Drug Utilization Review Board
Minutes Draft

Name of Meeting:	Drug Utilization Review Board
Date of Meeting:	June 13, 2024
Length of Meeting:	2 hours and 50 minutes
Location of Meeting:	DMAS Board Room 102

Members Present:
Rachel Cain, PharmD, Chair
Elizabeth Gaughan, MD, Vice-Chair
Denese Gomes, NP
Jack Weisskohl, NP
Kristi Fowler, RPh
Matthew Estes, PharmD
Melissa Chouinard, MD
Michele Thomas, PharmD
Wendy Nash, PharmD

Members Not Present:
Denise Lowe, PharmD
Seth Brant, MD

DMAS Attendees:
MaryAnn McNeil, RPh, Pharmacy Manager
JoeMichael Fusco, PharmD, MCO Pharmacy Compliance Manager
Kiara Jasper, MHA, CPhT, Pharmacy Systems Administrator

Contractors:
Nancy Eldin, PharmD, Pharmacist Account Executive, Prime Therapeutics
David D'Amico, PharmD, Pharmacist Account Executive, Prime Therapeutics
Jeni Hodzic, CPhT, Senior Account Management Specialist, Prime Therapeutics

Visitors:
Brad Burmeister
Brian Trentler
Caroline Faber
David Nathanson
Jackie Yost
Joe Kupiec
Kathrin Kucharski
Kristie Bryerton
Laurie Mauthe
Lisa Barefoot
Rob Berringer
Ira Bloomfield

Call to Order and Introductions

Dr. Rachel Cain welcomed and thanked everyone for attending the DUR meeting.

Dr. Cain called the meeting to order at 1:05 pm.

Minutes – March 14, 2024

Dr. Melissa Chouinard motioned to approve the March 14, 2024 meeting minutes as submitted. Dr. Matthew Estes seconded the motion.

Physician Administered Drugs (PADs) – Gene Therapies

The DUR Board reviewed Casgevy™ (exagamglogene autotemcel), Lyfgenia™ (lovotibeglogene autotemcel), Skysona® (elivaldogene autotemcel), Zynteglo™ (betibeglogene autotemcel), Elevidys (delandistrogene moxeparvovec), Hemgenix® (etranacogene dezaparvovec), Luxturna® (voretigene neparvovec-rzyl), Roctavian™ (valoctocogene roxaparvovec), Vyjuvek® (beremagene geperpavec) and Zolgensma® (onasemnogene abeparvovec-xioi). The Impact Reports and the report for the utilization of these ten gene therapy drugs for Fee-For-Service (FFS) and Managed Care Organizations (MCOs) were also reviewed.

The DUR Board reviewed the service authorization (SA) criteria for Casgevy™ and the new Physician Administered Drugs SA form that will be used for all PADs. After discussion by the DUR Board, Dr. Michele Thomas motioned to accept the Casgevy SA criteria with the following new updates: add the statement - Casgevy must be prescribed by or in consultation with a hematologist or a specialist in hematopoietic stem cell transplant (HSCT); and to accept the new PADs SA form with the following updates: remove the gender question, change on the SA form “Patient Information” to “Member Information”, and update the return address on the form to the DMAS address. Denese Gomes seconded the motion.

After much discussion, a decision was made to suspend voting on the remaining gene therapies, record the board’s recommendations on the drug criteria, and readdress at a future DUR Board meeting.

The DUR Board reviewed the SA criteria for Lyfgenia™. The Board recommended to include that Lyfgenia must be prescribed by or in consultation with a hematologist or a specialist in hematopoietic stem cell transplant (HSCT). The DUR Board had a question if the member would still meet the criteria if the member **does have** a known 10/10 human leukocyte antigen matched related donor willing to participate in an allogeneic

HSCT, but the member does not want to do the allogeneic HSCT. This scenario will be researched further for clarification for all drugs that have this as part of the criteria. The DUR Board asked to clarify for Casgevy and Lyfgenia criteria what HbS percentage would be considered significant for the “Identification of significant quantities of HbS with or without an additional abnormal β-globin chain variant by hemoglobin assay”. The DUR Board would like clarification if every single criteria item needs to be met for approval.

The DUR Board reviewed the SA criteria for Skysona®. The Board recommended to include that Skysona must be prescribed by or in consultation with a physician who specializes in the treatment of adrenoleukodystrophy (ALD). For the statement, “Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), and human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines prior to collection of cells for manufacturing”, add that the member is negative and does not have any of these viruses.

The DUR Board reviewed the SA criteria for Zynteglo™. The Board recommended to include that Zynteglo must be prescribed by or in consultation with a hematologist or a specialist in hematopoietic stem cell transplant (HSCT). For the statement, “Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), and human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines prior to collection of cells for manufacturing”, add that the member is negative and does not have any of these viruses.

The DUR Board reviewed the SA criteria for Elevidys. The Board recommended to include that Elevidys must be prescribed by or in consultation with a pediatric neuromuscular specialist with expertise in the diagnosis of Duchenne Muscular Dystrophy (DMD). Remove from the criteria the statement that the member must be receiving physical and/or occupational therapy.

The DUR Board reviewed the SA criteria for Hemgenix®. The Board recommended to include that Hemgenix must be prescribed by or in consultation with a hematologist or a specialist in hemophilia. Remove the “s” in members in the statement “Member**s** with preexisting risk factors for hepatocellular carcinoma (e.g., members with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age) will have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration”.

The DUR Board reviewed the SA criteria for Luxturna®. The Board recommended to include that Luxturna must be prescribed by or in consultation with an Ophthalmologist.

The DUR Board reviewed the SA criteria for Roctavian™. The Board recommended to include that Roctavian must be prescribed by or in consultation with a hematologist or a specialist in hemophilia. Remove the “s” in members in the statement “Member**s** with preexisting risk factors for hepatocellular carcinoma [e.g., members with hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age] will have regular (e.g., annually) liver ultrasounds performed and will be tested for alpha-fetoprotein (AFP) elevations following administration”.

The DUR Board reviewed the SA criteria for Vyjuvek®. The Board recommended to include that Vyjuvek must be prescribed by or in consultation with a dermatologist, wound care specialist, geneticist, or dermatopathologist.

The DUR Board reviewed the SA criteria for Zolgensma®. The Board recommended to include that Zolgensma must be prescribed by or in consultation with a physician who specializes in the treatment of spinal muscular atrophy.

Old Business

The DUR Board reviewed reports on an in-depth analysis of the utilization of oral oncology – lung cancer and other neoplasm drugs. The DUR Board decided to do an intensive review of a different oral oncology class yearly.

DUR Quarterly Newsletter - The March 2024 DUR Quarterly Newsletter was available in the DUR binder for review.

Prime Therapeutics Pipeline - The April 2024 Prime Therapeutics Pipeline Report was available on the DUR Webportal for review.

Topics for Discussion

Concurrent Use of Opioids and Benzodiazepines – The DUR Board reviewed Concurrent Use of Opioids and Benzodiazepines reports for FFS and MCOs. The DUR Board requested to look over the past years to see the trend and have it displayed in a chart/graph.

Concurrent Use of Opioids and Antipsychotics – The DUR Board reviewed Concurrent Use of Opioids and Antipsychotics reports for FFS and MCOs. The DUR Board requested to look over the past years to see the trend and have it displayed in a chart/graph for all biweekly reports. For members with overdose ICD-10 codes, include the dates for each ICD-10 code that appears to see if multiple overdose episodes occurred or if one overdose episode occurred and the physician used more than one ICD-10 code to identify the one overdose episode. For members with overdose ICD-10 codes, check to see if they had a fill for naloxone.

Overlaps in Opioids, Benzodiazepines and Antipsychotics – The DUR Board reviewed Overlaps in Opioids, Benzodiazepines and Antipsychotics reports for FFS and MCOs.

Naloxone and Buprenorphine Utilization for Members on Opioids – The DUR Board reviewed Naloxone and Buprenorphine Utilization for Members on Opioids reports for FFS and MCOs. The DUR Board suggested to reach out to other states on the Listserve and ask how they are increasing their naloxone use in members on chronic opioids.

The topics below were tabled for the next DUR meeting on September 12, 2024.

Reports

- **ProDUR**
- **RetroDUR**
- **Utilization Analysis Reports**

Next DUR Meeting

September 12, 2024

Dr. Chouinard motioned to adjourn the meeting. Dr. Gaughan seconded the motion.
Meeting adjourned at 3:55 pm