



Commercial Formulary Exception Criteria

Purpose:

To provide an objective, evidence-based, consistent review of each individual case in collaboration with a member's clinician. The Pharmacy Services team reviews requests for services. The Pharmacy Services team consists of pharmacy technicians, clinical pharmacists, pharmacy director, and medical directors. Requests are prioritized based on the date received, urgency status, and type of request. Consideration is also given to plan benefits and the needs of individual members. The attending physician and/or the primary care physician are consulted during the review process as appropriate and as needed. With all approval and denial decisions, letters are issued to providers and members.

Exception Criteria:

- Documented intolerance or failure to the formulary alternatives for the submitted diagnosis
- Review for Food and Drug Administration (FDA) approved label and dosing
- Has the provider 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, Uptodate, DrugDex, Clinical Pharmacology, Lexi-Drugs)
- 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 a policy for situations where quantity limitations will apply to drugs and the circumstances that will be considered to approve requests for additional quantities. Quantity limits are applied to encourage appropriate and cost-effective prescribing of drugs in accordance with labeling approved by the Food and Drug Administration (FDA), 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 patient 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
- Requested dose is considered medically safe and reasonable
- 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 requirements for tier exception (TE) in which a drug is to be 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
- 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