THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: COVID-19 Testing, Prevention and Treatment

Effective Date: 1/21
Revision Date: 12/22

POLICY

Effective February 4, 2020, through the duration of the public health emergency, as declared by the Secretary of Health and Human Services (HHS), the following testing items and services outlined in this policy are covered at 100% without any cost-sharing, prior authorization or network restrictions.

DEFINITIONS

COVID-19: At the end of 2019, a novel coronavirus was identified as the cause of a cluster of pneumonia cases in Wuhan, China. It spread rapidly to other countries, including the United States. In February 2020, the World Health Organization designated the disease COVID-19, which stands for coronavirus disease 2019. The virus that causes COVID-19 is designated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); previously, it was referred to as 2019-nCoV.

POLICY GUIDELINES

Effective February 4, 2020, through the duration of the public health emergency, as declared by the Secretary of Health and Human Services (HHS), the following items and services are covered at 100% without any cost-sharing, prior authorization or network restrictions:

- In vitro diagnostic tests for the detection of SARSCoV-2 or the diagnosis of the virus that causes COVID-19, and the administration of such a test, that:
    - Is FDA-approved, cleared or authorized; or
    - The test developer has requested, or intends to request, emergency use authorization under the Food, Drug and Cosmetic Act; or
    - Is developed in and authorized by a state that has notified HHS of its intention to review tests intended to diagnose COVID-19; or
    - HHS otherwise has approved in guidance.
- Serological tests for COVID-19 used to detect antibodies against the SARS-CoV-2 virus are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus that causes COVID-19.
- Items and services furnished during a visit to a provider's office (including via telehealth), urgent care, an emergency room, drive up testing site or other (even nontraditional) provider visit that results in an order for or administration of an in vitro diagnostic test described above, but only to the extent the item or service relates to:
    - The furnishing or administration of the diagnostic test; or
    - The evaluation of the individual to determine need for the diagnostic test.

Effective January 15, 2022, OSU Health Plan will cover up to eight (8) OTC tests per month per covered person. The university's pharmacy benefit administrator, Express Scripts (ESI) is facilitating this coverage.

During the public health emergency for COVID-19 and as recommended by the governing preventive service agencies, coronavirus preventive services will be covered at 100% with no out-of-pocket costs or network restrictions. These services include an item, service or immunization[1] intended to prevent or mitigate the coronavirus disease and that is:

- An evidence-based item or service that has in effect a rating of "A" or "B" in the current recommendations of the U.S. Preventive Services Task Force; or
- An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved.

Treatment of COVID-19 and related complications is covered according to the plan guidelines outlined in the OSU Faculty and Staff Health Plans Specific Plan Details (SPD) Document.

PROCEDURE S

<u>At-Home, Over the Counter (OTC) Testing</u>

The federal government mandates health insurance coverage pertaining to certain at-home, over the counter (OTC) COVID-19 diagnostic tests. Effective January 15, 2022, the Ohio State University Faculty and Staff Health Plan covers up to eight (8) OTC tests per month per covered person. The university's pharmacy benefit administrator, Express Scripts (ESI) is facilitating this coverage. Covered OTC COVID-19 test purchases will be processed with $0 out-of-pocket expense when obtained through the ESI Express Advantage Network.

Tests are only covered when they are purchased for the personal use of individuals covered under OSU Health Plan. Members cannot use tests covered by the Plan for any other purpose. Members may be asked to acknowledge that any use other than personal use constitutes fraud under the terms of the Plan.

This coverage requirement does not include tests used for employment purposes.

Tests must be authorized by the U.S. Food and Drug Administration (FDA) for coverage. Some examples of the FDA-authorized brands include:

- InteliSwab COVID-19 Rapid Test
- BinaxNOW COVID-19 Antigen Self-Test
- QuickVue At-Home COVID-19 Test
- Ellume COVID 19 Home Test
- Flowflex COVID-19 Antigen Home Test

Members should contact Express Scripts for additional information regarding coverage of FDA-approved OTC COVID-19 tests.

<u>Testing Ordered by Health Care Professional</u>

During the public health emergency exception period[2], OSU Health Plan will cover medically necessary COVID-19 (molecular PCR or antigen) testing when ordered by a physician or health care professional for diagnostic purposes or to determine the need for member treatment. This applies to direct-to-consumer/home-based diagnostic or antigen tests. OSU Health Plan generally does not cover a test performed at the direction of a member's employer in order to obtain or maintain employment or to

perform the member's normal work functions or for return to school or recreational activities, except as required by applicable law. Testing required solely for travel requirements is not covered.

OSU Health Plan (OSUHP) will cover the following codes for COVID-19 testing ordered by a health care professional, including collection, at 100%[2] when billed with a diagnosis other than ICD-10 Z71.84:

Code	Description
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
86408	Neutralizing antibody, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen
86409	Neutralizing antibody, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer
86413	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
86769	Antibody, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; Severe Acute Respiratory Syndrome Coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])
87428	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; Severe Acute Respiratory Syndrome Coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B
87635	Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
87636	Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
87637	Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
87811	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected [BioFire® Respiratory Panel 2.1 (RP2.1), BioFire® Diagnostics, BioFire® Diagnostics, LLC]
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected [QIAstat-Dx Respiratory SARS CoV-2 Panel, QIAGEN Sciences, QIAGEN GmbH]
0224U	Antibody, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed [COVID-19

	Antibody Test, Mt. Sinai]
0225U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 21 targets, including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected [ePlex® Respiratory Pathogen Panel 2, GenMark Dx, GenMark Diagnostics, Inc.]
0226U	Surrogate viral neutralization test (sVNT), Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum [Tru-Immune, Ethos Laboratories, GenScript® USA Inc.]
0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
0241U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
C9803	Hospital outpatient clinic visit specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2023	Specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
G2024	Specimen collection for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source
G2025	Payment for a telehealth distant site furnished by a Rural Health Clinic (RHC) or Federally Qualified Health Center (FQHC) only
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
U0002	2019-nCoV Coronavirus SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
U0003	Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) amplified technique, making use of high throughput technologies as described by CMS-2020-01-R
U0004	2019-nCoV Coronavirus SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R
U0005	Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) amplified technique, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (list separately in addition to either HCPCS code U0003 or U0004) as described by CMS-2020-01-R

In addition to the codes for testing, items and services that result in an order for, or administration of an in vitro diagnostic test described above will also be covered at 100%[2] when billed with a diagnosis other than ICD-10 Z71.84. Examples of common sites for COVID-19 evaluation and testing include:

- Office visit (including via telehealth)
- Convenient Care visit
- Urgent care visit
- Emergency room visit
- Drive up testing site

Modifier CS can be utilized to identify those services required to determine the necessity of a COVID-19 test or related to the administration of a COVID-19 test.

Modifier	Description
CS	Cost-sharing waived for specified COVID-19 testing-related services that result in an order for, or administration of, a COVID-19 test and/or used for cost-sharing waived preventive services furnished via telehealth in Rural Health Clinics and Federally Qualified Health Centers during the COVID-19 public health emergency

Prevention

OSU Health Plan will cover the COVID-19 vaccine[1] and administration at 100%[2]. Currently, there are no quantity restrictions on COVID-19 vaccinations. Depending on the brand of vaccine, the member's age and comorbid conditions, the number of recommended vaccinations may vary. For example, an adult member who is immunosuppressed may need an additional vaccination dose during the primary series.

Covered codes include:

Code	Description
91300	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted, for intramuscular use [Pfizer-BioNTech COVID-19 vaccine]
91301	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein preservative free, 100 mcg/0.5 mL dosage, for intramuscular use [Moderna COVID-19 vaccine]
91302	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19] vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use [AstraZeneca Oxford 1 (ChAdOx1) vaccine]
91303	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use
91304	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, for intramuscular use
91305	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use
91306	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use
91307	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use
91308	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use
91309	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use
91310	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease

	[COVID-19]) vaccine, monovalent, preservative free, 5 mcg/0.5 mL dosage, adjuvant AS03 emulsion, for intramuscular use
91311	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use
91312	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use
91313	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use
91314	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use
91315	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use
0001A	Immunization administration by intramuscular injection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; first dose
0002A	Immunization administration by intramuscular injection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; second dose
0003A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; third dose
0004A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted; booster dose
0011A	Immunization administration by intramuscular injection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage, first dose
0012A	Immunization administration by intramuscular injection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage, second dose
0013A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage; third dose
0021A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19] vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free; 5x1010 viral particles/0.5mL dosage; first dose
0022A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19] vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free; 5x1010 viral particles/0.5mL dosage; second dose
0031A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral

	particles/0.5mL dosage, single dose
0034A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage; booster dose
0041A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; first dose
0042A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; second dose
0051A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; first dose
0052A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; second dose
0053A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; third dose
0054A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation; booster dose
0064A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, booster dose
0071A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose
0072A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose
0073A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; third dose
0074A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; booster dose
0081A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose
0082A	Immunization administration by intramuscular injection of severe acute respiratory

	syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose
0083A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; third dose
0091A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage; first dose when administered to individuals 6 through 11 years
0092A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage; second dose when administered to individuals 6 through 11 years
0093A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage; third dose when administered to individuals 6 through 11 years
0094A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, booster dose
0104A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, monovalent, preservative free, 5 mcg/0.5 mL dosage, adjuvant AS03 emulsion, booster dose
0111A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus (SARS-Co-V-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; first dose
0112A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus (SARS-Co-V-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; second dose
0113A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus (SARS-Co-V-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; third dose
0124A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, booster dose
0134A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, booster dose
0144A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, booster dose
0154A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, booster dose

M0201	COVID-19 vaccine administration inside a patient's home; reported only once per individual home, per date of service, when only COVID-19 vaccine administration is performed at the patient's home

Treatment

Treatment of COVID-19 and related complications will be covered per the member's plan guidelines. Deductible, coinsurance and network restrictions may apply. The following guidelines apply to distinguish evaluation and testing from treatment:

- Emergency Room:
  - Covered at 100%[2]:
    - Facility visit charge (e.g., Revenue Code 450)
    - Physician visit charge (e.g., CPT 99281 – 99288)
    - Testing (refer to *Testing* section of policy)
  - Remaining charges covered per plan guidelines (e.g., deductible, coinsurance)
- Inpatient Hospitalization:
  - Emergency room visit and testing covered at 100%[2] (see above)
  - Remaining charges covered per plan guidelines (e.g., deductible, coinsurance)
- Other:
  - Services billed with ICD-10 U07.1 covered per plan guidelines (e.g., deductible, coinsurance)

Refer to the Prior Authorization Code List available online at https://osuhealthplan.com/health-plan-tools/forms-policies to determine if specific treatments require prior authorization. Examples of specific COVID-19 treatments requiring medical necessity review through the medical benefit include (not an all-inclusive list):

- Tocilizumab (Actemra) [HCPCS J3262, Q0249, M0249, M0250]: *Covered, when medically necessary*
  - FDA issued a EUA on June 24, 2021, that permits use of tocilizumab for treatment of COVID-19 in hospitalized adults and pediatric patient's ≥2 years of age who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
  - Recommended dosage:
    - Adults and pediatric patients ≥2 years of age weighing <30 kg:
      - 12 mg/kg given as a single 60-minute IV infusion; may administer a second infusion ≥8 hours after first infusion if clinical signs or symptoms worsen or do not improve after initial dose.
    - Adults and pediatric patients ≥2 years of age weighing ≥30 kg:
      - 8 mg/kg (maximum of 800 mg per infusion) given as a single 60-minute IV infusion; may administer a second infusion ≥8 hours after first infusion if clinical signs or symptoms worsen or do not improve after initial dose.
- Inhaled Prostacyclins (e.g., epoprostenol, iloprost) [HCPCS J1325, Q4074]: *Covered, when medically necessary*
  - The NIH COVID-19 Treatment Guidelines Panel and the Surviving Sepsis Campaign state that a trial of inhaled pulmonary vasodilator as rescue therapy may be considered in mechanically ventilated adults with COVID-19, severe ARDS, and hypoxemia despite optimized ventilation and other rescue strategies.
  - If no rapid improvement in oxygenation is observed, the patient should be tapered off treatment.
  - Recommended dosage:
    - Epoprostenol: 20-30 ng/kg/min
    - Iloprost: 20 mcg every 8 hours for 5 days
- Interferons [HCPCS J9215, J9214, J9213]: *Not Covered*

- The NIH COVID-19 Treatment Guidelines Panel recommends against use of interferons for treatment of severe or critical COVID-19, except in the context of a clinical trial.
- The NIH COVID-19 Treatment Guidelines Panel states there are insufficient data to recommend either for or against use of interferon beta for the treatment of early mild or moderate COVID-19.
- The Surviving Sepsis Campaign COVID-19 subcommittee states that there is insufficient evidence to issue a recommendation on use of interferons, alone or in combination with antivirals, in critically ill adults with COVID-19.

- COVID-19 Convalescent Plasma [No specific code]: *Not Covered*
  - There are no convalescent blood products currently licensed by the FDA. COVID-19 convalescent plasma is regulated as an investigational product.
  - The Emergency Use Authorization (EUA), issued 8/23/20, states that COVID-19 convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19. The FDA states that adequate and well-controlled randomized trials remain necessary to determine optimal product attributes and to identify appropriate subpopulations for its use and that ongoing clinical trials of COVID-19 convalescent plasma should not be amended based on issuance of the EUA.
  - The NIH COVID-19 Treatment Guidelines Panel states there are insufficient data to recommend for or against the use of convalescent plasma in patients with COVID-19 and that COVID-19 convalescent plasma should not be considered a standard of care for the treatment of patients with COVID-19.
  - The Surviving Sepsis Campaign COVID-19 subcommittee suggests that convalescent plasma not be used routinely in critically ill adults with COVID-19 because efficacy and safety is not established and uncertainty surrounding optimal preparation of convalescent plasma.
- Immune Globulin [HCPCS J1459, J1460, J1556, J1557, J1560, J1561, J1562, J1566, J1568, J1569, J1599]: *Not Covered*
  - The NIH COVID-19 Treatment Guidelines Panel recommends against the use of commercially available immune globulin for the treatment of COVID-19, except in the context of a clinical trial.
  - The Surviving Sepsis Campaign COVID-19 subcommittee suggests that immune globulin not be used routinely in critically ill adults with COVID-19 because efficacy data is not available, currently available preparations may not contain antibodies against SARS-CoV-2, and it can be associated with increased risk of severe adverse effects.
- SARS-CoV-2-Specific Monoclonal Antibodies
  - Medication: Most SARS-CoV-2-specific monoclonal antibodies (mAbs) are not commercially available. Allocation of monoclonal antibodies for use under their respective EUAs is directed by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) in collaboration with state and territorial health departments.
    - **Bamlanivimab** [No code]: *Not Covered*
      - EUA issued 11/9/20
      - EUA revoked 4/16/21
    - **Bamlanivimab and etesevimab** [Q0245]: *Not Covered*
      - EUA issued 2/9/21
      - FDA announced on 1/24/22 that bamlanivimab and etesevimab is not authorized in any US region.
    - **EVUSHELD** (tixagevimab co-packaged with cilgavimab) [Q0221]: *Not Covered*
      - EUA issued 12/8/21
      - FDA released important information about certain viral variants that tixagevimab and cilgavimab may not neutralize on 10/3/22
    - **REGEN-COV** (casirivimab and imdevimab) [Q0240, Q0243, Q0244]: *Not Covered*

- EUA issued 11/21/20
- FDA announced on 1/24/22 that REGEN-COV is not authorized in any US region.

- **Sotrovimab** [Q0247]: *Not Covered*
  - EUA issued 5/26/21
  - FDA announced on 4/5/22 that sotrovimab is not authorized in any US region.
- **Bebtelovimab** [Q0222]: *Covered 8/15/22 – 11/30/22, when medically necessary*
  - EUA issued 2/11/22
  - On 8/15/22, drug manufacturer, Eli Lilly, started commercial distribution of bebtelovimab.
  - EUA revoked 11/30/22
  - Bebtelovimab is medically necessary for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg):
    - with positive results of direct SARS-CoV-2 viral testing, and
    - who are at high risk for progression to severe COVID-19, including hospitalization or death, and
    - for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate, and
    - administered between 8/15/22 – 11/30/22.
  - Bebtelovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to this drug and regional variant frequency.
  - Bebtelovimab is not authorized for use in patients who:
    - are hospitalized due to COVID-19, or
    - require oxygen therapy and/or respiratory support due to COVID-19, or
    - require an increase in baseline oxygen flow rate, or
    - respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity.

- <u>Administration</u>:
  - M0220, M0221*: *Covered starting 12/8/21*
    - EUA issued for EVUSHELD (tixagevimab and cilgavimab) on 12/8/21
  - M0222, M0223*: *Covered 2/11/22 – 11/30/22*
    - EUA for bebtelovimab issued 2/11/22
    - EUA revoked 11/30/22
  - M0240, M0241*, M0243, M0244*: *Covered 11/21/20 – 1/24/22*
    - EUA for REGEN-COV (casirivimab and imdevimab) issued 11/21/20.
    - On 1/24/22, the FDA advised REGEN-COV (casirivimab and imdevimab) is not authorized in any US region.
  - M0245, M0246*: *Covered 2/9/21 – 1/24/22*
    - EUA for bamlanivimab and etesevimab issued 2/9/21
    - On 1/24/22, the FDA advised use of bamlanivimab and etesevimab is not authorized in any US region.
  - M0247, M0248*: *Covered 5/26/21 – 4/5/22*
    - EUA for sotrovimab issued 5/26/21
    - On 4/5/22, the FDA advised use of sotrovimab is not authorized in any US region.
  - *Administration in the home requires prior authorization.

- Ivermectin (Stromectol) [No Specific Code]: *Not Covered*
    - NIH COVID-19 Treatment Guidelines Panel states that data are insufficient to date to recommend either for or against the use of ivermectin for the treatment of COVID-19. These experts state that clinical trials reported to date have significant methodological limitations and incomplete information; results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin in the treatment of COVID-19.
    - NIH panel recommends against use of ivermectin for preexposure prophylaxis (PrEP) or postexposure prophylaxis (PEP) for prevention of SARS-CoV-2 infection, except in a clinical trial.
    - Manufacturer (Merck) states that, to date, there is no scientific basis from preclinical studies for a potential therapeutic effect of ivermectin against COVID-19, no meaningful evidence of clinical activity or clinical efficacy of the drug in patients with COVID-19, and a concerning lack of safety data in the majority of studies.
    - FDA issued a warning concerning possible inappropriate use of ivermectin products intended for animals as an attempt to self-medicate for the treatment of COVID-19.

EXCLUSIONS

The following services are not covered by OSUHP:

- Non-diagnostic COVID-19 testing and related services for travel (ICD-10 Z71.84)
- Testing and/or treatment provided without a referral from a physician or licensed health care professional for diagnostic purposes or to determine the need for member treatment (except FDA-approved OTC COVID-19 tests)
- FDA-approved OTC COVID-19 tests obtained prior to January 15, 2022
- Non-FDA approved OTC COVID-19 tests
- More than 8 FDA-approved OTC COVID-19 tests per covered individual per month
- Coverage for OTC COVID-19 tests through the medical benefit
- CPT 99072
- Any treatment or service considered experimental or investigational for use in COVID-19

FOOTNOTES

[1] At this time, the COVID-19 vaccine will be paid for by the federal government through funding authorized by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, but administration of the vaccine by a provider will be paid for by the applicable plan or insurance policy. OSU Health Plan will cover the vaccine, as well as the administration, if the vaccine was not provided free of charge by the federal government.

[2]During the public health emergency, as declared by the Secretary of Health and Human Services (HHS), no network restrictions apply to the services outlined in this policy. For In Network providers, including those priced through Zelis, coverage will be 100% of the allowed amount. For Out-of-Network providers without a Global LOA, claims will be sent to Zelis for pricing. If no pricing available, coverage will be at 100% of the cash price listed on the provider's website. If no cash price available, coverage will be at 100% of the billed amount.

REFERENCES

American Medical Association. (Sept. 2020). COVID-19 Coding Update. *CPT Assistant, 30*.

American Society of Health-System Pharmacists. (2021). *Assessment of Evidence for COVID-19-Related Treatments: Updated 8/19/21*. Retrieved September 16, 2021, from https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/ASHP-COVID-19-Evidence-Table.ashx

CMS. (2020, September 4). *Medicare Claims Processing Manual: Chapter 26 - Completing and Processing Form CMS-1500 Data Set*. Retrieved January 11, 2021, from https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf

CMS. (2022, December 2). COVID-19 Monoclonal Antibodies. Retrieved December 2, 2022, from https://www.cms.gov/monoclonal

McIntosh, K. (2020, December 17). *Coronavirus disease 2019 (COVID-19): Clinical features* (M. S. Hirsch & A. Bloom, Eds.). Retrieved January 11, 2021, from https://www.uptodate.com/contents/coronavirus-disease-2019-covid-19-clinical-features?search=undefined&source=covid19_landing&usage_type=main_section

National Institutes of Health. *Coronavirus disease 2019 (COVID-19) treatment guidelines*. Updated 2020 Dec 3. From NIH website (https://www.covid19treatmentguidelines.nih.gov/). Accessed 2020 Dec 9.

S. 3548, 116th Cong., https://www.congress.gov/116/bills/s3548/BILLS-116s3548is.pdf (2020) (enacted).

U.S. Departments of Labor, Health and Human Services (HHS)/U.S. Department of the Treasury. (2021). *FAQs about families first coronavirus response act and coronavirus aid, relief, and economic security act implementation part 44*. https://www.cms.gov/files/document/faqs-part-44.pdf