Clinical Policy Title:	bebtelovimab
Policy Number:	RxA.758
Drug(s) Applied:	Bebtelovimab
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of bebtelovimab 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;
- Who are at high risk for progression to severe COVID-19, including hospitalization or death, and;
- For whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

Limitations of authorized use:

Bebtelovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to this drug and regional variant frequency.

- Bebtelovimab is not authorized for use in patients who:
  - Are hospitalized due to COVID-19;
  - Require oxygen therapy and/or respiratory support due to COVID19;
  - Require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID19 related comorbidity.

Bebtelovimab is not approved for any use, including for use as treatment of COVID-19.

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Bebtelovimab	Treatment of COVID-19	Adult and pediatric patients (12 years of age and older weighing ≥ 40 kg): 175 mg as a single intravenous injection. Administer as soon as possible after the positive test for	175 mg

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
		SARS-CoV-2 and within 7 days of symptom onset.	

Dosage Forms

- Injection: 175 mg/2 mL (87.5 mg/mL) in a single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. COVID-19 (must meet all):

1. Diagnosis of mild-to-moderate coronavirus disease 2019 and meet the following (a, b, and c):
   a. Positive results of direct SARS-CoV-2 viral testing;
   b. Member is at high risk for progression to severe COVID-19, including hospitalization or death;
   c. Alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate;
2. Age ≥ 12 years of age;
3. Weight ≥ 40 kg;
4. Dose does not exceed 175 mg intravenously.

Approval Duration
Commercial: 7 days
Medicaid: 7 days

II. Continued Therapy Approval

A. COVID-19 (must meet all):

1. Re-authorization is not permitted. Bebtelovimab is not indicated for continuous use for this indication. Members must meet the initial approval criteria.

Approval Duration
Commercial: Not applicable
Medicaid: Not applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
EUA: Emergency Use Authorization

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
nirmarelvir/ritonavir (Paxlovid™)	Adults, children, and adolescents 12 years and older weighing ≥ 40 kg: 300 mg nirmatrelvir (two 150 mg tablets) and 100 mg ritonavir (one 100 mg tablet) with all 3 tablets taken together by mouth twice daily for 5 days.	≥ 40 kg: 600 mg nirmatrelvir and 200 mg ritonavir per day orally. < 40 kg: Use not authorized.
remdesivir (Veklury®)	Hospitalized patients: 200 mg as a single dose on day 1, followed by 100 mg once daily. Duration is generally 5 days or until hospital discharge; Non-hospitalized patients: 200 mg as a single dose on day 1, followed by 100 mg once daily on days 2 and 3. Initiate as soon as possible and within 7 days of symptom onset	200 mg intravenously on day 1, followed by 100 mg intravenously once daily.
molnupiravir	800 mg (four 200 mg capsules) by mouth every 12 hours for 5 days. Initiate treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.	1,600 mg per day orally

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions: Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of other SARS-CoV-2 monoclonal antibodies and could occur with administration of bebtelovimab.

References

1. US Food and Drug Administration (FDA). Fact sheet for healthcare providers: emergency use authorization for bebtelovimab; March 30, 2022. Available at: https://www.fda.gov/media/156152/download. Accessed April 18, 2022.
2. Bebtelovimab, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed April 18, 2022.
3. Clinical Pharmacology. Available at: http://www.clinicalkey.com. Accessed April 18, 2022.
4. Clinical management summary. National Institutes of Health. Available at:

https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/clinical-management-summary/?utm_source=site&utm_medium=home&utm_campaign=highlights. Accessed April 18, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	04/18/2022	04/18/2022