ALABAMA MEDICAID AGENCY

Pharmacy and Therapeutics Committee

TOPIC: Operating Procedures

DATE: October 2004 P&T Policy #3
Updated: March 2016
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As defined by Alabama Code §22-6-122, the Medicaid Pharmacy and Therapeutics (P&T) Committee shall review and may recommend drugs or classes of drugs (drug class as defined by the American Hospital Formulary Service or AHFS classification system) to the Alabama Medicaid Agency for inclusion in the Medicaid Preferred Drug Program. Drugs will be reviewed according to the AHFS classification. Each therapeutic class review will contain agents that share the same first six digits of the AHFS product code and are active on the Alabama Medicaid drug file. Combination products that share similar Food and Drug Administration (FDA) approved indications as other drugs within that AHFS class may be reviewed with the single entity agents from within that same AHFS class.

The P&T Committee must develop its preferred drug list recommendations by considering the clinical efficacy and safety of a product. Generics and over the counter (OTC) drugs covered by Medicaid may be considered preferred drugs without appearing on the preferred drug list. The P&T Committee will consider recommending preferred status for brand products only. However, the P&T Committee has the ability to recommend generic products be removed from preferred status.

For the purposes of P&T reviews and manufacturer reconsiderations, the recommendations of the Medicaid P&T Committee must be based on sound clinical evidence found in labeling, drug compendia and published peer reviewed clinical literature pertaining to the use of the drug. Poster board presentation, abstracts or data on file cannot be included for the review of the class or drug if no full study has been conducted and published in peer reviewed literature. Also while agents within this therapeutic class may have demonstrated positive activity via in vitro trials, the clinical significance of this activity remains unknown until fully demonstrated in well-controlled, peer-reviewed in vivo clinical trials. As such, class/product reviews and the recommendations provided are based exclusively upon the results of such clinical trials. Therefore, in vitro studies will not be included for the review of the class or drug.

Public Notice

Medicaid will provide notice to the public of Pharmacy and Therapeutics (P&T) Committee meetings and agenda items not less than (30) calendar days in advance of scheduled meetings. The notice will be provided via the Medicaid website.

Medicaid will send written notification not less than (30) calendar days prior to a meeting of the P&T Committee to pharmaceutical manufacturers whose brand name drug(s) may be considered for preferred status at said meeting. This notice will be provided via email and

the Medicaid website. For those manufacturers without an email address on file, a copy of the meeting notification letter will be mailed via US Certified Mail. If an issue arises during a clinical review conducted by the P&T Committee that requires follow-up consideration at the next P&T Committee meeting, a minimum of thirty (30) days notice will be given to affected manufacturers.

Medicaid will maintain a database of industry representatives for the purpose of correspondence and notice regarding the Preferred Drug Program. It is the responsibility of the manufacturer to provide accurate contact information to the Medicaid Pharmacy Director delegated representative and to provide update information as needed. Contact information is to be provided on the Pharmaceutical Manufacturer Contact Information Form located on the Medicaid website. It is also available from the Medicaid Pharmacy Program Office at (334) 242-5050. In the event no contact information is provided to Medicaid, the Legal Contact on file with the Medicaid Drug Rebate Program will be utilized for notices.

Request For Product Review

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 (approved under a New Drug Application and identified as a Reference Listed Drug in the FDA Online Orange Book), including but not limited to combination products and line extensions, that has not been previously commercially available.

If a product that is currently commercially available has 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 unless there is a new indication for the product.

a. Requests for product reviews by pharmaceutical manufacturers must be submitted in writing and directed to the Medicaid Pharmacy Director or delegated representative.

b. Requests by pharmaceutical manufacturers 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.

c. 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 by a pharmaceutical manufacturer.

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 after the 180 day requirement. However, the scheduling of the product's review will be at Medicaid's discretion.

Manufacturer Written Comments

Manufacturers have the opportunity to present comments to the Medicaid P&T Committee as required by Act No. 2003-297 through written comments directed to the Medicaid Pharmacy Director or delegated representative.

a. Comment period is for a period of 21 calendar days prior to the Pharmacy and Therapeutics Committee meeting. It is the responsibility of the manufacturer to verify receipt by Medicaid or its designee. If the deadline falls on a business day, the summary must be received by 5:00 p.m. Central Time (CT). If the deadline falls on a weekend or holiday, comments must be received by noon CT of the next business day.

b. Manufacturer comments will be restricted to products that are being reviewed for preferred status.

c. All manufacturer comments received by the deadline must be approved to be included in the review packet provided to the P&T Committee members. Manufacturer comments **must** meet the following criteria:
   1. be limited to sound clinical evidence only,
   2. be limited to evidence-based clinical information and to Food and Drug Administration (FDA)-approved indications covered under the Alabama Medicaid Pharmacy benefit,
   3. exclude any reference to cost,
   4. exclude anecdotal content , and
   5. exclude general drug or disease specific economic information.

   Any comments found to contain non-compliant information regarding the above criteria will be rejected in their entirety.

d. Manufacturer written comments should be clearly labeled as "written comments" and should indicate the product and drug class the comments represent. Manufacturer comment submissions should be limited to one drug product per packet. Manufacturers wanting to provide written comments on more than one drug product must submit a separate packet for each product.

e. Manufacturer comment submissions are limited to 100 pages.

f. Manufacturer written comment submissions are limited to email, PDF format only not hard copy or CD Rom, etc.

g. Manufacturers will receive formal written communication from the Medicaid Pharmacy Director or delegated representative alerting them if the written comments have been accepted or rejected.

h. All manufacturer comment submissions must meet all criteria, received by the stated deadline and be approved Medicaid or its designee to be included in the review

packet. Failure to abide by all of these requirements upon submission will result in a rejection of the clinical comments in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. **No submissions or resubmissions will be accepted after the designated deadline**.

Manufacturer Oral Presentations

Manufacturers have the opportunity to make oral presentations to the Medicaid P&T Committee as required by Act No. 2003-297 through a brief oral summary of their product. Oral Presentations will be restricted to products that are being reviewed for preferred status.

1. Oral Presentation Summary

a. Written submission of a one page summary (1 copy, single-sided) of the material to be presented at the P&T meeting must be received by the Medicaid Pharmacy Director or delegated representative a minimum of 21 calendar days prior to the scheduled P&T meeting. It is the responsibility of the manufacturer to verify receipt by Medicaid or its designee. If the deadline falls on a business day, the summary must be received by 5:00 p.m. CT. If the deadline falls on a weekend or holiday, the summary must be received by noon CT of the next business day.

b. Oral presentation summaries will be restricted to products that are being reviewed for preferred status.

c. The summary must include all major points to be made during the presentation and a complete summary of the information to be shared at the meeting. This document including any references must be included on a single side of the document. The summary may not include references, package inserts or any other information on the reverse side of the document. Copies, provided by Medicaid, will be distributed to the P&T Committee members at the time of the meeting.

d. The oral presentation summary should be clearly labeled as "Oral Presentation Summary".

e. Submissions are limited to email, PDF format only, not hard copy or CD-Rom, etc.

f. Manufacturer oral comments **must** meet the following criteria:
    1. be limited to sound clinical evidence only,
    2. be limited to evidence-based clinical information and to Food and Drug Administration (FDA)-approved indications covered under the Alabama Medicaid Pharmacy benefit,
    3. exclude any reference to cost,
    4. exclude anecdotal content,
    5. exclude general drug or disease specific economic information, and
    6. reference statistical information.

Any comments found to contain non-compliant information regarding the above criteria will be rejected in their entirety.

g. The oral presentation summary should be limited to one drug product per submission. Manufacturers wanting to provide an oral presentation on more than one drug product must submit a separate one-page summary for each product.

h. All statistics identified for discussion must be supported by noting the source from which the information was obtained. This information does not have to be in formal reference form.

i. Manufacturers will receive formal written communication from the Medicaid Pharmacy Director or delegated representative alerting them if the oral presentation summary has been accepted or rejected.

j. All oral presentation summary submissions must meet all criteria, received by the stated deadline and be approved Medicaid or its designee to be included in the review packet. Failure to abide by all of these requirements upon submission will result in a rejection of the oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. **No submissions or resubmissions will be accepted after the designated deadline**.

2. Oral Presentations

a. Oral presentations will be restricted to products that are being reviewed for preferred status.

b. Presentations will be limited to a maximum of five (5) minutes per representative per drug product. Each drug product will be treated as a separate presentation. In the event a manufacturer has more than one drug product in a drug class, each drug product is allowed a five (5) minute presentation. The same representative may perform the separate presentations in a drug class.

c. Presentations will be limited to one representative per product. Only one presentation per product will be permitted.

d. Presenters must register with Medicaid at P&T meetings a <u>minimum</u> of ten (10) minutes prior to the scheduled start time of the meeting. A sign-in sheet will be provided at a registration table at the meeting location. Those not registered by the designated cut off time will not be allowed to make presentations. It is the sole responsibility of the manufacturer to ensure that the presenter has signed in by the designated timeframe.

e. Representatives will be called to present in the order in which they signed in by drug class. At the initiation of the 5 minute presentation, the speaker will be required to

state any financial interest in or other relationship with the manufacturer of any of the product(s) the speaker intends to discuss.

f. The Chairman will call for presentations by drug class. The oral presentation period will immediately precede the clinical review of each drug class. Medicaid's Contractor will then present clinical reviews by class. All questions regarding specific products and/or AHFS drug classes will be answered by the clinical contractor after the clinical review of the class.

g. Presentations must be limited to verbal comments. No visual aids other than the designated handouts are permitted.

h. Presentations must be limited to comments regarding the branded products within the class being considered for preferred status at the current meeting.

i. Presentations are to be limited to clinical issues approved in the single sided oral presentation summary. Presenters will be stopped if information other than the approved oral presentation summary is presented. Oral presentations should follow the one page summary that was submitted to and approved by Medicaid.

j. Oral Presentations will be allowed subject to time constraints at the discretion of the Chairman or the Medicaid Commissioner so that the P&T Committee's ability to complete the planned agenda is not impeded.

Meeting Attendance

Attendees of meetings are to limit distractions to a strict minimum. Cellular telephones, pagers and other media devices must be turned off or to silent mode before entering the meeting room.

All attendees of the P&T Committee meetings are to sign-in at the registration table.

Public Information

P&T Committee review packet will be posted to the Medicaid website by close of business the day prior to the P&T meeting. The review packet will not be available for distribution or purchase at the sign-in table.

Medicaid shall post the PDL decisions to the Medicaid website on the 10th business day following the date of the P&T Committee meeting.

Medicaid shall post the meeting minutes to the Medicaid website within 45 days following the date of the P&T Committee meeting.

Notice of prior authorization will be posted to the Medicaid website a minimum of two weeks prior to the implementation of the PA. In addition, the prior authorization request form and criteria updates (or their location on the website) will also be posted with this notice.

Reconsideration Process

Manufacturers may request a reconsideration of a clinical recommendation of the P&T Committee if there is new clinical evidence-based, peer reviewed information to consider 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 website.

A request must meet the following criteria:

1. be submitted via email, PDF format only, not hard copy or CD-Rom, etc.,
2. be clearly labeled as a Clinical Reconsideration Request,
3. include new clinical evidence-based information to consider that was not presented during the P&T review, and
4. include manufacturer contact information.

Medicaid will respond in writing to all appeals within ninety (90) calendar days of receipt. Responses will be sent via US Mail.

General

Medicaid staff reserves the right to delete agenda items if deemed necessary due to time constraints of the meeting.

General information, requests or questions regarding P&T or PDL should be directed to Alabama Medicaid P&T designated contact person unless otherwise stated.

This policy is posted on Alabama Medicaid's website as the Pharmacy and Therapeutic Committee's Operating Procedures.

P&T and PDL CONTACT INFORMATION:

Alabama Medicaid Agency
Kelli Littlejohn Newman, Pharm.D., Director
Clinical Services and Support
501 Dexter Avenue
P. O. Box 5624
Montgomery, AL 36103-5624
Telephone: (334) 242-5050
Fax: (334) 353-7014
Email: Kelli.Littlejohn@medicaid.alabama.gov
Medicaid website: www.medicaid.alabama.gov