Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Outpatient Part B COVID-19 Treatment		
MNG #: 047	☒**SCO** ☒**One Care** ☒ **MAPD-MA Medicare Preferred** ☒ **MAPD-MA Medicare Value** ☒ **MAPD-RI Medicare Preferred** ☒ **MAPD-RI Medicare Value** ☒ **DSNP-RI Medicare Maximus**	**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; 1/4/2022, 1/20/2022, 3/3/2022;	**Next Annual Review Date:** 1/7/2022; 07/27/2022; 01/04/2023; 03/03/2023;	**Retire Date:**

OVERVIEW:

This Medical Necessity Guideline addresses the use of U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) treatment for coronavirus disease 2019 (COVID-19) infection covered under the Medicare Part B benefit in the outpatient setting. During the COVID-19 Public Health Emergency, Commonwealth Care Alliance (CCA) covers medically necessary COVID therapies in outpatient settings without Prior Authorization (PA) when administration adheres with FDA EUA criteria. Providers should refer to information from CMS, CDC, and FDA for drug-specific clinical eligibility and administration.

DEFINITIONS:

COVID-19: Coronavirus disease 2019
EUA: Emergency Use Authorization
FDA: United States Food and Drug Administration
OON: Out-of-network

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).

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Product	Product Code	Administration Code
Sotrovimab	Q0247 **Long descriptor:** Injection, sotrovimab, 500 mg **Short descriptor:** Sotrovimab	M0247 **Long Descriptor:** Intravenous infusion, sotrovimab, includes infusion and post administration monitoring **Short Descriptor:** Sotrovimab infusion
Sotrovimab	Q0247 **Long descriptor:** Injection, sotrovimab, 500 mg **Short descriptor:** Sotrovimab	M0248 **Long Descriptor:** 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 **Short Descriptor:** Sotrovimab inf, home admin
Tixagevimab and cilgavimab	Q0220 **Long descriptor:** 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 **Short descriptor:** Tixagev and cilgav inj	M0220 **Long descriptor:** 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 **Short descriptor:** Tixagev and cilgav inj
Tixagevimab and cilgavimab	Q0220 **Long descriptor:** 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	M0221 **Long descriptor:** 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),

	adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 300 mg **Short descriptor:** Tixagev and cilgav inj	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 **Short descriptor:** Tixagev and cilgav inj hm
Bebtelovimab	Q0222 **Long descriptor:** Injection, bebtelovimab, 175 mg **Short descriptor:** Bebtelovimab 175 mg	M0222 **Long Descriptor:** Intravenous injection, bebtelovimab, includes injection and post administration monitoring **Short Descriptor:** Bebtelovimab injection
Bebtelovimab	Q0222 **Long descriptor:** Injection, bebtelovimab, 175 mg **Short descriptor:** Bebtelovimab 175 mg	M0223 **Long Descriptor:** 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 **Short Descriptor:** Bebtelovimab injection home
Remdesivir	J0248 **Long descriptor:** Injection, remdesivir, 1 mg **Short descriptor:** Inj, remdesivir, 1 mg	

RELATED REFERENCES:

1. Centers for Medicare and Medicaid Services COVID-19 Monoclonal Antibodies. https://www.cms.gov/monoclonal. Accessed 2/25/2022.
2. U.S. Food and Drug Administration Coronavirus Disease 2019 (COVID-19) EUA Information. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs. Accessed 2/25/2022.

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

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2/14/2022	Changes reflect FDA's authorization of bebtelovimab (Feb 11).
1/20/2022	Changes reflect Masshealth's coverage for remdesivir.
1/4/2022	Changes reflect FDA's authorization of evusheld (tixagevimab and cilgavimab) (Dec 20).
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]**
	
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Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
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Lori Tishler, MD	Senior Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
	
Signature	**Date**