



Advisory Council on Rare Diseases and Personalized Medicine

<u>Date</u>	<u>Time</u>	<u>Location</u>
July 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
Francis Cole, MD
Jennifer Heeley, MD
Jonathan Cooper, PhD
Matthew McLaughlin, MD, MS
Rosemary Britts
Sherry Graf, RN, BSN
Shivarajan Amudhavalli, M.B.B.S

Board Members Absent

Daniel Rosenbluth, MD
Gerald Wyckoff, PhD
Jonathan Wagner, DO
Michael Burke

MO HealthNet Staff Present

Ambra Stotler-Bauda, Pharmacy Specialist
Carmen Burton, Pharmacy Support Assistant
Connie Sutter, Fiscal Manager
Danielle Dodd, Special Counsel
Elizabeth Short, Program Development Specialist
Elizabeth Sissom, RN, Clinical Review Nurse
Jennifer Colozza, PharmD, Clinical Pharmacist
Joshua Moore, PharmD, Director of Pharmacy
Kathrine Heriford, Pharmacy Benefit Specialist
Katie Affolder, UHSP Pharmacy Student
Laurel Gibson, UMKC Pharmacy Student
Lisa Smith, Pharmacy RFP Coordinator
Mark Roaseau, R.Ph., Clinical Pharmacist
Nikki Ashley, Pharmacy Program Specialist
Olivia Rush, PharmD, Program Integrity Pharmacist
Timothy Kling, MD, Acting Medical Director

Contractors Present

Amanda Williams, PharmD, RPh, GWT
Ashley Lytton, RN, BSN, Wipro
Chelsea Pendleton, RN, BSN, Wipro
John Crowley, PharmD, BCPS, CPPS, Conduent
Karen Powell, PharmD, MS, GWT
LeAnna Kirsch, RN, Wipro
Lokendra Upadhyay, PharmD, Conduent
Lynn Morsches, PharmD, Conduent
Mandy Nilges, RN, Wipro
Megan Fast, PharmD, GWT
Sandy Kapur, PharmD, GWT
Serena Barden, PharmD, BCPS, GWT

Others Present:

Angela Hailes

Bryan Steffan

Cindy Pennington

Cortney Rogers

Daphne Ni

Ed Paiewonsky

Folger Tuggle

Frank McCutchan

Gary Parenteau

Gene McCarty

Jessica Petrie

John Bullard

Jon Vlasnik

Jon Yochum

Kemi Olabisi

Kevin Mann

Kim Witte

Kyle McNerney

Mark Stephens

Neil White

Paola Mascia

Rachel Boyer

Rob Kilo

Robert Jaramillo

Rushi Parikh

Scott Symes

Sean Jones

Shawn Hayes

Steve Patterson

Tom Cogan

Waleed Al-Homoud

<p>Welcome, Announcements and Introductions</p>	<p>Josh Moore, MHD Pharmacy Director, introduced himself, Jennifer Colozza, MHD's new Clinical Pharmacist, Katie Affolder, UHSP Pharmacy Student, and Laurel Gibson, UMKC Pharmacy Student. Josh called the meeting to order and facilitated the meeting on behalf of the MHD.</p>
<p>Minutes Review</p>	<p>Discussion: Minutes were reviewed from the April meeting.</p> <p>Decision: The Council voted to accept these approved minutes with no revisions.</p>
<p>Pharmacy Program and Budget Update</p>	<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"> - May 2023 Enrollees and Expenditures - July 2022 – May 2023 Expenditures by Service - FY20 – FY23 Pharmacy Expenditures vs Total Medicaid Expenditures - May 2023 Medicaid Expansion Participants, Expenditures, and Claim Count - FY19 to FY23 Mavyret Expenditures - FY23 Top 10 Drug Classes - CY23 Per User Per Month Drug Claim Reimbursement - FY20 – FY23 Rare Disease Expenditures Per Day - Additional information provided regarding <ul style="list-style-type: none"> o Automatic Refill Regulation o CGM Utilization o Project Hep Cure winning the Governor's Award for Quality and Productivity in the area of Innovation o CMS – Diagnosis Code Requirement Comments o High Cost Medications Utilization Increases o Drug Shortages o Provider Manual and MHD Website Updates
<p>Old Business</p>	<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>

<p style="text-align: center;">Givlaari 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. - Ed Paiewonsky with Alnylam Pharmaceuticals, Inc. provided public comment. - Clarification was provided on the requirement that all three random (spot) urine tests are required for approval of this product. <p>Decision: The Council voted to accept the recommended criteria with no modifications.</p>
<p style="text-align: center;">Tzield 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. - Neil White and Kyle McNerney, both with Washington University and Rushi Parikh with Prevention Bio/Sanofi provided public comment. - It was moved and seconded that the recommended criteria change as follows: <ul style="list-style-type: none"> o Approval Criteria Changes: <ul style="list-style-type: none"> ▪ Evidence of abnormal glucose tolerance as confirmed by one or more of the following (within 7 weeks of baseline visit): <ul style="list-style-type: none"> • FPG greater than 100mg/dL and less than 126 mg/dL OR • Hemoglobin A1c ≥ 5.7% and < 6.5% OR • Hemoglobin A1c increase ≥ 10% from baseline 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 • <p>Decision: The Council voted to accept the recommended criteria with the added modifications outlined above.</p>

New Business	
Daybue 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. - Kemi Olabisi with Acadia provided public comment. - Josh informed the Council of the Centers of Excellence located in St. Louis. - Clarification was provided regarding the neurologist being experienced in the management of RTT – MHD understands not every neurologist will be experienced in the management of RTT, therefore MHD will allow for consultation with a neurologist who is. - It was moved and seconded that the recommended criteria change as follows: <ul style="list-style-type: none"> o Approval Criteria – Continuation of Therapy Changes: <ul style="list-style-type: none"> ▪ Documentation of clinical benefit of therapy through improvement, stabilization, or less than expected decline in disease progression <p>Decision: The Council voted to accept the recommended criteria with the added modifications outlined above.</p>
Filspari 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. - Tom Cogan with Traverre Therapeutics provided public comment. - It was moved and seconded that the recommended criteria change as follows: <ul style="list-style-type: none"> o Approval Criteria – Initial Therapy Changes: <ul style="list-style-type: none"> ▪ Documented therapeutic trial of an ACEI or ARB at a maximally tolerated dose for at least 3 months of therapy <p>Decision: The Council voted to accept the recommended criteria with the added modifications outlined above.</p>

<p style="text-align: center;">Joenja 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. - Shawn Hayes with Pharming Healthcare provided public comment. - It was moved and seconded that the recommended criteria change as follows: <ul style="list-style-type: none"> o Approval Criteria Changes: <ul style="list-style-type: none"> ▪ Documentation of baseline liver function tests o Denial Criteria Changes: <ul style="list-style-type: none"> ▪ Concurrent use of immunosuppressant therapy (e.g., rituximab, sirolimus) ▪ Participant is currently pregnant or lactating ▪ Participant has documented moderate to severe hepatic impairment <p>Decision: The Council voted to accept the recommended criteria with the added modifications outlined above.</p>
<p style="text-align: center;">Lamzede 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. - Paola Mascia with Chiesi Global provided public comment. - It was moved and seconded that the recommended criteria change as follows: <ul style="list-style-type: none"> o Approval Criteria – Continuation of Therapy Changes: <ul style="list-style-type: none"> ▪ Documentation of clinical benefit of therapy, such as improvement in stair climbing, walking, or forced vital capacity from baseline or less than expected decline in disease progression o Denial Criteria Changes: <ul style="list-style-type: none"> ▪ Participant is currently pregnant <p>Decision: The Council voted to accept the recommended criteria with the added modifications outlined above.</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>Other Business/ Rare Disease Topic of Discussion</p>	<p>Annual Sickle Cell Report Expectations:</p> <ul style="list-style-type: none">- Review in October- Brief overview of pipeline- New approved therapies- MHD utilization data:<ul style="list-style-type: none">o Children vs adult populationo Approved productso Opioids/other pain related medicationso ER/inpatient visits- Statewide planning draft report from WashU- Council asked for MHD to work in collaboration with Dr. Alison King and Dr. Morey Blender as they are experienced in treating Sickle Cell
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NEXT MEETING: Wednesday, October 11, 2023; 615 Howerton Court, Conference Room 202 Jefferson City, MO 65109 or WebEx

Roll Call for July 12, 2023

Council Member	April 2023 Minutes	Givlaari Clinical Edit	Tzield Clinical Edit	Daybue Clinical Edit	Filspari Clinical Edit	Joenja Clinical Edit	Lamzede Clinical Edit	Closing	Adjournment
Christopher Oermann	A	A	A	Y	Y	SY	SY	Y	SY
Claire Elson	Y	Y	SY	Y	Y	Y	Y	Y	Y
Daniel Rosenbluth	A	A	A	A	A	A	A	A	A
Francis Cole	Y	MY	MY	MY	Y	MY	MY	Y	Y
Gerald Wyckoff	A	A	A	A	A	A	A	A	A
Jennifer Heeley	Y	Y	Y	Y	Y	Y	Y	Y	Y
Jonathan Cooper	Y	AB	Y	Y	Y	Y	Y	Y	Y
Jonathan Wagner	A	A	A	A	A	A	A	A	A
Matthew McLaughlin	MY	SY	AB	Y	Y	AB	AB	MY	Y
Michael Burke	A	A	A	A	A	A	A	A	A
Rosemary Britts	A	Y	Y	Y	SY	Y	Y	Y	Y
Sherry Graf	SY	Y	Y	SY	MY	Y	Y	SY	MY
Shivarajan Amudhavalli	Y	Y	Y	Y	Y	Y	Y	Y	Y

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