

Medical Coverage Determination Acute COVID-19 Publish Date: August 2, 2021

- I. Title: Acute COVID-19
- II. Description: Coverage of Medically Necessary Acute COVID-19 Diagnostic and Treatment Services for Clinical Centers of Excellence (CCE) and Nationwide Provider Network (NPN) Members

III. Coverage Overview

COVID-19 is a systemic respiratory disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or SARS-CoV-2 infection). The virus spreads through respiratory droplets or very small particulates produced when an infected person coughs, sneezes, or talks. Some people infected may be asymptomatic. For those who are symptomatic, illness may range from mild to severe. Adults 65 years and older and people with certain underlying medical conditions¹ are at higher risk for severe COVID-19.²

The WTC Health Program may provide coverage of acute COVID-19 diagnostic and treatment services that are medically necessary to manage, ameliorate, or cure a certified WTC-related health condition or medically associated health condition and which meet relevant prior authorization criteria. The CCE/NPN Clinical Director may authorize acute COVID-19-related services only when the member meets all of the applicable requirements described in this medical coverage determination (MCD).

IV. Overview of Covered COVID-19 Services

As the COVID-19 Public Health Emergency (PHE) has evolved since the beginning of the pandemic in 2020, CDC has determined that certain underlying conditions are risk factors for more serious cases of COVID-19 ("CDC list").³ Additionally, these underlying conditions are likely to be exacerbated by COVID-19, and have poorer outcomes as a result of SARS-CoV-2 infection.

Some of these underlying conditions on the CDC list are health conditions certified by the Program as WTC-related health conditions or certified as health conditions medically associated with WTC-related health conditions. The WTC Health Program will cover acute COVID-19 treatment and classify COVID-19 as an adjunct⁴ (previously ancillary) condition when it co-occurs with a certified

¹ See People with Certain Medical Conditions, CDC, <u>https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html</u> (last updated May 13, 2021) and detailed list in Footnote 10 on page 3. The CCES/NPN are responsible for maintaining awareness of any updates made to this list.

² See Coronavirus Disease 2019 at <u>https://www.cdc.gov/dotw/covid-19/index.html</u> (last updated February 25, 2021).

³ See Footnote 1.

⁴ An adjunct (previously ancillary) condition is an acute or chronic health condition co-occurring with a certified WTC-related or medically associated health condition, that, if left untreated, would interfere with reasonable treatment (i.e. manage, ameliorate, or cure) of a

condition on the CDC list and when the untreated SARS-CoV-2 infection would interfere with reasonable treatment (i.e. manage, ameliorate, or cure) of that member's certified health condition.

Acute COVID-19 treatment services are available for coverage under the WTC Health Program only during the acute and subacute (up to a maximum interval of 90 days after diagnosis of initial COVID-19 infection) period of SARS-CoV-2 infection. The WTC Health Program does not cover any healthcare services beyond 90 days after diagnosis of initial COVID-19 infection.

The type of COVID-19 care covered includes: outpatient management, telehealth, pharmaceutical management, ⁵ inpatient hospitalizations, post-acute care, and severe complication management during the acute and sub-acute phase of COVID-19. Coverage of COVID-19 services is permitted only when all criteria outlined in this MCD are met, appropriate prior authorizations are in place, and in accordance with the Program formulary and other Program guidelines.^{6,7}

V. Prior Authorization (PA) Level Descriptions

A. Level 2 – Authorization by CCE/NPN Clinical Director

If a Prior Authorization Level 2 (PA2) is required, as noted below, the CCE/NPN Clinical Director must determine that the services are medically necessary to manage, ameliorate, or cure the member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. The CCE/NPN Clinical Director will also ensure that the member meets the Prior Authorization Criteria listed in this MCD and confirm that the criteria are appropriately documented in the member's medical record.

B. Level 3 – Authorization by the WTC Health Program

If a Prior Authorization Level 3 (PA3) is required, as noted below, the WTC Health Program reviews the written medical justification provided by the CCE/NPN Clinical Director and determines that the services are medically necessary to manage, ameliorate, or cure the member's certified WTC-related health condition, or health condition medically associated with a certified WTC-related health condition. The WTC Health Program will also ensure that the member meets the Prior Authorization Criteria listed below in this MCD and confirm that the criteria are appropriately documented in the member's medical record.

For detailed Prior Authorization procedures, see instructions found in the WTC Health Program's Administrative Manual.⁸

VI. COVID-19 Clearance Testing

certified WTC-related health condition. The Program does not require certification of the adjunct condition and covers adjunct condition care using the principle of medically necessary treatment.

⁵ The CCES/NPN are responsible for maintaining awareness of any updates and/or changes to EUA drugs or products.

⁶ See generally WTC Health Program Administrative Manual for a full description of Program guidelines, policies, and procedures, at <u>https://www.cdc.gov/wtc/ppm.html</u>.

⁷ In some situations, the WTC Health Program may cover relevant services beyond those referenced in this MCD. Refer to the WTC Health Program Public Health Emergency Codebook for a full list of covered medical services, procedures, and diagnosis codes.

⁸ See WTC Health Program Administrative Manual [Chapter 4, Section 3.4] at <u>https://www.cdc.gov/wtc/ppm.html#medical_prior</u>.

- **A.** The WTC Health Program may cover COVID-19 clearance testing for all enrolled or certified CCE/NPN members who require evidence of a negative COVID-19 test (i.e., "medically necessary clearance testing") to obtain Program-related services listed below:
 - 1. Initial health evaluations (IHEs);
 - **2.** Monitoring visits;
 - 3. Diagnostic tests including cancer screenings;⁹

AND/OR

4. Treatment visits (including surgery and procedures).

For all COVID-19 diagnostic clearance testing billing instructions, please refer to the most updated Medical Benefits COVID-19 Guidance sent by the Program. There is no service limitation or prior authorization requirement for COVID-19 clearance testing.

VII. Qualifying Underlying Health Conditions for Acute COVID-19 Treatment Services

Coverage of acute COVID-19 treatment services is generally limited to members with a certified WTC-related health condition or medically associated health condition that is included on the CDC list as described above and in Footnote 10 below.¹⁰ When a certified condition (not on the CDC list) has similar pathophysiological characteristics to the conditions on the CDC list, the WTC Health Program may deem that certified condition as qualifying for acute COVID-19 treatment services.

Accordingly, one or more of the following criteria must be met:

- A. The member must be certified¹¹ for one or more of the following WTC-related health conditions or health conditions medically associated to a certified WTC-related health condition on the CDC's Underlying Condition list:
 - **1.** Active WTC-related cancer;
 - **2.** Obstructive Airway Diseases, including chronic lung diseases, chronic obstructive pulmonary disease (COPD), and moderate-to-severe asthma;
 - 3. Interstitial Lung Disease, including pulmonary fibrosis;

⁹ See WTC Health Program Administrative Manual [Chapter 4, Section 2.5] at <u>https://www.cdc.gov/wtc/ppm.html#medical_cancer</u>.

¹⁰ See <u>https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html</u> (last updated May 13, 2021). As of July 13, 2021, the underlying medical conditions often certified or treated in WTC Health Program members include: Cancer; Chronic lung diseases, including COPD, asthma (moderate-to-severe), interstitial lung disease, and pulmonary hypertension; Immunocompromised state (weakened immune system); Solid organ or blood stem cell transplant; and Substance use disorders. This list may be updated in the future based on CDC guidance. In all cases, only those members with underlying conditions named by the CDC as risk factors for severe COVID-19 disease that also are certified as WTC-related may be considered for coverage of COVID-19 disease as outlined in this MCD.

¹¹ Any condition or disease that is a certifiable WTC-related health condition or health condition medically associated to a WTC-related health condition temporarily associated with COVID-19 must instead be directly linked to existing guidance on WTC-related exposure to justify certification. The WTC Health Program will not certify diseases on CDC's Underlying Condition List that are not the result of WTC exposure.

4. Substance use disorder.

AND/OR

- **B.** The member must be receiving the following treatment for a certified WTC-related health condition or health condition medically associated to a certified WTC-related health condition on the CDC's Underlying Condition list:
 - 1. Immunosuppression due to medication used to treat a certified WTC-related health condition or health condition medically associated to a certified WTC-related health condition;
 - **2.** Solid organ or blood stem cell transplant.

AND/OR

- **C.** The member must be certified¹² for one or more of the following WTC-related health conditions or health conditions medically associated to a certified WTC-related health condition that is not on the CDC list but which has similar pathophysiologic characteristics to other conditions on the CDC's Underlying Conditions list.¹³ Examples include:
 - 1. Chronic bronchitis;
 - 2. Emphysema;
 - **3.** Pulmonary hypertension.

Case exceptions may be considered through a written PA3 Request to the WTC Health Program that provides evidence that the treatment of acute COVID-19 is medically necessary to manage, ameliorate, or cure the certified WTC-related health condition or health condition medically associated to a certified WTC-related health condition and complies with all Program requirements.

VIII. Covered COVID-19 Diagnostic and Treatment Services

When a member has a qualifying health conditions as described in Section VII, the member is eligible to receive the following services:

A. COVID-19 Diagnostic Testing

COVID-19 diagnostic testing, as medically indicated, may be covered for members with a qualifying health condition due to possible or actual exposure to COVID-19. For billing instructions, please refer to the most updated Medical Benefits COVID-19 Guidance sent by the Program. There is no service limitation or prior authorization requirement for COVID-19

¹² Any condition or disease that is a certifiable WTC-related health condition or health condition medically associated to a WTC-related health condition temporarily associated with SARS-CoV-2 infection must instead be directly linked to existing guidance on WTC-related exposure to justify certification. The WTC Health Program will not certify diseases on CDC's Underlying Condition List that are not the result of WTC exposure.

¹³ See Footnote 10.

diagnostic testing for members with a qualifying health condition.

B. COVID-19 Treatment Services

A member with a qualifying health condition who has COVID-19 is eligible to receive medically necessary acute COVID-19 treatment services limited to those directly <u>associated with initial</u> <u>active acute SARS-CoV-2 infection/COVID-19 (acute period) and up to a maximum interval of</u> <u>90 days post-SARS-CoV-2 infection/COVID-19 (sub-acute period)</u>. COVID-19 treatment services may be provided via telehealth,¹⁴ as appropriate, or during in-person visits. COVID-19 treatment services include the following:

1. Outpatient COVID-19 management, including treatment and interim progress follow-up visits – PA2 required

- a. Clinical standard of care, including medical services and pharmaceuticals;
- **b.** COVID-19 Telehealth Check-ins may be provided by Physicians/Providers multiple times a week to mitigate the risk of spreading SARS-CoV-2 and to support in the medical management of acute/subacute COVID-19. For billing/coding guidelines, please refer to the most updated Medical Benefits COVID-19 Guidance sent by the Program;
- **c.** Pulse oximeters may be provided, as medically necessary. For coverage, bill with one of the following codes: 94760, 94761, or 94762;
- **d.** Home oxygen therapy may be provided for outpatient management and treatment of the initial active acute SARS-CoV-2 infection:
 - 1) Additional PA2 required.
 - 2) The CCE/NPN Clinical Director may authorize Durable Medical Equipment (DME) only when the equipment is used to manage, ameliorate, or cure a certified WTC-related health condition, or a health condition medically associated with a certified WTC-related health condition. Please see the DME MCD on the Secure Access Management Services (SAMS) Web Portal for additional coverage details.
- e. Phlebotomy may be provided in conjunction with a telehealth or in-person outpatient visit. For billing/coding guidelines, please refer to the most updated Medical Benefits COVID-19 Guidance sent by the Program.

2. Inpatient hospitalizations – PA3 Required

a. When the CCE/NPN is first made aware of a member currently in the hospital for COVID-19, or if a member has already been discharged, the CCE/NPN must assess the member for Intensive Case Management (ICM) needs. The CCE/NPN Clinical Director must also request authorization from the WTC Health Program for coverage of the hospital stay, utilizing the General PA3 Request Form located on the SAMS Web Portal. The form <u>must</u> <u>include</u> the following:

¹⁴ See TGD 013 – Technical Guidance Document for Public Health Emergencies, as well as the most recent COVID-19 Medical Benefits Guidance document for telehealth billing instructions.

- 1) Member, provider, and facility information;
- 2) Currently certified health conditions and respective ICD-9/ICD-10 codes;
- **3)** Evidence that the inpatient hospital stay is required to manage, ameliorate, or cure one of the qualifying health conditions **specifically** listed in Section VII of this MCD;
- 4) Request codes and descriptions (if known);
- 5) Clinical summary (obtained by CCE/NPN Case Management) to support the request including a **timeline of illness** with the following specific information:
 - i. Dates of service (admission date, discharge date, or notation that the member is still hospitalized);
 - ii. Date of COVID-19 test collection, type of test, and results or explanation of presumptive clinically positive diagnosis;
 - iii. COVID-19 vaccination status, and manufacturer if vaccinated;
 - iv. Past medical history and co-morbidities as applicable (certified and non-certified health conditions);
 - v. Symptom type and symptom onset;
 - vi. Treatment plan;
 - vii. Treatments and/or procedures performed during the hospital stay;
 - viii. Prognosis of COVID-19;
 - ix. Documentation attributing the admission to COVID-19 as related to the qualifying condition, as **specifically** listed in Section VII. of this MCD;
 AND
 - x. Discharge plans, if still hospitalized.

AND

- 6) CCE/NPN Clinical Director or designee signature, to include credentials.
- b. The PA3 for inpatient hospitalizations related to COVID-19 only covers an initial 30-calendar day authorization period. Evaluation for subsequent episodes of COVID-19 services should occur prior to the end of the previous 30-calendar day authorization. If the member still requires COVID-19 inpatient hospitalization at the end of the 30-calendar day authorization period, an additional PA3 request will be required to justify a new authorization at the end of the previous authorization (i.e., day 31 and day 61). Reauthorization will continue to be required as long as the member is eligible for a COVID-19 inpatient hospital stay.

3. Pharmaceutical management of COVID-19:

a. The WTC Health Program may cover drugs for outpatient treatment that align with all Program formulary requirements and WTC Health Program's Administrative Manual¹⁵ when deemed medically necessary by the treating provider to manage the disease;

¹⁵ See WTC Health Program Administrative Manual [Chapter 12] at <u>https://www.cdc.gov/wtc/ppm.html#pharmacy</u>

- b. The WTC Health Program may cover COVID-19 therapies allowed under an FDA Emergency Use Authorization (EUA), including, but not limited to monoclonal antibodies and antivirals, with a PA3.¹⁶
- 4. Severe complications¹⁷ may also be covered on a case-by-case basis and limited to complications directly associated with acute COVID-19 from the beginning of the acute period to the end of the sub-acute period PA3 required
 - a. When the CCE/NPN is first made aware of a member who requires inpatient hospitalization as a direct result of complications from COVID-19 as related to the WTCrelated health condition(s). The CCE/NPN Clinical Director must request authorization from the WTC Health Program for coverage of the hospital stay, utilizing the General PA3 Request Form located on the SAMS Web Portal. The form must include the required information in Section VIII.B.2.a, as well as:
 - 1) Documentation that all other reasonable etiologies have been ruled out;

AND

2) Documentation that the complication(s) directly impacts the ability to medically manage a certified WTC-related health condition or health condition medically associated with a WTC-related health condition.

AND

A. Post-acute care services¹⁸

The Program covers services in post-acute care settings that are medically necessary to manage, ameliorate, or cure a certified WTC-related health condition, or a health condition medically associated with a certified WTC-related health condition. Post-acute care services related to COVID-19 may be covered if all criteria in MCD above are met, and only during the acute and sub-acute periods of infection (coverage of no more than 90 days since the initial SARS-CoV-2 infection was diagnosed). Such post-acute care settings include: Long-Term Care Hospital, Skilled Nursing Facilities, Hospice, Inpatient Rehabilitation, Outpatient Rehabilitation, and Home Health Care.¹⁹

IX. Documentation Requirements

Each CCE/NPN Clinical Director and/or designee is required to maintain documentation in member records when a member with a qualifying health condition as outlined in Section VII is diagnosed with COVID-19, regardless of whether any treatment was provided by the Program or the CCE/NPN directly. The documentation should address acute (temporary) and/or prolonged (permanent)

¹⁶ The Program will evaluate coverage of prescription drugs and other products available through the FDA EUA on a case-by-case basis. Any coverage decision made by the Program for an EUA drug or product will be interim and is subject to change when (1) there is no longer a public health emergency; (2) the product is approved by the FDA; or (3) clinical evidence no longer supports coverage.

¹⁷ Severe complications, such as hypercoagulability manifestations, etc.

¹⁸ For the provision of post-acute care services for COVID-19, the member must meet all qualifications outlined in this MCD, as well as all of the requirements outlined in the post-acute care MCDs, which can be found on the SAMS Web Portal. Post-acute care services related to COVID-19 are limited to the acute and subacute periods of COVID-19.

¹⁹ See WTC Health Program Administrative Manual [Chapter 4, Section 4.6] at <u>https://www.cdc.gov/wtc/ppm.html#medical_postAcute</u>

negative impacts on the member's certified WTC-related health conditions and certified health conditions medically associated with a WTC-related health condition and applicable treatments and plans of care.

X. Prior Authorization Request Submission Requirements

When a PA2 authorization is required for COVID-19-related services, the authorization must be signed and authorized by the CCE/NPN Clinical Director or designee and maintained in the member's medical record. The CCE/NPN Clinical Director or designee will maintain documentation that demonstrates MCD criteria has been met in the member's medical record, as well as documentation related to the PA2.

When a PA3 authorization is required for COVID-19-related services, the PA3 form must be signed by the requesting CCE/NPN Clinical Director or designee and submitted to the Health Program Support (HPS) contractor through the Secure File Transfer Protocol (SFTP) server. The WTC Health Program will decide whether to authorize the service and will inform the HPS contractor, who will subsequently inform the CCE/NPN of the decision. The CCE/NPN will maintain documentation that demonstrates MCD criteria have been met in the member's medical record, as well as documentation related to the PA3 Request. Incomplete or inaccurate requests will be returned to the requesting CCE/NPN for additional information.

The CCE/NPN Clinical Director may complete a PA2/PA3 for COVID-19-related services retrospectively only when an urgent need for COVID-19-related services arises. The retrospective PA2 must be signed and authorized within 14 calendar days of the start date of the COVID-19-related services. The PA3 Request must be submitted within 14 calendar days of the start date of COVID-19-related services.

All documentation for completed COVID-19 service authorizations are subject to audit by the WTC Health Program.

XI. Coverage Exclusions

The following COVID-19-related services are excluded from coverage for all members enrolled in the Health Program:

A. COVID-19 Vaccines²⁰

The WTC Health Program does not provide coverage of/reimbursement for any manufactured COVID-19 vaccine at this time. For information on where to get the COVID-19 vaccine, visit our webpage: <u>https://www.cdc.gov/wtc/covid19.html#vaccines</u>.

B. COVID-19 Antibody Testing

The WTC Health Program does not provide coverage of/reimbursement for COVID-19 antibody tests.

²⁰ The CDC Advisory Committee on Immunization Practices (ACIP) must have issued a recommendation regarding the vaccine before the Program may consider coverage, according to 42 U.S.C. § 300gg-13 – Coverage of preventive health services – see https://www.law.cornell.edu/uscode/text/42/300gg-13.

C. Experimental/Investigational Pharmaceutical Treatments, with no FDA Emergency Use Authorization (EUA); Clinical Trials; Expanded Access Drugs; Right-to-Try Drugs; and Dietary supplements and/or ingredients.

The CCES/NPN are responsible for maintaining awareness of any updates and/or changes to EUA drugs or products.

D. Personal Protective Equipment and other related supplies

E. Post-COVID Conditions (PCCs)²¹

PCCs represent a diverse group of physical and mental health consequences that present more than four weeks after SARS-CoV-2 infection. These conditions represent general consequences of SARS-CoV-2 infection, including hospitalization and post-acute sequelae of COVID-19 (PASC), and Long-Haul COVID-19.²² This also includes people who have recovered from acute COVID-19 who subsequently develop a number of yet unexplained signs and symptoms.

Post-intensive care syndrome (PICS) or other complications of hospitalization and general illness such as hospital-acquired infections or treatment side effects may be covered by the WTCHP up to a maximum of 90 days when medically necessary to manage, ameliorate, or cure the member's certified WTC-related condition or certified medically associated condition and when all criteria in MCD above are met.²³

System-specific sequelae or pathophysiologic changes in organ function (PASC) represent other types of PCCs the WTCHP will generally <u>not</u> provide coverage for, **unless necessary** to manage, ameliorate, or cure the member's certified WTC-related condition or certified medically associated condition. The CCE/NPN Clinical Director must justify that this is medically necessary and follow a PA3 procedure for Program authorization of services. Examples of PASC include structural organ damage (ex: myocarditis, chronic kidney disease), hypercoagulability-related events, Multisystem Inflammatory Syndrome (MIS), and exacerbation or new onset of other non-WTC related conditions (ex: hypertension, diabetes, autoimmune disease). The WTCHP will also generally not provide coverage for persistent or new symptoms or objective findings of unclear pathophysiology or clinical significance.

XII. Billing/Coding Guidelines

For relevant billing/coding guidelines, please refer to the most updated Medical Benefits COVID-19 Guidance sent by the Program.

All applicable codes are listed in the WTC Health Program Codebook, located on the SAMS portal.

For consideration of codes that are not currently included in the WTC Health Program codebook, please submit a WTC-5 Medical Code Request form via the standard <u>WTCMedCode@csra.com</u> mailbox process.

²¹ For more information on PCCs, see <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-conditions.html</u>

²² For more information on PASC, see <u>https://covid19.nih.gov/news-and-stories/when-COVID-19-symptoms-linger</u>

²³ The WTC Health Program will cover COVID-19 treatment and classify COVID-19 as an adjunct (previously ancillary) condition when it co-occurs with a certified condition on the CDC list and when the untreated SARS-CoV-2 infection would interfere with reasonable treatment (i.e. manage, ameliorate, or cure) of that member's certified health condition

XIII. Revision History