

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 25, 2012 (Wednesday)
Time: 1:00 pm – 5:00 pm Mountain Time
Location: Holiday Inn Downtown
22 North Last Chance Gulch Street, Helena

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.

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

- ANGIOTENSIN MODULATORS (ARBS) - Edarbyclor
- ANGIOTENSIN MODULATORS (ACE & DRI) -FDA Update
- ANGIOTENSIN MODULATORS COMBINATIONS - FDA Update
- ANTICONVULSANTS - Onfi, Category expansion to include PB, Diastat, diazepam rectal
- BETA BLOCKERS & COMBOS - Dutoprol
- INCRETIN ENHANCERS/MIMETICS - Bydureon , Byetta, Janumet XR, Jentaduetto, Juvissync, Kombiglyze XR, Onglyza,
- LIPOTROPICS, STATINS - FDA labeling update
- PROTON PUMP INHIBITORS - Updated FDA warning

The Department proposes no changes to the Formulary Committee's clinical recommendations to **GROUP 2** unless manufacturers submit **NEW** information:

- ALZHEIMER'S AGENTS
- ANTIEMETICS
- ANTIPARKINSONS AGENTS (non-ergotamine dopamine agonists)
- CALCIUM CHANNEL BLOCKERS
- INSULINS
- MEGLITINIDES
- LIPOTROPICS, OTHERS (TGLA & NIACINS)
- MULTIPLE SCLEROSIS AGENTS
- PAH AGENTS, ORAL & INHALATION
- PANCREATIC ENZYMES
- ULCERATIVE COLITIS AGENTS

The Department proposes no changes to **GROUP 1** as all available chemical entities are preferred:

- ALPHA-GLUCOSIDASE INHIBITORS
- SULFONYLUREAS-2ND GENERATION

Public Testimony 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. Sign-up for public comment will occur between 12:30pm -12:55 pm outside the Conference Room. 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) may be sent by e-mail on the drug classes listed above by April 11, 2012, to:

dcampana@mt.gov and 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**. 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. All information sent will be posted on a public website for viewing. Department Personnel will not sign manufacturer release of information waivers.

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

1. Thirty minutes prior to the beginning of the DUR Board Meeting, a sign-up sheet for Public Comment will be posted for Pharmaceutical Manufacturers and Special Interest Groups for each Drug Class to be reviewed.
2. Sign-up will close 5 minutes 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.
 - a. New Information is considered the following: new product in the drug class, new indication since the last review or new studies published since the last review, excluding placebo only studies. New studies must be submitted in electronic format no later than two weeks prior to the scheduled meeting.
 - b. Public comment will be allowed for up to 10 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 10 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. Access to computers or other technology presentation devices for slide presentations will not be available during this comment period.
 - 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 at least thirty (30) copies that will be distributed by Foundation 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.