Preemptive policy: This is a P&T approved policy and can be used until it is superseded by an updated policy.

CENTENE® Corporation

Clinical Policy: Sotrovimab (VIR-7831)

Reference Number: CP.PHAR.541
Effective Date: 05.26.21
Last Review Date: 08.22
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sotrovimab (VIR-7831) is a recombinant human IgG1-kappa monoclonal antibody that binds to a conserved epitope on the spike protein receptor binding domain of SARS-CoV-2.

EUA Approved Indication(s)

Sotrovimab is authorized for emergency use for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (≥ 12 years of age and weighing ≥ 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Limitation(s) of authorized use:

- Sotrovimab is not authorized for treatment of mild to moderate COVID-19 in geographic regions where infection is likely to have been caused by non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to these drugs and regional variant frequency.
  - FDA's determination and any updates will be available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.
- Sotrovimab is not authorized for use in adults or pediatric patients:
  - who are hospitalized due to COVID-19, or;
  - who require oxygen therapy and/or respiratory support due to COVID-19, or;
  - who require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 in those on chronic oxygen.
- Benefit of treatment with sotrovimab has not been observed in patients hospitalized due to COVID-19. SARS-CoV-2 monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that sotrovimab is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. COVID-19 (must meet all)**:**

1. Diagnosis of COVID-19 infection via a positive viral test for SARS-CoV-2 within the last 5 days;
2. Member has one or more mild to moderate COVID-19 symptoms;
3. Member is within 7 days of symptom onset;
4. Prescribed by or in consultation with an infectious disease specialist;
5. Age ≥ 12 years;
6. Member's body weight is ≥ 40 kg;
7. Member meets one of the following criteria for being at high risk for progressing to severe COVID-19 and/or hospitalization (a-n):
   a. Age ≥ 65 years;
   b. Obesity or overweight (e.g., adults with body mass index (BMI) > 25, or if aged 12-17 years, have BMI ≥ 85th percentile for their age and gender based on CDC growth charts (https://www.cdc.gov/growthcharts/clinical_charts.htm);
   c. Pregnancy;
   d. Chronic kidney disease;
   e. Diabetes;
   f. Immunosuppressive disease;
   g. Currently receiving immunosuppressive treatment;
   h. Cardiovascular disease (including congenital heart disease);
   i. Hypertension;
   j. Chronic lung diseases (e.g., chronic obstructive pulmonary disease, asthma [moderate to severe], interstitial lung disease, cystic fibrosis, pulmonary hypertension);
   k. Sickle cell disease;
   l. Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies);
   m. Having a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]);
   n. Other medical conditions or factors that may place individual patients at high risk for progression to severe COVID-19 *(see Appendix D for additional information on medical conditions and factors associated with increased risk for progression to severe disease)*;
8. At the time of request, member meets all of the following (a, b, c, and d):
   a. Member is not hospitalized due to COVID-19;
   b. Member does not require oxygen therapy or respiratory support due to COVID-19;
   c. For members on chronic oxygen: member does not require an increase in baseline oxygen flow rate or respiratory support due to COVID-19;
   d. Member is not in a geographic region where infection is likely caused by non-susceptible COVID-19 variant based on variant susceptibility to this drug and regional variant frequency;

9. Sotrovimab will be administered to the member in a setting in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system, as necessary;
10. Dose does not exceed 500 mg one time.

Approval duration: One time

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. COVID-19 (must meet all)**:**

1. Re-authorization is not permitted.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMI: body mass index
COVID-19: coronavirus disease 2019
EUA: Emergency Use Authorization
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings [Pending]

- Contraindication(s): history of anaphylaxis to sotrovimab or to any of the excipients in the formulation
- Boxed warning(s): none

Appendix D: General Information

- Certain medical conditions or factors (for example, race or ethnicity) may place individual patients at high risk for progression to severe COVID-19. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient.
- Circulating SARS-CoV-2 viral variants may be associated with resistance to monoclonal antibodies. Healthcare providers should review the Antiviral Resistance information in Section 15 of the sotrovimab Fact Sheet for details regarding specific variants and resistance, and refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-surveillance.html) as well as information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.
- Per the sotrovimab EUA, sotrovimab 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 the ability to activate the emergency medical system, as necessary.
- Infusion-related reactions have been observed with administration of sotrovimab. Signs and symptoms of infusion-related reactions may include: fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrial fibrillation, sinus

tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vaso-vagal reactions (e.g., presyncope, syncope), dizziness, and diaphoresis.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COVID-19 Infection	500 mg IV one time	500 mg

VI. Product Availability

Sotrovimab vial: 500 mg

VII. References

1. Sotrovimab EUA letter of authorization. February 2022. Available at: https://www.fda.gov/media/149532/download. Accessed May 17, 2022.
2. Fact sheet for health care providers Emergency Use Authorization (EUA) of sotrovimab. Available at: https://www.fda.gov/media/149534/download. Accessed May 17, 2022.
3. ClinicalTrials.gov. VIR-7831 for the early treatment of COVID-19 in outpatients (COMET-ICE). Available at: https://www.clinicaltrials.gov/ct2/show/NCT04545060.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Clinical policy created pre-emptively	06.02.21	08.21
RT4: updated Limitations of Authorized Use to mirror FDA EUA fact sheet; revised that member is within 7 [instead of 10] days of symptom onset.	03.11.22	
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.17.22	08.22
Template changes applied to other diagnoses/indications.	10.05.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.