

**Subject: COVID-19 Antibody (Serological) Testing****Background:**

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.

**Policy and Coverage Criteria:**

Harvard Pilgrim Health Care (HPHC) considers COVID-19 Antibody Testing as medically necessary when documentation confirms ALL of the following:

- Test is being ordered by the member's treating physician or appropriately licensed care professional; AND
- 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
- Test is being conducted by a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory; AND
- Requested COVID antibody serology test has received Food and Drug Administration (FDA) approval and/or FDA emergency use authorization (EUA)

**Exclusions:**

Harvard Pilgrim Health Care (HPHC) considers COVID-19 antibody testing as not medically necessary for all other indications. In addition, HPHC 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)

**Coding:**

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

<b>CPT® Code</b>	<b>Description</b>
<b>86328</b>	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])
<b>86408</b>	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen
<b>86409</b>	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer
<b>86413</b>	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
<b>86769</b>	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
<b>0224U</b>	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed

### Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

### References:

1. 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. <https://www.idsociety.org/COVID19guidelines/serology>.
2. 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>.
3. 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.
4. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Updated March 17, 2021. Accessed August 23, 2021. <https://www.covid19treatmentguidelines.nih.gov/>. Accessed August 23, 2021.
5. FDA Individual EUAs for Serology and Other Adaptive Immune Response Tests for SARS-CoV-2. Accessed September 8, 2021. <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>
6. Maine Insurance Code: Title 24-A: Chapter 56-A: Subchapter 1. Accessed September 1, 2021. <https://legislature.maine.gov/statutes/24-A/title24-Asec4303.html>.
7. Public Law No: 116-136 (03/27/2020) Coronavirus Aid, Relief, and Economic Security Act (CARES Act)
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.

### Summary of Changes:

<b>Date</b>	<b>Change</b>
<b>9/21</b>	New policy

**Approved by Medical Policy Committee: 9/28/21**

**Approved by Clinical Policy Operational Committee: 9/21**

**Policy Effective Date: 10/1/21**

**Initiated: 9/21**