

**Alabama Medicaid Agency
Pharmacy Services
Preferred Drug Program
Frequently Asked Questions by Manufacturers
Updated: August 2021**

Pharmacy and Therapeutics (P&T) Committee/Meetings

What is the P&T Committee? As directed by legislation, the Alabama Medicaid Agency shall utilize a Medicaid Pharmacy and Therapeutics (P&T) Committee within the Agency for the purpose of advising and assisting Medicaid in the development of a drug plan. Alabama Medicaid's mandatory Preferred Drug Program began in 2003.

Who are the members on the Committee? As directed by legislation, the Medicaid P&T Committee shall be comprised and consist of three clinical pharmacists licensed to practice in the State of Alabama and at least five physicians licensed to practice medicine in the State of Alabama. Members of the P&T Committee should be enrolled as Medicaid providers and have experience developing or practicing under a preferred drug list. A listing of the current members is available on Alabama Medicaid's website at www.medicaid.alabama.gov.

How are the Committee members selected? Physician members are appointed by the Medicaid Commissioner from a list of a nominees submitted by the Medical Association of the State of Alabama. Clinical pharmacist members are nominated by the Alabama Pharmacy Association and appointed by the Medicaid Commissioner. Members will serve two year terms and may be reappointed to the Committee for additional terms.

How often are P&T meetings held? The P&T Committee shall meet at least quarterly. Additional meetings may be called by the Medicaid Commissioner and Committee chairperson as needed.

How do I register to attend a P&T meeting? P&T meetings are open to the public and meet the requirements of the State's open meetings law. Therefore, no prior registration is required to attend. However, to participate during the meetings, please visit our website at www.medicaid.alabama.gov to view the Pharmacy and Therapeutics Committee Operating Procedures and the Manufacturer Notification (for the applicable meeting) for information on oral presentations. These documents are located on the Pharmacy Services page. Attendees cannot participate in the meeting unless approved by Alabama Medicaid prior to the meeting.

Can I contact a P&T committee member to discuss a product to be reviewed prior to a P&T meeting? While Alabama Medicaid understands there is a level of coordination between members of the manufacturing industry and a provider through the normal course of business, Alabama Medicaid asks manufacturers to respect P&T Committee members' commitment to the State of Alabama by following the procedures available through the P&T Operating Procedures policy. Also, as outlined in the P&T Committee Statement of Integrity, Committee members agree not to have ex parte contacts or discussions with manufacturers or representatives whose drugs are presented for review. This is specifically regarding drugs to be reviewed in an upcoming Medicaid P&T meeting. Examples of contacting the provider include but are not limited to telephone calls, emails, face-to-face visits and mailing correspondence.

My company's product was recommended by the P&T Committee to be preferred. When will the preferred status become effective? Pending Medicaid Commissioner's approval of the Committee's recommendation, all preferred drug updates occur quarterly. The status will be effective with the quarterly update following the P&T meeting. Updates usually occur in January, April, July and October of each year. These updates occur the first day of the month unless otherwise noted.

What can I do if I disagree with the recommendation of the P&T Committee regarding my company's product? Manufacturers may request a reconsideration of a clinical recommendation by the P&T Committee if there is new clinical evidence-based, peer reviewed information available that was not presented during the P&T review. A written request must be submitted to the Medicaid Pharmacy Director or designated representative and must be received within thirty (30) calendar days of the posting of the PDL decisions to the Medicaid web site. For more information regarding the submission of the request for a reconsideration of a clinical recommendation, please see the Reconsideration Process section of the Pharmacy and Therapeutics Operating Procedures available on the website at www.medicaid.alabama.gov.

What is an AHFS class? AHFS is the acronym for American Hospital Formulary Service. The AHFS Class represents a therapeutic grouping of drugs as defined by AHFS. The Agency's review of "drug classes as defined by the American Hospital Formulary Service" (AHFS) is required by PDL legislation.

Are there any products that are exempt from the Preferred Drug Program? Yes. The classes of anti-retroviral and anti-psychotic drugs are not included in the Preferred Drug Program (PDP).

Which drugs are included in Alabama Medicaid's Preferred Drug Program? Drugs classified in AHFS classes that have been reviewed by the P&T Committee are included in the program. For a complete listing of the classes included, please view the Prior Authorization Criteria Booklet on our website at www.medicaid.alabama.gov.

New Products

My company has a new product. How will Alabama Medicaid cover this product? Medicaid will cover all eligible products. New brand products that are classified in an AHFS class that is included in the Preferred Drug Program will be non-preferred and require prior authorization.

What is considered a new product? A new product is defined as any new drug entity, including combination products, that has not been previously commercially available. For more information, see the Request for Product Review section of the Pharmacy and Therapeutics Committee Operating Procedures document at www.medicaid.alabama.gov.

I want my company's new product to be reviewed by the P&T Committee. What is the process? Manufacturers may request a product review for a new pharmaceutical product falling within the scope of the Preferred Drug Program. A new product is defined as any new drug entity, including combination products, that has not been previously commercially available.

If a product that is currently available commercially becomes available in a new dosage form, it is not considered a new product and would not be eligible for a new product review before the

P&T Committee. These products would be included in the review of the entire AHFS class. Previously reviewed products may be re-reviewed if there is a new FDA-approved indication for the product. The following information should be considered regarding the request for product review process:

- a. Requests for product reviews must be submitted in writing and directed to the Medicaid Pharmacy Director or delegated representative.
- b. A product or a product with a new indication must have been on the market for a minimum of 180 days prior to a request for product review.

Manufacturers may submit written evidence supporting inclusion of a product on the Preferred Drug List to the Medicaid Pharmacy Clinical Support Personnel or delegated representative and should be clearly labeled as a request for product review. This information may be submitted to Medicaid or its delegated representative at any time. Requests for product reviews of drugs will be considered in the order in which they are received unless Medicaid identifies a need to place a higher priority on a particular class/drug. However, the scheduling of the product's review will be at Medicaid's discretion.

Prior Authorization for Products

My company's product is not preferred. What do doctors need to do so that Medicaid will pay for the patient's prescription? In the event the patient does not automatically meet criteria through the Electronic Prior Authorization (EPA) process, or the drug is not included in the EPA, the provider should submit a Prior Authorization (PA) Request form. The PA forms and criteria can be found on our website at www.medicaid.alabama.gov on the Pharmacy Services page. PAs can be submitted electronically, via fax or mail and in most instances, verbally by the prescriber or the prescriber's representative.

My company's product is not in a class that is included in the Preferred Drug Program but I am being told by providers that the product still requires a PA. Why is this? There could be numerous reasons why the product requires prior authorization (PA). However, one possible reason could be that the product is a drug or in a class of drugs that required prior authorization prior to the implementation of the Preferred Drug Program. For a listing of drugs or classes of drugs not included in the mandatory Preferred Drug Program but do require PA, visit our website at www.medicaid.alabama.gov and view our Prior Authorization Criteria Booklet.

Supplemental Rebates

When can I submit a supplemental rebate offer for my company's product? Supplemental rebate offers can be submitted 365 days a year for any drug that has been clinically reviewed by the P&T Committee. The Supplemental Rebate Offer Form is available on the Alabama Medicaid website at www.medicaid.alabama.gov in the Pharmacy Services section under Manufacturer Information. The offer form can also be received via email in Excel format upon request by the manufacturer. For these supplemental rebate offers to be considered for a quarterly Preferred Drug List update, they must be received at least 21 calendar days prior to the next scheduled P&T Committee meeting.

In addition, if the manufacturer contact person receives notification that the P&T Committee is reviewing an AHFS class that includes a drug manufactured by their company, a supplemental rebate offer form can be submitted for that drug. Alabama Medicaid will not send a formal solicitation for the manufacturer to make a supplemental rebate offer. The Supplemental Rebate Offer Form is available on the Alabama Medicaid website at www.medicaid.alabama.gov in the Pharmacy Services section under Manufacturer Information. The offer form can also be received via email in Excel format upon request from the manufacturer. The deadline for receipt of these supplemental rebate offers is 21 calendar days prior to the meeting and is listed on the meetings timeline on the website at www.medicaid.alabama.gov in the Pharmacy Services Section under Pharmacy and Therapeutics Committee. Supplemental rebate offers received by the deadline will be considered for the quarterly Preferred Drug List update following the P&T Meeting.

In the normal course of supplemental rebate offer submission, there is no need for a formal meeting between Alabama Medicaid and the manufacturer to discuss supplemental rebate offer. All correspondence, including submission of the offer, can be handled via email.

Preferred Drug Lists

How often are the preferred drug lists updated? Quarterly. Updates usually occur in January, April, July and October of each year. These updates occur the first day of the month unless otherwise noted. The current listing can be viewed on our website at www.medicaid.alabama.gov on the Pharmacy Services page. There are three listings: (1) the alphabetical listing that lists the preferred products in alphabetical order; (2) the therapeutic category listing that lists the preferred drugs by therapeutic groups and (3) the PDL Reference Tool. This document details the preferred and non-preferred products for each therapeutic category included in the Preferred Drug Program.

I do not see my company's product listed on the preferred drug list. What does this mean?

Only brand name preferred products are listed on the alphabetical and therapeutic preferred drug lists (PDLs). In most cases, all generic products are preferred. If your brand name product is in a class that is included in the Preferred Drug Program and is not listed, it is non-preferred and will require a prior authorization (PA).

How can I get my company's product listed on the PDL? All products considered for inclusion in the Preferred Drug Program (PDP) must be reviewed by the P&T Committee. The P&T Committee makes recommendations to the Medicaid Commissioner regarding the preferred status of the product reviewed based on clinical information. Only after clinical decisions are made, are financial considerations reviewed. Manufacturers are encouraged to submit supplemental rebate offers for drugs that are being/have been reviewed by the P&T Committee in order to make their drugs financially cost effective for consideration to be added to the preferred drug listings once all clinical decisions have been made. The Medicaid Commissioner makes the final designation regarding the status of the products included in the Preferred Drug Program. Please visit our website at www.medicaid.alabama.gov for supplemental rebate submission information. For these supplemental rebate offers to be considered for a quarterly Preferred Drug List update, they must be received at least 21 calendar days prior to the next scheduled P&T Committee meeting.

Miscellaneous

Does Alabama Medicaid utilize a PBM vendor to maintain its PDL? No. Alabama Medicaid does not utilize a Pharmacy Benefits Management vendor. However, Alabama does utilize a clinical contractor to compile the clinical review packet for each P&T meeting. All financial and supplemental rebate matters are coordinated by Alabama Medicaid staff.

Preferred Drug List/Program Definitions

Preferred Drug: A drug listed on the Agency's Preferred Drug Lists as preferred. These products do not require prior authorization (PA).

Non Preferred Drug: A non-preferred drug is a drug that is covered by Alabama Medicaid, but that will require prior authorization (PA). A non-preferred drug may be approved for dispensing if clinically appropriate criteria established by Alabama Medicaid is met. This criteria is available at www.medicaid.alabama.gov.

Non Covered Drug: In accordance with Medicaid Drug Amendments contained in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90 federal legislation), the Agency has the option to non cover some drugs. Alabama Medicaid does not cover or pay for the following:

- Drugs used for anorexia, weight loss or weight gain, with the exception of those specified by the Alabama Medicaid Agency
- Drugs used to promote fertility with the exception of those specified by the Alabama Medicaid Agency
- Drugs used for cosmetic purposes or hair growth
- Over the counter (OTC)/non prescription drugs, with the exception of those specified by the Alabama Medicaid Agency
- Covered outpatient drugs when the manufacturer requires as a condition of sale that associated test and/or monitoring services be purchased exclusively from the manufacturer or designee
- DESI (Drug Efficacy Study Implementation [less than effective drugs identified by the FDA]) and IRS (Identical, Related and Similar [drugs removed from the market]) drugs which may be restricted in accordance with Section 1927(d) (2) of the Social Security Act
- Agents when used for the symptomatic relief of cough and colds except for those specified by the Alabama Medicaid Agency
- Prescription vitamin and mineral products, except prenatal vitamins and fluoride preparations and others as specified by the Alabama Medicaid Agency
- Agents when used for the treatment of sexual or erectile dysfunction, unless authorized for pulmonary hypertension.

(From Alabama Medicaid Agency Administrative Code, Chapter 16 and Alabama Medicaid Agency Provider Billing Manual, Chapter 27.)

Prior Authorization (PA): Prior authorization is the process that requires drugs to be reviewed for clinical appropriateness prior to reimbursement. Drugs may require PA if they are in non-preferred status or if they required PA prior to the PDL.

Medicaid may require prior authorization for generic drugs only in instances when the cost of the generic product is significantly greater than the net cost of the brand product in the same

AHFS therapeutic class or when there is a clinical concern regarding safety, overuse or abuse of the product.

Override: An override is different from a prior authorization and is required when a claim falls outside of a predetermined limit or criteria. When an override is required, the provider must submit an Override Request Form. The Override Request Form can be found on our website at www.medicaid.alabama.gov on the Pharmacy Services page. The different types of overrides include:

- Accumulation Override
- Brand Limit Switchover
- Dispense as Written Override
- Early Refill
- Maintenance Supply Override
- Maximum Cost Limitations
- Maximum Unit Limitations
- Therapeutic Duplication

Electronic PA (EPA): Certain classes of drugs are included in the EPA Program. Once the pharmacy sends an electronic claim for a drug in the EPA program, the system reviews medical and pharmacy claims history for the patient. If the criteria are met, the claim is automatically assigned an authorization number and is approved. If the PA criteria are not met, a message is returned to the pharmacy instructing the submitter to submit a manual (paper or online) request. An EPA rejected claim does not constitute a PA denial, only a notice to the pharmacy that a manual PA request is needed. Electronic PA results in a reduction in workload for providers because the claim is electronically approved within a matter of seconds with no manual PA required.

Pharmacy Services Staff Contact Information:

Preferred Drug Program and Supplemental Rebate

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