Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: EUA Antibody Therapies for COVID-19		
MNG #: 047	**☒SCO ☒One Care**	**Prior Authorization Needed? ☐Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: ☐Yes ☐No	**Approval Date:** 1/7/2021	**Effective Date:** 04/01/2021
Last Revised Date:	**Next Annual Review Date:** 1/7/2022	**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 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

Clinical Coverage Criteria: The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg and who are at high risk of progressing to severe COVID-19 and/or hospitalization. High risk is defined by the following criteria set forth under the EUA:

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age

Are ≥55 years of age AND have

- cardiovascular disease, OR
- hypertension, OR
- chronic obstructive pulmonary disease/other chronic respiratory disease.

Are 12 – 17 years of age AND have

- BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
- Sickle cell disease, OR

- Congenital or acquired heart disease, OR
- Neurodevelopmental disorders, for example, cerebral palsy, OR
- A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
- Asthma, reactive airway or other chronic respiratory disease that requires
- daily medication for control.

LIMITATIONS/EXCLUSIONS:

Bamlanivimab is not authorized by the FDA 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 flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

CASIRIVIMAB AND IMDEVIMAB

Clinical Coverage Criteria: The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products casirivimab and imdevimab to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have
    - o cardiovascular disease, OR
    - o hypertension, OR
    - o chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
    - o BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
    - o sickle cell disease, OR
    - o congenital or acquired heart disease, OR
    - o neurodevelopmental disorders, for example, cerebral palsy, OR
    - o a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR

o asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

LIMITATIONS/EXCLUSIONS:

Casirivimab and imdevimab are not authorized for use in patients: o who are hospitalized due to COVID-19, OR

- Who require oxygen therapy due to COVID-19, OR
- Who require an increase in baseline oxygen flow 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).

Q0239:
Long descriptor: Injection, bamlanivimab-xxxx, 700 mg
Short descriptor: bamlanivimab-xxxx

M0239:
Long Descriptor: intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring
Short Descriptor: bamlanivimab-xxxx infusion

Q0243:
Long descriptor: Injection, casirivimab and imdevimab, 2400 mg
Short descriptor: casirivimab and imdevimab

M0243:
Long Descriptor: intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring
Short Descriptor: casirivi and imdevi infusion

REGULATORY NOTES:

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

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RELATED REFERENCES:

1. https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf
2. https://www.fda.gov/media/143603/download
3. https://www.fda.gov/media/143892/download

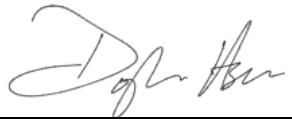
ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

Doug Hsu	VP, Medical Policy & 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**
	Sr. VP Medical Services
Lori Tishler, MD	
CCA CMO or Designee [Print]	**Title [Print]**
	1/7/2021
Signature	**Date**