

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

Effective: November 16, 2022

Prior Authorization Required	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	
<p>Applies to: COMMERCIAL Products <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p>TUFTS HEALTH PUBLIC PLANS Products <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304 *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p>SENIOR Products • Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List • Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</p>	

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. 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 COVERAGE CRITERIA

Tufts Health Plan considers COVID-19 Antibody Testing as 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-19 antibody serology test has received Food and Drug Administration (FDA) approval and/or FDA emergency use authorization (EUA)

LIMITATIONS

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

- Antibody testing required by a third party (e.g. employer, school, travel, court) that is not otherwise medically necessary
- 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
- Public health and epidemiologic surveillance (e.g. vaccine efficacy, release from isolation)

CODES

Table 1: CPT Codes

CPT Code	Description
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, 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. FDA Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2. Accessed September 8, 2021. [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](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)
2. Public Law No: 116-136 (03/27/2020) Coronavirus Aid, Relief, and Economic Security Act (CARES Act)
3. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Updated March 17, 2021. Accessed August 23, 2021. [covid19treatmentguidelines.nih.gov/](https://www.covid19treatmentguidelines.nih.gov/). Accessed August 23, 2021.
4. Commonwealth of Massachusetts Division of Insurance Bulletin 2020-16. Accessed August 27, 2021. [mass.gov/doc/bulletin-2020-16-covid-19-coronavirus-testing-issued-05182020/download](https://www.mass.gov/doc/bulletin-2020-16-covid-19-coronavirus-testing-issued-05182020/download).
5. Commonwealth of Massachusetts. Recommendations for diagnostic COVID-19 testing. [mass.gov/info-details/COVID-19-testing-guidance](https://www.mass.gov/info-details/covid-19-testing-guidance). Updated June 14, 2021. Accessed September 1, 2021.
6. Caliendo AM, MD, PhD, Hanson, KE, MD, MHS. Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19: Serologic Testing. Accessed September 3, 2021. [idsociety.org/COVID19guidelines/serology](https://www.idsociety.org/COVID19guidelines/serology).
7. Maine Insurance Code: Title 24-A: Chapter 56-A: Subchapter 1. Accessed September 1, 2021. legislature.maine.gov/statutes/24-A/title24-Asec4303.html.
8. 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 HISTORY

September 15, 2021: Reviewed by the Integrated Medical Policy Advisory Committee

Subsequent endorsement date(s) and changes made:

- February 17, 2022: Freedom removed from template
- November 16, 2022: Reviewed by MPAC, renewed without changes

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.

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.

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