CRITERIA FOR MEDICATIONS NEW-TO-MARKET OR WITH LABEL EXPANSIONS

MANUAL GUIDELINES: Pertains to new-to-market FDA approved drugs available on the Medicaid drug file or drugs with a label expansion including new indication, dosage change, or age change prior to being reviewed by the Arkansas Medicaid DUR Board.

APPROVAL CRITERIA:

- Medication must be an 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 FDA-approved indication(s) does not match the client's diagnosis, the medication must have support for the requested diagnosis either in treatment guidelines or the official Compendia (MicroMedex®)
- 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 be added as a non-preferred option.
  - The new-to-market medication will require a prior authorization with documentation of the medical necessity over preferred options.
  - If the PDL class has multiple preferred options, the client 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 client must have documentation of trial and failure from each MOA unless there is a contraindication.

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

- 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.
  - An exception—New-to-market antiepileptic drugs require a trial of 3-4 different AEDs available without a PA.
- 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 clients <7 years of age or clients identified as NPO).
  - New-to-market is an extended-release formulation.
  - New-to-market is a sprinkle formulation.
- If the new-to-market medication is a novel product and/or requires extensive monitoring, a 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
- 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.

Effective July 21, 2021