



Commercial Formulary Exception Criteria

Purpose:

The purpose of this policy is to establish criteria for which exceptions to the formulary, or drug list, may be allowed. A drug formulary is used to encourage safe, effective, and economical prescribing of drugs.

Exception Criteria:

- The member has documented intolerance or failure to the formulary alternatives for the submitted diagnosis.
- The dosage and indication are within the Food and Drug Administration (FDA) approved labeling.
- The provider has demonstrated that there are no other medically reasonable formulary options.

Resources used for making utilization decisions and developing criteria may include:

- Food and Drug Administration (FDA) approved label
- Nationally recognized utilization management criteria and established practice guidelines such as National Comprehensive Cancer Network (NCCN)
- Medicare approved compendia (American Hospital Formulary Service-Drug Information (AHFS-DI), NCCN, Micromedex)
- Peer-reviewed medical literature
- In-network and out-of-network physician specialty consultants
- Members of the Pharmacy and Therapeutics (P&T) committee or outside consultants
- Other commercial health plan criteria including posted PacificSource medical prior authorization criteria for requested treatment

Reauthorization will require documentation of treatment success and a clinically significant response to therapy.

Approval Duration: 12 months, unless otherwise specified

*If approved, drug will pay at Tier 3 (if non-specialty) and Tier 4 (if specialty) copay

**Maximum Allowable Cost (MAC) penalty may apply



Commercial Quantity Limit Exception Criteria

Purpose:

The purpose of this policy is to establish criteria for which exceptions to quantity limits may be allowed.

A quantity limit is the maximum amount of drug that may be dispensed within a specified amount of time. A quantity limit is applied to encourage appropriate and cost-effective prescribing of drugs in accordance with labeling approved by the Food and Drug Administration (FDA), pharmaceutical manufacturer and peer-reviewed literature.

Exception Criteria:

Requests will be evaluated based on FDA labeling, compendia listing, or primary literature supporting the request.

Considerations for coverage include:

- The member requires additional quantities of medication due to dosage titration up to the FDA-approved maximum daily dose.
- The member has exhausted higher dosage strengths of the medication.
- The requested dose is considered medically safe and effective.
- The daily dosage and dosing frequency for the indication are within the FDA-approved labeling.

For at home COVID-19 testing kits (request for more than 8 tests per 30 days):

Your provider must show a medical reason you need more than 8 at home COVID-19 tests per month. If your employer requires extra testing, these tests are not covered by your health plan. The Centers for Disease Control and Prevention (CDC) recommends up to twice weekly testing along with social distancing to reduce the risk of infection. It can take up to 14 days for the test to detect the virus in your body. Therefore, those at high risk should test once a week.

Reauthorization will require documentation of treatment success and a clinically significant response to therapy.

Approval Duration: 12 months, unless otherwise specified



Commercial Tier Exception Criteria

Purpose:

The purpose of this policy is to establish criteria for which exceptions to the benefit tier structure may be allowed.

A Tier Exception (TE) is when a drug is covered at a lower cost sharing tier.

Considerations for TE approval include:

- Tier exceptions are only available from Tier 3 to Tier 2
- Tier 1 and Specialty drugs are not eligible for Tier Exceptions
- All lower tier options have been tried and found not effective
- Must be considered high risk medication:
 - Anti-seizure treatment
 - Transplant immunosuppressant
- Drug must be on member's current formulary (non-formulary drugs, including approved formulary exception authorizations, are not eligible for a tier exception)

Approval Duration: 12 months, unless otherwise specified