Pharmacy Policy Bulletin

Title: Interim Clinical Policies

Policy #: Rx.01.184

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for new or recently introduced products as provided under the member's prescription drug benefit.

Description:

An interim clinical policy is the written description of the plan's utilization management position concerning the use or application of a new or recently introduced product that is covered under the pharmacy benefit. These policies are implemented prior to review by the Pharmacy and Therapeutics Committee. Criteria are based on an initial clinical review performed by Clinical Pharmacy Services. The intent of the interim policy is to provide a means to manage newly approved products while allowing sufficient time for a thorough clinical review and evaluation by the Pharmacy and Therapeutics Committee. The product to which an interim clinical policy applies is considered medically necessary when requested for an indication approved by the Food and Drug Administration and, when available, there is inadequate response or inability to tolerate one generic alternative and one preferred brand with the same indication. The policy is effective as of the date of market entry. A clinical policy, if issued, will be available when approved by the Pharmacy and Therapeutics Committee within 180 days of the drug market entry, designated by the Medispan release date. If a clinical policy is not approved within 180 days, the interim clinical policy will be retired. Interim clinical policy will remain in effect until the clinical policy effective date.

Policy:

A new or recently introduced product will be considered medically necessary when both of the following are met:

A. Diagnosis of an FDA approved indication; and
B. Inadequate response or inability to tolerate BOTH of the following (when available):
    1. One generic alternative with the same indication; and
    2. One preferred brand with the same indication

Authorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed

in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

None

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Applicable drugs will vary as new products are released to market.

Cross References:

Off-Label Use Rx. 01.33

Policy Version Number:	6.00
P&T Approval Date:	June 10, 2021
Policy Effective Date:	October 01, 2021
Next Required Review Date:	June 10, 2022