Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
COVID-19 Antibody (Serological) Testing

Effective: January 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Serology testing may detect the presence of antibodies in the blood as a result of an adaptive immune response to SARS-CoV-2. In the early days of a COVID-19 infection, the body's adaptive immune response is still building, and antibodies may not be detected. This limits the effectiveness of antibody testing and is one major reason serology testing should not be used to diagnose or exclude an acute COVID-19 infection. Serology testing can be used to identify and provide late COVID-19 diagnosis of previously infected individuals who may have developed an adaptive immune response to SARS-CoV-2.[6] Current studies will better inform the appropriate use of antibody testing, including level of protection needed to prevent or reduce the severity of infection or re-infection and the duration for which this protection may last.

Clinical Guideline Coverage Criteria

The Plan may consider COVID-19 Antibody Testing as reasonable and medically necessary when documentation confirms **ALL** of the following:

1. Test is being ordered by the member's treating physician or appropriately licensed care professional; **and**
2. COVID-19 antibody test is necessary to make decisions required to treat a member's immediate medical condition (e.g. pediatric/adult multisystem inflammatory syndrome [MIS-C, MIS-A]); **and**

3. Test is being conducted by a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory; **and**
4. Requested COVID antibody serology test has received Food and Drug Administration (FDA) approval and/or FDA emergency use authorization (EUA)

Limitations

The Plan considers COVID-19 antibody testing as not medically necessary for all other indications. In addition, The Plan does not cover:

1. Antibody testing required by a third party (e.g., employer, school, travel, court) that is not otherwise medically necessary
2. Antibody testing to assess immunity to SARS-CoV-2 infection following COVID-19 vaccination, to assess the need for vaccination in an unvaccinated individual or to assess the need for re-vaccination in a vaccinated individual
3. Public health and epidemiologic surveillance (e.g., vaccine efficacy, release from isolation)

Codes

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Table 1: CPT/HCPCS Codes

Code	Description
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiqualitative, single-step method (e.g., 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])
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed

References:

1. Commonwealth of Massachusetts Division of Insurance Bulletin 2020-16. Accessed August 27, 2021. https://www.mass.gov/doc/bulletin-2020-16-covid-19-coronavirus-testing-issued-05182020/download.
2. Commonwealth of Massachusetts. Recommendations for diagnostic COVID-19 testing. https://www.mass.gov/info-details/COVID-19-testing-guidance. Updated June 14, 2021. Accessed September 1, 2021.
3. FDA Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2. Accessed November 14, 2024. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2#individual-serological
4. Hayden MK, El Mikati IK, Hanson KE, et al. Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19: Serologic Testing. *Clin Infect Dis*. Published online March 15, 2024. doi:10.1093/cid/ciae12.
5. Maine Insurance Code: Title 24-A: Chapter 56-A: Subchapter 1. Accessed November 14, 2024. https://legislature.maine.gov/statutes/24-A/title24-Asec4303.html.
6. Public Law No: 116-136 (03/27/2020) Coronavirus Aid, Relief, and Economic Security Act (CARES Act)
7. Son MBF, MD, Friedman K; COVID-19. Multisystem inflammatory syndrome in children (MIS-C) clinical features, evaluation, and diagnosis. Available by subscription UpToDate. Accessed September 1, 2021.

Approval And Revision History

September 15, 2021: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- February 17, 2022: Freedom removed from template
- November 16, 2022: Reviewed by MPAC, renewed without changes
- September 20, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to One Care effective January 1, 2024
- December 1, 2023: Reviewed and approved by UM Committee
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee, effective January 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.