Policy and Procedures for Coverage of Drugs

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I. Authority

The *Policy and Procedures for Coverage of Drug*s is based on the James Zadroga 9/11 Health and Compensation Act of 2010 (Act), as amended,[1] and the World Trade Center (WTC) Health Program's regulations.[2]

II. Drugs Eligible for Coverage by the WTC Health Program[3]

The WTC Health Program (the Program) evaluates all drugs[4] to determine if they are eligible for coverage based on the requirements outlined in Section II.A. Once a drug is approved as eligible for coverage, it is added to the WTC Health Program Pharmacy Formulary (i.e., formulary drug).[5] In some limited circumstances, a drug that has not met the criteria for inclusion in the WTC Health Program Pharmacy Formulary may be eligible for coverage by the Program if certain other criteria are met; those unique situations are outlined further in Section III below.

[1] Pub. L. 111-347, as amended by Pub. L. 114-113, Pub. L. 116-59, and Pub. L. 117-328; Title I of the Zadroga Act is codified at 42 U.S.C. §§ 300mm to 300mm-62.
[2] *See* 42 C.F.R. Part 88.
[3] The Program benchmarks to coverage policies from other Federal health programs including Centers for Medicare and Medicaid (CMS), TRICARE, the Veterans Health Administration, and the Department of Labor Office of Workers' Compensation Programs (OWCP) when determining drug coverage criteria. In limited situations, the Program may authorize coverage of a drug outside the scope of this *Policy and Procedure* at the discretion of the Administrator.
[4] For purposes of this *Policy and Procedures*, the term "drug" refers to human prescription drugs and biological drug products, as well as over-the-counter (OTC) drugs and OTC pharmacy products. The Food, Drug, and Cosmetic Act (FDCA) defines the term "drug" as "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; [or] (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; [or] (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; [or] (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)."
See 52 Stat. 1040 (June 25, 1938), as amended (codified at 21 U.S.C. § 301 *et seq); see also* 21 U.S.C. § 321(g)(1).
[5] The WTC Health Program Pharmacy Formulary is provided to the Clinical Centers of Excellence (CCEs) and the Nationwide Provider Network (NPN) on a quarterly basis.

The WTC Health Program may require certain restrictions be applied to formulary drugs to ensure they are prescribed in a manner that meets all the requirements in Sections II.A. and III. This includes but is not limited to prior authorization criteria and quantity limits. These restrictions are listed in the WTC Health Program Pharmacy Formulary. For more detailed information on prior authorization procedures and other medication restrictions, see the WTC Health Program's Administrative Manual.[6]

Once a drug is added to the WTC Health Program Pharmacy Formulary, a WTC Health Program provider[7] must determine that prescribing the drug is appropriate for the member and treatment of their certified WTC-related health condition(s) and that the prescription to the member aligns with any criteria set forth in the formulary. The WTC Health Program may cover drugs that are determined to be medically necessary treatment[8] for the member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition, by a WTC Health Program provider.

A. Criteria for Adding Drugs to the WTC Health Program Pharmacy Formulary

Drugs included in the WTC Health Program Pharmacy Formulary are eligible for coverage in the Program. Each of the following criteria must be met for the WTC Health Program to add a drug to the WTC Health Program Pharmacy Formulary:

1. The drug must be approved for marketing by the U.S. Food and Drug Administration (FDA);[9]

2. The clinical use of the drug must adhere to the FDA-approved indications, dose regimens, patient population, and administration as described in the FDA-approved drug label (i.e., package insert);[10]

3. The drug and drug regimen are considered part of well-established clinical practice guidelines[11] for the care of a certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition;

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[6] *See* WTC Health Program Administrative Manual Chapter 12, Sections 3.0 and 7.0 at https://www.cdc.gov/wtc/ppm.html#pharmacy.

[7] WTC Health Program providers must be affiliated with the Program provider network and agree to the Program's terms and conditions. The Program only covers formulary drugs prescribed by WTC Health Program providers.

[8] The WTC Health Program defines medically necessary treatment as the provision of services to a WTC Health Program member by a physician or health care provider, including prescription drugs and other care that is appropriate, to manage, ameliorate, or cure a WTC-related health condition or a health condition medically associated with a WTC-related health condition, and which conforms to medical treatment protocols developed by the Program. *See* 42 C.F.R. § 88.1.

[9] A drug is approved for marketing and manufacturing in the United States upon FDA approval of a new drug application (NDA) demonstrating the drug's safety and effectiveness per the FDA's requirements. *See* the FDA Drug Glossary of Terms, New Drug Application at https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#N.

[10] Note that the Program may also allow accepted indications as it pertains to off-label drug use. *See* the WTC Health Program Coverage of Off-Label Use of FDA-Approved Drugs Medical Coverage Determination (MCD).

[11] *See* the Medicare Prescription Drug Benefit Manual Section 30.1.5, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

4. The drug therapy must have a billable medical code or National Drug Code (NDC)/Generic Product Identifier (GPI);[12]

AND

5. The drug therapy must be covered by one or more federal payers.[13]

III. Categories of Drugs and Products Approved for Coverage in the WTC Health Program

A. FDA-Approved Prescription Drugs

The FDA approves prescription drugs within the United States. An FDA-approved prescription drug is a "drug that is intended for use by man which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or it is one that is limited by an FDA-approved application for use only under the professional supervision of a practitioner licensed by law to administer such drug."[14]

The FDA approves prescription drugs for one or more indications. An indication is a particular use for the drug, such as treatment of a specific health condition. Approved use conforms to the specific health condition indication, dosage, duration, population, and any other use criteria specified by the FDA, which is included in the information provided in the package insert or drug label.[15]

1. Coverage of FDA-Approved Prescription Drugs

The WTC Health Program provides coverage of FDA-approved, manufactured prescription drugs[16] that are included in the WTC Health Program Pharmacy Formulary when prescribed by a WTC Health Program provider as medically necessary treatment for a member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. The drug must meet all the criteria for coverage set forth in the WTC Health Program Pharmacy Formulary.

B. Compounded Prescription Drugs

Drug compounding is a process by which the ingredients of a drug are combined, mixed, or altered to create a custom medication to meet the needs of an individual patient.[17] Compounded prescription drugs may be prescribed by a physician to meet a patient's unique health needs that cannot be met by an FDA-approved medication.[18] For

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[12] *See* FDA National Drug Code Directory, available at https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm.
[13] Payers considered include CMS, TRICARE, the Veterans Health Administration, and OWCP.
[14] *See* 21 U.S.C. § 353(b) for exemptions and consideration for certain drugs, devices, and biological products.
[15] *See* 21 U.S.C. § 321(k)-(n) for general requirements for drug labeling. *See also* 21 C.F.R. § 201.56 at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-B/section-201.56.
[16] Legacy drugs under the Federal Food, Drug and Cosmetic Act of 1938 may be covered by the Program if FDA approved. *See* 21 U.S.C. § 321(p)(1).
[17] *See* FDA, Compounding and the FDA: Questions and Answers, at https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers#approved.
[18] Compounded medications are not approved by the FDA *per se*. Generally, state boards of pharmacy have primary responsibility for the day-to-day oversight of state-licensed pharmacies that compound drugs in accordance with the FDA's prescription drug requirement. *See* 21 U.S.C. § 353a.

example, compounded drugs may be prescribed if a patient has an allergy and needs a medication to be made without a certain dye, or if a patient cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available. A compounded prescription drug may be made up of one or more active pharmaceutical ingredients[19] and inactive ingredients (e.g., fillers, dyes).[20]

1. Coverage of Compounded Prescription Drugs

The WTC Health Program, in limited situations, will provide coverage of compounded prescription drugs when prescribed by a WTC Health Program provider as medically necessary treatment for a member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. The compounded drug must meet all the criteria for coverage set forth in the WTC Health Program Pharmacy Formulary.[21] Only FDA-approved ingredients in the compound will be covered (e.g., crushed tablets). Bulk powders (i.e., active pharmaceutical ingredients for compounding) are not FDA-approved and are, therefore, not covered.[22] Pharmacies are reimbursed for compound medications based on their contracted rate of reimbursement for each ingredient billed in the compound drug claim. In cases of a compound kit containing two or more pre-measured drug ingredients that are combined prior to use based on a prescription order and sold as one product, the kit itself must be FDA-approved (not the individual ingredients within the kit).

C. "Off-Label" Use of FDA-Approved Prescription Drugs

Off-label prescription drug use (sometimes called "unapproved use") refers to the use of an FDA-approved drug for an unapproved indication, dosage, dosage formulation, or patient population (i.e., not indicated in the package insert or drug label).[23, 24]

1. Coverage of Off-Label Prescription Drug Use (OLDU)

The WTC Health Program may provide coverage of OLDU if the drug is approved for marketing by the FDA; the off-label use indication, dosage, dosage formulation, and patient population is supported by one or more compendia

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[19] Compound drugs are sometimes made using bulk drug substances, also known as active pharmaceutical ingredients. *See* FDA, Bulk Drug Substances Used in Compounding, at https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding.

[20] Per 21 C.F.R. § 210.3(b)(8), an inactive ingredient means any drug component other than an active ingredient. *See* FDA, Inactive Ingredients in Approved Drug Products Search: Frequently Asked Questions, at https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredients-approved-drug-products-search-frequently-asked-questions#what%20is%20inactive%20ing.

[21] *See* WTC Health Program Administrative Manual, Chapter 12, Section 7.5, at https://www.cdc.gov/wtc/ppm.html#pharmacy_compoundDrugs.

[22] *See* Medicare Prescription Drug Benefit Manual, Section 10.4 at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

[23] Wittich, C.M., Burkle, C.M., & Lanier, W.L. (2012). Ten common questions (and their answers) about off-label drug use. Mayo Clinic Proceedings, 87(10):982-90. DOI: 10.1016/j.mayocp.2012.04.017 at https://www.mayoclinicproceedings.org/article/S0025-6196(12)00683-0/fulltext.

[24] As an example, Prazosin is an FDA-approved drug for hypertension but may be used off-label to treat post-traumatic stress disorder (PTSD).

followed by the Program;[25] and the drug is determined to be medically necessary treatment for a member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition.[26] Full coverage criteria are described in the WTC Health Program Medical Coverage Determination (MCD) "Coverage of Off-Label Use of FDA-Approved Drugs."[27]

In limited situations, the WTC Health Program may authorize coverage of an OLDU that is not supported by a compendium if the prescriber identifies peer-reviewed literature supporting the off-label use.[28]

D. Emergency Use Authorization (EUA) Medical Products

During a public health emergency,[29] the FDA may grant an Emergency Use Authorization (EUA) authorizing use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternative medical countermeasures.[30]

1. Coverage of Medical Products under an EUA

During a public health emergency, the WTC Health Program may provide coverage of medical products[31] under an EUA which do not meet the criteria for inclusion in the WTC Health Program Pharmacy Formulary.

The WTC Health Program may provide coverage of an EUA product if such use is determined to be medically necessary treatment for a member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. The product must meet all the criteria for coverage set forth by the Program.

Any coverage decision made by the Program for an EUA will be temporary and is subject to change when: (1) there is no longer a public health emergency; (2) the

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[25] Drug compendia are summaries of drug information compiled by experts who have reviewed clinical data on drugs. The WTC Health Program follows the following compendia supported by CMS: American Hospital Formulary Service Drug Information (AHFS-DI), Micromedex® DrugDex®, Clinical Pharmacology, National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines©), and Lexi-Drugs®.

[26] *See* Medicare Benefits Policy Manual, Chapter 15, Section 50.4.2, Unlabeled Use of Drug, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

[27] *See* WTC Health Program Coverage of Off-Label Use of FDA-Approved Drugs MCD for more information on Program coverage.

[28] *See* WTC Health Program Coverage of Off-Label Use of FDA-Approved Drugs MCD for more information on such authorizations.

[29] 42 U.S.C. § 247d; *see also* Public Health Emergency Declaration, HHS, at https://aspr.hhs.gov/legal/PHE/Pages/Public-Health-Emergency-Declaration.aspx

[30] *See* Emergency Use Authorization, FDA, for at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#abouteuas.

[31] These medical products include drugs (e.g., antivirals and antidotes), biological products (e.g., vaccines, blood products, and biological therapeutics), and devices (e.g., in vitro diagnostics and personal protective equipment). For more information, see FDA "Emergency Use Authorization of Medical Products and Related Authorities," at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

product is or is not approved by the FDA; or (3) clinical evidence no longer supports coverage. If the EUA product is a vaccine, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) must have issued a recommendation regarding the vaccine use. The Program will consider coverage only when the ACIP recommendation is adopted by the CDC Director and published as official CDC/Department of Health and Human Services (HHS) recommendations in the Morbidity and Mortality Weekly Report (MMWR).[32]

E. Over-The-Counter (OTC) Drugs

The FDA has specified that any drug that is not a prescription drug but is considered safe and effective for use by the public without a provider's prescription is an OTC drug.[33]

1. Coverage of OTC Drugs

The WTC Health Program provides limited coverage of OTC drugs that are prescribed as medically necessary treatment for a member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. The WTC Health Program will provide coverage of a drug within the specified select categories of OTC drugs (see below) only if all criteria in Section II.A. are met, in addition to the following criteria:

a. Although OTC drugs are considered non-prescription products, for the WTC Health Program to cover the cost of a specific OTC drug, it must be prescribed by a WTC Health Program provider;

b. The OTC drug must be included on the WTC Health Program Pharmacy Formulary's list of select OTC drugs.[34]

AND

c. The supply of OTC drug dispensed must comply with the quantity or dosing interval limitations specified in the WTC Health Program Pharmacy Formulary, along with any requirements for prior authorization;

F. OTC Pharmacy Products

An OTC pharmacy product is a non-drug[35] item that is used to aid in the diagnosis or treatment of a health condition and which can be purchased without a provider's prescription (e.g., blood glucose self-testing equipment supplies). The WTC Health Program provides limited coverage of OTC pharmacy products that are prescribed as medically necessary treatment for a member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition.

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[32] *See e.g.,* CDC COVID-19 ACIP Vaccine Recommendations at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html.

[33] *See* Drugs@FDA Glossary, "Over-the-Counter" at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=glossary.page.

[34] *See* WTC Health Program Administrative Manual, Chapter 12, Section 7.6, available at https://www.cdc.gov/wtc/ppm.html#pharmacy_otcDrugs.

[35] The WTC Health Program manages select pharmacy products through benefit plans under the WTC Health Program Pharmacy Formulary, though these pharmacy products include non-drug items.

1. Coverage of OTC Pharmacy Products

The WTC Health Program provides limited coverage of specified select categories of OTC pharmacy products (see below) if all the following criteria are met:

a. Although OTC pharmacy products are considered non-prescription products, for the WTC Health Program to cover the cost of an OTC pharmacy product it must be prescribed by a WTC Health Program provider;

b. The OTC pharmacy product must be included on the WTC Health Program Pharmacy Formulary;[36]

AND

c. The OTC pharmacy product must be dispensed in compliance with the quantity and dosing limitations specified in the WTC Health Program Pharmacy Formulary, along with any requirements for prior authorization;[37]

IV. Categories of Drug Uses Not Approved for Coverage in the WTC Health Program

Investigational or experimental use refers to use of a drug whose maximum tolerated dose, toxicity, safety, or efficacy has not been established through clinical trials and is not approved by the FDA (other than products under an EUA).[38] The WTC Health Program does not cover the use of investigational or experimental drugs. Drugs that are considered investigational or experimental include, but are not limited to, the following categories:

A. Clinical Trial Drugs

A clinical trial is a research study involving human subjects who voluntarily test new treatments and therapies to evaluate the health effects of those interventions.[39] The study of investigational drugs under clinical trials may be used to determine if the drug is safe and effective, how the drug might be used for a certain indication, how much of the drug is needed, and information about the potential benefits and risks of taking the drug.[40]

1. Coverage of Clinical Trial Drugs

The WTC Health Program does not cover any pharmaceutical or medical services related to a clinical, investigational, or experimental trial/study. FDA-approved

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[36] *See* WTC Health Program Administrative Manual, Chapter 12, Section 7.6, available at https://www.cdc.gov/wtc/ppm.html#pharmacy_otcDrugs.

[37] *See* WTC Health Program Administrative Manual, Chapter 12, Section 7.6, available at https://www.cdc.gov/wtc/ppm.html#pharmacy_otcDrugs. Note, the WTC Health Program Pharmacy Formulary lists specific OTC drugs that have been selected within the covered OTC categories as eligible for coverage by the WTC Health Program.

[38] *See generally* Civilian Health and Medical Program of the Veterans' Administration (CHAMPVA) Operational Policy Manual**, "**02.16.05 Experimental Investigational (Unproven) Procedures" at https://www.vha.cc.va.gov/system/templates/selfservice/va_ssnew/help/customer/locale/en-US/portal/554400000001036/content/554400000008964/02.16.05-EXPERIMENTAL-INVESTIGATIONAL-.

[39] *See* National Institute of Health Glossary of Common Terms at https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms.

[40] *See* FDA Glossary at: https://www.fda.gov/patients/clinical-trials-what-patients-need-know/glossary-terms#I-1.

formulary drugs that are used as part of a clinical trial are not covered.[41] The Program will not cover any expenses related to participation in or any adverse effect (mental or physical) arising from a clinical, investigational, or experimental trial/study. A WTC Health Program member may seek to participate in a clinical trial outside of the Program at their own expense.

B. Expanded Access Drugs

The FDA describes "expanded access" to drugs (i.e., compassionate use) as the use of an investigational drug (i.e., one that has not been approved by FDA) outside of a clinical trial setting.[42] FDA has the discretion to grant an individual expanded access to investigational drugs for the diagnosis, monitoring, or treatment of a serious disease or condition, if a list of specific conditions are met.[43]

1. Coverage of Expanded Access Drugs

The WTC Health Program does not provide coverage of expanded access drugs. The Program will not cover any expenses related to the use of, or adverse effect (mental or physical) arising from the use of, expanded access drugs. A WTC Health Program member may seek expanded access approval from the FDA outside of the Program at their own expense.

C. Right-to-Try Drugs

"Right-to-try" use refers to the availability of eligible investigational drugs for individuals who have been diagnosed with a life-threatening disease or condition, have exhausted approved treatment options under state or federal law, and are unable to participate in a clinical trial involving the eligible investigational drug.[44] Right-to-try use is distinct from expanded access approval from the FDA, as right-to-try requests go directly to the manufacturer and do not require FDA permission for use.

1. Coverage of Right-to-Try Drugs

The WTC Health Program does not provide coverage of a right-to-try use of a drug. The Program will not cover any expenses related to the use of, or adverse effect (mental or physical) arising from the use of, right-to-try drugs. A WTC Health Program member may seek right-to-try drugs outside of the Program at their own expense.

D. Dietary Supplements and Dietary Ingredients

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[41] For example, if the drug being studied in the clinical trial is chemotherapy that requires it be used in combination with methotrexate, the methotrexate will not be covered either even though it is an FDA-approved drug on the WTC Health Program Pharmacy Formulary. If the drug being studied in the clinical trial causes gastroesophageal reflux disease (GERD) as a side effect and therefore requires a prescription for a GERD medication, the Program will not cover the cost of the GERD medication even if it is an FDA-approved drug on the WTC Health Program Pharmacy Formulary.

[42] *See* FDA Expanded Access (sometimes called "Compassionate Use") at https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm.

[43] *See* FDA, Requirements for all Expanded Access Uses at https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm. *See also* 21 C.F.R. § 312.310.

[44] *See generally* "Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017," Pub. L. 115-176 (May 30, 2018), available at https://www.congress.gov/115/bills/s204/BILLS-115s204enr.pdf.

The FDA describes dietary supplements and ingredients as any vitamin, mineral, herb, botanical, amino acid, or dietary substance that supplements an individual's dietary intake. Unlike drugs, dietary supplements are not FDA-approved to treat, diagnose, prevent, or cure diseases.[45]

1. Coverage of Dietary Supplements and Dietary Ingredients

The WTC Health Program does not cover dietary supplements or dietary ingredients, including natural products such as herbs, fish oil, melatonin, probiotics, and other non-FDA approved drugs. The Program will not cover any expenses related to the use of, or adverse effect (mental or physical) arising from the use of, dietary supplements or ingredients.

[45] *See* FDA Dietary Supplement Products & Ingredients at https://www.fda.gov/food/dietary-supplements/dietary-supplement-products-ingredients