



OREGON HEALTH AUTHORITY  
DRUG USE REVIEW/PHARMACY AND THERAPEUTICS COMMITTEE

OPERATING PROCEDURES

Updated: November 2016

MISSION:

Evaluate available evidence-based research using a transparent process to inform drug policies that promote safe and effective use of high value medications for patients served by the Oregon Health Plan and other health care programs under the Oregon Health Authority.

DUTIES:

As defined by Oregon House Bill 2100 the Pharmacy and Therapeutics (P&T) Committee was established to perform functions previously fulfilled by the Drug Use Review Board and Health Resources Commission. Responsibilities of the P&T committee include:

1. Evaluate evidence-based reviews of prescription drug classes or individual drugs to assist in making recommendations to the Oregon Health Authority for drugs to be included on the preferred drug list (PDL).
  - a. The Committee may direct a Subcommittee to prepare these reviews.
2. Advise the Oregon Health Authority on administration of Federally mandated Medicaid retrospective and prospective drug use review (DUR) programs which includes recommending utilization controls, prior authorization requirements, quantity limits and other conditions for coverage.
3. Recommendations will be based on evaluation of the available evidence regarding safety, efficacy and value of prescription drugs, as well as the ability of Oregonians to access prescriptions that are appropriate for their clinical conditions.
4. Publish and distribute educational information to prescribers and pharmacists regarding the committee activities and the drug use review programs.
5. Collaborate with the Health Evidence Review Commission (HERC) on topics involving prescription drugs that require further considerations under the purview of the HERC.

AD-HOC EXPERT INVOLVEMENT:

1. A medical expert may be chosen and appointed by the Director of the OHA to provide clinical or treatment expertise in response to a request by the P&T Committee or an interested outside party. The ad-hoc expert must be a licensed physician in Oregon who manages patients who would potentially receive the particular drug(s) and must be approved by the P&T Committee.
2. If an interested outside party requests that an ad-hoc expert be appointed for a particular drug, this request must be made 90 days before the scheduled Committee meeting to ensure adequate time for the appointment process.



3. The medical experts shall have full voting rights with respect to the PDL drugs for which they have been selected and appointed including all utilization controls, prior authorization requirements, review of confidential pricing information or other conditions for the inclusion of a drug on the PDL. The medical experts may participate but may not vote in any other activities of the committee.

#### CONDUCT OF MEETINGS:

1. All meetings and notice of meetings will be held in compliance with the Oregon Public Meetings Law.
2. The P&T Committee will elect a Chairperson and Vice Chairperson to conduct the meetings. Elections shall be held the first meeting of the calendar year.
3. Quorum consists of 6 permanent members of the P&T Committee. Quorum is required for any official vote or action to take place throughout a meeting.
4. All official actions must be taken by a public vote. Any recommendation from the Committee requires an affirmative vote of a majority of the Committee members.
5. The committee shall meet in executive session for purposes of reviewing the prescribing or dispensing practices of individual prescribers or pharmacists; reviewing profiles of individual patients; and reviewing confidential drug pricing information to inform the recommendations regarding inclusion of drugs on the PMPDP or any preferred drug lists adopted by the OHA.
6. Meetings will be held at least quarterly but the Committee may be asked to convene up to monthly by the call of the OHA Director or a majority of the members of the Committee. DUR programs will be the focus of the meeting quarterly.

#### CONFLICT OF INTEREST POLICY:

The P&T Committee will function in a way that ensures the objectivity and credibility of its recommendations.

1. All potential initial committee members, future applicants, and ad-hoc medical experts selected for individual P&T Committee meetings are subject to the Conflict of Interest disclosure requirements in ORS Chapter 244 and are required to submit a completed disclosure form as part of the appointment process and must update when necessary.
2. All disclosed conflicts will be considered before an offer of appointment is made.
3. If any material conflict of interest is not disclosed by a member of the Committee on his or her application or prior to participation in consideration of an affected drug class or other action of the Committee, that person will not be able to participate in voting decisions of the particular drug class and may be subject to dismissal.

4. Any person providing public testimony will also be required to disclose all conflicts of interest including industry funded research prior to any testimony pertaining to issues before the Committee.

#### PUBLIC COMMENT:

1. The P&T Committee meetings will be open to the public
2. The Committee shall provide appropriate opportunity for public testimony at each meeting
  - a. Testimony can be submitted in writing or provided in-person
  - b. Maximum of 3 minutes per speaker/institution per agenda item
    - i. Information that is most helpful to the Committee is evidence-based and comparative, limited to new information not previously reviewed by the Committee and related to dossier information or prepared reviews.
    - ii. Oral presentation of the FDA approved label is not helpful information.
  - c. Written testimony can be submitted by interested parties for the P&T Committee to consider on agenda items. Written testimony that includes clinical information should be submitted for evaluation by staff at least 2 weeks prior to the scheduled meeting through the public comment link found on the P&T Committee website:  
<http://oregonstate.edu/tools/mailform?to=osupharm.di@oregonstate.edu&recipient=Drug+Use+Research+and+Management>.
  - d. Written documents provided during the scheduled public testimony periods of the P&T Committee meetings will be limited to 2 pages of new information that was not included in previous reviews. Prescribing Information (i.e., package insert) is not considered new information; only clinically relevant changes made to Prescribing Information should be submitted.

#### REVIEW STANDARDS AND PREFERRED SOURCES OF EVIDENCE

1. The P&T Committee and department staff will evaluate drug reviews that are based on sound evidence-based research and processes widely accepted by the medical profession.
2. The P&T Committee will rely primarily on high quality systematic reviews in making its decisions. High quality clinical practice guidelines and relevant clinical trials are also used as supplementary evidence. Clinical judgment will still need to be used by the Committee to determine whether the available evidence is sufficient and compelling enough to affect drug benefit decisions.
3. The following are considered preferred sources of high quality evidence:
  - a. OHSU's Drug Effectiveness Review Project (DERP)
  - b. U.S. Department of Veterans Affairs/Department of Defense
  - c. Agency for Healthcare Research and Quality (AHRQ)
  - d. Canadian Agency for Drugs and Technologies in Health (CADTH)
  - e. The Cochrane Collaboration

- f. National Institute for Clinical Excellence (NICE)
  - g. Institute for Clinical and Economic Review (ICER)
  - h. Published systematic reviews from validated Evidence-Based Medicine sources
4. The following types of evidence are preferred and will be considered if they are of high quality:
- a. Systematic reviews of randomized controlled trials
  - b. Individual comparative effectiveness randomized controlled trials (RCTs) evaluating clinically important outcomes
  - c. FDA review documents
  - d. Clinical Practice Guidelines developed using explicit evidence evaluation processes.
5. The following types of literature are considered unreliable sources of evidence and will rarely be reviewed by the P&T Committee:
- a. Observational studies, case reports, case series
  - b. Unpublished studies (posters, abstracts, presentations, non-peer reviewed articles) that do not include sufficient methodological details for quality evaluation, with the exception of FDA review documents.
  - c. Individual studies that are poorly conducted, do not appear in peer-reviewed journals, are inferior in design or quality to other relevant literature, or duplicate information in other materials under review
  - d. Studies that are not designed to investigate clinically relevant outcomes.
6. Before a review is evaluated at a P&T meeting, a final draft shall be made publicly available for a period of at least 30 days after considering all written public comments submitted during the draft comment period.

## DRUG AND DRUG CLASS REVIEWS:

### 1. Drug Class Reviews and New Drug Evaluations:

- a. The P&T Committee will review drugs and drug classes that have not been previously reviewed for PDL inclusion or for clinical PA criteria as the committee sees appropriate and will be prioritized based on:
  - i. Potential benefit or risk
  - ii. Use or potential use in covered population
  - iii. Potential for inappropriate use
  - iv. Alternatives available
  - v. OHP Coverage based on opportunities for cost savings, to ensure medically appropriate drug use, or address potential safety risks.
- b. The P&T Committee will make a reasonable effort to perform a timely review of new FDA-approved drug products following their market release, when they are a new molecular entity and are candidates for coverage under the pharmacy benefit.
- c. Line Extension and Combination Product Policy
  - i. Line extensions include new strengths or new formulations for an existing drug
    1. When a new strength or formulation becomes available for a drug previously reviewed for the PDL and has PA criteria and the new product does not

significantly differ from the existing drug based on clinical evaluation, the same utilization restrictions as the existing drug will apply until a new drug evaluation is presented to the P&T Committee for review.

2. If a new strength or formulation becomes available for an existing preferred drug and the new product significantly differ from the existing medication, has a new indication, or significantly differs in cost, the drug will not be preferred until presented to the P&T Committee for a new drug evaluation.
  - ii. When a new combination product becomes available that is a formulation of one or more drugs that have been reviewed for the PDL, where applicable, the product will be designated a non-preferred drug until the P&T Committee reviews the product.
- d. P&T staff may engage relevant health care professionals with clinical specialty to serve as expert reviewers, in addition to the ad-hoc experts, if needed.

## 2. Drug Class Literature Scans:

- a. Literature of drug classes that have previously been reviewed for the PDL will be scanned and evaluated routinely to assess need to update drug policies based on clinically relevant information published since the last review.
  - i. All drugs and drug class literature scans reviewed for a potential update will be listed on the meeting and agenda and available to the public.