Drug Utilization Review Board
Minutes Draft

Name of Meeting:	Drug Utilization Review Board
Date of Meeting:	June 10, 2021
Length of Meeting:	2 hours and 55 minutes
Location of Meeting:	Electronic Meeting

Members Present:
John Morgan, MD, Chief Clinical Innovation Officer, Chair
Rachel Cain, PharmD
Denese Gomes, NP
Denise Lowe, PharmD
Kathryn Reid, PhD
Melissa Chouinard, MD
Michele Thomas, PharmD
Seth Brant, MD
Wendy Nash, PharmD

Members Not Present:
Chethan Bachireddy, MD, Chief Medical Officer
Randy Ferrance, MD

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 introduced Dr. John Morgan, Chief Clinical Innovation Officer and the DUR Board Designee Chair. Dr. John Morgan is an Internal Medicine physician with experience in health services research.

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

Dr. Melissa Chouinard motioned to call the DUR meeting to order. Dr. Kathryn Reid seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

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

Minutes – December 10, 2020

Dr. Reid motioned to approve the meeting minutes as submitted. Dr. Cain seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

DUR Board Updates

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

New Drugs

The DUR Board reviewed Bronchitol® (mannitol), Eysuvis™ (loteprednol etabonate), Imcivree™ (setmelanotide), Lupkynis™ (voclosporin), Orgovyx™ (relugolix), Phexxi™ (lactic acid, citric acid, and potassium bitartrate), Tepmetko® (tepotinib), Ukoniq™ (umbralisib), Verquvo™ (vericiguat), Xyrem® (sodium oxybate), Xywav™ (calcium, magnesium, potassium, and sodium oxybates) and Zokinvy™ (lonafarnib). The report for the utilization of these 12 new DUR drugs was reviewed.

Dr. Nancy Eldin reviewed the Drug Utilization Review (DUR) Criteria Development Process.

The DUR Board discussed the service authorization (SA) criteria and the Impact Reports for Bronchitol®. The DUR Board members discussed removing question number 10 (Is there confirmation that the member has NOT experienced any treatment restricting adverse effects (e.g., cough, hemoptysis)?) from the SA criteria. Also, to add to question number 7 the volume of greater than 60 mL in the previous 3 months for referring to significant hemoptysis. Dr. Morgan motioned to accept the service authorization criteria with the removal of question number 10 (Is there confirmation that the member has NOT experienced any treatment restricting adverse effects (e.g., cough, hemoptysis)?) from the SA criteria and to add to question number 7 the volume of greater than 60 mL in the previous 3 months for referring to significant hemoptysis. Dr. Michele Thomas seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the new drug Eysuvis™ and the Impact Reports for Eysuvis™. Debbie Moody discussed adding Eysuvis™ and the entire Ophthalmics, Anti-Inflammatory Immunomodulator Class to the upcoming Pharmacy and Therapeutics (P&T) Meeting in September 2021. The DUR Board discussed adding a quantity limit of 1 bottle in 3 months and sending a message back to the pharmacist stating the need of an intraocular pressure (IOP) test if needing more than 1 bottle in 3 months. This quantity limit will be added to the call center criteria. Dr. Morgan motioned to accept the quantity limit of 1 bottle in 3 months and sending a message back to the pharmacist stating the need of an intraocular pressure (IOP) test if needing more than 1 bottle in 3 months. Dr. Reid seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the SA criteria and the Impact Reports for Imcivree™. Imcivree™ was added to the current DUR Anti-Obesity Drugs SA fax form. The DUR Board members discussed for question number 2 to separate and make "Saxenda only covered for members 18 years or older" its own bullet point. In addition, to remove the statement "Quantity Limit: 34 days supply" from the SA criteria. Also, for question number 3 to add "AND" after the first three bullets, add "OR" after the fourth bullet, and to add "AND" after the fifth bullet. Dr. Morgan motioned to accept the SA criteria with adjustments to question number 2 by separating and making "Saxenda only covered for members 18 years or older" its own bullet point; to remove the statement "Quantity Limit: 34 days supply" from the SA criteria; and for question number 3 to add "AND" after the first three bullets, add "OR" after the fourth bullet, and to add "AND" after the fifth bullet. Denese Gomes seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the SA criteria and the Impact Reports for Lupkynis™. The DUR Board discussed for question number 8 to remove "background immunosuppressive therapy, with the exception of cyclophosphamide" and to replace it with mycophenolate mofetil and corticosteroids. Also, for question number 14 to remove "hypertension" and to add "irreversible" before hyperkalemia. Dr. Cain motioned to accept the SA criteria with adjustments to question number 8 by removing "background immunosuppressive therapy, with the exception of cyclophosphamide" and to replace it with mycophenolate mofetil and corticosteroids and for question number 14 to remove "hypertension" and to add "irreversible" before hyperkalemia. Dr. Thomas seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the SA criteria, the Impact Reports, and the AutoPA criteria for Orgovyx®. The DUR Board discussed adding a urologist to question number 1. Also, to add "significant" in front of "QT/QTc interval prolongations" for question number 7. Dr. Morgan motioned to accept the SA criteria with adding a urologist to question number 1 and adding "significant" in front of "QT/QTc interval prolongations" for question number 7 and the AutoPA criteria with the addition of adding a urologist. Dr. Reid seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the SA criteria and the Impact Reports for Tepmetko®. The DUR Board discussed making the word "not" all capitalized in question number 4. Dr. Cain motioned to accept the SA criteria with making the word "not" all capitalized in question number 4. Dr. Thomas seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the SA criteria and the Impact Reports for Ukoniq™. The DUR Board discussed removing the headers "B-Cell Lymphomas" and "Universal Criteria" from the fax form. Also, to combine question numbers 5 and 6 into one question and listing the two different diagnoses (marginal zone lymphoma and follicular lymphoma) as two bullets under the one question instead of having it as two separate questions. Additionally, to remove question number 7. Dr. Morgan motioned to accept the SA criteria with removing the headers "B-Cell Lymphomas" and "Universal Criteria" from the fax form, and to combine question numbers 5 and 6 into one question and listing the two different diagnoses (marginal zone lymphoma and follicular lymphoma) as two bullets under the one question instead of having it as two separate questions, and to remove question number 7. Dr. Reid seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the SA criteria and the Impact Reports for Verquvo®. The DUR Board discussed changing the wording to question number 8 from "Does the member continue to meet the above criteria?" to "Does the member continue to meet the criteria for question numbers 5 – 7?". Dr. Thomas motioned to accept the SA criteria with changing the wording to question number 8 from "Does the member continue to meet the above criteria?" to "Does the member continue to meet the criteria for question numbers 5 – 7?". Dr. Cain seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

The DUR Board discussed the SA criteria and the Impact Reports for Zokinvy™. The DUR Board discussed removing the wording “in member’s signs and/or symptoms and/or disease status (e.g., no new or worsening heart failure, no stroke incidence, evidence of decreased carotid-femoral pulse wave velocity, evidence of decrease carotid artery wall echodensity)” from question number 9 and replacing it with “, change in the rate of decline, or a decrease in disease progression?”. Dr. Morgan motioned to accept the SA criteria with removing the wording “in member’s signs and/or symptoms and/or disease status (e.g., no new or worsening heart failure, no stroke incidence, evidence of decreased carotid-femoral pulse wave velocity, evidence of decrease carotid artery wall echodensity)” from question number 9 and replacing it with “, change in the rate of decline, or a decrease in disease progression?”. Dr. Thomas seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

New Drugs: DUR Drugs with New Generics; DUR Drugs with New Dosage Forms/Strengths; Biosimilars; New PDL-Eligible Drugs and New Physician Administered Drugs

The DUR Board reviewed the new drugs in this section and had no questions.

Specialty Drugs

MRx Pipeline - The DUR Board reviewed the April 2021 and January 2021 MRx Pipeline Reports. The DUR Board expressed interest in bringing back information on pipeline drug teplizumab IV for the September 2021 DUR meeting.

Topics for Discussion

Concurrent Use of Opioids and Benzodiazepines – The DUR Board reviewed Concurrent Use of Opioids and Benzodiazepines utilization reports for FFS and MCOs.

Concurrent Use of Opioids and Antipsychotics – The DUR Board reviewed Concurrent Use of Opioids and Antipsychotics utilization reports for FFS and MCOs.

Antipsychotic Medications in Children – The DUR Board reviewed the Antipsychotic Medications in Children reports for FFS and MCOs.

Respiratory Drugs (excludes ICS and SABAs) in Members Less than 4 Years of Age – The DUR Board reviewed the Respiratory Drugs (excludes ICS and SABAs) in Members Less than 4 Years of Age reports for FFS and MCOs.

Utilization of Anticoagulant Reversals When Using the Novel Oral Anticoagulants – The DUR Board reviewed the Utilization of Anticoagulant Reversals When Using the Novel Oral Anticoagulants reports for FFS and MCOs.

DUR Quarterly Newsletter – The March 2021, December 2020, and September 2020 DUR newsletters were provided in the binder 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.

Reports

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

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 22451: Diabetes and Hypertension (by diagnosis) and no ACEI or ARB in history. Also, do a comparison to the last time this criterion was run back in September 2019.
- Criterion number 8038: Benzodiazepines – increased FDA warnings for abuse and misuse
- Criterion number 7871: Non-adherence to antidepressants

The DUR Board members expressed an interest in post COVID-19 criteria. Magellan will research to see the possibility of having post COVID-19 criteria.

Other Business

Updates to Lucemyra® Clinical Criteria – The DUR Board reviewed recent updates to the American Society of Addiction Medicine (ASAM) guidelines in reference to Lucemyra®. Due to recent updates to the ASAM guidelines, the DUR Board discussed removing question number 7 “Member has tried and failed, had a contraindication to, or experienced an adverse reaction/intolerance to

clonidine?" from the Lucemyra® clinical criteria. Dr. Cain motioned to remove question number 7 "Member has tried and failed, had a contraindication to, or experienced an adverse reaction/intolerance to clonidine?" from the Lucemyra® clinical criteria. Dr. Reid seconded the motion. (Reference Attachment 1 for the Committee Vote Tally)

Next DUR Meeting

September 9, 2021

Dr. Cain motioned to adjourn the meeting. Dr. Reid seconded the motion. Dr. Morgan adjourned the meeting at 4:00 pm. (Reference Attachment 1 for the Committee Vote Tally)

Attachment 1 – Committee Vote Tally

Committee Vote Taken:	John Morgan, MD (Chair)	Rachel Cain, PharmD	Denise Gomes, NP	Denise Lowe, PharmD	Kathryn Reid, PhD	Melissa Chouinard, MD	Michele Thomas, PharmD	Seth Brant, MD	Wendy Nash, PharmD
Called DUR Meeting to Order	A	A	A	A	S	M	A	A	A
DUR Committee Meeting Minutes from December 10, 2020	A	S	A	A	M	A	A	A	A
Bronchitol® Service Authorization (SA) Criteria with the removal of question number 10 (Is there confirmation that the member has NOT experienced any treatment restricting adverse effects (e.g., cough, hemoptysis)?) from the SA criteria and to add to question number 7 the volume of greater than 60 mL in the previous 3 months for referring to significant hemoptysis.	M	A	A	A	A	A	S	A	A
Eysuvis™ -- adding a quantity limit of 1 bottle in 3 months and sending a message back to the pharmacist stating the need of an intraocular pressure (IOP) test if needing more than 1 bottle in 3 months. The entire Ophthalmics, Anti-Inflammatory Immunomodulator Class will be reviewed at the upcoming Pharmacy and Therapeutics (P&T) Meeting in September 2021.	M	A	A	A	S	A	A	A	A
Imcivree™ SA Criteria with adjustments to question number 2 by separating and making "Saxenda only covered for members 18 years or older" its own bullet point; to remove the statement "Quantity Limit: 34 days supply" from the SA criteria; and for question number 3 to add "AND" after the first three bullets, add "OR" after the fourth bullet, and to add "AND" after the fifth bullet	M	A	S	A	A	A	A	A	A
Lupkynis™ SA criteria with adjustments to question number 8 by removing "background immunosuppressive therapy, with the exception of cyclophosphamide" and to replace it with mycophenolate mofetil and corticosteroids and for question number 14 to remove "hypertension" and to add "irreversible" before hyperkalemia.	A	M	A	A	A	A	S	A	A
Orgovyx® SA criteria with adding a urologist to question number 1 and adding "significant" in front of "QT/QTc interval prolongations" for question number 7 and the AutoPA criteria with the addition of adding a urologist.	M	A	A	A	S	A	A	A	A
Tepmetko® SA Criteria with making the word "not" all capitalized in question number 4.	A	M	A	A	A	A	S	A	A

Committee Vote Taken:	John Morgan, MD (Chair)	Rachel Cain, PharmD	Denise Gomes, NP	Denise Lowe, PharmD	Kathryn Reid, PhD	Melissa Chouinard, MD	Michele Thomas, PharmD	Seth Brant, MD	Wendy Nash, PharmD
Ukoniq™ SA criteria with removing the headers "B-Cell Lymphomas" and "Universal Criteria" from the fax form, and to combine question numbers 5 and 6 into one question and listing the two different diagnoses (marginal zone lymphoma and follicular lymphoma) as two bullets under the one question instead of having it as two separate questions, and to remove question number 7.	**M**	**A**	**A**	**A**	**S**	**A**	**A**	**A**	**A**
Verquvo® SA criteria with changing the wording to question number 8 from "Does the member continue to meet the above criteria?" to "Does the member continue to meet the criteria for question numbers 5 – 7?".	**A**	**S**	**A**	**A**	**A**	**A**	**M**	**A**	**A**
Zokinvy™ SA criteria with removing the wording "in member's signs and/or symptoms and/or disease status (e.g., no new or worsening heart failure, no stroke incidence, evidence of decreased carotid-femoral pulse wave velocity, evidence of decrease carotid artery wall echodensity)" from question number 9 and replacing it with ", change in the rate of decline, or a decrease in disease progression?".	**M**	**A**	**A**	**A**	**A**	**A**	**S**	**A**	**A**
Lucemyra® SA criteria with removing question number 7 "Member has tried and failed, had a contraindication to, or experienced an adverse reaction/intolerance to clonidine?".	**A**	**M**	**A**	**A**	**S**	**A**	**A**	**A**	**A**
Motion to Adjourn Meeting	**A**	**M**	**A**	**A**	**S**	**A**	**A**	**A**	**A**

KEY

M = member made motion

S = member seconded motion

A = member approved

D = member voted against

X = member did not vote