

Montana Healthcare Programs Drug Utilization Review Board Agenda

Hosted by Mountain Pacific Quality Health

October 21, 2020

1-4 PM

Virtual Call Only

[Register in advance for this meeting:](https://mpqhf.zoom.us/meeting/register/tJA1c-CvqD0rG90DXxvwcMzjsOvGY7obVlBf)

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1. Introductions
2. Public Comment
3. Meeting Minutes
4. Department Update
5. PDL Meeting follow up discussion

At this time the Montana Healthcare Programs DUR Board/Formulary Committee will review the following drug classes for Preferred Drug List (PDL) review:

All drugs reviewed pertain to oral drugs unless otherwise indicated

NI—New Information, ND—New Drug, NG—New Generic

**HYPOGLYCEMICS, INCRETIN MIMETICS - ND-Rybelsus, NI-Victoza, Ozempic, Trulicity, Qtern
HYPOGLYCEMICS, INSULINS – NI-Toujeo, FIASP**

Please see attached information regarding providing public testimony for the PDL portion of this meeting.

6. Multiple Sclerosis Agent Discussion
7. Specialty Clinic discussion
8. New Criteria Development
 - a. Fintepla
 - b. Dayvigo
 - c. Evrysdi
9. Existing Criteria Updates
 - a. Epidiolex – Tuberos Sclerosis Indication
10. Physician Administered Drug Program
 - a. Physician Administered Drugs already approved by Board
 - i. Cinqaur
 - ii. Exondys 51
 - iii. Sublocade
 - iv. Xolair
 - v. Vivitrol
 - vi. Krystexxa
 - vii. Nucala
 - b. New Medications
 - i. Prolia
 - ii. Entyvio

- iii. Ocrevus
 - iv. Simponi Aria
 - v. Evenity
 - vi. Fasenra
 - vii. Xgeva
 - viii. Spinraza
- 11. PDL/DURB meeting follow-up items
 - a. December Meeting 12/9/20?
 - 12. Closed Session

Public Testimony must be limited to aforementioned PDL classes (Agenda item # 5) . It will NOT be permitted for DUR discussion topics.

Public Testimony via **teleconference** will be taken into consideration in the committee's recommendations as to which drugs should be given preferred status in the above listed classes of medications for the state's Medicaid program. **Those wishing to provide public testimony must inform the Department via the pdl email listed below by 12pm on October 20th.** See the General Procedures for Public Comment section of this document for further details

Clinical Information: New clinical information (in electronic format in PDF in the AMCP style dossier or desired style. All submitted documents must be compliant with Section 508 of the Federal Rehabilitation and Service Act and may be sent by [e-mail on the drug classes listed above by October 15, 2020 to PDL@mt.gov](mailto:PDL@mt.gov)

Note: If you wish to submit clinical information pertaining to the PDL review process for drugs within the designated classes, peer-reviewed literature including off label peer-reviewed studies or AMCP style – dossiers will be accepted in electronic PDF format **only** and **must** be compliant with Section 508 of the Federal Rehabilitation and Service Act. Please note that all information sent is subject to public disclosure and that proprietary and confidential material should not be sent and that the sender accepts responsibility for all information sent. The department receives frequent communications from Pharmaceutical manufacturers. Please indicate whether the information submitted is intended for PDL informational posting. All PDL information sent will be posted on a public website for viewing. Department Personnel will not sign manufacturer release of information waivers.

**Montana Healthcare Programs
Department of Public Health and Human Services
DUR Board/Formulary Committee Meeting
General Procedures for Public Comment**

1. Requests by Pharmaceutical Manufacturers and Special Interest Groups to provide Public Comment for each Drug Class to be reviewed must be submitted to the Department via email between the time of posting of the agenda until 12pm the day prior to the meeting.

2. Sign up will close by 12pm the day prior to the beginning of the DUR Board Meeting.

3. Speakers will be asked to present NEW INFORMATION ONLY on their corresponding product or interest. New drugs, indications, or studies must have been publicly available at least 45 days prior to the scheduled meeting.

a. New Information is considered the following:

1. New drugs/indications for drugs in categories on the agenda (since last review)
2. New randomized comparative controlled trials that have been published in a peer-reviewed journal (published since last review)
3. New randomized controlled trials (this can include placebo) with true health outcomes data not surrogate endpoints, disease markers, or subjective assessment endpoints (same frequency cadence as noted above)
4. Significant safety changes for existing drugs such as black box warnings.

Information to be presented MUST be emailed to the Department (pdl@mt.gov) at least 1 week prior to the meeting so that the Department may determine if it meets the criteria listed above. Information not submitted for review in a timely manner may not be presented.

b. Public comment will be allowed for up to 3 minutes to present new information about their product. However, please be respectful of your other colleagues and also of the Board's time. Please do not take 3 minutes if it is not needed. The DUR Board Coordinator has the option to end a speaker's comment time if the information is not relevant to the topic of discussion.

c. Speakers must state their name, their affiliation, and whom they are speaking on behalf of or on request of, with any funding or payment agreements disclosed. Any studies cited during the presentation should be referenced with the primary source of funding included.

d. Handouts are limited to two (2) pages (paper size: 8.5" by 11", one side only) of documentation. Handouts must be emailed to the Department with the request to provide Public Comment. They will be forwarded to the DUR Board, and any member of the public requesting a copy, prior to the meeting.

e. Public Comment will be limited to clinical and social comments; pricing or financial information regarding products and outcomes will not be permissible. The Board will be utilizing clinical information only. Information regarding pricing, cost or any other information of a financial nature will not be permissible and should not be discussed in handouts or during presentation by any public speaker.

f. The speakers presenting handouts are asked to provide **an electronic copy in pdf format** that will be distributed by Mountain-Pacific Quality Health (MPQH) staff to the DUR Board members, State staff and for public distribution.

g. The State, MMA and the DUR Board will be allowed to ask questions if needed during the presentation or after for clarification or discussion. Presenters will only be allowed to answer questions when specifically requested to do so by the Board during the remainder of the meeting.

h. It is not permissible for presenters to interject or ask questions to DUR Board members during the session.

4. Individual products may only be represented by one presentation. For example, a product jointly ventured by two pharmaceutical companies can only be represented once.

Note: These procedures may be revised at the discretion of the Department.