

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

Council Members Present:

Patricia Dickson, MD, Chair
Jonathan Cooper, PhD
Gerald Wyckoff, PhD
Francis Cole, MD
Christopher Oermann, MD
Jonathan Wagner, DO
Matthew McLaughlin, MD, MS
Rosemary Britts
Claire Elson, PharmD
Sherry Graf, RN
Daniel Rosenbluth

Council Members Absent:

Michael Burke
Eric Rush, MD

MO HealthNet Staff Present:

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

Contractors in Attendance:

Jennifer Colozza, PharmD, Conduent
Megan Fast, PharmD, Conduent
Karen Powell, PharmD, Conduent
Janelle Sheen, PharmD, Conduent
Sandy Kapur, PharmD, Conduent
April Ash, PharmD, Conduent
Geri Roling, RN, Wipro
Chelsea Pendleton, RN, BSN, Wipro
Valerie Schmitz, RN, BSN, Wipro
Anson Williams, Conduent

Others Attending:

Brent Young
Gina Heinen
Jeff Knappen
Jessica Petrie
Karen Floeder
Mandy Schnelten
Mary Stoots
Matthew Sheffield
Melissa DuVall
Sean Jones
WITTEK1

| | |
|--|---|
| <p>Welcome, Announcements and Introductions</p> | <p>Patricia Dickson, Council Chair, called the meeting to order.</p> <p>Joshua Moore introduced himself and welcomed everyone to the meeting.</p> |
| <p>Minutes Review</p> | <p>Discussion: Minutes were reviewed from the November meeting.</p> <p>Decision: The Council voted to accept these approved minutes with no revisions.</p> |
| <p>Pharmacy Program and Budget Update</p> | <p>Joshua Moore presented a brief power point of the Pharmacy Program and Budget Updates. Information presented included:</p> <ul style="list-style-type: none"> - December 2020 Eligibles by Group - July – December 2020 Expenditures by Enrollment Group - July – December 2020 Expenditures by Service - FY21 Pharmacy Spend vs July – December 2020 Total Medicaid Spend - FY21 July 2020 – January 2021 Pharmacy Expenditures - July 2020 – January 2021 Rare Disease Expenditures - FY2019 – FYTD2021 Rare Disease Expenditures - Missouri COVID-19 websites: covidvaccine.mo.gov OR mostopscovid.gov |
| <p>PA Committee and DUR Board Update</p> | <p>Joshua Moore discussed updates from the December Drug PA Committee meeting and January DUR Board meeting which included:</p> <ul style="list-style-type: none"> - No changes were made by either committee on the edit recommendations provided by the November Rare Disease Advisory Council meeting - Informational: reductions in MME limits from 200 MME to 150 MME coming April 2021 |
| <p>Old Business</p> | <p>Joshua Moore discussed the Edit Implementation Schedule and the criteria for Previously Approved Clinical Edits, Step Therapies and PA's.</p> |

New Business

Orladeyo – Hereditary Angioedema Treatment Agents PDL Edit, Prophylactics Agents

Discussion:

- Joshua Moore introduced the product for discussion to the Council.
- The Council discussed the recommended criteria for this product.
 - o Questions arose around:
 - Trial/failure criteria – MHD’s bid solicitation and preferred drug list process was further explained
 - Low/quantitative C4 levels – explained some literature states it can be difficult to obtain this level and for providers to use reference lab levels
 - Pregnancy considerations for this drug and class as a whole – discussion showed there was no pregnancy or lactation contraindications listed in the package insert, therefore no need for additional criteria
 - Continuation of therapy needs to include demonstration of benefit for re-approval – benefit of drug could vary between participants so it could be hard to determine efficacy (see additional criteria below)
 - o Recommended criteria changes:
 - **Initial Therapy:**
 - **Prescribed by or in consultation with an allergy-immunologist, maternal fetal medicine specialist, or other appropriate specialist for the treated disease state**
 - **Continuation of Therapy:**
 - **Documented compliance on current therapy regimen AND**
 - **Documented benefit of therapy based on goals**
- No public comments provided

Decision: The Council voted to accept the recommended criteria with the above revisions in **blue**.

| | |
|--|---|
| <p>Trikafta – Outcomes Review</p> | <p>Discussion:</p> <ul style="list-style-type: none"> - Joshua Moore introduced the Trikafta outcomes for discussion to the Council. <ul style="list-style-type: none"> o Outcomes on MOHealthNet participants based on available claims data - The Council discussed the initial outcomes and made recommendations on additional outcomes they would like to see going forward <ul style="list-style-type: none"> o Overall, outcomes were put together very well, just needing additional details - No public comment provided <p>Decision: There was no vote taken on this agenda topic.</p> |
| <p>Oxlumo Clinical Edit</p> | <p>Discussion:</p> <ul style="list-style-type: none"> - Joshua Moore introduced the product for discussion to the Council. - The Council discussed the recommended criteria for this product. <ul style="list-style-type: none"> o Questions arose around: <ul style="list-style-type: none"> ▪ Subcutaneous administration via healthcare professional – discussion showed that administration by a healthcare professional is found within the package insert o Recommended criteria changes: none - No public comments provided <p>Decision: The Council voted to accept the recommended criteria with no changes.</p> |
| <p>Other Business</p> | <p>No other rare disease topics of discussion were presented to the Council.</p> |
| <p>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 via WebEx only on Tuesday, May 11, 2021.</p> |

| Roll Call for February 9, 2021 | | | | | |
|---------------------------------------|------------------------------|-------------------------------|-----------------------------|----------------|--------------------|
| Council Member | November 2020 Minutes | Orladeyo/ HAE PDL Edit | Oxlumo Clinical Edit | Closing | Adjournment |
| Patricia Dickson | Y | Y | AB | Y | Y |
| Sherry Graf | Y | Y | Y | Y | Y |
| Michael Burke | A | A | A | A | A |
| Jonathan Cooper | Y | Y | A | Y | Y |
| Gerald Wyckoff | MY | Y | MY | Y | MY |
| Francis Cole | SY | SY | SY | Y | Y |
| Claire Elson | Y | Y | Y | Y | Y |
| Christopher Oermann | Y | MY | Y | Y | Y |
| Daniel Rosenbluth | Y | Y | Y | Y | Y |
| Jonathan Wagner | Y | Y | Y | SY | Y |
| Matthew McLaughlin | Y | Y | Y | MY | SY |
| Eric Rush | A | A | A | A | A |
| Rosemary Britts | Y | Y | Y | Y | Y |

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