



Advisory Council on Rare Diseases and Personalized Medicine

<u>Date</u>	<u>Time</u>	<u>Location</u>
May 10, 2022	10:30am – 2:00pm (CST)	Howerton Building, Room 202 615 Howerton Court Jefferson City, MO 65109 OR WebEx

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

Council Members Present:

Patricia Dickson, MD, Chair
Gerald Wyckoff, PhD
Christopher Oermann, MD
Matthew McLaughlin, MD, MS
Eric Rush, MD, FAAP, FACMG
Jonathan Cooper, PhD
Rosemary Britts

Council Members Absent:

Daniel Rosenbluth, MD
Jonathan Wagner, DO
Sherry Graf, RN, BSN
Claire Elson, PharmD
Francis Cole, MD
Michael Burke

MO HealthNet Staff Present:

Joshua Moore, PharmD, Director of Pharmacy
Mark Roaseau, R.Ph, Clinical Pharmacist
Angela Wilson, Pharmacy Operations Manager
Olivia Rush, PharmD, Program Integrity Pharmacist
Elizabeth Sissom, RN, Clinical Management
Lisa Smith, RFP Coordinator
Carmen Burton, Administrative Assistant
Timothy Kling, MD, Acting Medical Director
Elizabeth Short, Program Development Specialist
Connie Sutter, Fiscal Manager
Denise Sappenfield, Benefit Program Senior Specialist
Jamie Hurst, Benefit Program Senior Specialist

Contractors Present:

April Ash, PharmD, Conduent
Blake ShROUT, PharmD, AAHIVP, Conduent
Jennifer Colozza, PharmD, Conduent
Megan Fast, PharmD, Conduent
Paul Fung, PharmD, Conduent
Chelsea Pendleton, RN, BSN, Wipro
Geri Roling, RN, Wipro
Valerie Schmitz, RN, BSN, Wipro
Ashley Lytton, RN, BSN, Wipro

Others Present:

Angela Hailes

Dave Poskey

Eddie

Jeff Knappen

Jenny Carrell

Jessica Petrie

Jim Maxson

John Bullard

Jon Kendter

Louis Hudspeth

Nila Stevens

Raquel Jordan

Rob Kilo

Rocco Iannetta

Sam Marshall

Sue Rahman

<p>Welcome, Announcements and Introductions</p>	<p>Patricia Dickson, Council Chair, called the meeting to order.</p> <p>Josh Moore, MHD Pharmacy Director, introduced himself along with Jamie Hurst, MHD's new Benefit Program Senior Specialist and facilitated the meeting on behalf of the MHD.</p>
<p>Minutes Review</p>	<p>Discussion: Minutes were reviewed from the February 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 a brief power point of the Pharmacy Program and Budget Updates. Information presented included:</p> <ul style="list-style-type: none"> - July 2021 – March 2022 Eligibles by Group - July 2021 – March 2022 Expenditures by Enrollment Group - July 2021 – March 2022 Expenditures by Service - FY22 Pharmacy Spend vs July 2021 – March 2022 Total Medicaid Spend - Medicaid Expansion Participants, Expenditures and Claim Counts October 2021 – March 2022 - July 2021 – April 2022 Pharmacy Expenditures - FY2019 – FYTD2022 Rare Disease Expenditures Per Day - Trikafta Expenditures FYTD22 - Additional discussions arose around: <ul style="list-style-type: none"> o Utilization management strategies for albuterol inhaler quantity limits and continuous glucose monitors. o Forthcoming Rare Disease and Pipeline Dashboard
<p>Old Business</p>	<p>Josh Moore discussed the Edit Implementation Schedule and the criteria for Previously Approved Clinical Edits, Step Therapies and Prior Authorizations.</p> <p>These handouts were also provided to all attendees and will be posted to the Division's web page: https://dss.mo.gov/mhd/cs/advisory/rdac/meeting.htm</p>

New Business	
<p>Besremi Clinical Edit</p> <p>Targeted Immune Modulators, Small Molecule JAK Inhibitors Clinical Edit</p>	<p>Discussion:</p> <ul style="list-style-type: none"> - Josh Moore introduced the products and proposal to the Council for discussion. - The Council discussed the recommended criteria for these products. <ul style="list-style-type: none"> o Discussion arose around: <ul style="list-style-type: none"> ▪ Open label studies and the approval pathway for the medication ▪ Hydroxyurea requirements and the equity across other edits ▪ Mental health denial criteria and how MHD will be completing manual reviews for this portion of the edit to ensure appropriateness for individual participants o No recommended criteria changes. - No public comment provided. <p>Decision: The Council voted to accept the recommended criteria with no changes.</p>
<p>Enjaymo 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. <ul style="list-style-type: none"> o Discussion arose around: <ul style="list-style-type: none"> ▪ Clinical study design including: <ul style="list-style-type: none"> • Open label study • Short follow period of 6 months • Few enrollees • Primary outcomes • FACIT Fatigue Scale ▪ Coverage of Rixutimab – MHD does approve the medication for this indication ▪ Potential requirement of iron supplementation prior to Enjaymo – it was decided this type of requirement may cause iron overload in this population o No recommended criteria changes. - Public comments provided by: <ul style="list-style-type: none"> o Jon Kendter with Sanofi Genzyme <p>Decision: The Council voted to accept the recommended criteria with no changes.</p>

<p align="center">Enzyme Deficiency, Select Agents 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 <ul style="list-style-type: none"> o For Brinura, it was explained TPP1 is the gene while CLN2 is the disease state o It was clarified that the specialist requirement is for all medications within the edit o Questions arose around the age criteria and if it would make more sense to remove this criteria for the patient populations that would benefit from starting the medications earlier in life compared to the FDA label age o For Strensiq, questions arose around the need for one vs two pathogenic variants in the requirements. After discussion, it was decided to leave the criteria as is. - No public comments provided. <p>Decision: The Council voted to table this edit with the recommendation to break the edit apart into the different disease states.</p>
<p align="center">Vyvgart 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. <ul style="list-style-type: none"> o No recommended criteria changes. o No public comments provided <p>Decision: The Council voted to accept the recommended criteria with no changes.</p>
<p align="center">Other Business/ Rare Disease Topic of Discussion</p>	<p>Potential topics for MHD or the Council to present at future meetings:</p> <ul style="list-style-type: none"> - Sickle Cell annually - DMD/SMA in August – Dr. McLaughlin - Indications for whole exome mapping in November – Dr. Rush <p>Discussion arose around:</p> <ul style="list-style-type: none"> - Feedback MHD receives on the recommended criteria from the Council. - Human growth hormone and IVIG progress following the decrease in MHD approved indications. - Potential term expirations for the current Council members
<p align="center">Closing</p>	<p>Matthew McLaughlin motioned for the meeting to be closed (see attached roll call).</p>

NEXT MEETING: Tuesday, August 9, 2022; 615 Howerton Court, Conference Room 202 Jefferson City, MO 65109 or WebEx

Roll Call for May 10, 2022								
Council Member	February 2022 Minutes	Besremi Clinical Edit	TIMS JAK Clinical Edit	Enjaymo Clinical Edit	Enzyme Deficiency Clinical Edit	Vyvgart Clinical Edit	Closing	Adjournment
Patricia Dickson	Y	Y	Y	Y	Y	Y	Y	Y
Sherry Graf	A	A	A	A	A	A	A	A
Michael Burke	A	A	A	A	A	A	A	A
Jonathan Cooper	AB	Y	Y	Y	Y	Y	Y	Y
Gerald Wyckoff	SY	MY	Y	Y	Y	Y	Y	SY
Francis Cole	A	A	A	A	A	A	A	A
Claire Elson	A	A	A	A	A	A	A	A
Christopher Oermann	MY	Y	MY	Y	MY	Y	SY	Y
Daniel Rosenbluth	A	A	A	A	A	A	A	A
Jonathan Wagner	A	A	A	A	A	A	A	A
Matthew McLaughlin	Y	SY	SY	MY	Y	MY	MY	Y
Eric Rush	Y	Y	Y	Y	Y	Y	Y	Y
Rosemary Britts	Y	Y	Y	SY	SY	SY	Y	MY

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