PREFERRED DRUG LIST MEETING SCHEDULE

State of Montana
Department of Public Health & Human Services
Montana Medicaid Drug Use Review (DUR) Board/Formulary Committee Meeting

The State of Montana Medicaid DUR Board/Formulary Committee will hold a meeting on :

Date: April 22, 2020 (Wednesday)
Time: 1:00 pm – 5:00 pm Mountain Time
Location: Due to the COVID-19 pandemic this meeting will be conducted by teleconference only. Register in advance for this meeting. After registering, you will receive a confirmation email containing information about joining the meeting. Those wishing to provide public testimony must follow the additional instructions provided below.
https://mpqhf.zoom.us/meeting/register/tZckc0morzIvj5TB3LLK7sgyDoG48EeWYQ

At this time the Montana Medicaid 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

The Department will review **GROUP 3** as **NEW** information is known to exist:

- ACNE AGENTS- ND – Aklief, Amzeeq, NI Aczone,
- ANTI-ALLERGENS, ORAL – ND Palforzia
- ANTIBIOTICS, GI – NI Dificid
- ANTIPSORIATICS, TOPICAL – NI Sorilux
- ANTIVIRALS, ORAL (HSV/Influenza)- NI Xofluza
- COPD AGENTS – ND Duaklir Pressair
- CYTOKINES & CAM ANTAGONIST –ND Skyrizi, Rinvoq NI- Cosentyx, Otezla, Stelara, Taltz, Xeljanz/Xeljanz XR
- FLUOROQUINOLONES, ORAL- ND-Baxdela
- GLUCOCORTICOIDS, INHALED–NI-Dulera, Asmanex HFA
- GLUCOCORTICOIDS, ORAL- NI Emflaza
- HEPATITIS C AGENTS – NI Mavyret, Sovaldi, Harvoni
- IMMUNOMODULATORS, ATOPIC DEMATITIS- NI Dupixent
- LEUKOTRIENE MODIFIERS- FDA montelukast

The Department will validate **GROUP 2** Formulary Committee's clinical recommendations unless manufacturers submit **NEW relevant clinical** information prior to the deadline noted below.

- ANTIBIOTICS, INHALED
- ANTIBIOTICS - TOPICAL
- ANTIBIOTICS, VAGINAL
- ANTIFUNGALS, ORAL
- ANTIFUNGALS, TOPICAL
- ANTIHISTAMINES- MIN SEDATING
- ANTINEOPLASTIC AGENTS, TOPICAL
- ANTIPARASITICS, TOPICAL
- ANTIVIRALS, TOPICAL
- BLADDER RELAXANTS
- BPH AGENTS
- BRONCHODILATORS, BETA AGONISTS
- CEPHALOSPORINS & RELATED AGENTS
- EPINEPHRINE, SELF-INJECTED
- IMMUNOMODULATORS, TOPICAL
- IMMUNOSUPPRESSANTS
- INTRANASAL RHINITIS AGENTS
- MACROLIDES & KETOLIDES
- METHOTREXATE AGENTS
- PHOSPHATE BINDERS
- ROSACEA AGENTS, TOPICAL
- SMOKING CESSATION
- STEROIDS, TOPICAL
- TETRACYCLINES

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 April 21st. 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 April **8, 2020** to email 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.

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 the posting of the agenda until 12 pm the day prior to the meeting.

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

3. Speakers will be assigned on a first come basis respective to each Drug Class discussion.

4. Speakers will be asked to present NEW INFORMATION ONLY on their corresponding product or interest. New drugs, indications, or studies must have been publically 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 or within the last 12 months-whichever is shorter)
    2. New randomized comparative controlled trials that have been published in a peer-reviewed journal (published since last review or within the last 12 months-whichever is shorter)
    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 2 weeks 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 requesiting 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 MPQH staff to the DUR Board members, State staff and for public distribution.

g. Copies will be collected by Foundation staff members at the time of sign-up.

h. 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.

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

5. 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.