Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
Office of MaineCare Services - Pharmacy Unit
11 State House Station
Augusta, Maine 04333-0011
Toll Free: (866) 796-2463; TTY: Dial 711 (Maine Relay)
Fax: (207) 287-8601

TO: Maine Drug Utilization Review Board
DATE: 09/15/24
RE: Maine DUR Board Meeting minutes from September 10, 2024

ATTENDANCE	UNEXCUSED	EXCUSED	IN-PERSON	REMOTELY
Linda Glass, MD				X
Kathleen Polonchek, MD				X
Erin Ackley, PharmD.				X
John Deason, PharmD.				X
Caitlin Morrow, PharmD.				X
Non –Voting				
Mike Ouellette, R.Ph., Optum			X	
Bradford Curtis, MD, Optum			X	
Anne-Marie Toderico, PharmD MaineCare			X	

Guests of the Board: Gavin Gillespie PharmD, Optum

CALL TO ORDER: 6:00PM

Erin Ackley called the meeting to order at 6:00 PM.

PUBLIC COMMENTS

Shari Orbach from Madrigal: Highlighted the attributes of Rezdiffra.

Kevin Borth from Day One Bio: Highlighted the attributes of Ojemda.

Brad Winn from Pfizer: Highlighted the attributes of Beqvez.

Board Discussion:

MAINECARE UPDATE- ANNE-MARIE TODERICO

- With the end of the American Rescue Plan Act on Sept 30, 2024, Pharmacy copays will return on October 1, 2024
- As we have continued the recovery from the Change Healthcare cyber attack we have restored 2 more services
  - Our website is back up - mainecarepdl.org
  - Prior Authorizations were restored on Aug 5, 2024
- Leveraging our standing order authority, we have active standing orders for
  - Opill - over the counter oral contraception
  - Naloxone - over the counter inhaled naloxone products
  - COVID-19 - over the counter tests
  - Over the counter nicotine replacement therapies

OLD BUSINESS

DUR MINUTES

Approval of June DUR meeting minutes

Board Decision: The Board unanimously approved the above recommendation.

NEW BUSINESS

NEW CANCER MEDICATIONS

Recommendations: Add Imdelltra, Ogsiveo, Ojemda and Rytelo to non-preferred.

Criteria: All non-preferred: A clinical PA is required to confirm appropriate clinical indication for the individual drug request. Specific to each drug all age, clinical testing requirements, previous step therapies, adjunctive drug therapy requirements, and response without disease progression will be also be evaluated for clinical appropriateness. The standard for the appropriate indication will include the FDA label as well as current NCCN guidelines

Board Decision: The Board unanimously approved all the above recommendations.

RETRODUR

Use of stimulants in children has significantly improved the quality of life of those with Attention Deficit and Hyperactivity Disorder. However, use of the medications has grown substantially in the last decade and monitoring is necessary to ensure that there is not inappropriate use. Concerns include that the diagnosis is incorrect, that behavioral therapy is not being done in conjunction with therapy, that monitoring is not adequate, that there is treatment noncompliance and that there is co-prescribing of other medications for behavioral issues that may not be appropriate.1 There is concern about using stimulants in those who may have substance abuse issues or where diversion of medication is a possibility, or in situations where other behavioral diagnoses may be treated inappropriately with stimulants.

While stimulants are the mainstay of treatment and have been shown to improve a child's functional status and behavior, the norepinephrine uptake inhibitors atomoxetine and viloxazine, and the alpha-2 adrenergic agonists are used when there is intolerance or lack of effectiveness with stimulants. Alpha-2 adrenergic agonists are sometime used along with stimulants when the effectiveness of stimulants alone is not optimal.2 Guidelines exist for determining who should be offered stimulants and how those on stimulants should be monitored. We will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2022, excluding members with Part D, TPL and Maine RX coverage. We will use paid, non-reversed Medicaid medical claims, excluding members with Part D, MaineRX and TPL.

This analysis will identify children ages 1-18 on stimulants, norepinephrine uptake inhibitors and alpha-2 adrenergic agonists. The parameters used will include age, sex, diagnoses, doses of medications used, co-prescribing of the drugs in this study, uninterrupted duration of use of the medications (considering eligibility limitations) and concurrent use of drugs for depression or anxiety.

Board Decision: None needed.

NEW DRUG REVIEW

Alvaiz® (eltrombopag tab); **PDL category- Hematological Agents-** Thrombopoietin Receptor Agonists

Eltrombopag, the active ingredient of Alvaiz®, is a small molecule thrombopoietin (TPO) receptor agonist for oral administration. It interacts with the transmembrane domain of the human TPO-receptor (also known as cMpl) and initiates signaling cascades that induce proliferation and differentiation of megakaryocytes leading to increased platelet production. It is indicated for the Treatment of thrombocytopenia in patients with persistent or chronic immune thrombocytopenia: for the treatment of thrombocytopenia in adults and pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Alvaiz® should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Treatment of thrombocytopenia in patients with hepatitis C infection: for the treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. It should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Treatment of severe aplastic anemia: for the treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. Limitations of use include: Alvaiz® is not indicated for the treatment of patients with myelodysplastic syndromes (MDS). The safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection. The effectiveness of Alvaiz® has been established based on adequate and well-controlled studies of eltrombopag olamine in adult and pediatric patients 6 years and older with persistent or chronic ITP, adult patients with chronic hepatitis C-associated thrombocytopenia, and adult patients with refractory severe aplastic anemia. The studies included in the Alvaiz® prescribing information (eltrombopag choline) were the same studies as in the Promacta® prescribing information (eltrombopag olamine). Alvaiz® is not substitutable with other eltrombopag products on a milligram per milligram basis due to the observed bioavailability in studies conducted on Alvaiz®.

Recommendation: Alvaiz® to non-preferred.

Board Decision: The Board unanimously approved all the above recommendations.

Beqvez® (fidanacogene elaparvovec-dzkt); **PDL category-** Antihemophillc Agents

Beqvez® (fidanacogene elaparvovec-dzkt) is an adeno-associated virus (AAV)-based gene therapy that is based on recombinant DNA technology that consists of a recombinant viral capsid (AAVRh74var) derived from a naturally occurring AAV serotype (Rh74) vector containing the human coagulation factor IX transgene modified to a high-specific factor IX activity variant known as FIX-R338L. The AAVRh74var capsid is derived from the Rh74 AAV, which is not known to cause disease in humans. It is indicated as an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who: Currently use factor IX prophylaxis therapy, or Have current or historical life-threatening hemorrhage, or Have repeated, serious spontaneous bleeding episodes, and, Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. Select patients for therapy based on an FDA-approved companion diagnostic for Beqvez®. The efficacy of Beqvez® was assessed in clinical study 1, an ongoing, prospective, open-label, single-arm, multinational study that enrolled adult male patients (N=45) with moderately severe to severe hemophilia B (factor IX activity ≤2 IU/dL). The main efficacy outcome was a non-inferiority test of annualized bleeding rate (ABR) during the efficacy evaluation period, week 12 to data cutoff following Beqvez® treatment, compared with baseline ABR during the lead-in period. Results suggested that the model derived mean ABR was 4.5 bleeds/year during the baseline period and

2.5 bleeds/year during post-Beqvez® efficacy evaluation period, resulting in a difference of -2.1 bleeds/year, meeting the non-inferior study success criterion. The median ABR was 0 post-Beqvez® efficacy evaluation period.

Recommendation: Beqvez® to non-preferred.

Criteria:

- Add Beqvez: FDA Approved Indication: An adeno-associated virus vector-based gene therapy indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who:
  · Currently use factor IX prophylaxis therapy, or
  · Have current or historical life-threatening hemorrhage, or
  · Have repeated, serious spontaneous bleeding episodes, and,
  · Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA- approved test.

Board Decision: The Board unanimously approved all the above recommendations.

Filsuvez® (birch triterpenes gel); PDL category- Topical- Wound/Decubitus Care

Filsuvez® topical gel is a sterile botanical drug product that contains birch triterpenes in an oil base. Birch triterpenes is a botanical drug substance composed of a mixture of pentacyclic triterpenes. The mechanism of action for its approved indication is not known. It is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adult and pediatric patients 6 months of age and older. The efficacy of Filsuvez® for the treatment of partial-thickness wounds associated with inherited EB was assessed in a randomized, double-blind, placebo-controlled study (EASE) that included adults and pediatric patients 6 months of age and older with dystrophic EB (DEB) and junctional EB (JEB). The primary endpoint was the proportion of subjects with first complete closure of the target wound by day 45 of the 90-day double-blind phase of the study, based on clinical assessment by the investigator. Results suggested that more in the Filsuvez® group obtained first complete closure of target wound within 45 days compared with the placebo group (NNT 9). This topical gel offers providers a treatment option for patients with either DEB or JEB.

Criteria:

- Add Filsuvez: The patient has a diagnosis of dystrophic or junctional epidermolysis bullosa. The patient is at least 6 months old and does not have current evidence or history of squamous cell carcinoma or active infection in the area requiring Filsuvez application. The patient has used standard wound care treatments, including silicone or foam dressings without wound resolution

Board Decision: The Board unanimously approved all the above recommendations.

Focinvez® (fosaprepitant dimeglumine); **PDL category-** Antiemetic-5-HT3 Receptor Antagonists/Substance P Neurokinin

Focinvez® is a solution containing fosaprepitant dimeglumine, a prodrug of aprepitant, a substance P/neurokinin-1 (NK-1) receptor antagonist. Its antiemetic effects are attributable to aprepitant. It is indicated in combination with other antiemetic agents, is indicated in adult and pediatric patients 6 months of age and older for the prevention of: Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose

cisplatin. Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). The safety and efficacy of Focinvez® have been established based on adequate and well-controlled adult studies of another IV formulation of fosaprepitant for the prevention and of chemotherapy induced nausea and vomiting. There is no evidence at this time to support that Focinvez® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation: Focinve® to non-preferred.

Criteria:

- Add Approvals will require diagnosis of chemo-induced nausea/vomiting and failed trials of all preferred anti-emetics, including 5-HT3 class (Ondansetron) and Marinol.
- Add Clinical PA is required for members on highly emetic anti-neoplastic agents.

Board Decision: The Board unanimously approved all the above recommendations.

Iqirvo® (elafibranor); **PDL category**- GI- Miscellaneous

Elafibranor and its main active metabolite GFT1007, the active ingredient of Iqirvo®, are peroxisome proliferator-activated receptor (PPAR) agonists. Elafibranor and GFT1007 both activate PPAR-alpha, PPAR-gamma, and PPAR-delta in vitro. However, the mechanism of action for its approved indication is not well understood. Pharmacological activity that is potentially relevant to therapeutic effects includes inhibition of bile acid synthesis through activation of PPAR-alpha and PPAR-delta. The signaling pathway for PPAR-delta was reported to include Fibroblast Growth Factor 21 (FGF21)-dependent downregulation of CYP7A1, the main enzyme for the synthesis of bile acids from cholesterol. It is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). The efficacy of Iqirvo® was assessed in Study 1, a multicenter, randomized, double-blind, placebo-controlled study that included adults (N=161) with PBC with an inadequate response or intolerance to UDCA. This indication is approved under accelerated approval based on reduction of alkaline phosphatase. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Use of Iqirvo® is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy). Its efficacy was assessed in phase 3, double-blind, placebo-controlled study that included adults with PBC. Most patients in the study (95%) received study treatment in combination with UDCA. The primary endpoint was biochemical response at week 52. Results suggested that Iqirvo® demonstrated greater improvement on biochemical response and ALP normalization at week 52 as compared to placebo (NNT 3 for primary endpoint of biochemical response).

Recommendation: Iqirvo® to non-preferred.

Criteria:

- Add Iqirvo: For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as

monotherapy in patients unable to tolerate UDCA. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Board Decision: The Board unanimously approved all the above recommendations.

Kisunla® (donanemab-azbt); **PDL category-** AIzheimer's Agents

Donanemab-azbt, the active ingredient of Kisunla®, is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against insoluble N-truncated pyroglutamate amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. Donanemab-azbt reduces amyloid beta plaques, as assessed in Study 1. It is indicated for the treatment of Alzheimer's disease. Treatment with Kisunla® should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. The efficacy of Kisunla® was assessed in a double-blind, placebo-controlled, parallel-group study (Study 1) in patients with Alzheimer's disease (patients with confirmed presence of amyloid pathology and mild cognitive impairment or mild dementia stage of disease, consistent with Stage 3 and Stage 4 Alzheimer's disease). Results suggested that patients treated with Kisunla® demonstrated a statistically significant reduction in clinical decline on iADRS compared to placebo at week 76 (primary endpoint) in the combined population and the low/medium tau population. Head-to-head active comparator studies with other monoclonal antibodies were not currently found.

Recommendation: Kisunla® to non-preferred.

Board Decision: The Board unanimously approved all the above recommendations.

Libervant® (diazepam film); **PDL category-** Anticonvulsants

Diazepam, the active ingredient of Libervant®, is a benzodiazepine anticonvulsant. The exact mechanism of action is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA-A receptor. It is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age. The safety and efficacy of Libervant® in pediatric patients 2 to 5 years of age are supported by evidence from adequate and well controlled studies of diazepam rectal gel in adult and pediatric patients, adult bioavailability studies comparing Libervant® with diazepam rectal gel, adult and pediatric Libervant® pharmacokinetic data, and an open-label safety study of Libervant® including patients 2 years to 5 years of age. Libervant® is the only oral, non-device diazepam-based treatment with its approved indication.

Recommendation: Libervant® to non-preferred.

Criteria:

- Add Libervant: For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age as long as all preferred therapies have been tried and failed at full therapeutic doses.

Board Decision: The Board unanimously approved all the above recommendations.

Ohtuvayre® (ensifentrine); **PDL category-** Antiasthmatic- Phosphiesterase 4 Inhibitors

Ensifentrine, the active ingredient of Ohtuvayre®, is an inhibitor of phosphodiesterase 3 and 4 (PDE3 and PDE4). It is a small molecule that is an inhibitor of the PDE3 and PDE4 enzymes. PDE3 mainly hydrolyzes the second-messenger molecule cyclic adenosine monophosphate (cAMP) but is also capable of hydrolyzing cyclic guanosine monophosphate (cGMP). PDE4 hydrolyzes cAMP only. Inhibition of PDE3 and PDE4 results in accumulation of intracellular levels of cAMP and/or cGMP, resulting in various downstream signaling effects. It is indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. The efficacy of Ohtuvayre® was assessed in two 24-week randomized, double-blind, placebo-controlled, parallel-group clinical trials (ENHANCE-1 and ENHANCE-2) that enrolled adults (N=1553) with moderate to severe COPD. The primary endpoint for both studies was the change from baseline in FEV1 AUC0-12h post dose at week 12. In both trials, Ohtuvayre® demonstrated a statistically significant improvement in the primary endpoint as compared with placebo. Head-to-head active comparator trials were not currently found, but Ohtuvayre® offers providers and their patients with another treatment option.

Recommendation: Ohtuvayre to non-preferred. Add Roflumilast to preferred.

Criteria:

- Add For the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients

Board Decision: The Board unanimously approved all the above recommendations.

Rextovy® (naloxone spray); **PDL category-** Narcotic- Antagonists

Naloxone, the active ingredient of Rextovy®, is an opioid antagonist. It antagonizes opioid effects by competing for the same receptor sites. Naloxone reverses the effects of opioids, including respiratory depression, sedation, and hypotension. It can also reverse the psychotomimetic and dysphoric effects of agonist-antagonists such as pentazocine. It is indicated for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients. Rextovy® nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present. It is not a substitute for emergency medical care. No new clinical trials were found for this product, but this offers providers and patients another treatment option.

Recommendation: Rextovy® to non-preferred.

Board Decision: The Board unanimously decided to table this drug until the November meeting.

Rezdiffra® (resmetirom); **PDL category-** GI- NASH

Resmetirom, the active ingredient of Rezdiffra®, is a thyroid hormone receptor-beta agonist. It is a partial agonist of the thyroid hormone receptor-beta (THR-β). Resmetirom produced 83.8% of the maximum response compared to triiodothyronine (T3). THR-β is the major form of THR in the liver, and stimulation of THR-β in the liver reduces intrahepatic triglycerides, whereas actions of thyroid hormone outside the liver, including in heart and bone, are largely mediated through THR-α. It is indicated in conjunction with diet and exercise for the treatment of adults with non-cirrhotic nonalcoholic steatohepatitis (NASH) with

moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Limitations of use include to avoid use of Rezdiffra® in patients with decompensated cirrhosis. The efficacy of Rezdiffra® was assessed based on an efficacy analysis at month 12 in Trial 1, a 54- month, randomized, double-blind, placebo-controlled trial. This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. A limitation of use includes to avoid use of Rezdiffra® in patients with decompensated cirrhosis. Results suggested that both the 80mg and 100mg dosages of Rezdiffra® demonstrated improvement on these histopathology endpoints at month 12 compared to placebo. Furthermore, in a statistical analysis incorporating both pathologists' independent readings, Rezdiffra® achieved statistical significance on both histopathology endpoints for both doses. Rezdiffra® is the first FDA approved, once-daily treatment for adults with NASH with liver fibrosis.

Recommendation: Rezdiffra® to non-preferred.

Criteria:

- Add new sub-category GI-NASH.
- Add Rezdiffra: The patient must have a diagnosis of NASH with fibrosis Stage 2 or 3 and a NAFLD Activity Score (NAS) of at least 4 AND the patient does not have evidence of decompensated cirrhosis

Board Decision: The Board unanimously approved all the above recommendations.

Rivfloza® (nedosiran injection); **PDL category-** Primary Hyperoxaluria Type 1 (PH1)

Nedosiran, the active ingredient of Rivfloza®, is a double-stranded small interfering RNA (siRNA) with four covalently attached N-acetyl-D-galactosamine (GalNAc) residues. After subcutaneous administration, the GalNAc-conjugated sugars bind to asialoglycoprotein receptors (ASGPR) to deliver nedosiran to hepatocytes. It is indicated to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function (e.g., eGFR ≥30ml/min/1.73m^2). It is for once monthly subcutaneous injection, with dosing based on actual body weight. The safety and efficacy of Rivfloza® were assessed in a randomized, double-blind study that included patients with PH1 or PH2 and an eGFR ≥30ml/min/1.73m^2. The primary endpoint was the area under the curve, from days 90 to 180, of the percent change from baseline in 24-hour urinary oxalate excretion (AUC24-hour Uox), and Rivfloza® was significantly more effective than placebo for the primary endpoint. Rivfloza® offers providers and patients an at-home treatment option that may be self-administered or administered by a caregiver.

Recommendation: Rivfloza® to non-preferred.

Criteria:

- Add Rivfloza: 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 m2 or urinary oxalate: creatinine ratio is above the upper limit of normal for age AND is at least 9 years of age AND medication is being prescribed by, or in consultation, with a nephrologist or urologist

Board Decision: The Board unanimously approved all the above recommendations.

Xolremdi® (mavorixafor); **PDL category-** WHIM Syndrome Agents

Mavorixafor, the active ingredient of Xolremdi®, is an orally bioavailable CXC Chemokine Receptor 4 (CXCR4) antagonist that blocks the binding of the CXCR4 ligand, stromal-derived factor-1α (SDF-1α)/CXC Chemokine Ligand 12 (CXCL12). SDF-1/CXCR4 plays a role in trafficking and homing of leukocytes to and from the bone marrow compartment. Gain of function mutations in the CXCR4 receptor gene that occur in patients with WHIM syndrome lead to increased responsiveness to CXCL12 and retention of leukocytes in the bone marrow. Mavorixafor inhibits the response to CXCL12 in both wild-type and for mutated CXCR4 variants associated with WHIM syndrome. Treatment with mavorixafor results in increased mobilization of neutrophils and lymphocytes from the bone marrow into the peripheral circulation. It is indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes. The efficacy of Xolremdi® was assessed in a randomized, double-blind, placebo-controlled portion of Study 1 that included patients aged 12 years and older with WHIM syndrome. The results over the 52-week period demonstrated that TAT-ANC was statistically significantly greater in patients treated with Xolremdi® compared with placebo (15 hrs vs 2.8 hrs; $p<0.0001$). Xolremdi® is the first targeted therapy FDA approved for WHIM syndrome.

Recommendation: Xolremdi® to non-preferred.

Criteria:

- Add new sub-category Whim Syndrome Agents
- Add Xolremdi: **I**n patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

Board Decision: The Board unanimously approved all the above recommendations.

FDA SAFETY ALERTS

None at this time.

Board Decision: No action.

ADJOURNMENT: 8:30PM

The next meeting will be held on November 5 2024 1 – 530p hybrid.