GSK Co-pay Program for Sotrovimab Patients
For Emergency Use Authorization

Sotrovimab is not FDA-approved and is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of sotrovimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About the Co-pay Program

- The **GSK Co-pay Program for Sotrovimab Patients** helps eligible commercial patients with their out-of-pocket costs for sotrovimab and the cost of administration
- If eligible, patients may receive assistance for sotrovimab of up to a maximum of $2000 **AND** may receive up to $100 for the cost of administration*†

*Residents of Massachusetts, Minnesota, or Rhode Island are not eligible for reimbursement of administrative fees.
†Eligibility restrictions and program maximums apply. For more eligibility information and the complete Program Terms and Conditions, visit GSKCopayPrograms.com.

AUTHORIZATION FOR USE

Sotrovimab is authorized for use under an Emergency Use Authorization (EUA) 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 progression to severe COVID-19, including hospitalization or death.

LIMITATIONS OF AUTHORIZED USE

- Sotrovimab is not authorized 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).
- 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

There are limited clinical data available for sotrovimab. Serious and unexpected adverse events may occur that have not been previously reported with sotrovimab use.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of sotrovimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care.

Please see additional Important Safety Information for sotrovimab throughout. Please click here for the most current Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents, and Caregivers, and FDA Letter of Authorization for sotrovimab.

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Getting Started

Patients who have incurred out-of-pocket costs required under their health plan benefit should follow these 4 steps to apply for co-pay assistance:

1. Pay the out-of-pocket costs required under their health plan benefit
2. Confirm eligibility as outlined on page 1 of the **GSK Co-pay Program Enrollment Form**
3. Complete the **GSK Co-pay Program Enrollment Form**, available for download from sotrovimab.com or by calling the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684)
4. Mail or fax the form along with the Explanation(s) of Benefits (EOB) provided by their insurance company, payment receipt(s), and copies of their insurance card(s)

If approved, patients will receive a check in approximately 7-10 business days, sent directly to the address indicated on the enrollment form.

Online enrollment will be available in the coming months at sotrovimab.com

GSK COVID Contact Center

1-866-GSK-COVID (866-475-2684), 9 AM - 6 PM ET, Mon-Fri (excluding holidays)

IMPORTANT SAFETY INFORMATION (*cont'd*)

WARNINGS AND PRECAUTIONS (*cont'd*)

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions (*cont'd*)

Infusion-related reactions, occurring during the infusion and up to 24 hours after the infusion, have been observed with administration of sotrovimab. These reactions may be severe or life threatening.

Signs and symptoms of infusion-related reactions may include: fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (eg, 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 (eg, pre-syncope, syncope), dizziness and diaphoresis.

Consider slowing or stopping the infusion and administer appropriate medications and/or supportive care if an infusion-related reaction occurs.

Hypersensitivity reactions occurring more than 24 hours after the infusion have also been reported with the use of SARS-CoV-2 monoclonal antibodies under Emergency Use Authorization.

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Co-pay Program Eligibility

Only patients under commercial health plans are eligible for the GSK Co-pay Program for Sotrovimab Patients. Patients enrolled in government-funded programs, such as Medicare, Medicaid, VA, or Tricare, are not eligible for the GSK Co-pay Program for Sotrovimab Patients. Medicare-eligible patients who are enrolled in a government-subsidized retiree prescription drug benefit plan or an employer group waiver health plan are also ineligible for the co-pay program. For full Program Terms & Conditions please visit GSKCopayPrograms.com.

Please call the GSK COVID Contact Center at 1-866-475-2684 for information about the GSK Co-pay Program for Sotrovimab Patients, including patient eligibility.

IMPORTANT SAFETY INFORMATION (*cont'd*)

WARNINGS AND PRECAUTIONS (*cont'd*)

Clinical Worsening After SARS-CoV-2 Monoclonal Antibody Administration

Clinical worsening of COVID-19 after administration of SARS-CoV-2 monoclonal antibody treatment has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (eg, atrial fibrillation, tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to SARS-CoV-2 monoclonal antibody use or were due to progression of COVID-19.

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. Therefore, sotrovimab is not authorized 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.

ADVERSE EVENTS

The most common treatment-emergent adverse events observed in the sotrovimab treatment group in COMET-ICE were rash (2%) and diarrhea (1%), all of which were Grade 1 (mild) or Grade 2 (moderate). No other treatment-emergent adverse events were reported at a higher rate with sotrovimab compared to placebo.

Reporting Adverse Events:

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all medication errors and serious adverse events potentially related to sotrovimab within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "Sotrovimab use for COVID-19 under Emergency Use Authorization (EUA)" in the description section of the report.

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IMPORTANT SAFETY INFORMATION (*cont'd*)

ADVERSE EVENTS (*cont'd*)

Reporting Adverse Events *(cont'd)*:

Submit adverse event reports to FDA MedWatch using one of the following methods:

- Complete and submit the report online at http://www.fda.gov/medwatch/report.htm, or
- Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by: Mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or Call 1-800-FDA-1088 to request a reporting form.

In addition, please provide a copy of all FDA MedWatch forms to: GlaxoSmithKline, Global Safety; Fax: 919-287-2902; Email: WW.GSKAEReportingUS@gsk.com; Or call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684) to report adverse events.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcome. Sotrovimab should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

Lactation

There are no available data on the presence of sotrovimab in human milk, the effects on the breastfed infant, or the effects on milk production. Individuals with COVID-19 who are breastfeeding should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Please see additional Important Safety Information for sotrovimab throughout. Please click here for the most current Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents, and Caregivers, and FDA Letter of Authorization for sotrovimab.

831BROC210002 July 2021
Produced in USA.