Drug Monograph

Drug Name: **Sotrovimab vial**
Drug Class: **COVID-19 Monoclonal Antibody**
Prepared For: MO HealthNet
Prepared By: Conduent

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose:	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
Dosage Forms:	Sotrovimab is available as a single-dose vial containing 500 mg of sotrovimab for intravenous injection.
Manufacturer:	Manufactured by: GlaxoSmithKline LLC, Philadelphia, PA 19112.
Summary of Findings:	Sotrovimab is authorized for use under an Emergency Use Authorization for the treatment of mild-to-moderate 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 progression to severe COVID-19, including hospitalization and death. The EUA was approved based on one Phase 1/2/3 on-going clinical trial, which at the time of interim analysis, enrolled 583 patients. An 85% reduction in the progression to severe COVID was observed in the sotrovimab-treated group compared to placebo.

Status Recommendation:	☐ Clinical Edit ☒ Open Access	☐ PA Required ☐ PDL
Type of PA Criteria:	☐ Appropriate Indications ☒ No PA Required	☐ Non-Preferred ☐ Preferred

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payers are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction [1,2]

Corona virus disease 2019 (COVID-19) is an infectious disease caused by a new coronavirus (SARS-CoV-2). As of July 1st, 2021, there have been a total of 33,496,454 cases of COVID-19 in the United States in which 602,401 of those cases have ended in death. COVID-19 affects all people differently, from mild to severe symptoms. COVID-19 is spread through respiratory droplets from an infected person with an incubation period of up to 14 days. People who have an underlying medication condition such as cardiovascular disease, diabetes, chronic respiratory disease and cancer are more likely to develop a serious illness. Symptoms include fever, chills, cough, shortness of breath or difficulty breathing, fatigue, new loss of taste or smell, headache, muscle and body aches, nausea, vomiting and diarrhea.

Dosage Form [3]

Sotrovimab is available as a single-dose vial containing 500 mg of sotrovimab for intravenous injection.

Manufacturer [3]

Manufactured by: GlaxoSmithKline LLC, Philadelphia, PA 19112.

Indication(s) [3]

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 older and weighting at least 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. Sotrovimab is not authorized for use in patients who are hospitalized due to COVID-19, who require oxygen therapy due to COVID-19, or who require an increase in baseline oxygen flow rate due to COVID-19.

Clinical Efficacy [3,4,5] (mechanism of action/pharmacology, comparative efficacy)

Sotrovimab is a recombinant human $IgG1_K$ monoclonal antibody that binds to a conserved epitope on the spike protein receptor binding domain of SARS-CoV-2. Sotrovimab inhibits an undefined step that occurs after virus attachment and prior to fusion of the viral and cell membranes.

Pharmacokinetics:

Absorption	NA
Metabolism	NA
Excretion	NA
Half-life	NA

Clinical Trials Experience

STUDY DESIGN (COMET-ICE, NCT04545060)	Ongoing, Phase 1/2/3, randomized, double-blind, placebo-controlled trial (N=583)
INCLUSION CRITERIA	• Participant must be aged 18 years or older AND at high risk of progression of COVID-19 or ≥ 55 years old • Participants must have a positive SARS-CoV-2 test result and oxygen saturation ≥94% on room air and have COVID-19 symptoms and be less than or equal to 5 days from onset of symptoms
EXCLUSION CRITERIA	• Currently hospitalized or judged by the investigator as likely to require hospitalization in the next 24 hours • Symptoms consistent with severe COVID-19 • Participants who, in the judgement of the investigator are likely to die in the next 7 days • Severely immunocompromised participants
TREATMENT REGIMEN	Patients were randomized to receive sotrovimab (n=291) 500 mg as a single infusion over 1 hour or placebo (n=292).
RESULTS	The primary outcome measure was progression of COVID-19 at day 29, defined as hospitalization for >24 hours for acute management of any illness or death from any cause. 1% of patients in the sotrovimab group vs 7% of the placebo group had progression of COVID-19. Progression was reduced by 85% in patients who received sotrovimab vs placebo (p=0.002).
SAFETY	Discussed in the Adverse Effects section below.

Contraindications [3,4]

- None

Warnings and Precautions [3,4]

- Hypersensitivity including anaphylaxis and infusion-related reactions have been observed with sotrovimab.
- Clinical worsening after SARS-CoV-2 monoclonal antibody administration has been reported.
- Limitations of benefit and potential for risk in patients with severe COVID-19: 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.

Adverse Effects [3,4]

- Clinical trials evaluating safety of sotrovimab are on-going. The most common treatment-emergent adverse events observed in the interim analysis of the sotrovimab group were rash (2%) and diarrhea (1%)

Drug Interactions [3,4]

- NA

Dosage and Administration [3,4]

- Recommended dose of sotrovimab in adults and pediatric patients (12 years of age and at least 40 kg) is a single IV infusion of 500 mg over 30 minutes
- Sotrovimab should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset.
- Sotrovimab must be diluted.

Cost

Generic Name	Brand Name	Manufacturer	Dose	Cost**/Dose
Sotrovimab	NA	GlaxoSmithKline	500 mg as a one-time dose	$2,100 (if not available from the National Stockpile)

** Wholesale Acquisition Cost

Conclusion

Sotrovimab, an antiviral monoclonal antibody, is authorized for use under an Emergency Use Authorization for the treatment of mild-to-moderate 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 progression to severe COVID-19, including hospitalization and death. The EUA was approved based on one Phase 1/2/3 on-going clinical trial, which at the time of interim analysis, enrolled 583 patients. An 85% reduction in the progression to severe COVID was observed in the sotrovimab-treated group compared to placebo. The most common adverse events were rash and diarrhea, but reporting is on-going.

Recommendation

MO HealthNet Division recommends Open Access status for this product.

References

1) COVID-19. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed July 1, 2021.
2) Coronavirus. World Health Organization. https://www.who.int/health-topics/coronavirus#tab=tab_1. Accessed July 1, 2021.
3) Product Information: Sotrovimab. 2021. GlaxoSmithKline LLC; Philadelphia, PA 19112.
4) Veklury: Drug Information. Lexi-Drugs. Wolters Kluwer Clinical Drug Information Inc.
5) A Randomized, Multi-center, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of Monoclonal Antibody VIR-7831 for the Early Treatment of Coronavirus Disease 2019 (COVID-19) in Non-hospitalized Patients. NCT 04545060. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04545060?term=04545060&draw=2&rank=1. Accessed July 1, 2021.

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