



Policy:	New Drug Prior Approval (Global Prior Authorization)	Annual Review Date: 08/22/2024
		Last Revised Date: 08/22/2024

OVERVIEW

Prior authorization is required to ensure that medications are being used safely and that they will be effective for the prescribed indication.

POLICY STATEMENT

Prior authorization is recommended for pharmacy benefit coverage of specified new drugs. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of the requested drug is recommended in those who meet the following criteria:

- 1. The requested drug is prescribed for an indication that is noted on the product's most recent FDA-approved labeling (package insert); AND
- 2. Member does not have any contraindications listed in product's most recent FDA-approved labeling (package insert); AND
- **3.** The requested dose follows the dosing guidelines found in the product's most recent FDA-approved labeling (package insert); AND
- **4.** The requested drug is appropriate for the member's current age per the product's most recent FDA-approved labeling (package insert); AND
- 5. The requested drug will only be used for recommended duration for the indication per the product's most recent FDA-approved labeling (package insert), if specified; AND

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- **6.** If the indication in the product's most recent FDA-approved labeling (package insert) specifies the prior use of another medication, the member has had a prior trial on the agent specified; AND
- 7. If there are alternative medications available for the same indication, the patient must have tried, had an intolerance or failure to, or has contraindications to the alternative medication(s) for the same indication.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 6 months **B)** *Extended Approval:* 6 months

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.