



Formulary Exceptions Program Summary for Medicaid Formulary

APPLICATION

These criteria apply only to FDA approved legend drugs which are covered under the member's current benefit plan. Medications which are investigational or otherwise not a covered benefit should be forwarded for review under the appropriate process.

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

A coverage exception will be granted when BOTH of the following are met:

1. The request is NOT for a drug/drug class/medical condition that is on the list of drugs/drug classes/medical conditions which are excluded from coverage under the pharmacy benefit

AND

2. ONE of the following:

- A. The requested agent is an antipsychotic AND the prescribing physician has certified in writing that they have considered all equivalent drugs on the formulary and have determined that the medication prescribed will best treat the patient's condition

OR

- B. BOTH of the following:

- i. ONE of the following:

- a. The requested agent is an estrogen or testosterone product AND is being prescribed for a diagnosis related to gender reassignment

OR

- b. The patient's diagnosis is an FDA approved or CMS approved compendia accepted indication for the requested agent

AND

- ii. ONE of the following:

- a. If the request is for an oral liquid form of a medication, then BOTH of the following:

1. The patient has an FDA approved indication

AND

2. The patient uses an enteral tube for feeding or medication administration

OR

- b. The requested agent is a glucose test strip AND ONE of the following:

1. The patient uses an insulin pump OR continuous glucose monitor which requires a specific non-formulary glucose test strip

OR

2. The prescriber has documented that the patient requires a non-formulary glucose test strip due to other physical or mental disability

OR

- c. The requested agent has formulary alternatives (tier 1, 3, or 4) that can be prescribed in a dose to fit the patient's needs AND ALL of the following:

1. If the requested agent is a brand product with an available formulary generic equivalent, ONE of the following:
 - A. The patient has tried and had an inadequate response to at least one formulary generic equivalent(s), if available

OR

 - B. The prescriber has provided information stating that the available formulary generic equivalent(s) to the requested agent is contraindicated, is likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

2. If there is a formulary biosimilar agent(s) available for the requested agent, ONE of the following:
 - A. The patient has tried and had an inadequate response to at least three (or as many as available, if fewer than three) of the available formulary biosimilar agent(s) with at least a 3 month trial

OR

 - B. The prescriber has provided information stating that the available formulary biosimilar agent(s) is contraindicated, is likely to be less effective, or will cause an adverse reaction or other harm for the patient

AND

3. ONE of the following:
 - A. The patient has tried and had an inadequate response to at least three (or as many as available, if fewer than three) formulary alternatives for the diagnosis being treated with the requested agent

OR

 - B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient

OR

 - C. The prescriber certifies that the patient had been stabilized on the requested agent for a minimum of 90 days and that switching could potentially cause harm or a health risk

OR

- d. The requested agent does NOT have formulary alternatives that can be prescribed in a dose to fit the patient's needs

Length of Approval:

Due to drug shortage of formulary drug(s), 3 months, unless CPM/Client provides other duration approval length

All others: 12 months

Compendia Allowed: AHFS, DrugDex with 1 or 2A level of evidence, or NCCN with 1 or 2A level of evidence (for oncology agents also accept NCCN Compendium™ level of evidence 2B, DrugDex 2B, Wolters Kluwer Lexi-Drugs level A, and Clinical Pharmacology)