Reference number(s)
REG 5504-D

Post Step Therapy Prior Authorization Global Step Therapy Tennessee

Coverage Criteria

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The requested drug is being prescribed for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)
- The prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature and ONE of the following criteria is met:
    - The request is for a brand drug that has a generic equivalent or interchangeable biological product available and the following criteria is met:
        - The patient experienced a trial and failure of the generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient
    - The alternate drug is contraindicated or will likely cause a serious adverse reaction to, or physical or mental harm to, the patient due to a documented adverse event with a previous use of the required prescription drug or a documented medical condition, including a comorbid condition
    - The alternate drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen
    - The alternate drug is NOT in the best interest of the patient, based on clinical appropriateness, because the patient's use of the drug is expected to cause any of the following: cause a significant barrier to adherence to or compliance with the plan of care, worsen a comorbid condition, decrease ability to achieve or maintain a reasonable functional ability in performing daily activities
    - The patient is currently receiving a positive therapeutic outcome on the prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan, and the healthcare provider gives documentation that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the patient based on the known characteristics of the specific enrollee and the known

characteristics of the required prescription drug. [Note: Pharmaceutical drug samples of a required prescription drug is not considered a trial of the required prescription drug as part of a step therapy protocol.]

Duration of Approval (DOA)

- 5504-D: DOA: 12 months, or appropriate duration for requested drug

References

1. State of Tennessee Senate Bill 1310. May 2022.