Medical Necessity Guidelines: COVID-19 Monoclonal Antibody Therapy

Effective: August 23, 2022

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☐ No ☒**

Applies to:
COMMERCIAL Products
☒Tufts Health Plan Commercial products; Fax: 617.972.9409
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products
☒Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055
☒Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒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.

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

OVERVIEW

Monoclonal antibodies (mABs) are laboratory-produced molecules that act as substitute antibodies that can restore, enhance or mimic the immune system's attack on cells. Monoclonal antibodies may block the virus that causes COVID-19 from attaching to human cells, making it more difficult for the virus to reproduce and cause harm.

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 for non-hospitalized individuals with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death. According to EUAs, mAB treatment should be given as soon as possible after positive antigen or molecular testing, within 10 days of symptom onset and prior to hospitalization.

Certain mABs have been granted FDA EUA for post-exposure prophylactic use for specific individuals who have been exposed to COVID-19 (e.g. exposure to an individual infected with SARS-CoV-2) and are at high risk for progression to severe COVID-19, including hospitalization or death. Post-exposure prophylaxis, as authorized for mAB(s), is not a substitute for vaccination against COVID-19.

Although COVID-19 vaccination is the optimal and recommended method of pre-exposure prophylaxis in the general population, certain individuals may not benefit maximally from vaccination. The FDA has granted EUA for specific mAB(s) for pre-exposure prophylaxis against SARS-CoV-2 infection for these individuals. Pre-exposure prophylaxis, as authorized for mAB(s), is not a substitute for vaccination against COVID-19.

Monoclonal antibody therapy requires parenteral administration and may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and have the ability to activate the emergency's medical system (EMS), if necessary. Certain EUAs comprise of more than one MAB which must be administered together per EUA indication.

Emergency Use Authorizations will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Certain mABs may have limited effectiveness against certain disease variants. FDA EUA indications could change. Availability of some mAB products may be limited at times.

CLINICAL COVERAGE CRITERIA

Tufts Health 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. FDA EUA indications for treatment, post-exposure prophylaxis and pre-exposure prophylaxis may vary and dosing/repeat dosing for each mAB product may vary.

REFER TO FDA EMERGENCY USE AUTHORIZATIONS FOR DRUGS AND NON-VACCINE BIOLOGICAL PRODUCTS

FDA EUA indications are specific to each mAB product and **may** include, but are not limited to the following:

- Member's age
- Member's weight
- Symptom onset (e.g. fever, chills, aching, new loss of taste or smell, nausea, vomiting, cough, sore throat, nasal congestion, runny nose, diarrhea, shortness of breath, headache) within 10 days of administration
- Positive result of direct SARS-CoV-2 viral testing (antigen or molecular)
- Member is at high risk for progressing to severe COVID-19, including hospitalization or death[1]
- Member is not fully vaccinated or is not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination **and**:
    - Member has been exposed to an individual infected with SARS-CoV-2 consistent with close contact, defined as someone who has been within six feet of an infected person (laboratory-confirmed or a clinically compatible illness) for a cumulative total of 15 minutes or more over a 24-hour period[2]), **or**
    - Member is at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

Member has moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **or** vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended for member due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

The following medical conditions or other factors may place adults and pediatric patients (12 to 17 years of age weighing at least 40 kg) at higher risk for progression to severe COVID-19:

- Older age (for example, ≥65 years of age)
- Obesity or being overweight (for example, adults with BMI >25 kg/m2, or if 12 to 17, have BMI ≥85th percentile for their age and gender based on CDC growth charts,
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID 19])

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of mABs under the EUA is not limited to the medical conditions or factors listed above.

For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers.

LIMITATIONS

Tufts Health Plan considers monoclonal antibody therapy as not medically necessary for non-authorized indications and will not cover when documentation does not support FDA EUA indications and dosing specific to mAB. These may include, but are not limited to:

- Member hospitalized due to COVID-19
- Member who requires oxygen therapy and/or respiratory support due to COVID-19
- Member who requires an increase in baseline oxygen flow rate and/or respiratory support due COVID-19 and is on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity
- mAB administered in inappropriate setting
- Non-EUA indicated repeat dosing
- Age
- Weight
- Member has had an allergic reaction (hives, facial swelling, difficulty breathing, anaphylaxis, etc.) after receiving a monoclonal antibody therapy

CODES

Table 1: CPT Codes

CPT Code	Description
Q0220	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 300 mg
Q0221	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s), 600 mg
M0220	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring
M0221	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency
Q0222	Injection, bebtelovimab, 175 mg

CPT Code	Description
M0222	Intravenous injection, bebtelovimab, includes injection and post administration monitoring
M0223	Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency
Q0240	Injection, casirivimab and imdevimab, 600 mg
M0240	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection and post administration monitoring, subsequent repeat doses
M0241	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection, and post administration monitoring in the home or residence. This includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency, subsequent repeat doses
Q0243	Injection, casirivimab and imdevimab, 2400 mg
Q0244	Injection, casirivimab and imdevimab, 1200 mg
M0243	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection, and post administration monitoring
M0244	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring
M0246	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency
Q0247	Injection, sotrovimab, 500 mg
M0247	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring
M0248	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency

REFERENCES

1. Centers for Disease Control and Prevention (CDC): Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers. cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html accessed February 16, 2022.
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 February 16, 2022.
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 February 16, 2022.
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 February 16, 2022.

APPROVAL 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.

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.