

# Sotrovimab

# Infusion Playbook

Last updated: 1/13/22

## Physical space

- Minimum conditions
  - Physical barriers between other patients with a closing door
  - Ease of access to a medical provider
  - Access
- Ideal conditions
  - Room with negative pressure capabilities
  - Higher air exchange rates
  - Direct external access to space

## Supply needs

- Infusion supplies (IV start kits, tubing *with a filter*, locks)
- IV pump
- 0.9% saline flushes
- Simple dressing (bandaid/2x2/tape)
- Pulse oximeter
- Blood pressure cuff
- Stethoscope
- Thermometer
- Documentation capabilities

**Staffing:** RN capable of performing and monitoring an infusion patient on Isolation Precautions

# Ordering **Sotrovimab** monoclonal antibodies in the *ER*

- This is an open orderable drug to all providers
  - Currently ordered through paper documentation, available on toolkit
    - “Sotrovimab 500mg IV infusion x 1”
      - When ordered in the **ER** – paper order to be faxed to facilities’ pharmacy with a call to pharmacy to alert staff on when drug should be made.
      - **Option to order Sotrovimab as an intravenous infusion on paper order form**
      - Patient EUA fact sheet to be given to all patients as well as written documentation of consent, please see documentation slide
- Currently housed at CPH pharmacy with capacity for drug to be couriered if need be (please call CPH pharmacy for drug transportation guidance, requires refrigeration)

GH pharmacy: 7a-5p week days, closed on weekends and holidays

MH pharmacy: 8a – 4p week days, 8a-1p weekends

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Ordering Sotrovimab monoclonal antibodies

## *OUTPATIENT* at CPH

- This is an open orderable drug to all providers
  - Currently ordered through paper documentation, available on toolkit
    - “Sotrovimab 500mg IV infusion x 1”
      1. Ordering provider to document discussion regarding risks/benefits with patient and answer any clinical questions on order form
      2. Paper order to be faxed to CPH pharmacy 315-261-5513
      3. Orders will be reviewed by pharmacy for eligibility and to confirm drug availability
      4. Patient will be contacted directly with their scheduled appointment and receive appointment day instructions
      5. RN to confirm all patient’s questions have been answered, provide patient EUA fact sheet, review and document informed consent for an EUA drug
- Currently housed at CPH pharmacy with capacity for drug to be couriered if need be (please call CPH pharmacy for drug transportation guidance, requires refrigeration)

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Ordering Sotrovimab monoclonal antibodies

## *OUTPATIENT* at **MH**

- This is an open orderable drug to all providers
  - Currently ordered through paper documentation, available on toolkit
    - “Sotrovimab 500mg IV infusion x 1”
      1. Ordering provider to document discussion regarding risks/benefits with patient and answer any clinical questions (TE, virtual visit)
      2. Paper order to be faxed to MH pharmacy
      3. Call 315-769-4211 (MH infusion suite)
      4. Infusion nurse will confirm eligibility and call Pharmacy to confirm drug availability
      5. Infusion nurse will schedule infusion and contact ordering provider with date/time
      6. Provider will notify the patient of their scheduled infusion
      7. RN to confirm all patient’s questions have been answered, provide patient EUA fact sheet, review and document informed consent for an EUA drug
- Currently housed at CPH pharmacy with capacity for drug to be couriered if need be (please call CPH pharmacy for drug transportation guidance, requires refrigeration)

MH pharmacy: 8a – 4p week days, 8a-1p weekends, fax #315-769-4630

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Ordering Sotrovimab monoclonal antibodies

## *OUTPATIENT* at GH

- This is an open orderable drug to all providers (if ordering provider does not have active privileges, order will be signed by GH Hospitalist)
  - Currently ordered through paper documentation, available on toolkit
    - “Sotrovimab 500mg IV infusion x 1”
      1. Ordering provider to document discussion regarding risks/benefits with patient and answer any clinical questions (ie TE, virtual visit)
      2. Paper order to be faxed to GH ED 315-261-5738
      3. Call GH ER to discuss drug availability and scheduling
      4. Nurse will confirm eligibility and check ED fridge for Sotrovimab kit
      5. Nurse will schedule infusion and contact patient with date/time of appointment
      6. RN to confirm all patient’s questions have been answered, provide patient EUA fact sheet, review and document informed consent for an EUA drug
      7. Prior to giving, contact nursing supervisor. They must text CPH Pharmacy to let them know it is being used. CPH pharmacy will report to DOH on our behalf, and will also automatically send a replacement within roughly 24 hours. The phone number is listed in the kit instructions.

\*\* As pharmacy is not open on weekends, the courier will give replacement vial to nursing supervisor if it arrives on a Saturday/Sunday. It will need to be placed in the night cabinet refrigerator for pharmacy to restock. In the event that the ED runs out over the weekend, please check the night cabinet refrigerator. Paperwork kits will be made up in the night cabinet, so the supervisor will then just need to grab the kit and the vial from fridge. M-F pharmacy will be restocking to the ED fridge.\*\*

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Clinical Information - Contraindication/Unauthorized

- History of anaphylaxis to Sotrovimab or any of its excipients
- **Meets clinical criteria for hospitalization or anticipated to be hospitalized with COVID-19**
- Require O2 beyond baseline
- *\*Pregnancy/Lactation — there is insufficient data to evaluate drug risk should only be used if the potential benefits outweigh the potential risks for mother and child (pregnancy does not preclude use of Sotrovimab but should be considered with caution)*

# Clinical Information – Eligibility Criteria

*During a product shortage, severity criteria and symptom onset will be used to triage scheduling of patient for infusion*

- Documented COVID positive test
- Age 18+ (or 12+ if >40kg in clinical coordination with pediatrician)
- Documented positive test for SARS-COV-2 within the last **7 days**
- High risk criteria
  - Non-white
  - BMI 25+
  - Diabetes
  - CKD
  - Immunosuppressive condition/treatment
  - Cardiovascular disease
  - Hypertension
  - Chronic lung disease Medical technology dependence (ie tracheostomy, gastrostomy, etc)
  - Neurodevelopmental disorders
  - Sickle cell disease
  - \*Pregnancy
    - Limited data available to adequately assess drug related risk, clinical judgement should be used to assess risk benefit in pregnancy

*Above are the minimum eligibility criteria, prioritization for verifying orders may vary based on product availability please see next slide for current inclusion criteria. If patient is not going to be scheduled, ordering office will be contacted and informed.*

## Prioritization for outpatient anti-SARS-CoV-2-specific therapies

Priority tier	Risk group description
1	<ul style="list-style-type: none"><li>Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to underlying conditions, regardless of vaccine status (refer to immunocompromising conditions below*)</li><li><b>or</b></li><li>Unvaccinated individuals at the highest risk of severe disease (age <math>\geq 75</math> years or age <math>\geq 65</math> years with additional risk factors).</li></ul>
2	<ul style="list-style-type: none"><li>Unvaccinated individuals at risk of severe disease not included in Tier 1 (age <math>\geq 65</math> years or age <math>&lt; 65</math> years with clinical risk factors).</li></ul>
3	<ul style="list-style-type: none"><li>Vaccinated individuals at high risk of severe disease (age <math>\geq 75</math> years or age <math>\geq 65</math> years with clinical risk factors).</li></ul> <p><b>Note:</b> Vaccinated individuals who have <b>not</b> received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment over those who have received a booster.</p>
4	<ul style="list-style-type: none"><li>Vaccinated individuals at risk of severe disease (age <math>\geq 65</math> years or age <math>&lt; 65</math> with clinical risk factors).</li></ul> <p><b>Note:</b> Vaccinated individuals who have <b>not</b> received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment over those who have received a booster.</p>

The NIH COVID-19 Treatment Guideline Panel prioritizes risk groups for anti-SARS-CoV-2-specific therapy based on 4 key elements: age, vaccination status, immune status, and clinical risk factors. The groups are listed by tier in descending order of priority.

\* If anti-SARS-CoV-2-specific therapy cannot be provided to all moderately to severely immunocompromised individuals, the Panel suggests prioritizing their use for those who are least likely to mount an adequate response to COVID-19 vaccination or SARS-CoV-2 infection and who are at risk for severe outcomes, including (but not limited to) the following: patients who are within 1 year of receiving B-cell depleting therapies (eg, rituximab, ocrelizumab, ofatumumab, alemtuzumab); patients receiving Bruton tyrosine kinase inhibitors; chimeric antigen receptor T cell recipients; post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication; patients with hematologic malignancies who are on active therapy; lung transplant recipients; patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant); solid-organ transplant recipients with recent treatment for acute rejection with T- or B-cell-depleting agents; patients with severe combined immunodeficiencies; patients with untreated HIV who have a CD4 T lymphocyte cell count  $< 50$  cells/mm<sup>3</sup>. If supplies are extremely limited, the Panel suggests prioritizing those who are more severely immunocompromised (refer to above list) and who also have additional risk factors for severe disease for the outpatient therapies.

# Clinical Information – Adverse Reactions

- Allergic reactions
- Worsening symptoms after treatment
- Infusion site reactions
  - Pain
  - Burning
  - Bleeding
  - Infusion site infection
- May reduce immune function/increase risk for other infections
- May negatively impact response to SARS-COV-2 and guidance on administration of vaccination after infusion should be based on [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#antiviral-therapy](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#antiviral-therapy)

# Documentation Criteria

- Date of first positive SARS-COV-2 test
- Which high risk criteria are met
- Documentation that patient does not meet inpatient criteria and does not have additional O2 demand beyond baseline
- Standard EUA drug consent form (performed on date of service) to be included in chart
- Documentation of drug order (scan of paper documentation or written documentation of drug dose and infusion rate)
- *\*For outpatient providers: documentation of conversation regarding risk/benefits of using EUA drug*

# ***Sotrovimab***

Sotrovimab 500mg

single IV infusion

Cited from GSK administration recommendations

Sotrovimab infusion solution should be administered by a qualified healthcare professional.

Materials for infusion:

Polyvinyl chloride (PVC) or polyolefin (PO) infusion set, and

Use of a 0.2 micron polyethersulfone (PES) filter is strongly recommended.

- Attach the infusion set to the IV bag using standard bore tubing.
- Prime the infusion set.
- Administer the entire infusion solution in the bag **over 30 minutes**. Due to potential overfill of prefilled saline bags, the entire infusion solution in the bag should be administered to avoid underdosage.
- Do not administer as an IV push or bolus.
- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of sotrovimab with IV solutions and medications other than 0.9% Sodium Chloride Injection and 5% Dextrose Injection is not known.
- Once infusion is complete, **flush the tubing** with 0.9% Sodium Chloride or 5% Dextrose to ensure delivery of the required dose.
- If the infusion must be discontinued due to an infusion reaction, discard unused product.

Sotrovimab guidance recommended **1 HOUR OBSERVATION PERIOD**

- EUA Fact Sheet for PATIENTS
  - [SOTROVIMAB-PATIENT-FACT-SHEET.PDF](#)
- EUA Fact Sheet for PROVIDERS
  - [SOTROVIMAB-EUA.PDF](#)
- A consent form written consent needed
  - Document in toolkit

# Warnings

- Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions
  - Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of Sotrovimab. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy.
- Signs & Symptoms of Infusion-Related Reactions:
  - Fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrial fibrillation, tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions (e.g., pre-syncope, syncope), dizziness, and diaphoresis