

New Drug Review Process

1. New Product/Drug/Dosage Form is identified from First Data Bank weekly report and placed on prior authorization during a 30 business day review.
 2. Submission of the Product Dossier is necessary from the product manufacturer and may be found at <http://dss.mo.gov/mhd/cs/pharmacy/pdf/new-drug-letter-guidelines.pdf> . The manufacturer should ensure any clinical information they have to be considered is provided. Interested parties may follow on the Divisions web site <http://dss.mo.gov/mhd/cs/pharmacy/pdf/druglist.pdf> .
 3. At the end of the review period, the MO HealthNet Division (MHD) clinical staff makes coverage recommendations from the following: Continue to prior authorize, open access, clinical edit, or inclusion in the Preferred Drug List (PDL).
 - If the recommendation is PDL Product this indicates that the product is in a drug class that has already been implemented into the PDL Preferred Drug List. This recommendation triggers the supplemental rebate solicitation. The manufacturer and First Health Services, Inc. will work through the supplemental rebate process. MHD and First Health will pair clinical review and fiscal analysis to determine product status within the PDL (preferred or non –preferred) and make recommendation to advisory groups. The product will remain under new product prior authorization during this period.
 - If the recommendation is for clinical edits this indicates that an edit will be built allowing transparent approval of the product provided established criteria are met. The product remains under new product prior authorization during the period the edit is under development.
 - If the recommendation is open access the prior authorization will be removed. FUL/MAC pricing may apply.
 - If the recommendation is continued the product remains under prior authorization.
 4. The recommendations for products identified as new drugs during the previous quarter are presented to both advisory groups at their quarterly meetings. For example, products whose review date began in January, February or March are presented at the June and July quarterly meetings of the advisory groups. Meeting dates may be found on the Division's Calendar of Events at <http://dss.mo.gov/mhd/global/pages/calendar.htm> . Review dates may be found here at <http://dss.mo.gov/mhd/cs/pharmacy/pdf/druglist.pdf> .
- The Manufacturer's Government Affairs Representative may schedule presentation time during the public hearing portion of the Drug Prior Authorization Committee Meeting by contacting Beth.A.Mitchell@dss.mo.gov or call 573-751-7179, at least three days prior to the meeting date. Slides to be used should be electronically provided at least three days in advance as well. It is not recommended to schedule comment time until product coverage recommendations are posted to <http://dss.mo.gov/mhd/cs/pharmacy/pages/frequpdat.htm> . No formal hearing is scheduled for the DUR Board. Informal comments will be accepted at the Drug Utilization Review Board Chairman's discretion. Additional rules for public forum may be found on the Secretary of State's web site <http://www.sos.mo.gov/> .
5. Following evaluation of the recommendations from both of the advisory groups, the division finalizes the coverage parameters and implementation is scheduled. Tentative quarterly implementation dates for PDL products or Clinical Edits are posted to <http://dss.mo.gov/mhd/cs/pharmacy/pages/clinedit.htm> . MHD may determine that an implementation may be delayed but will never implement a coverage edit earlier than posted.