Administrative Policy

Effective Date 1/1/2024
Next Review Date… 1/1/2025
Administrative Policy Number.....A008

Authorized Generics

Table of Contents

Related Coverage Resources

Step Therapy - Standard/Performance Prescription Drug Lists (Employer Group Plans)
Step Therapy – Value and Advantage Prescription Drug Lists (Employer Group Plans)
Step Therapy – Legacy Prescription Drug Lists (Employer Group Plans)

PURPOSE
*Administrative Policies are intended to provide further information about the administration of **standard** Cigna benefit plans. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in an Administrative Policy. Coverage determinations require consideration of 1) the terms of the applicable benefit plan document; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Administrative Policies and; 4) the specific facts of the particular situation. Administrative Policies relate exclusively to the administration of health benefit plans. Administrative Policies are not recommendations for treatment and should never be used as treatment guidelines.*

Administrative Policy

An "Authorized Generic Drug" means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug (the "Reference Brand Drug")..

Coverage for Authorized Generic Drugs and their associated Reference Brand Drugs varies across benefit plans/formularies and therapeutic classes/categories. Coverage for any non-covered alternative is allowed only when the covered formulary alternative is not available in the market.

Cigna covers either or both of the Reference Brand Drug or associated Authorized Generic Drug noted in the tables below based on the customer's benefit plan, including the formulary.

Not every Authorized Generic Drug is addressed in this policy, so the omission of an Authorized Generic Drug does not mean that the Authorized Generic Drug or its associated Reference Brand Drug are covered or not covered by the customer's benefit plan. Refer to the customer's benefit plan document and/or formulary for specific coverage details.

Product Specific Coverage Tables By Plan Drug List:

Standard Drug List Plan Performance Drug List Plan	
Covered Product	**Not Covered Product**
Aciphex Sprinkle	Rabeprazole Sprinkle Authorized Generic

Flector	diclofenac epolamine 1.3% topical patch Authorized Generic
Mitigare	Colchicine 0.6 mg Capsule Authorized Generic
Tresiba	Insulin degludec
Triglide	Fenofibrate Nanocrystallized Authorized Generic
Value Drug List Plan Advantage Drug List Plan Cigna Total Savings Plan	
Covered Product	**Not Covered Product**
Flector	diclofenac epolamine 1.3% topical patch Authorized Generic
Mitigare	Colchicine 0.6 mg Capsule Authorized Generic
Tresiba	Insulin degludec
Triglide	Fenofibrate Nanocrystallized Authorized Generic
Legacy Drug List Plan	
Covered Product	**Not Covered Product**
Flector	diclofenac epolamine 1.3% topical patch Authorized Generic
Mitigare	Colchicine 0.6 mg Capsule Authorized Generic
Tresiba	Insulin degludec
Triglide	Fenofibrate Nanocrystallized Authorized Generic
Individual and Family Plans	
Covered Product	**Not Covered Product**
Flovent HFA	Flucticasone HFA Authorized Generic
Humalog	Insulin lispro (U-100 vials and U-100 pens) Authorized Generics
Humalog Junior Kwikpen	Insulin lispro (U-100 pen) Authorized Generic
Humalog Mix 75-25 Kwikpen	Insulin lispro protamine/lispro (U-100 pen) Authorized Generic

*in order to be covered, denoted products must also meet medical necessity criteria defined in the related coverage policy

General Background

From the US Food and Drug Administration:
The term “authorized generic” drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An authorized generic may be marketed by the brand name drug company, or another company with the brand company’s permission. In some cases, even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower cost than the brand name drug.

A generic drug, as that term is commonly understood to be a copy of a brand-name drug that is developed and made by a company other than the company that makes the brand-name drug. A generic drug is the same as the brand-name drug in active ingredient, conditions of use, dosage form, strength, route of administration, and (with certain permissible differences) labeling. However, a generic drug may have certain minor differences from the brand-name product, such as different inactive ingredients. To obtain approval of a generic drug, a company must submit an Abbreviated New Drug Application (ANDA) to the FDA and prove that the generic product is the same as the brand-name drug in the ways described above, and that it is “bioequivalent,” meaning it gets to the part of the body where the drug works at the same time and in the same amount. A generic drug must also meet the same standards of quality and manufacturing as the brand name drug. An ANDA applicant is not required to

provide independent evidence of the safety and effectiveness of a proposed generic drug. Instead, the applicant relies on the FDA's finding that a previously approved drug product is safe and effective.

Again, an authorized generic drug is the same as the brand-name drug but does not use the brand name on the label. In addition, an authorized generic version of a tablet or capsule may have a different color or marking. Because an authorized generic drug is marketed under the brand name drug's New Drug Application (NDA), it is not listed in FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book). An authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is in fact the same drug. This is true even if the brand-name drug is "single source," meaning there are no ANDAs approved for that product, or coded as non-equivalent (e.g., BN) by the FDA in the Orange Book. While a separate NDA is not required for marketing an authorized generic, the FDA requires that the NDA holder notify the FDA if it markets an authorized generic. The NDA holder may market both the authorized generic and the brand-name product at the same time.

Listing of Authorized Generic Drugs

As part of their required annual reports, NDA holders must notify the FDA of any authorized generic drugs marketed under their approved NDAs. The FDA publishes a list of reported authorized generics and updates that list quarterly. See References.

References

1. US Food and Drug Administration, FDA List of Authorized Generic Drugs, https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs
2. US Food and Drug Administration, FDA Listing of Authorized Generic Drugs, https://www.fda.gov/about-fda/center-drug-evaluation-and-research/fda-listing-authorized-generics