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Logan Regional Medical Center

COVID-19 Therapeutics Outpatient Treatment Order

FAX to the pharmacy 304-831-1278: completed order form, copy of insurance card/face sheet and + COVID Test

For remdesivir therapy, also fax lab work eGFR or creatinine, and hepatic enzymes

***Patient will be contacted with appointment time ***

PATIENT INFORMATION

First Name: _____M.I. _____ Last Name: _____ DOB_____

SSN#: _____ Allergies: _____

Address: _____City: _____ State: _____ Zip: _____

Phone: _____ Mobile ph: _____ work/other: _____

CRITERIA FOR USE (must meet all for approval):

1. Positive COVID-19 test date: ____ / ____ / ____ (MUST include lab result with packet or provider attestation of positive test)

2. Symptom Onset date: ____ / ____ / ____ (MUST be within 10 days for mAB; within 7 days for remdesivir)
3. ≥1 sign and symptoms of COVID-19 (Mark symptoms which apply):
   - ☐ Cough
   - ☐ Shortness of breath/difficulty breathing
   - ☐ Fever/Chills
   - ☐ Body aches
   - ☐ Fatigue
   - ☐ Sore throat
   - ☐ Headache
   - ☐ Loss of appetite
   - ☐ Nausea, vomiting, diarrhea
   - ☐ Loss of taste or smell
4. Patient is at high risk for progression to severe COVID-19, including hospitalization/death
   (Mark risk criteria which apply; calculate patient score):

☐ Age ≥ 80 years	3 points
☐ Age ≥ 65 years	2 Points
☐ Age ≥ 50 years	1 point
☐ Immunocompromised Status (due to disease or treatment)	3 points
☐ Active Cancer	2 points
☐ Chronic Lung Disease (asthma, COPD, sarcoidosis, cystic fibrosis, etc.)	2 points
☐ Diabetes mellitus	2 points
☐ BMI ≥ 40	2 points
☐ BMI ≥ 25	1 points
☐ Chronic Kidney Disease	3 points
☐ Cardiovascular disease or Hypertension	1 points
☐ Not fully vaccinated and no prior COVID-19 infection in past 90 days	2 points
☐ Primary vaccine series complete; but no booster or prior COVID-19 infection in past 90 days	1 points
☐ Pregnancy (recommend consult with OB/Ped regarding risk/benefit)	3 points
Calculate Total Points	**_____ total points**

Score of 4+ is eligible for authorized monoclonal antibody when available; Score of 2+ is eligible for remdesivir therapy

5. Exclusion Criteria for outpatient therapy (**ineligible** for treatment if any of the following):
   - ☐ Hospitalized due to COVID-19
   - ☐ Require oxygen therapy due to COVID-19 or require an increase in baseline oxygen flow rate due to COVID-19 (not eligible for mAB)
   - ☐ Active bacterial/fungal/AFB infection
   - ☐ Age < 12 years or weight < 40 kg
   - ☐ eGFR < 30 mL/min/1.73m2 hemodialysis or hemofiltration (not eligible for remdesivir)
   - ☐ Liver dysfunction defined as ALT ≥ 5 times the upper limits of normal (not eligible for remdesivir)
6. Special Considerations:
   - Pregnancy (recommend consult with OB/PED regard risk/benefit)
   - B-Cell Immunodeficiencies (theoretical risk for immune escape and emergence of resistance to therapeutics)

MEDICATION ORDER:

- ☐ In stock FDA Authorized COVID-19 monoclonal antibody therapy x 1 dose, Dx- U07.1 COVID-19
  OR
- ☐ Remdesivir 200 mg IVPB x 1 dose, then remdesivir 100 mg IVPB daily x 2 doses, Dx = U07.1 COVID-19
  ***must include renal and hepatic labwork for remdesivir therapy– eGFR or creatinine; and AST/ALT**
- ☐ Pharmacist to interchange above products if patients meets criteria based upon points calculation and/or supply/availability on date of service

Note: If both choices are marked, patient will receive one product to be selected by pharmacist based upon points calculation and supply on date of service

- ☑ Vital signs prior to start of infusion, during infusion, and for one hour after infusion.
- ☑ Zofran ODT 4 mg PO x 1 dose PRN for nausea/vomiting
- ☑ In the event of allergic reaction:
  - Diphenhydramine 50 mg IV x 1 prn allergic reaction.
  - Famotidine 20 mg IV x 1 prn allergic reaction.
  - Solu-Medrol 80 mg IV X 1 prn allergic reaction.
  - Epinephrine 0.3 mg IM x 1 prn severe anaphylactic reaction
- ☑ Monitor patient for at least 1 hour after infusion is complete for signs of hypersensitivity including anaphylaxis and infusion-related reactions.

As a healthcare provider, you must communicate to your patient or caregiver, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" prior to scheduling an appointment for administration of mAB. A copy of the Fact Sheet will be given to the patient or caregiver when she or he arrives for infusion visit. Ordering healthcare providers 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 any authorized monoclonal antibody therapy
c. Informed that monoclonal antibody therapy is an unapproved drug that is authorized for use under an Emergency Use Authorization.

Prescribing healthcare provider and/or designee is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to any mAB therapeutics treatment within 7 calendar days from onset of event. Submit adverse events reports to FDA MedWatch using one of the following methods:

a. Complete and submit the report online: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting
b. Use a postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178),
c. Call 1-800-FDA-1088 to request a reporting form

Conditions of use of mAB therapeutic agents from LRMC (Initial Each):

_____ You attest that all criteria for use met and correct, and patient does not meet any exclusion criteria

_____ You agree to submit all serious adverse events and all medication errors to the State of WV by reporting the event(s) to the West Virginia Poison Center at 1-800-222-1222 as soon as possible but no later than three days after time of error or adverse reaction.

PHYSICIAN INFORMATION

Requesting Physician/Provider:_____ NPI #_____

Phone: _____ Fax: _____ Contact Person:_____

Physician/Provider Signature_____Date_____

Providers call 304-831-1343 with questions