World Trade Center Health Program
Medical Coverage Determination
Generic First Program
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I. Coverage Overview

The World Trade Center (WTC) Health Program requires the use of generic drugs when available and clinically appropriate to treat a certified WTC-related health condition or health condition medically associated with a certified WTC-related health condition. A member must either have documented use of WTC Health Program covered generic drugs with inadequate clinical response or have documented contraindications to the generic drugs prior to requesting equivalent brand-name drugs.[1] Dispensing of a brand-name drug solely due to provider or member preference is not permitted.

By promoting generic drugs as therapeutically equivalent alternatives, the Program aligns with other federal payers and managed care best practices.[2] The Veterans Health Administration,[3] TRICARE Pharmacy Benefits Program,[4] and Centers for Medicare & Medicaid Services (CMS) Part D sponsors[5] require the use of generic drug alternatives and reserve brand-name drug coverage for medically necessary situations.

All drugs, including brand-name drugs, are subject to utilization management criteria including prior authorization (PA) rules. PA requirements are listed in the WTC Health Program Pharmacy Formulary. For detailed PA procedures, see instructions found in the WTC Health Program's Administrative Manual.[6] All documentation for completed PA requests is subject to audit by the WTC Health Program.

This Medical Coverage Determination (MCD) outlines the coverage of drugs under the Generic First Program for WTC Health Program members.

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[1] Both brand-name and generic drugs are reviewed for addition to the WTC Health Program Pharmacy Formulary in accordance with the criteria highlighted in the *Policy and Procedure for Coverage of Drugs. See* WTC Health Program, "Policy and Procedure for Coverage of Drugs" at https://www.cdc.gov/wtc/policies.html#coverageDrugs.
[2] *See* Academy of Managed Care Pharmacy (AMCP), "Generic Drugs" at https://www.amcp.org/legislative-regulatory-position/generic-drugs.
[3] *See* Department of Veterans Affairs (VA), "VHA Formulary Management Process" at https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=9889. *See also* VA, "Current VA Health Care Copay Rates" at https://www.va.gov/health-care/copay-rates/.
[4] *See* 32 C.F.R. § 199.21(j) at https://www.ecfr.gov/current/title-32/part-199/section-199.21#p-199.21(j).
[5] *See* 42 C.F.R. § 423.120(b)(1)(vii) at https://www.ecfr.gov/current/title-42/part-423/section-423.120#p-423.120(b)(1)(vii).
[6] *See* WTC Health Program Administrative Manual, Chapter 12, Section 6.5–6.6 at https://www.cdc.gov/wtc/ppm.html#pharmacy_priorAuthFormulary.

II. Generic First Program

The Program will only cover brand-name drugs when medically necessary to manage, ameliorate, or cure a certified WTC-related health condition or health condition medically associated with a certified WTC-related health condition, and when both of the following criteria are met. Exceptions to the Generic First Program are described in Section III.

A. Previous Use of Generic Drugs

A provider must submit rationale and clinical history documenting either the use of WTC Health Program-covered generic drugs with inadequate clinical response, significant adverse effects, or contraindications to the generic drugs prior to requesting a brand-name drug.

The generic drug must be used for a clinically appropriate length of time, which may vary by drug class or condition as determined by national clinical protocols consistent with FDA-approved labeling. The number of generic drugs that must be tried prior to approval of a brand-name drug may also vary by drug class and condition, as determined by national clinical protocols consistent with FDA-approved labeling. Providers must include the names of the drugs tried, their strength, and the duration of use on all PA requests for brand-name drug coverage based on inadequate clinical response or significant adverse effects.

AND

B. Use of Dispense as Written (DAW) Code 1

Once the above criteria are met, a prescription for a brand-name drug must be written by a Program-affiliated provider and must include a Dispense as Written (DAW) Code 1.[7]

A DAW 1 is a pharmacy point-of-sale code that indicates a substitution from brand-name to generic drug is not allowed by the prescriber.[8] This means the prescriber has explicitly instructed the pharmacist to dispense the specific brand-name drug as written.

III. Exceptions to the Generic First Program

Certain circumstances may require the dispensing of a brand-name drug without meeting the criteria outlined in Section II. The WTC Health Program allows brand-name drugs to be utilized without the trial of generic drugs in limited cases.

Brand-name drugs may be dispensed without meeting the criteria in Section II in circumstances related to: (1) market availability, (2) generic price inversions, (3) clinical appropriateness, or (4) operational considerations. Each of these circumstances is described in greater detail below.

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[7] DAW 1 should be utilized when a generic version of a brand-name drug exists.

[8] *See* National Council for Prescription Drug Programs (NCPDP), "The Proper Use of the NCPDP Telecommunication Standard Version D.0 as it applies to the Implementation of Medicaid Reimbursement Methodologies Based on Actual Acquisition Cost (AAC) Plus a Professional Dispensing Fee" at https://www.ncpdp.org/NCPDP/media/pdf/WhitePaper/Proper-Use-of-NCPDP-Telecommunication-Standard-in-Implementation-of-Medicaid-Reimbursement-Methodologies-v1-2.pdf?ext=.pdf.

A. Market Availability

1. Novel Treatment Options

Drugs that are the first to be FDA-approved for a condition are considered novel treatments.[9] When a novel drug is the only FDA-approved drug to treat a condition covered by the WTC Health Program, generic drug trials are not feasible and would not be required.

2. Drug Shortages

Drug shortages can occur for many reasons, including manufacturing and quality problems, delays (including supply delays), and discontinuations.[10] During an FDA-announced nationwide drug shortage, the Program may allow for the equivalent brand-name drug to be dispensed temporarily until the national supply has stabilized. Current drug shortages are available on the FDA Drug Shortage Database.[11]

3. Over-the-Counter Products (OTCs)

The WTC Health Program covers a select number of OTC products when they can be dispensed at a lower cost than their prescription counterparts.[12] Either brand or generic OTC drugs may be dispensed based on product availability due to their cost savings when compared to prescription versions.

B. Generic Price Inversion

Generic price inversion occurs when the cost of a generic drug exceeds the cost of the brand-name drug. In such instances, the Program may continue to cover the brand-name drug until the cost of the generic drug is lowered. Generic price inversion may occur due to FDA generic exclusivity periods, authorized generics, brand-name biosimilars, and PBM specific house generics.

1. FDA Generic Exclusivity Period

An exclusivity period is a time-limited period of up to 180 days when the FDA allows only one drug manufacturer to develop and market a generic drug.[13] During this time period, no additional generics may enter the market, potentially resulting in inflated cost of the exclusive generic drug. The Program may continue to cover the equivalent brand-name drug until the exclusivity period expires, and the generic drug cost is reduced.

2. Authorized Generics

[9] *See* FDA, "Novel Drug Approvals at FDA" at https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda.
[10] *See* FDA, "Drug Shortages" at https://www.fda.gov/media/163858/download?attachment.
[11] *See* FDA, "FDA Drug Shortages" at https://www.accessdata.fda.gov/scripts/drugshortages/.
[12] *See* WTC Health Program Administrative Manual, Chapter 12, Section 5.5 at https://www.cdc.gov/wtc/ppm.html#pharmacy_otcDrugs.
[13] *See* FDA, "Exclusivity and Generic Drugs: What Does It Mean?" at https://www.fda.gov/media/111069/download.

Unlike traditional generic drugs,[14] authorized generic drugs are brand-name drugs that are manufactured without the brand-name on their label.[15] These drugs are identical to the brand-name drug but differ only in labeling and packaging. Because authorized generic drugs may not guarantee cost savings compared to the brand-name drug, coverage of the brand-name drug may continue until a traditional generic drug becomes available.

3. Brand-name Biologics and Biosimilars

A biosimilar is a biological drug that is highly similar to an existing FDA-approved biological drug known as the reference product.[16, 17] Although there are no clinically meaningful differences between the reference product and the biosimilar, most biosimilars are dispensed under their own brand-names. Depending on cost savings to the Program, either the reference/brand-name product or brand-name biosimilar could be preferred.

4. House Generics

House generics are brand-name drugs that the PBM home delivery pharmacy can dispense at a price less than or equal to the price of the generic drug.

C. Clinical Appropriateness

1. Narrow Therapeutic Index (NTI) Drugs

Narrow therapeutic index (NTI) drugs are drugs where small differences in dose or blood concentration may lead to serious therapeutic failures and/or adverse drug reactions that may be life-threatening or result in persistent or significant disability or incapacity.[18] Members who are taking a brand-name NTI drug may continue to use the brand-name drug to maintain clinical response. If a generic drug is available before therapy is initiated, the Generic First Program's rules apply.[19]

D. Operational Considerations

1. Coordination of Benefits (COB)

Survivor members' primary health insurance may require the use of a brand-name drug instead of a generic drug. To satisfy the coordination of benefits (COB) requirement, the Program will cover the brand-name drug through the DAW 9 process if required by the member's primary insurance plan.

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[14] *See* FDA, "Generic Drug Facts" at https://www.fda.gov/drugs/generic-drugs/generic-drug-facts.
[15] *See* FDA, "FDA List of Authorized Generic Drugs" at https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs.
[16] *See* FDA, "Biosimilars Basics for Patients" at https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients.
[17] *See* FDA, 'What Are "Biologics' Questions and Answers" https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.
[18] *See* FDA "FY2015 Regulatory Science Research Report: Narrow Therapeutic Index Drugs" at https://www.fda.gov/industry/generic-drug-user-fee-amendments/fy2015-regulatory-science-research-report-narrow-therapeutic-index-drugs.
[19] *See* FDA, "FDA Drug Topics: Understanding Generic Narrow Therapeutic Index Drugs" at https://www.fda.gov/media/162779/download.

A DAW 9 is a pharmacy point-of-sale code that indicates a payer requires a brand-name product. Unlike the DAW 1 process, a provider may prescribe a generic drug, but the primary payer will cover the brand-name drug. This typically happens when a member's primary insurance plan has a contractual agreement with a drug manufacturer for purchasing. For a member with a primary insurance plan that does not allow for a DAW 9, the prescriber must follow the brand dispensing requirements highlighted in Section II.