Pharmacy Policy Bulletin

Title:	Authorized Generic Drugs
Policy #:	Rx.01.227

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 **insulin aspart (authorized generic for Novolog®)** and **budesonide-formoterol fumarate dihydrate (authorized generic for Symbicort®)** as provided under the member's prescription drug benefit.

Description:

Authorized generics are brand name drugs that are marketed without the brand name on its label. An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission. Although a Food and Drug Administration (FDA) approved drug, the authorized generic is not approved through the abbreviated new drug application (ANDA) process like a standard generic drug. For cost-sharing purposes, authorized generics are treated as brand name drugs and are not eligible for coverage on the generic tier(s).

Insulin aspart products are the authorized generic of brand Novolog®. It is a rapid acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. Insulins lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis and enhances protein synthesis. Novolog® is administered within 5-10 minutes before a meal.

Budesonide-formoterol fumarate dihydrate aerosol is the authorized generic of brand Symbicort®. It is a combination product containing a corticosteroid and a long-acting beta-adrenergic agonist indicated for the treatment of asthma in individuals 6 years of age and older. It is also indicated for the maintenance treatment of airflow obstruction and reducing exacerbations in individuals with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema.

Policy:

INITIAL CRITERIA: An authorized generic product will be approved when ALL of the following criteria are met:

1. FDA or compendia approved indication; and
2. Request is not for an excluded benefit (i.e. cosmetic); and

3. Trial of the brand product(s) listed for at least 6 months within the previous 365 days; and
4. Documentation is provided of the reason why the brand product would be less effective than the requested authorized generic product

Target	Prerequisite	Category
Insulin aspart (authorized generic for Novolog®)	One of the following: Novolin® or Novolog®	Anti-diabetic
Budesonide-formoterol fumarate dihydrate aerosol (authorized generic for Symbicort)	Brand Symbicort	Pulmonary

Initial authorization: 2 years

REAUTHORIZATION CRITERIA: An authorized generic product will be re-approved when there is documentation of positive clinical response to therapy.

Reauthorization: 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:

Novolog (insulin aspart) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc. March 2021. Available at: https://www.novo-pi.com/novolog.pdf. Accessed March 31, 2021.

Symbicort (budesonide and formoterol fumarate dihydrate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. July 2019. Available: https://www.azpicentral.com/symbicort/symbicort.pdf#page=1. Accessed March 31, 2021.

U.S. Food & Drug Administration Authorized Generic Drugs. Available at: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs. Accessed March 31, 2021.

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.

Authorized Generic	Brand Name
Insulin aspart	Novolog®

Budesonide-formoterol fumarate	Symbicort®

Cross References:

Off-Label Use Rx.01.33

Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit Rx.01.76

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