



# TENNCARE POLICY MANUAL

<b>Policy No:</b>	BEN 15-001		
<b>Subject:</b>	Coverage Review of Newly Released or Approved Pharmaceuticals		
<b>Approval:</b>	<i>[Signature]</i>	<b>Date:</b>	6/24/15

## PURPOSE:

This policy outlines the process used by the Bureau of TennCare ("Bureau") and the TennCare Pharmacy Advisory Committee ("PAC") to manage TennCare enrollees' access to newly released or approved ("launched") pharmaceuticals, by using available evidence-based research to encourage and recommend safe, effective and financially stable drug use guidelines.

## POLICY:

Tennessee Code Annotated §§ 71-5-2401, *et seq.*, require the PAC to conduct meetings to review and make recommendations regarding TennCare's Preferred Drug List ("PDL"), to govern all state expenditures for prescription drugs for the TennCare program. PAC meetings are held quarterly for the purpose of reviewing drugs, new indications for use and line extensions, approved or released by the United States Food and Drug Administration ("FDA") at least thirty (30) days prior to the meeting date.

As the FDA approves new drugs and new uses for existing drugs, the PAC will adhere to the following procedure before providing the Bureau with recommendations amending the PDL:

## PROCEDURE:

- 1. PAC reviews:** The PAC's review of a new FDA-approved product or use will be conducted timely, within 120 but no longer than 180 days from the date of FDA approval. A drug will be considered non-covered until the PAC completes a therapeutic class review. The primary clinical decision to be made is whether the drugs within the therapeutic class can be considered therapeutic alternatives to established drugs used to treat the same condition. Upon reviewing a class, the PAC will propose PDL status of preferred or non-preferred and, if necessary, prior authorization ("PA") criteria for coverage. Recommendations adopted by the Bureau will be implemented on day one of the first full month following adoption.

- a. New Molecular Entity**

A new molecular entity is a drug that is innovative and has not been approved by FDA previously, either as a single ingredient drug or as a part of a combination product. The PAC will review new molecular entities or new classes of drugs for PDL inclusion and PA criteria.

**b. New Indication, Line Extension and Combination Product**

- i. A new indication is granted when the FDA determines there is enough evidence to approve a drug for treatment of a disease not previously considered or submitted for review. When a new indication is approved for a drug previously reviewed for the PDL, current criteria will apply until a therapeutic class review can be completed by the PAC.
- ii. Line extensions include new strengths and new dosage formulations for an existing therapeutic class.
  1. When a new strength or dosage formulation becomes available for a therapeutic class previously reviewed for the PDL and the new product does not significantly differ from the existing drug(s), current criteria, including PA, will apply without requiring a therapeutic class review by the PAC.
  2. If a new formulation becomes available for an existing drug or drug class and the new product differs significantly from the existing medication and has a new indication or significantly differs in cost, the drug will be considered non-covered until the PAC conducts a therapeutic class review.
- iii. When a new combination product (a formulation of one or more drugs on the PDL) becomes available the product will be designated as a non-covered drug until completion of a therapeutic class review by the PAC.

**2. PDL Updates:** Drugs and therapeutic drug classes that have previously been reviewed for the PDL will be periodically evaluated for potential update based on new clinically relevant information available since the last PAC review. All drugs and therapeutic classes reviewed for a potential update will be listed on the meeting agenda and available to the public at <https://tenncare.magellanhealth.com/>.

**3. Review Standards and Preferred Sources of Evidence:**

- a. The PAC will evaluate class recommendations and proposed prior authorization criteria that are based on sound evidence-based research and guidelines accepted by the medical profession.
- b. The PAC will rely on high-quality systematic reviews and evidence-based guidelines in creating prior authorization criteria. PAC members will exercise their clinical judgment to determine whether the available evidence is sufficiently compelling to affect drug-benefit decisions.
- c. TennCare-employed pharmacists may engage relevant health care professionals with specialty clinical experience to serve as expert reviewers, in addition to ad hoc experts, if necessary based on the therapeutic class being reviewed.
- d. The PAC will consider the overall quality of the evidence available at the time of review and public comments, and will act as follows:
  - i. Accept or reject the review and recommendations as written; or
  - ii. Make edits to the review and recommendations and accept as modified; or
  - iii. Request additional information from the TennCare Pharmacy staff on the topic; and

- iv. If additional information is requested, the PAC review of the launched drug, indication, line extension, or combination product will be completed within the 180-day time-frame as outlined above; or
  - v. In the event the PAC is unable to convene due to extenuating circumstances, interim criteria will be implemented by the Bureau and used to determine coverage until the PAC takes action as outlined above.
- e. The following are considered preferred sources of high quality evidence:
- i. Oregon Health and Science University's (OSHU's) Drug Effectiveness Review Project (DERP);
  - ii. Veteran's Health Administration and the Department of Defense (VA/DoD) Clinical Practice Guidelines;
  - iii. Agency for Healthcare Research and Quality (AHRQ);
  - iv. Canadian Agency for Drug and Technologies in Health (CADTH);
  - v. The Cochrane Collaboration;
  - vi. National Institute for Clinical Evidence (NICE);
  - vii. Institute of Clinical and Economic Review (ICER);
  - viii. Published systematic reviews from validated evidence-based medical sources.
- f. The following types of evidence are preferred and will be considered if they have been independently evaluated and determined to be of high quality:
- i. Systematic reviews of randomized controlled trials (RCTs);
  - ii. Individual comparative effectiveness RCTs evaluating clinically important outcomes;
  - iii. FDA review documents;
  - iv. Guidelines developed using an explicit evidence evaluation process.
- g. The following types of literature are considered unreliable sources of evidence and will rarely be reviewed by the PAC:
- i. Case reports, case series;
  - ii. 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;
  - iii. 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; and
  - iv. Studies that are not designed to investigate clinically relevant outcomes.

**OFFICE OF PRIMARY RESPONSIBILITY:**  
Bureau of TennCare Pharmacy Program

**NECESSARY FORMS/REPORTS:**  
None

**REFERENCES:**

<http://www.lexisnexis.com/hottopics/tncode/>  
T.C.A. §§ 71-5-2401