Drug Utilization Review Board
Minutes Draft

Name of Meeting:	Drug Utilization Review Board
Date of Meeting:	September 9, 2021
Length of Meeting:	3 hours
Location of Meeting:	Electronic Meeting

Members Present:
John Morgan, MD, Chief Clinical Innovation Officer, Chair
Chethan Bachireddy, MD, Chief Medical Officer
Rachel Cain, PharmD
Denese Gomes, NP
Denise Lowe, PharmD
Kathryn Reid, PhD
Melissa Chouinard, MD
Michele Thomas, PharmD
Randy Ferrance, MD

Members Not Present:
Seth Brant, MD
Wendy Nash, PharmD

DMAS Attendees:
Maryann McNeil, RPh, Pharmacy Manager
Nettie Emmelhainz, PharmD, Senior Pharmacy Policy and Data Analyst
Kiara Jasper, MHA, CPhT, Pharmacy Systems Administrator

Contractors:
Debbie Moody, RPh, Director, Clinical Account Services, Magellan Health Services
Nancy Eldin, PharmD, Pharmacist Account Executive, Magellan Health Services
Jeni Hodzic, CPhT, Lead Formulary Analyst, Magellan Health Services
Marcie Morris, RPh, Rebate Pharmacist Operations, Magellan Health Services

Call to Order and Introductions

Dr. Rachel Cain explained that this is a virtual meeting and is informational only. Due to the regulations regarding virtual meetings and the fact that the emergency regulations were lifted by the governor a few months ago, the committee will not be able to vote on issues during this meeting. If we have an in-person quorum for

the December 2021 DUR meeting or if the regulations change by then, we will be able to vote on today's issues during the December 2021 DUR meeting.

Dr. Cain took a roll call of the Committee members since this was an electronic meeting.

Dr. John Morgan called the meeting to order at 1:03 pm.

Minutes – June 10, 2021

The DUR Board reviewed the June 10, 2021 DUR meeting minutes.

DUR Board Updates

Dr. Morgan welcomed and thanked everyone for attending the electronic meeting.

Dr. Morgan discussed the new section "Class Criteria" that will be presented during the DUR meeting. He mentioned that the current Virginia fee-for-service (FFS) Medicaid system has more service authorization (SA) criteria forms than any other Magellan Medicaid state clients. In review of these SA forms, DMAS recognized that many of these forms/criteria are used very infrequently, even if at all. DMAS has made preliminary efforts to attempt to streamline the operation of receiving SA approval for both the providers and to maximize access to these necessary drugs to members.

New Drugs

The DUR Board reviewed Empaveli™ (pegcetacoplan), Fotivda® (tivozanib), Lumakras™ (sotorasib), Myfembree® (relugolix, estradiol, and norethindrone acetate), Nextstellis® (drospirenone and estetrol), Truseltiq™ (infigratinib), Wegovy™ (semaglutide) and Zegalogue® (dasiglucagon). The report for the utilization of these 8 new DUR drugs for FFS and MCOs was reviewed.

The DUR Board discussed the SA criteria for Myfembree®, Truseltiq™ and Wegovy™. The DUR Board also reviewed the Impact Reports for Fotivda®, Lumakras™, Myfembree®, Truseltiq™ and Wegovy™.

Class Criteria

- **Hepatitis C**

  Dr. Chethan Bachireddy addressed the hepatitis C epidemic in Virginia and access to treatment. Dr. Bachireddy mentioned the worsening syndemic of acute and chronic hepatitis C cases between 2013 – 2017. During this time frame, hepatitis C virus (HCV) has doubled in Virginia. More than 2/3 of new cases are related to injection drug use and as the opioid epidemic worsens, the HCV epidemic worsens. HCV is among the most deadly infectious disease despite effective treatment and cure. Dr. Bachireddy mentioned that 45% of those nationally are unaware of their hepatitis C diagnosis. About 50% of those with HCV are Medicaid-eligible, particularly with Medicaid expansion. Medicaid has a huge role to play in ensuring access and really addressing patient suffering, morbidity and mortality as well as bending the curve of the epidemic in terms of transmission. Recent trends in costs are showing that treating is cost effective and reveals cost savings within a few years. Virginia Medicaid in recent years has successfully eliminated barriers to initiating treatment for HCV, in line with clinical guidelines and best practices. Despite these efforts, a significant percentage of eligible Medicaid members with hepatitis C remain untreated.

  Dr. Bachireddy discussed potential strategies:
  - How might we increase HCV diagnosis?
    - Partner intentionally
      - Public health
      - Prisons and jails
      - Health systems
      - Office Based Opioid Treatment (OBOT) feedback
  - How might we increase HCV treatment?
    - Remove barriers
      - Remove service authorization
    - Increase provider capacity
      - Provider trainings
      - Telehealth

  Dr. Bachireddy mentioned that we will be revisiting this at the next DUR meeting in December 2021 to talk more through these ideas, including the ability to make some decisions at the DUR Board level to facilitate the efforts of increasing patient access to HCV treatments.

- **Oral Hypoglycemic**

  Dr. Morgan discussed the consideration of removal or amendment of the metformin step edit for oral hypoglycemic medications to enhance the ability to efficiently provide evidence-based and tailored diabetic therapies. The DMAS Preferred Drug List (PDL) currently imposes a metformin step edit on all oral hypoglycemics, which prevents prescription of any other oral hypoglycemic agent without completing a 90-day trial of metformin, except in select narrowly defined scenarios (i.e., A1c > 7.5, history of intolerance, severe renal impairment, known metformin intolerance, metabolic/acidosis/DKA). Historically, there have been questions regarding the net impact of the edit on patients and providers, due to the burden imposed on providers/pharmacists, delay in patients' ability to start therapy, the fact that many of these medications are efficacious and well tolerated, and that providers tend to be well educated around these medications, making an edit unlikely to meaningfully redirect providers to more effective or lower side-effect alternatives. New professional clinical guidelines have raised additional concerns that this edit inappropriately delays initiation of evidence-based therapy. The 2018 ACC guidelines and 2020 ADA guidelines: Recommends access to SGLT-2s as first-line therapy in select patient populations such as patients with atherosclerotic cardiovascular disease (ASCVD), heart failure, or chronic kidney disease.

  DMAS is recommending 2 options:

  - Option 1: Remove the metformin step edit from **all** oral hypoglycemic medications:
    - sulfonylureas
    - meglitinides [i.e., repaglinide]
    - alpha-glucosidase inhibitors [i.e., acarbose]
    - Thiazolidinediones (TZD)
    - DPP-4
    - SGLT-2
  - Option 2: Remove the metformin step edit from SGLT-2 oral hypoglycemic medications only

  Dr. Morgan mentioned that this will be revisited and discussed again during the December 2021 DUR meeting.

- **Oral Oncology – Lung Cancer**
  The DUR Board reviewed the Oral Oncology, Lung Cancer SA criteria. The new criteria combines all the lung cancer oral oncology drugs to create one SA criteria for the entire class. This new SA form will eliminate the single SA criteria forms for individual lung cancer oral oncology drugs. The DUR Board also reviewed the utilization of these lung cancer oral oncology drugs for FFS.

- **Oral Oncology – Renal Cell Carcinoma**
  The DUR Board reviewed the Oral Oncology, Renal Cell Carcinoma SA criteria. The new criteria combines all the renal cell carcinoma oral oncology drugs to create one SA criteria for the entire class. This new SA form will eliminate the single SA criteria forms for individual renal cell carcinoma oral oncology drugs. The DUR Board also reviewed the utilization of these renal cell carcinoma oral oncology drugs for FFS.

MRx Pipeline and DUR Quarterly Newsletter- The July 2021 MRx Pipeline Report and the June 2021 DUR Quarterly Newsletter were available on the DUR Webportal for review.

Surveillance

Opioid Use with Risk Factors with and without Naloxone – The DUR Board reviewed Opioid Use with Risk Factors with and without Naloxone reports for FFS and MCOs. The DUR Board members mentioned they are interested in what the MCOs are doing in reference to opioids and naloxone.

Synagis® – The DUR Board reviewed the Synagis® Utilization Report for last season. DMAS has opened the service authorization Synagis season criteria to start earlier due to a sharp increase in RSV infection starting early this year in Virginia. The Synagis® service authorization season started on August 15, 2021.

Reports

The DUR Board reviewed the ProDUR, Recent RetroDUR Activity and Utilization Analysis reports. The Hemoglobin A1c Lab Value Over 9 and On Diabetic Meds for 6 Months Report was provided in the binder for review.

The DUR Board is interested in doing a re-review on the recent letter mailed in June 2021 in reference to Nonadherence with Antidepressants. Also, the Board members would like to see since these FFS members only stay in FFS for up to 45 days, if we can track these members progress once they have moved to the MCOs. Dr. Eldin will research to see if this can be done.

RetroDUR Criteria Estimates

Dr. Eldin reviewed the Criteria Exception Estimates Reports with the DUR Board. The reports were broken down to the Top 40 Criteria Exception Estimates by Members and the Top 40 Criteria Exception Estimates by Total Payment Amount for Fee-For-Service (FFS) and each individual Managed Care Organization (MCO) plan.

Members were interested in the following criteria for lettering:

- Criterion number 6412: Cyclobenzaprine; Duration of therapy > 3 weeks
- Criterion number 7742: CNS Polypharmacy
- Criterion number 7855: High Risk Medications in Person 65 or Older
- Criterion number 7879: Non-compliance with Anticonvulsant Medications

Other Business

teplizumab – The DUR Board reviewed a new pipeline drug, teplizumab. Dr. Eldin presented new information in reference to Provention Bio receiving a Complete Response Letter (CRL) to the Biologics License Application (BLA) for teplizumab for the delay of clinical type 1 diabetes in at-risk individuals.

Next DUR Meeting

December 9, 2021

Meeting adjourned at 4:00 pm.