FAX or EMAIL PATIENT STICKER

SUBJECT: COVID-19 Monoclonal Antibody Infusion Order
TO: Comanche County Memorial Hospital Infusion Services
FAX: (580) 585-5472
ADDRESS: 3126 NW Arlington Blvd Lawton, OK 73505
EMAIL: infusion@ccmhhealth.com
PHONE: (580) 355-8699 Option 1, Ext 4756 or Ext. 6194 for Scheduling

FORMS MUST BE COMPLETE (NO BLANKS) AND SIGNED BY THE PROVIDER FOR THE PATIENT TO BE CONSIDERED FOR Monoclonal Antibody Infusion

PLEASE PRINT

DATE:_____ **VACCINATION STATUS:**_____
PATIENT NAME:_____ **DOB:**_____
PHONE:_____ **HEIGHT (inches):**_____**INCHES** **WEIGHT:**_____**KG (at least 40kg for MABs)**
ALLERGIES:_____
DIAGNOSIS CODE:_____ **DIAGNOSIS NAME (REQUIRED)**_____
PROVIDER NAME (PRINT LAST & FIRST):_____
PROVIDER OFFICE PHONE#_____ **OFFICE FAX #**_____
CONTACT PERSON AT PROVIDER OFFICE:_____

SARS-CoV-2 Specific Monoclonal Antibody Guidelines

- CCMH SARS-CoV-2 Specific Monoclonal Antibody Guidelines available in CCMH COVID Toolkit.
- The FDA issued Emergency Use Authorization (EUA) to authorize the emergency use of Sotrovimab for the treatment of mild to moderate COVID-19 with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization. As well, for Remdesivir a revised EUA was made to additionally authorize the drug for treatment of pediatric patients less than 12 years of age weighing at least 3.5 kilograms, with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization of death.
- FDA approval has been expanded the indication for Veklury (remdesivir) to include its use in adults and pediatric patients (12 years of age and older who weigh at least 40 kilograms) with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.
- The FDA has authorized the emergency use of EVUSHELD for pre-exposure prophylaxis for prevention of COVID-19 under an Emergency Use Authorization (EUA).For adults and adolescents (12 years of age and older who weigh at least 88 pounds [40 kg]) for **preexposure prophylaxis** for prevention of COVID-19 in persons who are: • **not currently infected with SARS-CoV-2** and who have not had recent known close contact with someone who is infected with SARS-CoV-2 and • Who have moderate to severe immune compromise due to a medical condition or have received immunosuppressive medicines or treatments and may not mount an adequate immune response to COVID-19 vaccination or • For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (such as severe allergic reaction) to a COVID-19 vaccine(s) or COVID-19 vaccine ingredient(s).
- The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of bebtelovimab 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, and • for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

EUA provider fact sheets:

Sotrovimab EUA provider fact sheet available at GSK Sotrovimab Fact Sheet for HCP 02232022
Remdesivir provider fact sheet available at: HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use VEKLURY safely and effec & EUA 046 Veklury (remdesivir) FS for HCPs (01212022)
Evosheld provider fact sheet: Fact Sheet for Healthcare Providers: Emergency
Bebtelovimab provider fact sheet: Fact Sheet for Healthcare Providers: Emergency Use Authorization for Bebtelovimab

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Before ordering for active infection, review criteria for Paxlovid (also check for drug interactions) and prescribe Paxlovid if the patient is eligible. **Paxlovid (nirmatrelvir and ritonavir tablets) – Medication safety consideration**
If Paxlovid is contraindicated then continue through decision guide found here:
COVID-Therapeutics-Decision-Aid 030422.pdf

SARS-CoV-2 Active infection-MAB or Remdesivir CRITERIA FOR USE

☐ Symptom Onset Date: _____Positive COVID-19 test date_____ OR exposure date_____

Patients must meet **ALL** criteria to be eligible for Sotrovimab or Bebtelovimab

☐ at least 12 years of age and weighing at least 40 kg

☐ COVID-19 positive by PCR or Antigen testing

☐ **Within 7 days of symptom onset**

☐ Meets all of the following requirements:

- at high risk for progressing to severe COVID-19 and/or hospitalization
- is NOT hospitalized,
- is NOT requiring oxygen therapy due to COVID-19,
- is NOT requiring 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

☐ Does not have suspected or proven serious, active bacterial, fungal, viral, or other infection (excluding COVID-19)

☐ **High risk - defined as meeting one or more of the following criteria (select all that apply):**

☐ Body Mass Index (BMI > 25) ☐ Cardiovascular disease ☐ Chronic Kidney Disease

☐ Hypertension ☐ Diabetes ☐ COPD/other chronic respiratory disease ☐ Immunosuppressive Disease

☐ Pregnancy ☐ Medical related technology dependence e.g., gastrostomy)

☐ Receiving immunosuppressive treatment ☐ Sickle cell disease (e.g., gastrostomy)

☐ Age ≥ 65 years

☐ Neurodevelopmental disorders or other conditions that confer medical complexity(e.g., genetic, or metabolic syndrome)

OR

Pre-Exposure Prophylaxis Criteria For Use

☐ Pre-Exposure Prophylaxis to COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

• Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2

• Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or

• For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID19 vaccine component(s). In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

☐ **Patient or caregiver received a copy of the APPROPRIATE mAB INFUSION or antiviral fact sheet**

- Evusheld fact sheet: https://www.fda.gov/media/154702/download
- Sotrovimab fact sheet at https://www.fda.gov/media/149533/download
- Bebtelovimab fact sheet: EUA 111 Lilly bebtelovimab FS for PPCs (02112022).pdf
- Remdesivir fact sheet: 1 PATIENT INFORMATION VEKLURY® (VEK-lur-ee) (remdesivir) for injection VEKLURY® (VEK-lur-ee) (remdesivir) injection What is VE
- Pediatric < 12 yo, Remdesivir fact sheet:: EUA 046 (remdesivir) FS for Parents Caregivers (01212022)
- Patient was informed of risks and benefits of therapy, availability of alternatives and that the drug is an unapproved drug authorized for use under the Emergency Use Authorization, or FDA approved.
- Patients understand they have the option to accept or refuse treatments and, understanding the risks, benefits and alternatives, have agreed to accept treatment with casirivimab/imdevimab or bamlanivimab/etesevimab based on drug availability.

SARS-CoV-2 Specific Monoclonal Antibody & Antiviral DOSING

☐ Sotrovimab 500mg
- added to 100 mL 0.9% NaCl IV Infusion Once, Infuse over 31 minutes, use 0.2/0.22 micron in-line filter

☐ Bebtelovimab
- 175 mg administered as a single intravenous injection over at least 30 seconds

☐ remdesivir 200 mg IV in NS 40mL on ☐ Day 1 followed by remdesivir 100mg IV in NS 60mL on ☐ Day 2 & ☐ Day 3
- Infuse over 30-120 minutes

☐ **If CKD is present or an eGFR of <30 is suspected, please obtain renal panel prior to infusion**

Pre-Exposure Prophylaxis Dosing

☐ **Patient is not currently infected with SARS-CoV-2 and has not had a known recent exposure to an individual infected with SARSCoV-2**

AND

☐ **Patient has moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination**

OR

☐ **Patient can not be vaccinated with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID19 vaccine component(s)**

☐ Evusheld 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections at two separate sites (preferably one in each of the gluteal muscles, one after the other)

Post-Infusion:

- **Flush administration set with 0.9% sodium chloride to deliver residual volume.**
- **Leave IV in place for observation period; remove prior to discharge.**
- **Monitor patients for hypersensitivity reactions for a period of 60 minutes following infusion.**
- **Record vital signs immediately following infusion and prior to discharge.**
- **Provide patients with discharge instructions. Send record of treatment to prescriber at fax number as appropriate.**
- **If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy (see ADVERSE REACTIONS below)**

ADVERSE REACTIONS

MINOR REACTIONS (e.g. nausea, itching, joint pain, rash)	SEVERE REACTIONS (e.g. bronchospasm, loss of airway, fainting, severe flushing)
STOP infusion	**CALL A CODE OR RAPID RESPONSE**
diphenhydrAMINE 50 mg IV Push Once	**STOP** infusion
famotidine 20 mg IV Push Once	EPINEPHrine 0.3 mg/0.3 mL SubCutaneous Once
dexaMETHasone 10 mg IV Push Once	Oxygen PRN
Notify Physician	Notify Physician

Prescriber Signature_____ **Date/Time**_____