

TennCare Policy Manual	Section: Benefits
Policy No: BEN 15-001 (Rev. 2)	Date: May 24, 2023

## Coverage Review of Newly Released or Approved Pharmaceuticals

### Purpose

The purpose of this policy is to outline the process used by the Division of TennCare 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 establishes the PAC membership and rules to conduct meetings and make recommendations regarding TennCare's Autoexempt List. Tennessee Code Annotated § 71-5-2404 establishes the PAC as the state's expert panel for developing specific and general recommendations for the Preferred Drug List (PDL), which governs utilization management procedures for prescription drugs for the TennCare program. PAC meetings are held quarterly to review a drug or drug class, therapeutic efficacy, equivalency, relative costs, new indications and line extensions, as approved or released by the United States Food and Drug Administration (FDA).

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

### Procedure

1. **PAC reviews:** The primary clinical decision to be made by the PAC 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 standard recommendations based on comparative efficacy and safety information and, if necessary, prior authorization (PA) criteria for coverage. Recommendations adopted by TennCare 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 the FDA previously, either as a single-ingredient drug or as part of a combination product. The PAC will review new molecular entities or new classes of drugs for comparative efficacy and safety and will determine 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—either for the established use of the drug, or for the disease state the

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new indication is designed to treat—may 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 criteria, may 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 may be considered non-preferred 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 may be designated as a non-preferred 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 PAC meeting agenda and available to the public on the shared TennCare Pharmacy Benefits Manager web portal.

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

- a. The PAC will evaluate class recommendations and proposed PA 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 PA criteria. PAC members will exercise their clinical judgment to determine whether the available evidence is sufficiently compelling to affect drug-benefit decisions.
- c. The TennCare Pharmacy Division may engage relevant health care professionals with specialty clinical experience to serve as expert reviewers. In addition, ad hoc experts may be engaged, 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, findings may be presented to the PAC at the next scheduled quarterly meeting; or
  - v. TennCare reserves the right to apply interim criteria to determine coverage until the PAC takes action as outlined above.
- e. The following are considered preferred sources of high-quality evidence:

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- i. Oregon Health and Science University’s Drug Effectiveness Review Project (DERP);
  - ii. Veterans Affairs and the Department of Defense Clinical Practice Guidelines;
  - iii. Agency for Healthcare Research and Quality;
  - iv. Canadian Agency for Drugs and Technologies in Health;
  - v. The Cochrane Collaboration;
  - vi. National Institute for Clinical Evidence;
  - vii. Institute for Clinical and Economic Review;
  - viii. Published systematic reviews from validated, evidence-based medical sources.
- f. The following types of evidence are preferred and may 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

TennCare Pharmacy Division

## References

<http://www.lexisnexis.com/hottopics/tncode/>

T.C.A. § 71-5-2401

T.C.A. § 71-5-2404

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