Anti-COVID-19 Monoclonal Antibody (MAb) Order Packet
Treatment for COVID-19 Case

Ordering process:

1. Complete Patient Demographics information below.
2. Confirm patient's eligibility on MAb Physician Attestation form.
3. Review with patient the potential risks and benefits of MAb treatment as outlined in the consent form. Affirm the patient's desire to proceed. Provider signs the consent form, and has another person sign as witness to patient's verbal consent.
4. Fax the following materials to 724-543-8855. Any discrepancies will be reviewed by physician leadership.
    a. Order Packet (including Patient Demographics, Eligibility Form, and Order Set)
    b. Recent Demographics/Insurance Information
    c. Copy of positive COVID-19 test **(antigen or RT-PCR performed at a medical facility. No home tests)**
    d. Signed COVID-19 MAb therapy consent form
    e. List of current medications.
    f. H&P or most recent clinic note.
5. If approved for infusion, the ACMH Monoclonal Clinic Coordinator will contact provider to schedule patient.
6. At appointment, patient will receive required materials on drug.
7. If patient is hypoxic at arrival to appointment, MAb will NOT be administered.
8. Patient will be infused with MAb over 30 minutes, and he/she must stay for an hour of observation after infusion complete.

Patient Demographics

Patient Name: _____ Date of Birth: _____

Social Security Number: _____

Patient Phone Number: _____

Date of onset of COVID-19 symptoms: _____ (must be within 7 days of infusion)

Date of positive COVID-19 test: _____ (No home tests permitted)

Ordering Physician Name: _____ (Must be MD or DO - no APP orders permitted)

Physician Phone Number: _____

NUR 3859-LV
Org. 10/21; Rev 1/22

ACMH | Hospital

Patient Label

CONSENT TO ADMINISTRATION OF ANTI-COVID-19 MAb

I, _____ consent to the administration of monoclonal antibody (MAb) therapy for coronavirus disease 2019 (COVID-19), with Sotrovimab, casirivimab/imdevimab or bamlanivumab/etesevimab. These have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) for the treatment of mild to moderate COVID-19 in people at high risk of progressing to severe disease and/or hospitalization. No treatment will be administered if hypoxia (low oxygen levels) are present at the time of therapy appointment. The drug is administered intravenously by placing a small needle or catheter into a vein and slowly injecting the solution over an hour. You may or may not experience the listed side effects associated with these treatments. There may also be unforeseen complications, injury, or even death from unknown causes associated with this administration. Risks/complications involved: hypersensitivity including allergic reactions and infusion related reactions - fever, chills, nausea/vomiting, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness. Likelihood of success: I understand that there have been no guarantees made to me that this medication would improve my condition (This area is specific to the patient) _____
_____

Your signature below constitutes your acknowledgment: (1) that you have read and agreed to the foregoing, (2) that the associated risks and possible side effects have been explained to you and that you have all the information that you desire, (3) you have been provided the "Fact Sheet for Patients, Parents and Caregivers" prior to receiving therapy, (4) agree to remain for an hour of observation after infusion is completed, and (5) agree to not receive any vaccine against SARSCoV-2 for at least 90 days after monoclonal antibody therapy. I have been given ample time to ask questions regarding this administration, risks and alternatives with my physician and they have been answered.

Patient: _____ _____/_____
(Or person authorized to consent for patient) Date Time

_____ _____ _____/_____
Relationship to Patient Witness Date Time

If verbal/telephone consent,

2nd witness is required: _____ _____/_____
2 nd witness Date Time

I have explained to the patient, parent (guardian or representative) the nature of the above procedure or treatment as well as the reasonably anticipated risks, complications and alternatives to such treatment. The foregoing consent was read, discussed, and signed in my presence, and, in my opinion, the person(s) so signing did so freely with full knowledge and understanding.

_____ _____/_____
Physician Signature Date Time

NUR 3858 LV
Orig 10/2021; Rev 1/2022

ACMH HOSPITAL
One Nolte Drive
Kittanning, PA 16201

COVID 19 Outpatient Monoclonal Therapy Order Set ACMH

Authorization is given to the pharmacy to dispense and to the nurse to administer the generic or chemical equivalent unless otherwise ordered.

DATE	TIME	
		Requirements: Symptoms of COVID 19 for less than 7 days; Positive COVID-19 test (antigen of PCR)
		12 years of age or older, does not require oxygen therapy due to COVID-19 or an increase in baseline oxygen
		flow rate due to COVID-19 on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity
		and high risk for progression of severe COVID-19
		☐ **YES** ☐ **NO**
		Date of Symptom Onset: _____ **Date of Positive Test Result:** _____
		***If yes, then patient must meet the following criteria to receive Monoclonal Antibody Infusion*
		Medical Record Documentation
		• The fact sheet was given to patient and/or caregivers
		• Informed of Alternatives to Monoclonal Antibody treatment
		• Informed that the Monoclonal Antibody treatment is a unapproved drug and is Authorized for Emergency Use by the FDA
		• Patient Agrees to Treatment
		COVID-19 MONOCLONAL THERAPY
		Please Check Box:
		☐ Monoclonal Antibody Therapy (drug to be chosen by ACMH Pharmacy based on stock and availability)
		DIRECTIONS FOR ADMINISTRATION:
		Casirivimab/imdevimab (Regen-COV)
		• Attach infusion set containing 0.2 micron filter to IV bag
		• 600mg casirivimab with 600mg imdevimab in 0.9% sodium chloride IV Infusion x1
		• Infuse over 41 minutes. Total volume to be infused = 110 mL
		• Observe for Hypersensitivity within the first 5 minutes and then 1- hour post infusion
		• Set should be flushed with approximately 50mL of 0.9% sodium chloride at end of infusion to ensure patient has received entire dose.
		• Flush INT PRN
		• Discontinue IV and discharge patient, 1 hour after infusion completed and pt without reaction
		Bamlanivumab/etesevimab
		• Attach infusion set containing 0.2 micron filter to IV bag
		• 700mg bamlanivumab with 1400 mg etesevimab in 250mL 0.9% NaCl 0.9% IV Infusion over 1 hour
		• Infuse over 60 minutes. Total volume to be infused = 310 mL
		• Observe for Hypersensitivity within the first 5 minutes and then 1- hour post infusion
		• Set should be flushed with approximately 50mL of 0.9% sodium chloride at end of infusion to ensure patient has received entire dose.
		• Flush INT PRN
		• Discontinue IV and discharge patient, 1 hour after infusion completed and pt without reaction
		VORB/TORB: _____ Date: _____ Time: _____
		Physician Signature: _____ Date: _____ Time: _____

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One Nolte Drive
Kittanning, PA 16201

COVID 19 Outpatient Monoclonal Therapy Order Set ACMH

Authorization is given to the pharmacy to dispense and to the nurse to administer the generic or chemical equivalent unless otherwise ordered.

DATE	TIME	
		Sotrovimab
		• Attach infusion set containing 0.2 micron filter to IV bag
		• Sortrovimab 500mg in 50 ml 0.9% NaCl IV infusion over 30 minutes
		• Infuse over 30 minutes. Total volume to be infused = 58ml (the entire bag)
		• Set should be flushed with approximately 50mL of 0.9% sodium chloride at end of infusion to ensure patient has received entire dose.
		• Observe for Hypersensitivity within the first 5 minutes and then 1- hour post infusion
		• Flush INT PRN
		• Discontinue IV and discharge patient, 1 hour after infusion completed and patient without reaction
		REACTION MEDICATIONS (System COVID-19 Monoclonal Therapy)
		Mild / Moderate Reaction
		• Pause the infusion for fever, chills, nausea headache, rash including uritcaria, pruritus,
		• myalgia, or dizziness and call provider for further instructions
		Severe/ Anaphylactic Reaction
		• Turn off infusion for angioedema, shortness of breath, hypotension, dyspnea, wheezing or
		or stridor, administer IM epinephrine, call rapid response or code blue and begin CPR if
		necessary.
		Reaction Medications
		• EPINEPHrine (ADRENALIN) 0.3 mg IM every 5 mins PRN severe or anaphylactic reaction
		• (up to 3 doses)
		• methylPREDNISolone (SOLUMedrol)125 mg IV once PRN severe or anaphylactic reaction
		• diphenhydrAMINE (BENADRYL) 50 mg IV once PRN severe or anaphylactic reaction
		• Famotidine (PEPCID) 20 mg IV once PRN severe or anaphylactic reaction
		• Albuterol (PROVENTIL) 90 mcg/ actuation inhalation aerosol
		• *2 Puffs once PRN (SOB, wheezing, chest tightness)*
		VORB/TORB: _____ Date: _____ Time: _____
		Physician Signature: _____ Date: _____ Time: _____

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MAb Physician Attestation

Patient Name:_____ Date of Birth:_____

- ☐ Symptom onset not more than 7 days prior
- ☐ Patient is currently symptomatic and not hypoxic (does not require supplemental O2 beyond baseline)
- ☐ Positive Covid-19 test (antigen or PCR) by a medical institution (no home test)

Primary Consideration:

	Pregnant
	Current Cancer Treatment
	Solid Organ Transplant Recipient
	Hematopoetic Cell Transplant Recipient
	Severe Primary Immunodeficiency
	AIDS (CD4<200 or <15%)
	Age 65 or older with loss of 2 or more ADLs Bathing, Eating, Dressing, Transferring, Toileting, Continence

Secondary Consideration:

	Age 75 or older and unvaccinated
	Age 65 or older unvaccinated with evidence of clinical risk factors
	Age 65 or older unvaccinated
	Under age 65, unvaccinated with evidence of clinical risk factors
	Age 75 or older vaccinated
	Age 65 or older vaccinated with evidence of clinical risk factors
	Age 65 or older vaccinated
	Under age 65 vaccinated with evidence of clinical risk factors

Secondary Clinical Risk Factors:

- ☐ Chronic Kidney Disease
- ☐ Diabetes Mellitus
- ☐ Dependence on medical technology (describe)
- ☐ Immunocompromised- (describe)
- ☐ Chronic Lung disease
- ☐ BMI >= 30
- ☐ Cardiac Disease (inc congenital)
- ☐ Hypertension
- ☐ Sickle Cell Disease
- ☐ Neurodevelopmental dx (eg CP)

Describe: _____

Other: _____

I attest that the information provided is accurate to the best of my knowledge.

Physician Signature: _____ Date/Time:_____

Printed Physician Name:_____

FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS
Emergency Use Authorization (EUA) of Sotrovimab for the Treatment of Coronavirus Disease 2019 (COVID-19)

You are being given a medicine called **sotrovimab** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking sotrovimab, which you may receive.

Receiving sotrovimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about sotrovimab. Talk to your healthcare provider if you have any questions. It is your choice to receive sotrovimab or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 are fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness, including breathing problems, can occur and may cause your other medical conditions to become worse.

What is sotrovimab?
Sotrovimab is an investigational medicine used to treat mild-to-moderate symptoms of COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk of progression to severe COVID-19, including hospitalization or death. Sotrovimab is investigational because it is still being studied. There is limited information about the safety and effectiveness of using sotrovimab to treat people with mild-to-moderate COVID-19.

The U.S. Food & Drug Administration (FDA) has authorized the emergency use of sotrovimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

Who should not receive sotrovimab?
Do not take sotrovimab if you have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab.

What are the ingredients in sotrovimab?
Active ingredient: sotrovimab
Inactive ingredients: L-histidine, L-histidine monohydrochloride, L-methionine, polysorbate 80, and sucrose

What should I tell my healthcare provider before I receive sotrovimab?
Tell your healthcare provider about all of your medical conditions, including if you:
- Have any allergies
- Have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab
- Are pregnant or plan to become pregnant

- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

How will I receive sotrovimab?

- You will receive 1 dose of sotrovimab.
- Sotrovimab will be given to you through a vein (intravenous or IV infusion) over 30 minutes.
- You will be observed by your healthcare provider for at least 1 hour after you receive sotrovimab.

What are the important possible side effects of sotrovimab?

Possible side effects of sotrovimab are:

- **Allergic reactions.** Allergic reactions can happen during and after infusion with sotrovimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever; difficulty breathing; low oxygen level in your blood; chills; tiredness; fast or slow heart rate; chest discomfort or pain; weakness; confusion; nausea; headache; shortness of breath; low or high blood pressure; wheezing; swelling of your lips, face, or throat; rash including hives; itching; muscle aches; dizziness; feeling faint; and sweating.

The side effects of getting any medicine through a vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of sotrovimab. Not many people have been given sotrovimab. Serious and unexpected side effects may happen. Sotrovimab is still being studied, so it is possible that all of the risks are not known at this time.

It is possible that sotrovimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, sotrovimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?

Like sotrovimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with sotrovimab. Should you decide not to receive sotrovimab, or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?

There is no experience treating pregnant women or breastfeeding mothers with sotrovimab. For a mother and unborn baby, the benefit of receiving sotrovimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with sotrovimab?

Tell your healthcare provider right away if you have any side effects that bother you or do not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088, or call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684).

How can I learn more?

- Ask your healthcare provider
- Visit www.sotrovimabinfo.com
- Call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684)

- Visit https://www.covid19treatmentguidelines.nih.gov/
- Visit https://combatcovid.hhs.gov/i-have-covid-19-now/available-covid-19-treatment-options
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?

The FDA has made sotrovimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Sotrovimab has not undergone the same type of review as an FDA-approved medicine. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for sotrovimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these medicines, unless terminated or revoked (after which the products may no longer be used).

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