BEACON HEALTH SYSTEM

Outpatient Remdesivir/Bebtelovimab Order Form for COVID + Pediatric Patients 28 days to 17 Years of Age

Patient Name: _____ **Patient DOB:** _____ **Patient Phone**:_____

Patient Address: _____ **City:** _____ **State:** _____ **Zip Code:** _____

Patient Gender: _____ **Preferred Language**:_____ **Pregnant**: ☐ Yes ☐ No

Patient Weight (kg): _____ **Patient Height (in):**_____

Primary Insurance: _____ **Plan Number**:_____ **Policy Holder Name**:_____

Secondary Insurance: _____ **Plan Number**:_____ **Policy Holder Name**: _____

Accessibility: ☐ Patient is ambulatory ☐ Requires wheelchair ☐ Requires stretcher

Patient Allergies: _____ **Patient Diagnosis:** COVID-19

Date of COVID-19 positive test: _____ **Date of Symptom Onset:** _____

Last date eligible for outpatient remdesivir or bebtelovimab (7 days from symptom onset): _____

Outpatient Remdesivir Criteria & Bebtelovimab Emergency Use Authorization (EUA):

The criteria below are for the FDA approved use of remdesivir or emergency use authorization of bebtelovimab use for the treatment of mild to moderate COVID-19 in pediatric patients with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization.

High risk is defined as patients who meet at least one of the following criteria (check the qualifying condition for this patient):

- ☐ Younger than 1 year of age
- ☐ Pregnancy
- ☐ Immunosuppressive disease or immunosuppressive treatment
- ☐ Diabetes
- ☐ Sickle Cell disease
- ☐ Chronic kidney disease
- ☐ Obesity or being overweight (BMI ≥ 25 or BMI ≥ 85th percentile for their age and gender)
- ☐ Cardiovascular disease (including congenital heart disease) or hypertension
- ☐ Cerebrovascular disease (e.g. history of stroke)
- ☐ Chronic liver disease
- ☐ Active cancer
- ☐ Chronic obstructive pulmonary disease, moderate-to-severe asthma or other chronic respiratory disease.
- ☐ Neurodevelopmental disorders (for example, cerebral palsy)
- ☐ Medically related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
- ☐ **OR** is deemed by a health care provider to have other medical conditions or factors that place the patient at high risk for progression to severe COVID-19

Box 1: Inclusion criteria (first 4 must be true to qualify for any therapy, last 2 must also be true for bebtelovimab requests:

- ☐ Not currently hospitalized due to COVID-19
- ☐ Not initiated on oxygen therapy due to COVID-19
- ☐ For those on chronic oxygen therapy, baseline oxygen flow rate was not increased due to COVID-19
- ☐ Patient has a positive COVID test result **(Date: _____)**
- ☐ Patient ≥ 12 years old (requirement for bebtelovimab only)
- ☐ Patient ≥ 40 kg for (requirement for bebtelovimab only)

Proceed to Box 2 for remdesivir desired. Proceed to Box 4 for bebtelovimab if patient does not qualify for remdesivir.

Box 2: For remdesivir use, the patient must meet all of the following criteria (all must be true to qualify):

☐ Patient has aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels no higher than 5 times the upper limit of normal within the last 90 days

☐ Patient has an estimated glomerular filtration rate (eGFR) 30 or greater consistently within the last 90 days

☐ Patient is not breast feeding

☐ Patient weighs at least 3 kg

Proceed to Box 3.

Box 3: I authorize the following therapy:

☐ **Pediatric patient age 12 to less than 18 and weighing 40 kg or greater:**

- DAY 1: Remdesivir 200 mg IV once, given over 30 minutes
- DAY 2 and DAY 3: Remdesivir 100 mg IV daily for 2 doses, given over 30 minutes each

Observe for 1 hour following each infusion and then discharge. Take vital signs every 15 minutes during infusion then every 30 minutes x 2 after infusion is complete. Treat any allergic or infusion reactions per protocol. Maintain IV access until therapy is complete. Follow up with PCP or attending physician with any questions or concerns.

☐ **Pediatric patients younger than 12 years and weighing 40 kg or greater:**

- DAY 1: Remdesivir 200 mg IV once, given over 30 minutes
- DAY 2 and DAY 3: Remdesivir 100 mg IV daily for 2 doses, given over 30 minutes each

Observe for 1 hour following each infusion and then discharge. Take vital signs every 15 minutes during infusion then every 30 minutes x 2 after infusion is complete. Treat any allergic or infusion reactions per protocol. Maintain IV access until therapy is complete. Follow up with PCP or attending physician with any questions or concerns.

☐ **Pediatric patients 28 days of age and older weighing at least 3 kg but less than 40 kg:**

- DAY 1: Remdesivir 5 mg/kg IV once, given over 30 minutes
- DAY 2 and DAY 3: Remdesivir 2.5 mg/kg IV daily for 2 doses, given over 30 minutes each

Observe for 1 hour following each infusion and then discharge. Take vital signs every 15 minutes during infusion then every 30 minutes x 2 after infusion is complete. Treat any allergic or infusion reactions per protocol. Maintain IV access until therapy is complete. Follow up with PCP or attending physician with any questions or concerns.

Box 4: <u>Consent Statement for bebtelovimab:</u>

☐ As the patient's healthcare provider, I have communicated to the patient or parent/caregiver listed above, as age appropriate, the information consistent with the "Fact Sheet for Patients, Parents and Caregivers" prior to the patient receiving monoclonal antibody products.

I have documented in the patient's medical record that the patient/caregiver has been:

1. Given access to the "Fact Sheet for Patients, Parents and Caregivers" which can be accessed at: https://www.fda.gov/media/156153/download
2. Informed of alternatives to receiving monoclonal antibodies, and
3. Informed that monoclonal antibodies are unapproved drugs that are authorized for use under Emergency Use Authorizations.

☐ Patient/Caregiver agrees to proceed with COVID-19 antibody treatment and verbal consent has been given

Proceed to Box 5.

Box 5: Bebtelovimab criteria and medication order: for bebtelovimab use the patient must meet the following criteria:

☐ Patient is 12 years of age or greater and 40 kg or greater

☐ Patient is otherwise unable to receive nirmatrelvir/ritonavir (Paxlovid®) due to contraindications, drug interactions or unavailability

☐ Patient is otherwise unable to receive remdesivir (Veklury®) due to contraindications, drug interactions, or unavailability

☐ Drug Order: bebtelovimab 175mg IV once. Observe for 1 hour following administration and then discharge. Treat any allergic or infusion reactions per protocol. Follow up with PCP with any questions or concerns.

Box 6: Allergic Reaction Orders:

- ☒ Epinephrine 0.01 mg/kg IM Q 10 minutes x 2 doses PRN anaphylaxis, do not exceed 0.5 mg per dose
- ☒ Diphenhydramine 1 mg/kg IM on call, do not exceed 50 mg per dose
- ☒ Famotidine 0.25 mg/kg IV push on call, do not exceed 20 mg per dose
- ☒ Sodium chloride 0.9% 20 mL/kg IVPB on call, do not exceed 2 Liters, infuse at 999 mL/hour

Provider Signature: _____ **Date:** _____

Provider Printed Name: _____ **Provider DEA**: _____

Provider NPI: _____ **Provider License:** _____

Provider Address: _____

Provider Phone #: _____ **Provider Fax #:** _____

ONCE COMPLETED, PLEASE FAX TO:
Pediatric Hematology Oncology Clinic
615 N. Michigan Street
South Bend, IN, 46601
Fax: 574-647-6895
Phone: 574-647-6892

Incomplete / Illegible information may result in decreased prioritization; If appointment needs to be cancelled or there are additional questions, please call (574) 647-6892

Appointment Date 1: _____ **Appointment Time:** _____

Appointment Date 2 (if needed): _____ **Appointment Time:** _____

Appointment Date 3 (if needed): _____ **Appointment Time:** _____

Communicated with Patient/Caregiver Date: _____ **Time:** _____