

South Country Health Alliance

Medicare	X
Medicaid	

Policy & Procedure: Medical Coverage Policies

Policy Name	Coverage Criteria for Medicare Part B Medical Pharmacy Drug Continuation Therapy Authorizations
Policy Number	MCP 44
Regulatory Requirement(s)	Medicare Benefit Policy Manual Chapter 15 – section 50 FDA Approved Drug Indications NCQA UM 1, 2, 4, 10
Original Effective Date	April 24, 2020
Version Effective Date	April 15, 2024
Policy Owner(s)	Medical Director, Director of Health Services
Cross Reference(s)	

Purpose

Authorization of retail pharmacy and Medicaid medical pharmacy drug authorization benefits are managed by the contracted pharmacy benefit manager, PerformRx. For dual eligible members, providers may request authorization for pharmaceuticals under the Medicare Part B medical benefit, referred to as medical pharmacy authorization. To facilitate efficient authorization by the utilization management team, authorization will be allowed for the continuation of Medicare medical pharmacy benefit if the request meets the general criteria outlined in this policy.

FDA approved criteria for each prescription drug are summarized on each drug's published prescribing information, referred to as the drug label or package insert. Information on the Package insert is consistently formatted with any black box warning, recent major changes, indications and usage, dosage and administration, dosage forms and strengths, contraindications, warning and precautions, adverse reactions, and drug interactions. Additionally, full prescribing information also includes use in specific populations, drug abuse and dependence, overdose, description, clinical pharmacology, nonclinical toxicology, clinical studies, how supplied/stored and handled, and patient counseling information. The drug label information is available for many drugs on the FDA website: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm> (select drug, then select package insert)

Definitions

Continuation of Therapy is defined as having used the medication in the past.

Coverage criteria:

Authorization request is for continuation of therapy authorization and all of the following criteria are

met:

- Diagnosis meets covered uses criteria as listed on FDA approved Indication and Usage
- Dosage and Administration consistent with prescribing information
- Age restriction criteria met
- Coverage Duration up to one year
- Cost for authorization request does not exceed the threshold of \$10,000/month

Not Covered/Exclusions:

- Required medical information not provided upon request to satisfy indication criteria
- Off-label usage
- Drug is contraindicated for member conditions
- Exclusion criteria as listed under contraindications on the drug label
- Quantity and duration that exceeds plan benefit limit
- Known prescriber restrictions not met for certain classes of drugs

Referral to PharmD and/or Medical Director:

- Utilization management team will refer authorization to the PharmD and/or medical director for determination if:
 - initial authorization of the medical pharmacy benefit if there is not an available CMS NCD nor LCD or if coverage criteria are not met by available CMS NCD nor LCD.
 - the coverage criteria of this policy are not known to be met
 - exceeds the cost threshold
 - referencing pharmacy compendium is required

References

Last literature review: April 2024

U.S. Food & Drug Administration

<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>

Signatures:

Signature Approval: DocuSigned by:
Tim Miller
891618EF4837439... _____ Date: 4/16/2024
Medical Director

Signature Approval: DocuSigned by:
Kim Worrall
5FA0CFDD73C946B... _____ Date: 4/16/2024
Director of Health Services