer Dexcom G6 is designed to work without routine calibration but requires it before first-time use.
    - Abbott Libre does not require calibration.
    - Medtronic Guardian recommends 4 x/day
- Fingersticks
    - Dexcom G6 requires fingersticks during the 2-hour warmup and when symptoms do not match the sensor reading.
    - Abbott Libre requires fingersticks during the following situations: during the 1-hour warm up, during the first 11 hours of each new sensor, reading ≤ 70 mg/dL, symptoms of hyper or hypoglycemia, or for rapidly changing glucose levels.
    - Medtronic Guardian requires a FS for EVERY treatment decision (Note: they are NOT considered "therapeutic" CGM).

Recommendation:

- Move preferred CGM supplies from the medical benefit to the pharmacy benefit with a target date of 7/1/19.
- Add Dexcom G6 **Initial prescription:** 1 receiver, 1 wireless transmitter, and 1 3-pack of sensors, **Refill Quantity Limits:** 1 transmitter every 3 months, 1 sensor every 10 days (maximum of 3 sensors every 30 days) to preferred after clinical criteria are met.
- Add FreeStyle Libre Pro (10-day sensors) **Initial Prescription:** 1 reader, 3 sensors, **Refill Quantity Limits:** 1 sensor every 10 days (maximum of 3 sensors every 30 days) to preferred after clinical criteria are met.
- Add FreeStyle Libre 14 Day (14-day sensors) **Initial Prescription:** 1 reader, 2 sensors, **Refill Quantity Limits:** 1 sensor every 14 days (maximum of 2 sensors every 28 days) to preferred after clinical criteria are met.

- Add Medtronic Guardian™ Connect **Initial Prescription**: 1 transmitter, 5 sensors, **Refill Quantity Limits:** 1 sensor every 7 days (maximum of 5 sensors every 35 days) to non-preferred.
    - Clinical criteria:
        - Patient has a diagnosis of Diabetes Mellitus AND 2 years of age or older for Dexcom G6, ≥ 14 years for Medtronic Guardian, or ≥ 18 years for Freestyle Libre.
        - Patient requires use of insulin at least 3 times per day or is on an insulin pump.
        - Frequent adjustments to treatment regimen are necessary based on blood glucose testing results.
        - Patient is under the care of an endocrinologist or is regularly working with a certified diabetes educator.
        - At least one of the following are documented:
            - Hypoglycemic unawareness
            - Recurrent episodes of severe hypoglycemia (<55 mg/dL) or hyperglycemia (>300 mg/dL) persisting despite adjustments to therapy based on previous short-term CGM or self-monitoring.
            - Nocturnal hypoglycemia
            - Patient cannot achieve glycemic control (defined as HbA1c ≤ 7%) despite good compliance and understanding of current treatment plan. (Note: pharmacy claims will be reviewed for the past 6 months to assess compliance).
            - Recurring diabetic ketoacidosis

        Re-authorization: There is documented evidence of compliance to CGM (log data and/or office visit notes required). There is evidence of improved glycemic control (defined by patient achieving a hemoglobin A1c ≤ 7% or a reduction in of ≥ 0.5% from baseline) and/or reduced incidences of hypoglycemia or hyperglycemia. Replacement will be considered when medically necessary and not for recent technology upgrades (device must be malfunctioning and out of warranty).

Public Comment: Andrew Weiss from Abbott: Highlighted the attributes at FreeStyle Libre.

Board Decision: The Board unanimously approved the above recommendation with the amendment to remove the requirement that a patient is under the care of an endocrinologist or is regularly working with a certified diabetes educator.

b) Neuropathic Pain/Fibromyalgia

- No new drugs
- No new significant clinical changes.

Recommendation:

- Combine Fibromyalgia Agents category and Post Herpetic Neuralgia Agents to Neuropathic Pain & Fibromyalgia Agents
    - Clinical criteria
        - Add Lyrica solution: the patient is unable to use Lyrica capsules (e.g. Swallowing disorder)
        - Add Savella: The diagnosis or indication is treatment of fibromyalgia AND The patient has had a documented side effect, allergy, or treatment failure to TWO drugs from the following: gabapentin, tricyclic antidepressant, SSRI antidepressant, SNRI antidepressant, miscellaneous antidepressant, cyclobenzaprine or Lyrica.
        - Add Cymbalta: the patient has had a documented intolerance with generic duloxetine.
        - Revise Lidoderm, Lidocaine Patch: diagnosis or indication is neuropathic pain/postherpetic neuralgia AND patient has had a documented side effect, allergy, treatment failure or contraindication to 2 drugs in the tricyclic antidepressant (TCA) class and/or anticonvulsant class OR patient has a medical necessity for a transdermal formulation (ex. dysphagia, inability to take oral medications), AND if the request is for brand Lidoderm, the patient has had a documented intolerance to the generic equivalent..

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. Therapeutic Drug Classes- Periodic Review: Jeffrey Barkin, MD, Change Healthcare and Laurie Brady, RPh, Change Healthcare

a) Analgesics: Short acting opioids

- No new drugs.
- The CDC has published many recommendations and guidelines, but it is important that a pain management strategy be individualized for the patient.

Recommendation:

- Remove Capital® w/codeine (acetaminophen w/codeine), Fioricet® w/codeine (butalbital/acetaminophen/caffeine/codeine), Panlor DC® (acetaminophen/caffeine/dihydrocodeine), Reprexain® (hydrocodone w/ ibuprofen) and Talwin® (pentazocine) from the PDL.
    - Clinical criteria:
        - Remove **Nucynta, Opana, Oxymorphone** criteria. They will have the same criteria as "Other short acting Opioids."

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Analgesics: Long acting opioids

- No new drugs.
- No new significant clinical changes

Recommendation:

- Remove Exalgo® (hydromorphone XR) tablet and Ultram ER® (tramadol SR 24 hr) from the PDL.
- Add a look back in claims to see that an opioid has been filled prior to Fentanyl patch.
    - Clinical criteria
        - Remove Ultram ER from the criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Epinephrine Auto Injectors

- Synjepi® is a new drug in this class but has not been reviewed yet.
- No new significant clinical changes.
- Intermittent backorders continue to be an issue.

Recommendation:

- No changes at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Hepatitis B agents

- No new drugs.
- No significant clinical changes.

Recommendation:

- No changes at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Hepatitis C agents

- No new drugs.

- The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) collaboratively developed guidance with hepatology and infectious disease experts for Recommendations for Testing, Managing, and Treating Hepatitis C. These evidence-based recommendations are updated frequently, last updated in November 2018, as data becomes available in this rapidly evolving therapeutic area. They include a thorough review of the evidence and outline the treatment recommendations in detail by genotype, as well as other factors, such as prior treatment status and HIV status. This well-respected, evidence-based review does include use of some drugs based on available evidence outside of the FDA labeled indications. This guidance document is frequently updated and available at: http://www.hcvguidelines.org.

Recommendation:

- Remove Copegus® (ribavirin 200 mg tabs) and Olysio® (simeprevir) 150 mg Capsules from the PDL.
- Move Zepatier® (elbasvir/grazoprevir) to non-preferred.
- Add Ledipasvir/sofosbuvir (compare to Harvoni®) and Sofosbuvir/velpatasvir (compare to Epclusa®) to non-preferred.
    - Clinical criteria:
        - Add Ledipasvir/sofosbuvir and Sofosbuvir/velpatasvir to Direct Acting Agents criteria.
        - Revise Direct Acting Agents criteria, adding two additional bullet points:
            - Patient has evidence of infection for at least 6 months.
            - Specialist requirement will NOT apply for patients meeting all the following: treatment naïve, non-cirrhotic, HBV negative, and HIV negative.

Public Comment: Roxann Stubbs from Abbvie: Highlighted the attributes of Mavyret.
Laurie Williams from Gilead: highlighted the attributes of Epclusa and the new generics Ledipasvir/sofosbuvir and Sofosbuvir/velpatasvir.

Board Decision: The Board unanimously approved the above recommendation with the amendment that "Patient has evidence of infection for at least 6 months" be replaced with "An infection for at least 6 months has been documented or can be reasonably inferred."

f) Pseudobulbar Affect Agents

- No new drugs.
- No new significant clinical changes

Recommendation:

- No changes at this time.

Public Comment: from: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

g) Topical Corticosteroids (NDR Bryhali Lotion (halobetasol propionate) included)

- New drug Bryhali Lotion.
  Halobetasol propionate, the active ingredient of Bryhali®, is a corticosteroid. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action when used for its indication is not known. It is indicated for the topical treatment of plaque psoriasis in adults. The safety and efficacy of Bryhali® lotion were assessed in 2 prospective, multicenter, randomized, double-blind studies that included adults 18 years of age and older (N=430) with moderate to severe plaque psoriasis that covered a BSA between 3% and 12%, excluding the face, scalp, palms, soles, axillae, and intertriginous areas. It was found to be in the potent to super-potent range of potency as compared to other topical corticosteroids. Compared with vehicle, Bryhali® was found to be significantly more effective for IGA treatment success in adults with moderate-to-severe plaque psoriasis.
- No new significant clinical changes.

Recommendation:

- Add Bryhali® (halobetasol propionate) to non-preferred.
- Move clocortolone 0.1% C (compare to Cloderm®) and Hydrocortisone Butyrate 0.1% to non-preferred.
- Move clobetasol propionate (compare to Temovate®/Cormax®) 0.05% C, G, O, S to preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

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

Selected FDA Safety Alerts

- FDA recently approved revisions to the VIREAD (tenofovir disoproxil fumarate) product labeling to include safety and pregnancy-related outcome information from three published controlled trials in pregnant women with chronic hepatitis B virus infection who were administered VIREAD during their third trimester.

Public Comment: No public comment.

Board Decision: No action is needed.

12. Adjourn: Meeting adjourned at 8:28 p.m.