GENERAL CRITERIA FOR NEW-TO-MARKET MEDICATIONS, PRODUCTS WITH LABEL EXPANSIONS, OFF-LABEL REQUESTS, AND NON-PREFERRED MEDICATIONS ON THE PDL

MANUAL GUIDELINES: Pertains to new-to-market FDA approved medications available on the Medicaid drug file prior to being reviewed by the Arkansas Medicaid DUR Board, medications with a label expansion including new indication, dosage or age change, prior authorization (PA) requests for medications prescribed off-label, and non-preferred medications on the PDL.

APPROVAL CRITERIA:

- Medication must be a covered outpatient drug with a federal rebate agreement in place.
- Medication must be prescribed for an FDA-approved indication with age, dose, and frequency based on manufacturer's packet insert. If the beneficiary's age or dose/frequency requested is not FDA approved, the age or dose/frequency must have support in an official Compendia (i.e., American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (USP-DI), the DRUGDEX Information System).
- If the FDA-approved indication(s) does not match the beneficiary's diagnosis, the medication must have support for the requested diagnosis either in treatment guidelines or an official Compendia (i.e., American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (USP-DI), the DRUGDEX Information System).
- Off-label requests sent in for review without support found in an official Compendia will be reviewed on a case-by-case basis.
- Renewals for drugs requiring a PA requires a positive response and must continue to meet approval criteria

Label expansion

- Medications previously reviewed by the DUR Board with a new FDA approved label expansion will not require a new review by the DUR Board.
- Any prior authorization requests will be reviewed based on the updated package insert.
- The prior authorization criteria document will be updated with the new label information with the next quarterly document update if possible.

New-to-market medication with class on PDL

- If the new-to-market medication is included in an existing class/category on the preferred drug list (PDL):
    - The new-to-market medication will automatically be added as a non-preferred option and will not require DUR Board review.
    - The new-to-market medication will require prior authorization with documentation of the medical necessity over preferred options.
    - If the PDL class has multiple preferred options, the beneficiary must have documentation of trial and failure of at least 2 different chemical entities unless otherwise noted.
    - If the PDL class has multiple preferred options with multiple mechanisms of action (MOA), the beneficiary must have documentation of trial and failure from each MOA unless there is a contraindication or otherwise noted.

      Example: Second generation antidepressants have multiple MOA as preferred options (i.e., SSRI, SNRI, and aminoketone).

New-to-market medication with class not on PDL

- If the new-to-market medication's class/category is not on the preferred drug list (PDL), the documentation of medical necessity over older products in the same class is required along with a trial of at least 2 older products unless otherwise noted.
- If the class/category has PA criteria, the new-to-market medication will follow that criteria until DUR Board review if a review is warranted.

New-to-market medication with new formulation

- If the new-to-market medication is the same chemical entity as another medication already on the market but in a different dosage form, the existing dosage form must be tried first. If the original medication was a solid oral dosage form, the following scenarios would require a prior authorization with documentation of the medical necessity for the new formulation.
    - New-to-market is an oral, non-solid dosage form (may be considered in beneficiaries <7 years of age or beneficiaries identified as NPO).
    - New-to-market is an extended-release formulation.
    - New-to-market is a sprinkle formulation.

New-to-market medication requiring a PA

- If the new-to-market medication is a novel product and/or requires extensive monitoring, prior authorization will be required. The prescriber should submit the following for review:
    - Current chart notes and/or discharge summary
    - Documentation of all previous therapies tried with treatment timeframe and responses
    - Current labs if warranted (e.g., oncology and hemophilia)
    - Letter of Medical Necessity outlining the rationale for this medication over others currently on the market
- Certain new-to-market medications reviewed by the DUR Board will defer to the FDA approved package insert and treatment guidelines (e.g., oncology)
- Once the new-to-market medication has been reviewed by the DUR Board, required criteria for approval will be consistent with the DUR Board vote. All new and renewal prior authorization requests will refer to the DUR Board approved criteria.
- Prior authorization requests for new-to-market medications that have not been reviewed by the DUR Board will be reviewed on a case-by-case basis using the manufacturer's package insert and treatment guidelines.

Preferred drug list in general

- Preferred without criteria medications will not require prior authorization.
- Preferred with criteria medications will have point-of-sale criteria or will require prior authorization.
- Non-preferred medications
    - These medications will require prior authorization with documentation of the medical necessity over preferred options.
    - If the PDL class has multiple preferred options, the beneficiary must have documentation of trial and failure of at least 2 different chemical entities unless otherwise noted.
    - If the PDL class has multiple preferred options with multiple mechanisms of action (MOA), the beneficiary must have documentation of trial and failure from each MOA unless there is a contraindication or otherwise noted.

      Example: Second generation antidepressants have multiple MOA as preferred options (i.e., SSRI, SNRI, and aminoketone).