
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 is approved when ALL of the following 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. Both of the following:
 - a. Documentation is provided stating that the brand has been ineffective; and
 - b. Justification provided for why the authorized generic is expected to provide benefit when the Brand product has not been shown to be effective

| 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 duration: 2 years

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

Reauthorization 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:**

Novolog (insulin aspart) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc. March 2021. Available at: <https://www.novo-pi.com/novolog.pdf>. Accessed January 11, 2022.

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 January 11, 2022.

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 January 11, 2022.

▸ **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

Insulin aspart

Budesonide-formoterol fumarate

Brand Name

Novolog®

Symbicort®

▸ Cross References:

Off-Label Use Rx.01.33

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

Policy Version Number:

3.00

P&T Approval Date:

December 09, 2021

Policy Effective Date:

April 01, 2022

Next Required Review Date:December 09, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.