

RARE DISEASE ADVISORY COUNCIL MEETING
November 9, 2021
MO HealthNet
VIA WEBEX ONLY

Council Members Present:

Patricia Dickson, MD, Chair
Jonathan Cooper, PhD
Jonathan Wagner, DO
Rosemary Britts
Claire Elson, PharmD
Sherry Graf, RN, BSN
Eric Rush, MD, FAAP, FACMG
Christopher Oermann, MD
Matthew McLaughlin, MD, MS
Francis Cole, MD

Council Members Absent:

Michael Burke
Gerald Wyckoff, PhD
Daniel Rosenbluth, MD

MO HealthNet Staff Present:

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

Contractors Present:

April Ash, PharmD, Conduent
Blake Shrout, PharmD, AAHIVP, Conduent
Jennifer Colozza, PharmD, Conduent
Luke Boehmer, PharmD, Conduent
Megan Fast, PharmD, Conduent
Paul Fung, PharmD, Conduent
Sandra Kapur, PharmD, Conduent
Serena Barden, PharmD, BCPS, Conduent
Chelsea Pendleton, RN, BSN, Wipro
Geri Roling, RN, Wipro
Valerie Schmitz, RN, BSN Wipro

Others Present:

Aileen Chi
Akesha Coleman
Ann Lucas
Brian Strickland
Donald Nopper
Jamie Tobitt
Jeff Knappen
Jill Conner
Jim Maxson
JJ Roth
John
Jonathan Leesman
Karen Evenson
Mark Sveda
Nila Stevens
Praneeta Nagraj
Rob Kilo
Sarah Lott

<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 and facilitated the meeting on behalf of the MHD.</p>
<p>Minutes Review</p>	<p>Discussion: Minutes were reviewed from the May 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-Sept 2021 Eligibles by Group - July-Sept 2021 Expenditures by Enrollment Group - July-Sept 2021 Expenditures by Service - FY22 Pharmacy Spend vs July-Sept 2021 Total Medicaid Spend - July 2021-Oct 2021 Pharmacy Expenditures - Pharmacy Expenditures/Eligibles Per FY - FY2019 – FYTD2022 Rare Disease Expenditures Per Day - July 1, 2021 340B Reimbursement Changes - Trikafta Spend/Utilization Overview - Rare Disease Drugs Pipeline Update - Leukotrienes Policy Changes
<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 style="text-align: center;">Bylvay, Livmarli Bile Salt Agents PDL 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 the need for continuation therapy based on the discontinuation rate due to lack of improvement seen in the clinical trial o Recommended criteria changes: <ul style="list-style-type: none"> ▪ Initial approval of prior authorization is for 6 months. Renewal of prior authorization for up to 1 year may be given following documentation of clinical benefit as evidenced by decrease in pruritus symptoms - Public comments provided by: <ul style="list-style-type: none"> o Praneeta Nagraj with Albiero Pharma Inc. on Bylvay <p>Decision: The Council voted to accept the recommended criteria with the above revisions in blue.</p>
<p style="text-align: center;">Empaveli 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 these products. <ul style="list-style-type: none"> o Discussion arose around the default approval period. o No recommended criteria changes. - Public comments provided by: <ul style="list-style-type: none"> o Jamie Tobitt with Apellis on Empaveli <p>Decision: The Council voted to accept the recommended criteria with no changes.</p>

<p style="text-align: center;">Nexviazyme Pompe Disease 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 these products. <ul style="list-style-type: none"> o Discussion arose around the study results showing statistical vs clinical significance along with minimal clinical important differences shown. o No recommended criteria changes. - Public comments provided by: <ul style="list-style-type: none"> o Ann Lucas with Sanofi Genzyme on Nexviazyme <p>Decision: The Council voted to accept the recommended criteria with no changes.</p>
<p style="text-align: center;">Other Business</p>	<p>No other rare disease topics of discussion were presented to the Council.</p>
<p style="text-align: center;">Closing</p>	<p>Matthew McLaughlin motioned for the meeting to be closed (see attached roll call). The next meeting of the Rare Disease Advisory Council is scheduled on Tuesday, February 8, 2022.</p>

DRAFT

Roll Call for November 9, 2021						
Council Member	May 2021 Minutes	Bile Sale Agents PDL Edit	Empaveli Clinical Edit	Pompe Disease Clinical Edit	Closing	Adjournment
Patricia Dickson	Y	Y	Y	AB	Y	Y
Sherry Graf	Y	Y	SY	Y	Y	MY
Michael Burke	A	A	A	A	A	A
Jonathan Cooper	Y	Y	Y	SY	Y	Y
Gerald Wyckoff	A	A	A	A	A	A
Francis Cole	SY	A	A	Y	Y	Y
Claire Elson	Y	Y	Y	Y	Y	Y
Christopher Oermann	MY	MY	Y	MY	SY	Y
Daniel Rosenbluth	A	A	A	A	A	A
Jonathan Wagner	Y	Y	Y	Y	Y	Y
Matthew McLaughlin	AB	SY	Y	Y	MY	Y
Eric Rush	Y	Y	Y	Y	Y	Y
Rosemary Britts	A	Y	MY	Y	Y	SY

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