BlueCross BlueShield of Alabama

Coverage Exception Program Summary

This program applies to Commercial, NetResults, and Health Insurance Marketplace lines of business.

Coverage Exception Criteria

These criteria apply to any request for medication that is not included on the covered drug list (formulary) and can be used to treat a medical condition/disease state that is not otherwise excluded from coverage under the pharmacy benefit.

If the request is for a medication and disease state/medical condition that is addressed with current clinical review criteria that criteria set will be applied.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

The requested medication will be approved when ONE of the following is met:

1. The requested medication is not a drug, drug class, or medical condition excluded from coverage on the pharmacy benefit
   AND
2. The requested medication is not a drug, drug class, or medical condition restricted to coverage under the medical benefit **OR** the requested medication is appropriate for self-administration according to patient factors as determined by the provider
   AND
3. If the requested medication has additional clinical review criteria (e.g. prior authorization), that clinical review criteria has been met
   AND
4. The patient has an FDA approved or CMS-approved compendia accepted indication for the requested medication
   AND
5. If there are formulary alternatives available for the diagnosis being treated by the requested drug ONE of the following:
   i. The patient has tried and failed two formulary alternatives for the diagnosis being treated with the requested medication OR the patient has tried and failed the available formulary alternatives (one or none) if two are not available
   OR
   ii. The prescriber has provided documentation stating available formulary alternatives are contraindicated, likely to be less effective or cause an adverse reaction or other harm for the patient
   OR
   iii. The prescriber states that the patient is using the requested medication AND is at risk if therapy is changed

   AND
6. If the requested medication is for an Affordable Care Act Copay Waiver product, that criteria has been met

Length of Approval: 12 months

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA

approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.