Access & Reimbursement Information for Sotrovimab

June 2021

AUTHORIZED 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.

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.

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

Contents

Important information for healthcare providers

The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, the FDA has issued an EUA, as requested by GlaxoSmithKline, for the unapproved product, sotrovimab, 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 or death. As a healthcare provider, you must comply with the mandatory requirements of this EUA.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that sotrovimab may be effective for the treatment of mild-to-moderate COVID-19 in certain at-risk patients as specified in the Fact Sheet for Healthcare Providers. You may be contacted and asked to provide information to help with the assessment of the use of the product during this emergency.

This EUA for sotrovimab will end when the Secretary determines that the circumstances justify the EUA no longer exist or when there is a change in the approval status of the product such that an EUA may no longer be needed.

Population for treatment and requirements for administration under EUA

Population for treatment

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.

This patient population corresponds to those in stages 1 and 2 in the WHO Ordinal Scale for Clinical Improvement.[1]

Patients with **mild** COVID-19 illness may exhibit a variety of signs and symptoms (eg, fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell). They do not have shortness of breath, dyspnea, or abnormal chest imaging. **Moderate** COVID-19 illness is defined as evidence of lower respiratory disease during clinical assessment or imaging and an oxygen saturation (SpO_2) ≥94% on room air at sea level.[2]

Sotrovimab should be administered by intravenous (IV) infusion as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset. Please see Dosage and Administration section within the Fact Sheet for Healthcare Providers for more information.

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.

References: 1. WHO R&D Blueprint. Novel coronavirus: COVID-19 therapeutic trial synopsis. https://www.who.int/blueprint/priority-diseases/key-action/COVID-19_Treatment_Trial_Design_Master_Protocol_synopsis_Final_18022020.pdf. Accessed May 14, 2021. **2.** National Institutes of Health. Clinical Spectrum of SARS-CoV-2 Infection. https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/. Accessed May 14, 2021.

Population for treatment and requirements for administration under EUA (*cont'd*)

Population for treatment (*cont'd*)

Having at least ONE of the following may place patients at higher risk for progression to severe COVID-19:

- ☐ Older age (for example, ≥65 years of age)
- ☐ Obesity or being overweight (for example, adults with BMI >25 kg/m^2, or if 12 to 17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- ☐ Pregnancy
- ☐ Chronic kidney disease
- ☐ Diabetes
- ☐ Immunosuppressive disease or immunosuppressive treatment
- ☐ Cardiovascular disease (including congenital heart disease) or hypertension
- ☐ Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- ☐ Sickle cell disease
- ☐ Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- ☐ Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19])

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of sotrovimab under the EUA is not limited to the medical conditions or factors listed above. For additional information on these medical conditions and factors, see the CDC website. 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 Fact Sheet for Healthcare Providers for details regarding specific variants and resistance, and refer to the CDC website as well as information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

Population for treatment and requirements for administration under EUA (*cont'd*)

Mandatory requirements for administration of sotrovimab under EUA

In order to mitigate the risks of using this unapproved product under the EUA and to optimize the potential benefit of sotrovimab, the following steps are required. Use of sotrovimab under this EUA is limited to the following (all requirements **must** be met):

1. 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 or death.

2. As the healthcare provider, communicate to your patient or parent/caregiver information consistent with the Fact Sheet for Patients, Parents, and Caregivers prior to the patient receiving sotrovimab. Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:
   - **a.** given the Fact Sheet for Patients, Parents, and Caregivers,
   - **b.** informed of alternatives to receiving authorized sotrovimab, and
   - **c.** informed that sotrovimab is an unapproved drug that is authorized for use under this EUA.

3. Patients with known hypersensitivity to any ingredient of sotrovimab must not receive sotrovimab.

4. 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.

- **Submit adverse event reports to FDA MedWatch using one of the following methods:**
  - Complete and submit the report online at fda.gov/medwatch/report.htm, OR
  - Complete and submit a postage-paid FDA Form 3500 (available at 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.
  - Submitted reports should include in the field name "Describe Event, Problem, or Product Use/Medication Error" the statement **"Sotrovimab use for COVID-19 under Emergency Use Authorization (EUA)."**

***Serious adverse events that must be reported to FDA MedWatch are defined as:**

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

Population for treatment and requirements for administration under EUA (*cont'd*)

Mandatory requirements for administration of sotrovimab under EUA (*cont'd*)

5. The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of sotrovimab.

6. Other reporting requirements:
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.

See Sections 8 and 9 of the Fact Sheet for Healthcare Providers for reporting requirements.

Approved available alternatives

There is no adequate, approved, and available alternative to sotrovimab 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 or death. Additional information on COVID-19 treatments can be found at covid19treatmentguidelines.nih.gov/. The healthcare provider should visit clinicaltrials.gov/ to determine whether the patient may be eligible for enrollment in a clinical trial.

Contact Information

For additional information, visit sotrovimabinfo.com.
If you have questions, please contact 1-866-GSK-COVID (866-475-2684).

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.

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.

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.

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.

Availability, ordering, and support

Product availability

Sotrovimab is only available through AmerisourceBergen during the Emergency Use Authorization period approved by the FDA for infusion in appropriate patients as defined in the Sotrovimab Fact Sheet for Healthcare Providers.

Ordering from AmerisourceBergen

Sotrovimab is available for customers to purchase directly with AmerisourceBergen as the sole Specialty Distributor during the Emergency Use Authorization period. Customers can purchase directly by:

- Placing purchase order through the customer ordering portal at abcorder.amerisourcebergen.com
- Calling AmerisourceBergen Customer Service at 1-800-746-6273 Monday through Thursday 7:00 AM to 6:30 PM, and Friday 7:00 AM to 6:00 PM CT or
- Placing the purchase order through any of the AmerisourceBergen ordering platforms. Customers may search by product name, material item number, or NDC. For new customers please call AmerisourceBergen Customer Service or email c19therapies@amerisourcebergen.com

The sotrovimab material item number is **10258949**. Please include the item number when placing your order.

Please allow 1 to 2 days for product arrival following order placement. For new customers, please allow up to 2 days for the initial order following receipt of the required customer documentation. For any additional information regarding orders, product availability, or access/log-in information, please email c19therapies@amerisourcebergen.com or contact AmerisourceBergen's Customer Service Department.

Other available AmerisourceBergen customer service contacts

Emails	Phone numbers
• service@asdhealthcare.com • service@besse.com	ASD: 1-800-746-6273 Besse: 1-800-543-2111 Oncology Supply: 1-800-633-7555

Sites will be required to[1]:

- Provide AmerisourceBergen with a board of pharmacy license or physician letter of authorization if not already on file
- Attest to their designated class of trade and that they will administer sotrovimab according to terms of the FDA-issued EUA

Additional information

- Product availability may be subject to established criteria for minimum and maximum amounts based on previous orders and utilization history
- GSK and AmerisourceBergen will ensure that the authorized labeling (ie, Fact Sheets) will accompany the authorized sotrovimab. Please see most current Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents, and Caregivers
- GSK and AmerisourceBergen will ensure that appropriate storage and cold chain is maintained until the product is delivered to healthcare facilities and/or healthcare providers
- GSK and AmerisourceBergen will ensure that the terms of the sotrovimab EUA are made available to all relevant stakeholders (eg, U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving authorized sotrovimab
- GSK will provide all relevant stakeholders a copy of the FDA Letter of Authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (ie, Fact Sheets)

Reference: 1. Overview of Direct Order Process for COVID-19 Therapeutics, Public Health Emergency. https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf. Accessed May 14, 2021.

How supplied/dosage form, packaging, storage and handling

How supplied/dosage form and packaging

Drug Name	Sotrovimab
Strength	500 mg/8 mL (62.5 mg/mL)
Formulation	Sterile, preservative-free, clear, colorless or yellow to brown solution in a single-dose vial
Quantity	1
NDC	0173-0901-86

Sotrovimab is supplied in a carton containing one single-dose glass vial with a rubber vial stopper (not made with natural rubber latex) and a flip-off cap.

Dosage

The dosage of sotrovimab 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) is a single IV infusion of 500 mg. 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 and administered as a single intravenous infusion over 30 minutes.

Sotrovimab may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

Dosage Adjustment in Specific Populations

No dosage adjustment is recommended based on renal impairment, during pregnancy, while lactating, or for geriatric patients. Sotrovimab is not authorized for patients under 12 years of age or pediatric patients weighing less than 40 kg. See Section 11 of the Fact Sheet for Healthcare Providers.

How supplied/dosage form, packaging, storage and handling (*cont'd*)

Storage and handling

Storage Prior to Dilution

- Store unopened vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton. Do not freeze or shake. Protect from light.

Storage After Dilution

- The solution of sotrovimab in the vial is preservative-free and requires dilution prior to administration. The diluted solution of sotrovimab should be administered immediately. If immediate administration is not possible, store the diluted infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) including transportation and infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 15 minutes prior to administration.
- Sotrovimab is preservative-free. Discard unused portion.

Coding and reimbursement

The following information is for informational purposes only and is not intended to guarantee or provide reimbursement or legal advice. This information is subject to change without notice. Payer coding requirements vary, and may change over time. Please check with the patient's health plan to confirm payer-specific requirements.

ICD-10-CM Diagnosis Code

Code[1]	Description	Notes
U07.1	COVID-19	A confirmed diagnosis of COVID-19 as documented by the provider or documentation of a confirmed diagnosis with a positive COVID-19 test

Level II HCPCS Code

Code[2]	Description
Q0247 (for product)	Injection, sotrovimab, 500 mg
M0247 (for administration)	Intravenous infusion, sotrovimab, includes infusion and post-administration monitoring
M0248 (for administration)	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

NDC Number

Code	Concentration	Package size
0173-0901-86	500 mg/8 mL	1 vial per carton

*WAC[3]**	
Sotrovimab per vial	$2100

Payment allowances and effective dates for COVID-19 monoclonal antibodies during the public health emergency[2]

Code	CPT Short Descriptor	Labeler Name	Vaccine/Procedure Name	Payment Allowance	Effective Dates
Q0247	Sotrovimab	GSK	Injection, sotrovimab, 500 mg	$2394	05/26/2021
M0247	Sotrovimab	GSK	Intravenous infusion, sotrovimab, includes infusion and post-administration monitoring	$450	05/26/2021
M0248	Sotrovimab	GSK	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	$750	05/26/2021

*WAC is the listed price to wholesalers not including prompt pay, stocking or distribution allowances, or other discounts, rebates, or chargebacks. Listed price may not represent prices charged to other customers.

HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification; NDC = National Drug Codes; WAC = Wholesale Acquisition Cost.

References: 1. Centers for Disease Control and Prevention. ICD-10-CM Official Guidelines for Coding and Reporting FY 2021 (October 1, 2020 - September 30, 2021). Chapter 1: Certain Infectious and Parasitic Diseases, U07.1. https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2021.pdf. Accessed May 14, 2021. **2.** Centers for Medicare & Medicaid Services. Medicare Part B Payment for COVID-19 Vaccines and Certain Monoclonal Antibodies during the Public Health Emergency. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies. Accessed June 10, 2021. **3.** Sotrovimab WAC Pricing. GSK. May 2021. https://assets.gskstatic.com/pharma/us/veeva/SOTROVIMAB-WAC.pdf. Accessed June 15, 2021.

Coding and reimbursement (*cont'd*)
Additional considerations

Medicare[1]

The Centers for Medicare & Medicaid Services has released a set of toolkits for providers, states, and insurers to help the healthcare system prepare and assist in swiftly administering monoclonal antibodies once they become available during the public health emergency. These resources are designed to increase the number of providers that can administer the products and ensure adequate reimbursement for administration in Medicare. Medicare will publish codes and rates for administering new products as the FDA approves or authorizes each product. For more information on payment allowances and other related information for these products, review the COVID-19 provider toolkit.

Medicaid/CHIP[2]

States and the federal government fund Medicaid and the Children's Health Insurance Program (CHIP) jointly. The programs are administered by states according to federal requirements and comprehensive benefits offered to people who are determined eligible by states. For information on benefits offered in your state, where to access services, and how to apply for coverage, visit medicaid.gov. For additional information on the coverage of monoclonal antibody products to treat COVID-19, visit CMS.gov.

Uninsured[3]

The Health Resource and Service Administration (HRSA) is providing support to healthcare providers fighting the COVID-19 pandemic through the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured Program. This program provides reimbursements on a rolling basis directly to eligible providers for claims that are attributed to the testing, treatment, and vaccine administration for COVID-19 for uninsured individuals. For more information, see FAQs for COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment and Vaccine Administration.

Reimbursement from commercial payers

Commercial payer reimbursement for sotrovimab will vary based on the payer, hospital system, region, and payer policy during the public health emergency. Reimbursement and administration for sotrovimab will be based on the patient's health plan, coverage policy, and the provider's fee schedule. Please contact the reimbursement department for the patient's payer or health system with specific questions regarding billing and coverage.

Additional Resources for coding and reimbursement

Medicare Monoclonal Antibody COVID-19 Infusion Program Instructions
COVID-19 NDC-HCPCS Crosswalk
2021 Geographically-adjusted Payment Rates for Monoclonal Antibody Administration (for Providers & Suppliers Paid MPFS-Adjusted Rates)

References: 1. Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction. CMS.gov. https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf. Accessed May 14, 2021. **2.** The Children's Health Insurance Program (CHIP). Medicaid.gov. https://www.medicaid.gov/chip/index.html. Accessed May 14, 2021. **3.** COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured. Health Resources & Services Administration. https://www.hrsa.gov/CovidUninsuredClaim. Accessed May 14, 2021.

Resource links

You can find more information about monoclonal antibody drugs, including sotrovimab, from the CDC, state health departments, and the following resources:

Fact Sheet for Healthcare Providers for sotrovimab

Fact Sheet for Patients, Parents, and Caregivers for sotrovimab – English

Fact Sheet for Patients, Parents, and Caregivers for sotrovimab – Spanish

FDA Letter of Authorization for sotrovimab

CombatCOVID.HHS.gov

Coronavirus Prevention Network website

CDC website

Contact information

Customer support

GSK Customer Support and Resources

GSK has established a dedicated team to help customers with medical, product, and disease state information, as well as reimbursement support and other resources, and to provide information regarding clinical trial programs. Customers can call the GSK COVID Contact Center directly Monday through Friday 9 AM to 6 PM ET at 1-866-GSK-COVID (866-475-2684) or go to contactus.gsk.com/callback/covid.html.

HCP and healthcare settings should report all product quality claims directly to the GSK COVID Contact Center. For more information regarding GSK's Product Replacement Policies, please call the GSK Pharma Service Center at 1-800-877-1158 option 4 Monday through Friday 8 AM to 6 PM ET.

Co-pay assistance

GSK may be able to help eligible commercially insured patients with their out-of-pocket costs. Subject to program rules and limitations. Please call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684) for questions regarding the co-pay program eligibility requirements and find out how to enroll.

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