



Advisory Council on Rare Diseases and Personalized Medicine

<u>Date</u>	<u>Time</u>	<u>Location</u>
April 12, 2023	10:30am – 2:00pm (CST)	Howerton Building, Room 202 615 Howerton Court Jefferson City, MO 65109 OR WebEx

[* Click HERE for Meeting Documents *](#)

Board Members Present

Christopher Oermann, MD
Claire Elson, PharmD
Daniel Rosenbluth, MD
Francis Cole, MD
Gerald Wyckoff, PhD
Jennifer Heeley, MD
Jonathan Cooper, PhD
Jonathan Wagner, DO
Matthew McLaughlin, MD, MS
Rosemary Britts
Sherry Graf, RN, BSN
Shivarajan Amudhavalli, M.B.B.S

Board Members Absent

Michael Burke

MO HealthNet Staff Present

Angela Wilson, Pharmacy Operations Manager
Carmen Burton, Pharmacy Support Assistant
Connie Sutter, Fiscal Manager
Elizabeth Short, Program Development Specialist
Elizabeth Sissom, RN, Clinical Review Nurse
Joshua Moore, PharmD, Director of Pharmacy
Danielle Dodd, Special Counsel
Lisa Smith, Pharmacy RFP Coordinator
Mark Roaseau, R.Ph., Clinical Pharmacist
Olivia Rush, PharmD, Program Integrity Pharmacist
Timothy Kling, MD, Acting Medical Director
Zana Stephenson
Ryan Gesch
Somia Hamed, UMKC Pharmacy Student

Contractors Present

Amanda Williams, PharmD, RPh, GWT
Ashley Lytton, RN, BSN, Wipro
Chelsea Pendleton, RN, BSN, Wipro
Jennifer Colozza, PharmD, Conduent
John Crowley, PharmD, BCPS, CPPS, Conduent
Karen Powell, PharmD, MS, GWT
LeAnna Kirsch, RN, Wipro
Lynn Morsches, PharmD, Conduent
Mandy Nilges, RN, Wipro
Megan Fast, PharmD, GWT
Paul Fung, PharmD, MHA Conduent
Sandy Kapur, PharmD, GWT
Serena Barden, PharmD, BCPS, GWT
Vicki Revel, PharmD, GWT

Others Present:

Alison Bass

Bill Robie

Christine Donahue

Cindy Pennington

Dakota Rosenfelt

Duyen Le

Gary Parenteau

Jessica Petrie

JJ Roth

Josie Gamez

Kim Witte

Mariah Scott

Mary Brigid Schultz

Phil

Rob Kegler

Waleed Al-Homoud

Welcome, Announcements and Introductions	Josh Moore, MHD Pharmacy Director, introduced himself along with Danielle Dodd, MHD's Special Council, Somia Hamed, MHD's pharmacy student and Jennifer Heeley and Shivarajan Amudhavalli, the newest Council members. Josh called the meeting to order and facilitated the meeting on behalf of the MHD.
Minutes Review	<p>Discussion: Minutes were reviewed from the November meeting.</p> <p>Decision: The Council voted to accept these approved minutes with no revisions.</p>
Election of New Chair	<p>Discussion: A motion was made by Chris Oermann and seconded by Gerald Wyckoff to elect Claire Elson as the new Council Chair. Claire accepted the motion.</p> <p>Decision: The Council voted to elect Claire Elson as the new Council Chair.</p>
Pharmacy Program and Budget Update	<p>Elizabeth Short and Josh Moore presented information regarding the Pharmacy Program and Budget Updates.</p> <p>Information presented included:</p> <ul style="list-style-type: none"> - February 2023 Enrollees and Expenditures - July 2022 – February 2023 Expenditures by Service - FY20 – FY23 Pharmacy Expenditures vs Total Medicaid Expenditures - February 2023 Medicaid Expansion Participants, Expenditures, and Claim Count - FY19 to FY23 Mavyret Expenditures - CY2023 Per User Per Month Drug Claim Reimbursement - March 2023 Top Ten Reimbursed Drugs - March 2023 Top Ten Reimbursed Drugs for Children 0-17 - Reminder that pharmacists attending the meeting are eligible for continuing education - Example provided of the potential cost to the state regarding accelerated approval pipeline products - BlueBird Bio update – now participating in the Medicaid Drug Rebate Program, but MHD has yet to see a prior authorization request

Moving of Meeting Date	<p>Discussion: Josh Moore introduced the idea of changing the day of the RDAC meetings. Council members discussed the best days for the meetings based on their individual work schedules.</p> <p>Decision: The Council decided to keep the meetings on Wednesday for this current calendar year. MHD to work with the Council Chair to discuss moving the day for next year's meetings.</p>
Old Business	<p>Handouts for the Edit Implementation Schedule and criteria for Previously Approved Clinical Edits, Step Therapies, and Prior Authorizations will be posted to the Division's web page: https://dss.mo.gov/mhd/cs/advisory/rdac/meeting.htm</p>
New Business	
Hemgenix Clinical Edit	<p>Discussion:</p> <ul style="list-style-type: none"> - Josh Moore introduced the product and proposal to the Council for discussion. - The Council discussed the recommended criteria for this product. - Public comment was provided by Christine Donahue with CSL Behring. - It was moved and seconded that the recommended criteria change as follows: <ul style="list-style-type: none"> o Additional approval criteria to be added: <ul style="list-style-type: none"> ▪ Confirmed AAV5 titer level < 1,000 AND ▪ Baseline documentation of (within last six months): <ul style="list-style-type: none"> • Factor IX activity • AST/ALT • INR • Alkaline phosphatase • Total bilirubin • Blood creatine kinase • Hepatic ultrasound & elastography <p>Decision: The Council voted to accept the recommended criteria with the added modifications outlined above.</p>

<p style="text-align: center;">Tziel Clinical Edit</p>	<p>Discussion:</p> <ul style="list-style-type: none"> - Josh Moore introduced the product and proposal to the Council for discussion. - The Council discussed the recommended criteria for this product. - Public comment was provided by Duyen Le with Provention Bio - It was moved and seconded that the recommended criteria change as follows: <ul style="list-style-type: none"> o Change in approval criteria: <ul style="list-style-type: none"> ▪ Abnormal glucose tolerance by oral glucose tolerance test (OGTT) confirmed within 7 weeks of baseline visit using: <ul style="list-style-type: none"> • FPG greater than 100mg/dL and less than 126 mg/dL OR • 2 hour glucose greater or equal to 140 mg/dL and less than 200 mg/dL OR • 30, 60, or 90 minute value on OGTT greater than or equal to 200 mg/dL o Change in denial criteria: <ul style="list-style-type: none"> ▪ Participant is in Stage 1 or 3 of type 1 diabetes <p>Decision: The Council voted to accept the recommended criteria with the added modifications outlined above.* The criteria will be revisited and discussed further at the next meeting.</p> <p>*The Council originally voted to reject the recommended criteria. After the Council was reminded that the vote was solely for the criteria and not for the medication coverage, the vote was retaken.</p>
<p style="text-align: center;">Motion to Close</p>	<p>Matthew McLaughlin motioned for the meeting to be closed (see attached roll call).</p>
<p style="text-align: center;">Other Business/ Rare Disease Topic of Discussion</p>	<p>Zana Stephenson and Ryan Gesch with MHD presented a new dashboard, <i>High Investment Drug Pipeline Potential Impact</i>, to the Council during closed session.</p>

NEXT MEETING: Wednesday, July 12, 2023; 615 Howerton Court, Conference Room 202 Jefferson City, MO 65109 or WebEx

Roll Call for April 12, 2023							
Council Member	November 2022 Minutes	Election of Council Chair	Hemgenix Clinical Edit	Tziel Clinical Edit Original Vote	Tziel Clinical Edit Revote	Closing	Adjournment
Christopher Oermann	MY	MY	Y	N	N	Y	Y
Claire Elson	Y	Y	Y	N	Y	Y	Y
Daniel Rosenbluth	Y	Y	Y	A	A	A	A
Francis Cole	A	A	A	N	SY	Y	SY
Gerald Wyckoff	Y	SY	SY	SY	MY	Y	Y
Jennifer Heeley	Y	Y	Y	Y	Y	Y	Y
Jonathan Cooper	Y	Y	Y	N	Y	Y	Y
Jonathan Wagner	Y	Y	Y	N	N	Y	Y
Matthew McLaughlin	Y	Y	Y	A	Y	MY	Y
Michael Burke	A	A	A	A	A	A	A
Rosemary Britts	A	A	Y	MY	Y	Y	MY
Sherry Graf	SY	Y	MY	Y	Y	SY	Y
Shivarajan Amudhavalli	Y	Y	Y	N	N	Y	Y

Roll Call Abbreviations: A-Absent; AL-Alternate; R-Ratify; M-Motion; S-Second; Y-Yes; N-No; AB-Abstain