Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: EUA Antibody Therapies for COVID-19		
MNG #: 047	☒**SCO** ☒**One Care** ☒ **MAPD-MA Medicare Preferred** ☒**MAPD-MA Medicare Value** ☒ **MAPD-RI Medicare Preferred** ☒ **MAPD-RI Medicare Value** ☒ **DSNP-RI Medicare Maximum**	**Prior Authorization Needed?** ☒**Yes** ☐**No**
Clinical: ☒	**Operational:** ☐	**Informational:** ☐
Medicare Benefit: ☐**Yes** ☐**No**	**Approval Date:** 1/7/2021	**Effective Date:** 04/16/2021
Last Revised Date: 04/21/2021; 6/17/2021; 7/27/2021; 9/21/2021; 10/14/2021	**Next Annual Review Date:** 1/7/2022; 06/17/2022; 7/27/2022; 9/21/2022; 10/14/2022	**Retire Date:**

OVERVIEW:

This policy document addresses the use of U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) antibody treatments for coronavirus disease 2019 (COVID-19) infection. During the COVID-19 Public Health Emergency (PHE), Medicare will cover and pay for these infusions the same way it covers and pays for COVID-19 vaccines (when furnished consistent with the relevant EUA).

BAMLANIVIMAB AND ETESEVIMAB

Clinical Coverage Criteria: The FDA issued an EUA to permit the use of the unapproved product, Bamlanivimab and Etesevimab, to be administered together for the treatment of mild to moderate COVID-19 in adult patients who meet all of the following criteria:

- Who have positive results of direct SARS-CoV-2 viral testing, OR
- Who have been exposed or who are at a high risk of exposure to an individual infected with SARS-CoV-2 consistent with the close contact criteria per Centers for Disease Control and Prevention AND are not fully vaccinated OR who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination, AND
    - High risk of exposure may be due to the occurrence of SARS-CoV-2 infection in other individuals within the same institutional setting
    - Individuals who may not be able to mount an adequate immune response may include individuals who have immunocompromising conditions or who are taking immunosuppressive medications
- Who are at high risk for progression to severe COVID-19, including hospitalization or death.

  Patient must be or have one of the following in order to meet the definition of high risk:
    - Be ≥ 65 year of age,
    - Have a body mass index (BMI) > 25 kg/m^2,
    - Be pregnant,
    - Have at least one underlying medical condition(s):

        - Chronic kidney disease,
        - Diabetes,
        - Immunosuppressive disease or concurrent use of immunosuppressive treatment,
        - Cardiovascular disease (including congenital heart disease),
        - Hypertension,
        - Chronic lung diseases (e.g. chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension),
        - Sickle cell disease,
        - Neurodevelopmental disorders (e.g. cerebral palsy),
        - Other conditions that confer medical complexity (e.g. genetic or metabolic syndromes and severe congenital anomalies)
    - Have a medical -related technological dependence (e.g. tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]
- Who are in settings where the healthcare provider administering the monoclonal antibody therapy has both of the following:
    - Immediate access to medications to treat a severe infusion reaction (e.g. anaphylaxis), AND
    - The ability to activate the emergency medical system (EMS)

LIMITATIONS/EXCLUSIONS:

Bamlanivimab and Etesevimab is not authorized for use in patients:

- Who are hospitalized due to COVID-19, OR
- Who require oxygen therapy due to COVID-19, OR
- Who require an increase in baseline oxygen glow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

Bamlanivimab/Etesevimab is not authorized for use:

- In states, territories, and US jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab exceeds 5%
    - Refer to the FDA website for the most current list of states, territories, and U.S. jurisdictions in which Bamlanivimab/Etesevimab are authorized.
- For patients who have traveled to, resided in, or had close contact with an infected individual from an area where the frequency of resistant variants to bamlanivimab and etesevimab exceeds 5%
    - Healthcare providers should review a patient's travel and contact history within two weeks prior to infection.
- As a substitute for vaccination against COVID-19 or pre-exposure prophylaxis for prevention of COVID-19

CASIRIVIMAB AND IMDEVIMAB (REGEN-COV)

Clinical Coverage Criteria: The FDA has issued an EUA to permit the emergency use of the unapproved product, REGEN-COV (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab), supplied as

individual vials, to be administered together for the treatment of mild to moderate COVID-19 in adult patients who meet all of the following criteria:

- **Who have positive results of direct SARS-CoV-2 viral testing,** OR
- Who have been exposed or who are at a high risk of exposure to an individual infected with SARS-CoV-2 consistent with the close contact criteria per Centers for Disease Control and Prevention AND are not fully vaccinated OR who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination, AND
    - High risk of exposure may be due to the occurrence of SARS-CoV-2 infection in other individuals within the same institutional setting
    - Individuals who may not be able to mount an adequate immune response may include individuals who have immunocompromising conditions or who are taking immunosuppressive medications
- Who are at high risk for progressing to severe COVID-19, including hospitalization or death.

  Patient must be or have one of the following in order to meet the definition of high risk:
    - Be ≥ 65 year of age,
    - Have a body mass index (BMI) > 25 kg/m^2,
    - Be pregnant,
    - Have at least one underlying medical condition(s):
        - Chronic kidney disease,
        - Diabetes,
        - Immunosuppressive disease or concurrent use of immunosuppressive treatment,
        - Cardiovascular disease (including congenital heart disease),
        - Hypertension,
        - Chronic lung diseases (e.g. chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension),
        - Sickle cell disease,
        - Neurodevelopmental disorders (e.g. cerebral palsy),
        - Other conditions that confer medical complexity (e.g. genetic or metabolic syndromes and severe congenital anomalies)
    - Have a medical -related technological dependence (e.g. tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]
- Who are in settings where the healthcare provider administering the monoclonal antibody therapy has both of the following:
    - Immediate access to medications to treat a severe infusion reaction (e.g. anaphylaxis), AND
    - The ability to activate the emergency medical system (EMS)

<u>LIMITATIONS/EXCLUSIONS:</u>

REGEN-COV (casirivimab and imdevimab) is not authorized for use in patients:

- Who are hospitalized due to COVID-19, OR
- Who require oxygen therapy due to COVID-19, OR

- Who require an increase in baseline oxygen glow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

REGEN-COV (casirivimab and imdevimab) is not authorized for use as a substitute for vaccination against COVID-19 or pre-exposure prophylaxis for prevention of COVID-19.

SOTROVIMAB

Clinical Coverage Criteria: The FDA has issued an EUA to permit the emergency use of the unapproved product sotrovimab to be administered for the treatment of mild to moderate COVID-19 in adult patients who meet all of the following criteria:

- Who have positive results of direct SARS-CoV-2 viral testing,
- Who are at high risk for progressing to severe COVID-19, including hospitalization or death.
  Patients must be at or have one of the following in order to meet the definition of high risk:
    - Are ≥ 65 years of age,
    - Have a body mass index (BMI) > 25 kg/m^2,
    - Are pregnant,
    - Have at least one underlying medical condition(s):
        - Chronic kidney disease,
        - Diabetes,
        - Immunosuppressive disease or concurrent use of immunosuppressive treatment,
        - Cardiovascular disease (including congenital heart disease),
        - Hypertension,
        - Chronic lung diseases (e.g. chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension),
        - Sickle cell disease,
        - Neurodevelopmental disorders (e.g. cerebral palsy),
        - Other conditions that confer medical complexity (e.g. genetic or metabolic syndromes and severe congenital anomalites)
    - Have a medical -related technological dependence (e.g. tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]
- Who are in settings where the healthcare provider administering the monoclonal antibody therapy has both of the following:
    - Immediate access to medications to treat a severe infusion reaction (e.g. anaphylaxis), AND
    - The ability to activate the emergency medical system (EMS)

LIMITATIONS/EXCLUSIONS:

Sotrovimab is not authorized for use in patients:

- Who are hospitalized due to COVID-19, OR

Medical Necessity Guideline

- Who require oxygen therapy due to COVID-19, OR
  Who require an increase in baseline oxygen glow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

AUTHORIZATIONS:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not signify whether the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply. This Medical Necessity Guideline is subject to all applicable laws and regulations, Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

HCPCS Code	Description	
Q0240	**Long descriptor**	Injection, casirivimab and imdevimab, 600 mg
	Short descriptor	Casirivi and imdevi 600 mg
M0240	**Long descriptor**	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring and subsequent repeat doses
	Short descriptor	Casirivi and imdev repeat
M0241	**Long descriptor**	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
	Short descriptor	Casirivi and imdev repeat hm
Q0245	**Long descriptor**	Injection, bamlanivimab and etesevimab, 2100 mg
	Short descriptor	Bamlanivimab and etesevima
M0245	**Long descriptor**	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring
	Short descriptor	Bamlan and etesev infusion
M0246	**Long descriptor**	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
	Short descriptor	Bamlan and etesev infus home
Q0247	**Long descriptor**	Injection, sotrovimab, 500 mg

Medical Necessity Guideline

	Short descriptor	Sotrovimab
M0247	**Long descriptor**	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring
	Short descriptor	Sotrovimab infusion
M0248	**Long descriptor**	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring in hoe or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency
	Short descriptor	Sotrovimab inf, home admin

REGULATORY NOTES:

Bamlanivimab/Etesevimab, REGEN-COV (Casirivimab/Imdevimab) and Sotrovimab are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Bamlanivimab/Etesevimab, REGEN-COV (Casirivimab/Imdevimab) and Sotrovimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

RELATED REFERENCES:

1. Centers for Medicare & Medicaid Services. (2021). *Bamlanivimab and etesevimab states, territories, and U.S. jurisdictions.* Retrieved from https://www.fda.gov/media/151719/download
2. Centers for Medicare & Medicaid Services. (2021). *Monoclonal antibody COVID-19 infusion.* Retrieved from https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion
3. Centers for Medicare & Medicaid Services. (2021). *COVID-19: EUAs for monoclonal antibody products.* Retrieved from https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-06-17-mlnc#_Toc74742858
4. U.S. Food and Drug Administration. (2021). *Fact sheet for healthcare providers emergency use authorization (EUA) of bamlanivimab and etesevimab.* Retrieved from https://www.fda.gov/media/151719/download
5. U.S. Food and Drug Administration. (2020). *Fact sheet for healthcare providers emergency use authorization (EUA) of casirivimab and imdevimab.* Retrieved from https://www.fda.gov/media/149534/download
6. U.S. Food and Drug Administration. (2021). *Fact sheet for healthcare providers emergency use authorization (EUA) of sotrovimab.* Retrieved from https://www.fda.gov/media/149534/download
7. U.S. Food and Drug Administration. (2021). *Coronavirus (COVID-19) update: FDA revokes emergency authorization for monoclonal antibody bamlanivimab.* Retrieved from https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab

ATTACHMENTS:

EXHIBIT A:	

Medical Necessity Guideline

EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION
7/27/2021	Changes reflect FDA's recission of the EUA for the combination therapy of Bamlanivimab/Etesevimab (June 25). Addition to the criteria that healthcare providers who are administering these monoclonal antibody therapies, must have immediate access to medications to treat severe infusion reaction, and the ability to activate the emergency medical system.
6/17/2021	Changes reflect FDA's addition of the EUA for Sotrovimab (inpatient and in-home administration) (May 26) and updates for combination therapy of Bamlanivimab/Etesevimab (May 2021), and for combination therapy of Casirivimab/Imdevimab (June 3). Expanded to include additional medical conditions and factors, which includes: pregnancy, chronic lung diseases, neurodevelopmental disorders, and having a medical-related technological dependence.
04/21/21	Changes reflect FDA's rescission of the EUA for Bamlanivimab (outpatient treatment for COVID-19) and introduction of the combination therapy of Bamlanivimab and Etesevimab

APPROVALS:

Douglas Hsu, MD, MPH	Vice President, Medical Policy and Utilization Review
CCA Senior Clinical Lead [Print]	**Title [Print]**
	1/7/2021
Signature	**Date**
Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Lori Tishler, MD	Senior Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
	1/7/2021
Signature	**Date**