Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

COVID-19 Monoclonal Antibody Therapy

Effective: January 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX number 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

Currently, monoclonal antibodies are not US Food and Drug Administration (FDA)-approved to treat COVID-19. However, the FDA has issued emergency use authorization (EUA) for certain mABs for the treatment of COVID-19.

Several mABs have had limited effectiveness against certain disease variants and FDA EUA indications have been revoked.

Clinical Guideline Coverage Criteria

The Plan may cover monoclonal antibody therapy for COVID-19 when documentation confirms FDA EUA indication and dosing requirements for the specific mAB product are met.

Emergency Use Authorizations for Drugs and Non-Vaccine Biological Products | FDA

Limitations

The Plan considers monoclonal antibody therapy as not medically necessary for non-authorized indications and will not cover when documentation does not support FDA authorized and EUA indications and dosing specific to mAB.

References:

1. Centers for Disease Control and Prevention (CDC): Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers. Accessed May 17, 2023. Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals | CDC.
2. Centers for Disease Control and Prevention (CDC): Appendices. cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#Key-Terms accessed May 17, 2023.
3. COVID-19 Vaccines for Moderately or Severely Immunocompromised People: cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html_cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications accessed May 17, 2023.
4. FDA Emergency Use Authorization. fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid drugs Monoclonal antibodies for prevention of COVID-19 accessed May 17, 2023.
5. Centers for Disease Control and Prevention (CDC):End of the Federal COVID-19 Public Health Emergency (PHE) Declaration. Accessed May 17, 2023. End of the Federal COVID-19 Public Health Emergency (PHE) Declaration | CDC.
6. U.S. Food & Drug Administration: FDA authorizes revisions to fact sheets to address SARS-CoV-2 variants for monoclonal antibody products unde emergency use authorization. Accessed May 17, 2023. FDA authorizes revisions to fact sheets to address SARS-CoV-2 variants for monoclonal antibody products under emergency use authorization | FDA.
7. U.S. Food & Drug Administration: Emergency Use Authorizations for Drugs and Non-Vaccine Biological Products. Accessed May 17, 2023. Emergency Use Authorizations for Drugs and Non-Vaccine Biological Products | FDA.

Approval And Revision History

February 16, 2022 : Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- August 23, 2022: Coding update. HCPCS Q0221, Q0222, M0222, M0223 added.
- June 21, 2023: Reviewed by MPAC. Criteria updated to align with monoclonal antibody EUAs revoked by FDA, effective August 1, 2023
- September 20, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to OneCare effective January 1, 2024
- 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.