

**Colorado
Pharmacy and Therapeutics (P&T)
Committee
Policies and Procedures**



CO L O R A D O

**Department of Health Care
Policy & Financing**

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Colorado Medicaid Pharmacy and Therapeutics Committee Policies and Procedures

Mission

To serve as an advisory board to the Colorado Health Care Policy and Financing (Department) Medical Assistance Program, perform reviews and make recommendations which facilitate the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.800.

Administration

Administrative coordination of the Pharmacy and Therapeutics (P&T) Committee is performed by a PDL support vendor, as designated by the Department or by the Department itself.

Duties

The P&T Committee shall, among other things:

1. Review drugs or drug classes selected by the Department.
2. Consider drug safety and efficacy and other review criteria requested by the Department.
3. Make clinical recommendations on drugs or drug classes.
4. Perform any other act requested by the Department necessary for the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.800.
5. Meet at least quarterly at the discretion of the Department or the P&T Committee.

Membership

- A. The P&T Committee shall consist of a minimum of nine Committee members, but no more than thirteen members, appointed by the Executive Director of the Department. The P&T Committee membership shall include:
1. Four pharmacists;
 2. Two Medicaid member representatives;

3. One physician who specializes in the practice of psychiatry;
 4. One physician who specializes in the practice of pediatrics;
 5. One physician who specializes in the treatment of clients with disabilities;
 6. Four physicians from any other medical specialty.
- B. Physicians and pharmacists must be licensed and actively practicing in the State of Colorado while a member of the P&T Committee.
- C. The Department shall solicit recommendations for P&T Committee members from professional associations, client advocacy groups and other Medical Assistance Program stakeholders.
- D. The P&T Committee may meet and conduct business when at least any nine members are appointed to the P&T Committee. A majority of the appointed P&T Committee members constitute a quorum for the transaction of business at any P&T Committee meeting.
- E. P&T Committee members must disclose, at the beginning of any P&T Committee meeting, any conflicts of interest that would make it difficult to fulfill P&T Committee duties in an objective manner.
1. Disclosure to Committee and Recusal
 - i. If a P&T Committee member has an actual or apparent conflict of interest, to the member must announce that during the meeting and prior to voting.
 - ii. If the member has an actual conflict of interest, the member should recuse, despite voluntary disclosure. After announcing recusal, the member shall not participate in the deliberation and vote.
 2. Apparent conflict of interest
 - i. If the Committee member does not self-recuse, then the Committee shall vote to whether the member shall be permitted to participate in discussion and vote. The Department will consider the Committee's vote and make a final determination whether the member shall be permitted inclusion for the particular PDL class' discussion and vote.
- F. P&T Committee members should not meet or discuss PDL or P&T business outside of the scope of their normal practice setting or outside of the P&T Committee meeting. If a meeting does occur, the discussions shall be limited to clinical and evidence-based information.

1. If a meeting occurs, the P&T Committee member shall make a disclosure during the P&T meeting and prior to voting for the particular PDL class.

Committee Appointments and Terms

- A. P&T Committee members shall serve two-year terms and may be reappointed to additional terms at the discretion of the Executive Director.
- B. The terms shall be staggered so that in each year at least two pharmacists, one Medicaid member representative and any three physicians are reappointed.
- C. The Executive Director may appoint initial P&T Committee members to serve less than two years to provide for staggered terms.
- D. The Executive Director may terminate the appointment of any P&T Committee member for Good Cause.
- E. The Executive Director shall fill a vacancy occurring in the membership of the P&T Committee for the remainder of the unexpired term. Such replacement shall meet all applicable requirements as set forth in P&T Committee Policies and Procedures 10 C.C.R. 2505-10, 8.800

Meetings

- A. Meetings are held at least quarterly at a time and place agreed upon by the P&T Committee, in collaboration with the PDL support vendor, if any, and the Department.
- B. Unless otherwise notified, meetings will be held virtually.
- C. An agenda will be prepared and posted at least thirty days prior to meetings. The clinical data used for drug class review will be prepared and distributed to the P&T Committee members and Department staff at least one week in advance of meetings to allow sufficient review time.
- D. The agenda will include both more active and less active PDL drug classes for review. The review process will differ slightly between more and less active classes, as described in the mass review process (see Appendix 1). The agenda will include the less active classes under a mass review section.
- E. Pursuant to Open Meetings Law (Colorado Sunshine Law) Section 24-6-402, C.R.S., P&T Committee meetings shall be open to the public and Committee members may not discuss committee business with each other outside of the public meeting.

- F. If a P&T Committee meeting is required to be held in executive session pursuant to state or federal law, the executive session requires a vote of two-thirds of the committee and must be recorded.
- G. The P&T Committee shall discuss and vote on each drug class presented unless a two-thirds vote of appointed members agrees to table the matter. Tabled drug discussions will be brought before the P&T Committee at the next P&T meeting.

Stakeholder Comment and Oral Presentation

- A. Stakeholders have the opportunity to present comments to the P&T Committee through written comments directed to the Pharmacy Benefits Section or delegated representative.
 - 1. Stakeholder comments will be restricted to products that are being reviewed for PDL status.
 - 2. All stakeholder comments received by the deadline found on the meeting agenda, which will be at least 3 business days prior to the meeting (by 5pm MST) and approved, will be accessible to P&T Committee members. All stakeholders (including manufacturers) submitting comments shall include a one page summation (one side only) of the drug product that will be included in the review packet provided to the P&T Committee members. The summary must be limited to clinical information only.
 - 3. Stakeholder comments are to:
 - i. Be limited to clinical information only;
 - ii. Exclude any reference to cost;
 - iii. Exclude anecdotal content;
 - iv. Exclude general drug or disease specific economic information.
 - 4. Stakeholder comments should be clearly labeled as such and should indicate the product and drug class the comments represent.
- B. Stakeholders have the opportunity to present oral comments during a P&T Committee meeting.
 - 1. Oral presentations will be restricted to products that are being reviewed for PDL status. Presentations will be limited to a maximum of three minutes per stakeholder per drug product. Only one presentation per product will be permitted.
 - 2. Stakeholders will be called to present in the order in which they signed in by drug class. Stakeholders must sign up with Prime Therapeutic's clinical account manager (who will notify the Department) by the deadline stated on the meeting agenda, which will be at least 3 business days prior to the meeting. Stakeholders

that wish to provide testimony without prior notification may not be allowed to give testimony, depending on time available.

3. Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted. Presentations should follow the one page summary that was submitted to the Department.

C. **Factual Inaccuracy:**

During a Committee meeting, if a stakeholder believes that a factual inaccuracy has been stated by a Committee member, the stakeholder may hand a note or email the Department representative. The stakeholder must provide the factual inaccuracy or a summary of the inaccuracy on the note. The Department representative will forward any comment to the Chair or Vice Chair. The Committee Chair/Vice Chair will then determine if there is a need to publicly hear the inaccuracy prior to moving forward with motions and discussion. The Chair/Vice Chair will state the purported factual inaccuracy and will ask the Committee if they want to hear testimony regarding the factual inaccuracy. When providing testimony, the stakeholder must provide evidence to support the claim of inaccuracy and cannot provide opinions on the drug class being considered.

Responsibilities of the Chair, Vice-Chair and Secretary

- A. The Chair and Vice Chair shall be elected by the P&T Committee on an annual basis. The Chair presides over the meetings of the P&T Committee.
- B. The Committee shall elect a Chair and Vice-Chair who must have served on the P&T Committee for at least one year.
- C. The responsibilities of the Vice-Chair are to preside over meetings of the P&T Committee in the Chair's absence.
- D. The Secretary shall be a representative from the PDL support vendor or appointed by the Department.

Public Communication

- A. The Department is responsible for public notification of P&T Committee meetings. The proposed agenda shall be posted publicly at least thirty days before the meeting.
- B. If requests for information are made, the Department shall review and determine if the request shall be granted. If there is a PDL support vendor and it receives the request, the PDL support vendor shall forward the request to the Department for review and determination. If the request is approved, the Department will send the material, or give the PDL support vendor permission to provide the material.

Appendix 1: Mass Review Description for PDL classes

Prime Therapeutics assists with the management of P&T meetings and the preferred drug list (PDL). This provides additional clinical resources for the Department to develop and maintain the PDL.

Many drug classes are managed through the PDL but there are many other drugs that are covered by Medicaid that aren't managed through the PDL. Pursuant to the rules, the Pharmacy Office has the option to add new PDL drug classes to the PDL as determined appropriate. An example is the epinephrine products class, which was added and reviewed in October of 2016.

Prior to each P&T review, the PDL classes are categorized into two groups: "Less active" classes and "more active" classes.

Classes with any of the following attributes may be considered as a "less active" class:

- the majority, if not all preferred products are now generic;
- no utilization by members exists;
- there are no stakeholder comments (from the public or industry);
- no anticipated change in previous years' motions set forward for consideration by the Department;

The rest of the PDL drug classes that are not considered "less active" are given the status of "more active." All "less active" classes will be grouped together for a mass review for a more streamlined review during the meeting for the P&T committee's purpose. We continue to review all "more active" classes using the same process as previously used for all PDL classes. We will list all "less active" classes at the end of the agenda under a mass review section for discussion, if needed.

Status in the "less active" (or "more active") category may change year to year. "Less active" class disqualifiers:

- If public comments are received for a less active drug class, it will be removed from the mass review.
- If new drugs are added into an existing PDL drug class, the class will automatically be taken out of the mass review. This may include a newly available or FDA approved agent, or a currently available product being added to an existing class.
 - Classes that contain new biosimilar products may be mass reviewed if the biosimilar's indications are the same indications that are approved for the reference product.
 - Excluded from this, and not considered a disqualifier, is a new, branded product with the same active ingredient and same indication, route of administration and dosage form or a new biosimilar that is FDA approved for all of its reference products' indications.
- If a new PDL class is being added to the PDL for review, it will not be considered "less active".
- An objection is not needed to make any class with a 'less active' class disqualifier "more active".

Notification: The Department will make the initial determination if a class is more or less active and will provide that information to the P&T Committee members. A communication will be sent via email to the Committee members at the same time the PDL drug class review announcement is sent, at least 30 days prior to the meeting, informing which drug classes are given a less active status, and therefore will be planned to mass review during the meeting. The agenda will include the less active classes under a mass review section and will continue to be posted at least 30 days prior to the meeting on the P&T Committee section of the website for the public.

Preparation and Materials: All preparation material for both more and less active classes will remain the same. The materials provided for mass reviewed classes will continue to be sent out to the committee prior to the meeting or provided electronically in an access-only repository. These materials will include DERP materials, FDA updates, and guideline updates. The less active class printed materials will be grouped together in the binders (printed or electronic). The market share and FDA updates (including guideline updates) will be provided in the binders (printed or electronic) for the meeting. No stakeholder comments will be expected for the less active classes and therefore there will be none to provide in the binders for the meeting.

Less active class materials will be provided, but not printed, include therapeutic class reviews (TCRs) and drug tables/charts.

Objection: Objections can be made by any P&T Committee member or stakeholder and should be made by phone or email to the Prime Therapeutics Clinical Account Manager and/or Greg Miller, PharmD (greg.l.miller@state.co.us) up until 48 business hours prior to the P&T meeting. If this notification is met, the objection will be allowed and the less active class will be removed from the mass review. In this case, the class will be reviewed during the meeting in the same regard with the more active classes.

If during the meeting, a committee member wants to object and initiate discussion on the less active class, this will be allowed by a majority vote of the Committee.

Future changes to this process can occur as needed to facilitate the process and intent, but not without prior notice and opportunity for open discussion for P&T members.