

What is the purpose of the Pharmacy and Therapeutics (P&T) Committee?

The P&T Committee is an advisory panel that conducts in-depth clinical evaluations and recommends appropriate drugs for preferred status on the Division of Medicaid's (DOM's) Preferred Drug List (PDL) and/or drugs for prior authorization. Drugs and drug classes are evaluated for their safety, efficacy, and overall cost and value. The Committee makes recommendations to the Executive Director regarding PDL status and prior authorization criteria for these drugs and classes.

The decision of the Committee regarding any limitations to be imposed on any drug or its use for a specified indication shall be based on sound clinical evidence found in labeling, drug compendia, and peer reviewed clinical literature pertaining to use of the drug in the relevant population.

Who serves on the P&T Committee?

The Mississippi Division of Medicaid's P&T Committee is comprised of twelve participating physicians, nurse practitioners, and pharmacists who are active Mississippi Medicaid providers and in good standing with their representative organizations.

When does the P&T Committee meet?

The P&T Committee meets quarterly. Meetings are tentatively scheduled for March, April, September, and October. Meeting dates will be posted on the Pharmacy web page located at <u>Pharmacy and Therapeutics</u> <u>Committee - Mississippi Division of Medicaid (ms.gov)</u>

How does DOM determine which drugs are included in therapeutic class and/or drug reviews?

The PDL only addresses certain drug classes. Drugs which have historically been covered by Medicaid and are not listed on the Preferred Dug List will continue to be covered. Some drug classes will not be reviewed for preferred status because of no and/or limited cost savings, if the class is all and/or mostly generic, or if there is low utilization in that class. Be advised that DOM may opt to include or delete drug classes from PDL review in the future.

Rebated drugs are automatically included in therapeutic class reviews when they are in a managed class on the PDL. Drugs will be added to the PDL as non-preferred until they are reviewed at the next available P&T meeting. Drugs must be on the FirstDataBank (FDB) file 90 days prior to the P&T meeting in order to be included in the class review.

Can manufacturers review drug monographs prior to the P&T meetings?

This information is distributed only to the P&T Committee for their use.

Are P&T Committee meetings open to the public?

In accordance with the Mississippi Open Meetings Act, P&T Committee meetings are open to the public. This law requires that a public announcement of the meetings be made two weeks prior to the scheduled meeting date. Except for specific pricing information, proprietary information or confidential information, the records of the P&T Committee are available to the public as well. Registration prior to the P&T Committee Meeting is required.



How can a pharmaceutical manufacturer or a member of the public present comments to the P&T Committee?

There will be a public comment period during the P&T Committee meeting. During this time, speakers will be given up to 3 minutes per drug to make a presentation to the Committee about that medication. Advocates and advocacy groups designated to speak are allowed up to 3 minutes per person and/or group. Content is limited to drugs relevant to the drug classes on the agenda to be discussed during the meeting. The representative will not be permitted to ask questions of the Committee, the Division of Medicaid, or the State's vendor during this time. Providing handouts to the Committee or vendor is not permitted at this time. Registration prior to the P&T Committee Meeting is required. Speakers may register up to one (1) month in advance of the meeting date.

What is the extraction process?

After a brief summary of recommended changes, the Chairman calls for the first-round extractions. Extractions may be requested for financial considerations or for questions from a Committee member. Public comments follow the first round of extractions. Each person is allowed three minutes to address the Committee. Once the public comment period is concluded, the Chairman calls for a second round of extractions; at that time, a motion to approve all non-extracted categories as proposed is made and voted upon.

What is the Preferred Drug List?

The preferred drug list is a medication list recommended to the Division of Medicaid by the P&T Committee and approved by the Executive Director of the Division. Drugs designated as preferred have been selected for their efficacy, clinical significance, cost effectiveness and safety for Medicaid beneficiaries. Unless otherwise specified, the listing of a particular brand or generic name includes all dosage forms of that drug.

Medicaid-covered drugs noted as "non-preferred" will continue to be available through the prior authorization process. A three-day emergency supply of certain prior-authorized drugs can be dispensed by a pharmacy until authorization is completed; a complete list of those drugs is published on the DOM website: https://medicaid.ms.gov/providers/pharmacy/.

What is the general process for the PDL?

Each drug is reviewed on its clinical merits relative to other medications in the same therapeutic class. Published, peer-reviewed clinical trials are the primary source of information used by the State's vendor for this review. Data regarding efficacy, effectiveness, adverse effects, and tolerability is analyzed and compared to other drugs within the therapeutic class. From this analysis, the clinical staff determines an agent's clinical superiority, equivalency, or inferiority relative to the comparator drugs.

After the clinical review, a financial analysis is performed. This analysis incorporates utilization data from the State as well as net drug costs from the manufacturers. With this data, a determination is made regarding the fiscal impact of PDL preferred or non-preferred status of each medication. Incorporating all of



this information, the current vendor makes suggestions to the P&T Committee regarding the PDL status of each medication. After reviewing and discussing these suggestions, the P&T Committee makes recommendations to the Mississippi Division of Medicaid for final decisions.

How does a pharmaceutical manufacturer participate in this process?

DOM will determine which classes of drugs are most commonly utilized or where utilization challenges exist. DOM may choose to request a review of single drug classes alone or therapeutic groups (cardiovascular drugs, endocrine, etc.). After the order of drug class review is determined, notice will be posted to the DOM website. At that time, the manufacturer will be requested to submit any clinical information and a supplemental rebate offer for the product(s) in review. The supplemental rebate program is voluntary on the part of the manufacturer.

Is a Preferred Drug List (PDL) the same as a formulary?

A formulary is a list of drugs that are available and approved for use by an insurance company, managed care organization, or hospital. Drugs must be prescribed from the formulary and no exceptions are available.

A Preferred Drug List (PDL) is a component of the Prior Authorization (PA) process. All medications are covered; however, certain medications may require a PA before the prescription can be filled. The PA process requires that certain medications must be approved in order to be reimbursed by DOM. This approval is based on previously specified criteria.

Medications which have been deemed to be clinically and/or economically advantageous to other similar drugs will be preferred or have preferential status on the PDL. Most medications on the PDL can be prescribed and dispensed without prior authorization.

Who develops the DUR+ criteria?

DUR+ criteria are developed by DOM, in accordance with clinical guidelines and assistance from clinicians at Gainwell Technologies, MedImpact, and MS DUR.

Are new drugs included on the PDL?

If a therapeutic class has been reviewed by the P&T Committee and DOM has approved the recommended drugs in that category, new chemical entities will be considered non-preferred until the drug is reviewed at a subsequent meeting. If a new chemical entity is considered unique and has been classified as a priority drug by the FDA, DOM may approve the drug as preferred until the class is once again reviewed.

Recommendations regarding the PDL status of new medications will be made by the State's current vendor at the time of the next review of the therapeutic class to which that medication belongs. The schedule for these class reviews may be altered if new medications are determined to have a significant clinical and/or financial impact.



This process does not always apply to line-item extensions, such as new strengths or dosage forms of previously available medications.

How are decisions of the Division of Medicaid communicated to companies and public? The PDL is published on the DOM website: <u>https://medicaid.ms.gov/providers/pharmacy/</u>.

How often is the PDL updated?

The PDL is updated at least two times annually, on January 1st and July 1st, and as needed.

Who are the points of contact at the Division of Medicaid and MedImpact (MI)?

<u>MS Division of Medicaid</u> Terri Kirby, RPh, CPM Pharmacy Director Division of Medicaid - Office of Pharmacy Walter L. Sillers Building 550 High Street, Suite 1000 Jackson, Mississippi 39201 Phone: (601) 359-5253 <u>Terri.Kirby@medicaid.ms.gov</u> MedImpact Matthew Lennertz, PharmD, MS, MBA Managing Principal, Medicaid PDL and Rebate Strategy MedImpact Attn: GPS Medicaid Rebate Operations 10181 Scripps Gateway Ct. San Diego, CA 92131 Matthew.Lennertz@medimpact.com

Which types of questions go to DOM and which types go to MedImpact?

Except for information concerning DOM issues, all questions regarding the PDL process should be directed to MedImpact.

Who makes the final decision regarding which drugs are included on the PDL?

After considering the recommendation of the P&T Committee, DOM's Executive Director makes the final decision regarding which drugs will be included on the PDL.

I cannot find certain drugs listed on the PDL. What does this mean?

If drugs are not in a managed category, they are generally available if the manufacturer participates in the Federal Medicaid rebate program. They may be subject to certain authorization criteria or limits.

Will patients be required to switch their medications if they are stabilized to the preferred drugs when the PDL is revised?

Some medications in certain classes may be grandfathered. This means that patients already stabilized on a medication that is changed to non-preferred status on the PDL will not require a PA to continue on that medication. However, there are times when patients stabilized on a certain medication will be required to change to a different medication or different form of a medication. DOM recognizes the clinical and practical impacts of such changes and makes every effort to both minimize these occurrences and provide adequate notice.



Are there some therapeutic classes that will be excluded from the PA process?

Yes. The drug categories excluded from the PDL are exempt from the DUR+ process but may have a clinical prior authorization requirement in place (i.e. stimulants).

Why do some preferred drugs say PA is required? Isn't this the same as being non-preferred?

Some PDL drug categories are subject to PA requirements concerning medical necessity, which apply to any drug in the class. Despite this PA condition, some or all of the drugs in the category may be preferred if the basic medical necessity requirements for such a drug is satisfied. In such cases, preferred drugs in the category must be tried after authorization is given before non-preferred drugs will be considered.

Why are some brand name drugs preferred over generic versions?

State Medicaid programs participate in a federally negotiated rebate program with drug manufacturers. This means that they receive a varying percentage of the cost of every drug back from the manufacturer. Due to disproportionately large brand rebates, the net prices of certain brand drugs are significantly less than their generic counterparts.

Why are certain strengths of some medicines non-preferred?

Some drug strengths are non-preferred because they are priced very highly relative to other strengths in the category. For example, one fluoxetine 40 mg cap costs three times as much as two 20 mg caps. Requiring the use of multiple 20 mg caps will save several hundred thousand dollars annually.

Is there a possibility that existing prior authorizations will be removed?

DOM will regularly evaluate the advantages and disadvantages of any scenario posed. Removing or restructuring utilization controls will be strongly considered depending on the relative merits of each unique situation. Companies with non-preferred products may submit supplemental rebate offers at any time. If it is advantageous to the state and if there is no conflict with an existing supplemental rebate agreement, then a non-preferred drug may be designated as preferred.

Does prior authorization for a preferred drug affect the 2 brand or 5 prescription limit?

No. The monthly pharmacy service limit of 5 drugs, of which no more than 2 may be brand for a noninstitutionalized adult beneficiary, is MS state law. The prior authorization program works within state and federal laws.

Are over-the-counter (OTC) drugs on the PDL?

Some covered OTC drugs are listed on the Preferred Drug List. Typically, if an OTC drug is not listed on the PDL, its category may not be included as a managed drug class.