World Trade Center Health Program
Policy and Procedures for Coverage of Medical Services

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I. Authority

The *Policy and Procedures for Coverage of Medical Services* is based on the James Zadroga 9/11 Health and Compensation Act of 2010 (Act),[1] as amended, and the World Trade Center (WTC) Health Program's administrative regulations.[2,3]

II. WTC Health Program Coverage of Medical Services

The WTC Health Program (the Program) may cover medical services that are 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.[4] The WTC Health Program may cover medical services including medical devices,[5] therapies, treatments, and procedures that meet established Program requirements set forth in this *Policy and Procedures for Coverage of Medical Services*. Such coverage of medical services is permitted only when in accordance with all other Program policies.[6] Any covered services may be subject to service limitations or prior authorization criteria.

Note, this *Policy and Procedures for Coverage of Medical Services* only contains information related to the coverage of medical services and not pharmaceuticals. For further guidance on coverage of pharmaceuticals, please refer to the *Policy and Procedures for Coverage of Drugs*.[7]

A. Criteria for Coverage of Medical Services

For a medical service to be considered eligible for coverage by the WTC Health Program, the medical service must have a billable medical code and must be approved by the Centers for Medicare and Medicaid Services (CMS) for coverage under Medicare.

In limited circumstances, the WTC Health Program may be unable to align coverage with Medicare or may otherwise diverge from strict adherence to Medicare coverage requirements, such as where coverage criteria must be substantially adjusted for the

[1] Title I of Pub. L. 111-347, as amended by Pub. L. 114-113, Pub. L. 116-59, Pub. L. 117-328, and Pub. L. 118-31, added Title XXXIII to the Public Health Service (PHS) Act, codified at 42 U.S.C. §§ 300mm to 300mm-64.
[2] The WTC Health Program, as a Department of Health and Human Servies (HHS) entity, is also subject to applicable HHS guidelines.
[3] 42 C.F.R. pt. 88 at https://www.cdc.gov/wtc/regulations2.html.
[4] 42 C.F.R. § 88.1 at https://www.cdc.gov/wtc/regulations2.html.
[5] *See* 21 U.S.C. § 321(h) for the Food and Drug Administration (FDA) definition of a medical device. Note that a "medical device" is distinct from "durable medical equipment (DME)" as defined in the WTC Health Program Administrative Manual at https://www.cdc.gov/wtc/ppm.html#medical_dme.
[6] *See generally* the WTC Health Program Administrative Manual at https://www.cdc.gov/wtc/ppm.html; *see also* WTC Health Program Policies and Procedures at https://www.cdc.gov/wtc/policies.html.
[7] *See* WTC Health Program Policy and Procedures for Coverage of Drugs at https://www.cdc.gov/wtc/policies.html.

Program member population, where the Program has different or additional service criteria and/or service limitations, where CMS coverage criteria do not provide sufficient detail for Program implementation, or where CMS coverage is unclear or unavailable.[8] Where the Program is unable to align with Medicare coverage, the Program will consider coverage if the medical service has a billable medical code and:

1. The medical service is approved for coverage by another federal health program, with consideration given in the following order: TRICARE, the Department of Veteran Affairs (VA), and the Department of Labor's Office of Workers' Compensation Programs (OWCP).[9]

   AND

2. The use of the medical service for the specific certified WTC-related health condition or health condition medically associated with a certified WTC-related health condition, is supported by:

   a. Medically accepted clinical practice guidelines (CPGs)[10] and standards of care from reputable professional clinical societies and/or national medical policy organizations;[11]

   OR

   b. The clinical-evidence base. The clinical-evidence base is established by inclusion in one or more of the following acceptable peer-reviewed literature sources. Greater consideration will be given to the strongest evidence base in the following descending order:[12]

      i. Well-controlled studies of clinically meaningful endpoints[13] published in English language peer-reviewed medical literature;

      ii. Published formal technology assessments;[14]

      iii. Published reports of reputable national expert opinion organizations or reputable international medical expert opinion organizations when

[8] The Program will document when other service criteria and/or service limitations are implemented in addition to or in lieu of Medicare coverage requirements.
[9] Deviations from Medicare coverage are published as a Medical Coverage Determination (MCD). *See* the WTC Health Program Administrative Manual at https://www.cdc.gov/wtc/ppm.html and WTC Health Program Policies and Procedures at https://www.cdc.gov/wtc/policies.html.
[10] The WTC Health Program relies on CPGs that are produced by medical specialty associations, professional medical societies, or other relevant CPG development organizations. This includes, but is not limited to, the Emergency Care Research Institute (ECRI) Guidelines Trust which provides a compendium of CPGs that meet prespecified inclusion criteria. *See* ECRI Guidelines Trust, at https://guidelines.ecri.org. In all cases, the Program makes a determination regarding what is considered a high-quality CPG appropriate to establish medical coverage determinations in the Program. *See* The World Trade Center Health Program: An Introduction to Best Practices at https://www.tandfonline.com/doi/full/10.1080/19338244.2022.2156975.
[11] Examples include National Comprehensive Cancer Network (NCCN), American College of Obstetrics and Gynecology (ACOG), and Surveillance, Epidemiology, and End Results (SEER).
[12] *See generally* 32 C.F.R § 199.2(b), "reliable evidence," at https://www.ecfr.gov/current/title-32/part-199
[13] *See* the United States Preventive Services Taskforce (USPSTF) Procedure Manual, Section 4, "Evidence Review Development" for more information on what is considered strong evidence leading to the production of clinically meaningful endpoints at https://uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual/procedure-manual-section-4-evidence-review-development.
[14] Formal technology assessments are used to evaluate whether to use a new medical technology and must align with medically accepted guidelines from reputable professional clinical societies and medical policy organizations, including but not limited to, ECRI.

guidelines/standards of care from such national organizations are unavailable or outdated.

The following are **insufficient** to meet the Program's clinical evidence-base requirements:[15, 16]

i. Abstracts of conference proceedings or individual opinion/viewpoint articles;

ii. Non-English language articles or publications;

iii. Basic biomedical and pre-clinical research articles (e.g., animal studies, in vitro studies, ongoing experimental studies);

iv. Anecdotal evidence or personal professional recommendations from healthcare professionals or groups of healthcare professionals, outside of national or international medical/specialty organizations/societies.

B. Additional Criteria for Coverage of Medical Devices

In addition to the criteria in Section II.A., medical devices must also be approved by the U.S. Food and Drug Administration (FDA).[17] The FDA approval must be granted through the premarket approval (PMA) process,[18] the De Novo process,[19] or FDA clearance provided via the 510(k) premarket notification process.[20]

1. Medical Devices Exempt from FDA Review

The Program will consider coverage of medical devices that are exempt from FDA review[21] (e.g., Class I and some Class II devices on the FDA Medical Device Exemptions list)[22, 23] based on the requirements in Section II.A.

2. Off-Label Use of FDA-Approved Medical Devices

Off-label use of a medical device refers to the use of an FDA-approved medical device where the method of use,[24] or the indication for use, has not been explicitly

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[15] *See* TRICARE Policy Manual 6010.60-M, Chapter 1, "Unproven Drugs, Devices, Medical Treatments, and Procedures" at https://manuals.health.mil/pages/DisplayManualHtmlFile/2023-06-12/AsOf/TP15/C1S2_1.html.

[16] *See* Civilian Health and Medical Program of the Department of Veterans Affairs (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-(UNPROVEN)-PROCEDURES.

[17] FDA approval of devices includes approved indications for use, as well as a description of the patient population for which the device is intended and any other use criteria. *See* 21 C.F.R. Part 801 on medical device labeling at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H.

[18] *See* FDA, "Premarket Approval (PMA)" at https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.

[19] *See* FDA, "De Novo Classification Request" at https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request.

[20] *See* FDA, "Premarket Notification 510(k)" at https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k.

[21] Medical devices for which the FDA has granted an approval exemption have been classified by the FDA as presenting minimal potential for harm.

[22] *See* FDA's Center for Devices and Radiological Health (CDRH) Medical Device Exemptions 510(k) and Good Manufacturing Practice (GMP) Requirements at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm.

[23] Evidence of FDA approval must be cited directly from the FDA website. Citation of manufacturer's websites or articles describing the FDA approval **are not** sufficient evidence of approval.

[24] While the FDA does not authorize medical procedures, certain procedures may be associated with the use of an FDA-approved medical device.

approved by the FDA.[25] The WTC Health Program will determine coverage eligibility of off-label medical devices based on the requirements in Section II.A.

III. Special Categories of Use

A. Complementary and Integrative Therapy

Complementary health approaches and integrative therapies encompass a wide range of physical, psychological, and nutritional treatments and services that are not part of conventional, standard, or allopathic medical practice. When complementary therapy is used in conjunction with conventional medical modalities to treat a medical condition, either simultaneously or in tandem, this is known as integrative therapy.

The WTC Health Program may cover complementary and integrative therapy only in limited circumstances. In determining the scope of any available coverage, the Program relies on the service provisions contained in the regulations and guidelines of the Department of Health and Human Services (HHS),[26] Medicare, and National Comprehensive Cancer Network (NCCN).[27] The Program may require a prior authorization for these services. [28]

B. Investigational Use of Medical Services

Investigational (also known as experimental) use refers to use of medical services whose safety and efficacy have not been established and proven. Medical services are considered investigational/experimental (unproven) when safety, efficacy, maximum tolerated dose, or toxicity has not been clinically established and the medical service is not approved for marketing by the FDA.[29]

The WTC Health Program does not provide coverage of investigational use of any medical service, including those being studied in clinical trials. The Program will not cover any expenses related to the use of, or adverse effect (mental or physical) arising from the use of, investigational devices or services, including those provided in clinical trials. A WTC Health Program member may seek to participate in a clinical trial outside the Program and at their own expense.

C. Expanded Access of Non-FDA Approved Medical Devices

The FDA describes "expanded access" to devices as the use of an investigational medical device (i.e., one that has not been approved by FDA) outside of a clinical trial setting.[30] There are three different categories of expanded access for medical devices:

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[25] *See* 86 Fed. Reg. 41383 (Aug. 2, 2021), at https://www.federalregister.gov/documents/2021/08/02/2021-15980/regulations-regarding-intended-uses. *See also* TRICARE Policy Manual 6010.63-M, Chapter 8.5.1. Medical Devices, at https://manuals.health.mil/pages/DisplayManualHtmlFile/2025-01-08/AsOf/TPT5/C8S5_1.html.
[26] *See e.g.,* HHS, Pain Management Best Practices Inter-Agency Task Force Final Report at https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.
[27] *See generally* NCCN Clinical Practice Guidelines in Oncology at https://www.nccn.org/guidelines/category_3.
[28] *See* WTC Health Program Administrative Manual, Chapter 4, Section 3.4, "Prior Authorizations" at https://www.cdc.gov/wtc/ppm.html#medical_prior.
[29] *See* Civilian Health and Medical Program of the Department of Veterans Affairs (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-.
[30] *See* FDA, "Expanded Access Information for Physicians" at https://www.fda.gov/news-events/expanded-access/expanded-access-information-physicians.

emergency use,[31] compassionate use, and treatment investigational device exemption. FDA has the discretion to grant an individual expanded access to investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition, if a list of specific conditions is met.[32]

The WTC Health Program does not provide coverage of expanded access to any medical device. 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 devices.

D. Emergency Use Authorization of Medical Devices

The FDA may grant an Emergency Use Authorization (EUA) for use of unapproved medical devices, or unapproved uses of approved medical devices, 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.[33]

The WTC Health Program may provide coverage of an EUA device 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 device must meet all the criteria for coverage set forth by the Program.

Any coverage decision made by the WTC Health Program for an EUA will be temporary and is subject to change when: (1) the determination and declaration under section 564 of the Food, Drug, and Cosmetic Act no longer applies or FDA otherwise revokes it; (2) the device is or is not subsequently approved by the FDA; or (3) clinical evidence no longer supports coverage for the member.

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[31] Emergency use, in the context of expanded access for medical devices, is the use of an investigational device when an **individual patient** is in a life-threatening situation and needs immediate treatment. In such cases, there are no alternative options and no time to use existing procedures to get FDA approval for the use. This is distinct from an Emergency Use Authorization as described in Section III.E. *See* FDA, "Expanded Access for Medical Devices" at https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices.

[32] *See* FDA, "Expanded Access for Medical Devices" at https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices.

[33] *See* FDA, "Emergency Use Authorization" at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#abouteuas and https://www.fda.gov/emergency-preparedness-and-response/about-mcms/what-are-medical-countermeasures.