NCH BAKER HOSPITAL
DOWNTOWN
350 7th Street North
Naples FL 34102
(239) 624-5000

NCH NORTH NAPLES
HOSPITAL
11190 Health Park Blvd
Naples FL 34110
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NCH Offers Monoclonal Antibiotic Therapy to Our Community

NCH is pleased to offer Monoclonal antibiotic therapy to our community. We currently have Bamlanivimab and the combination casirivimand and imdevimab available. Both regimens are for the treatment of mild to moderate coronavirus disease in adults and pediatric patients with positive results of direct SARS-CoV2 viral testing who are 12 years of age and older weighting at least 40KG and who are at high risk for progressing to severe COVID_19 and/or hospitalization. Treatment is to be administered as soon as possible after positive results and within 10 days of symptom onset.

Providers with NCH ordering privileges:
Complete the attached order set and fax to the NCH Outpatient Infusion Center at **239.624.4371.**

Providers who do not have NCH ordering privileges:
Contact NCH at **239.624.0940** for patient evaluation and treatment orders.

Patient Name _____**Date:**_____
Address:_____
Phone:_____
Date of Birth_____
Height _____ **Weight** _____
Allergies _____
ICD-10 DIAGNOSIS CODES:

***Bamlanivimab/* casirivimab and imdevimab Infusion Orders (for Outpatient Infusion Services only). OPIS FAX 239.624.4371**
REFERRAL TO NCH CREDENTIALED PROVIDER (if ordering provider not privileged at NCH)**- CALL**(239) 624-0940

AUTHORIZED USE The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab or **casirivimab and imdevimab** for the treatment of mild to moderate coronavirus disease 2019 (COVID19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
LIMITATIONS OF AUTHORIZED USE

- **Bamlanivimab or casirivimab and imdevimab are not authorized for use in patients:**
  - o who are hospitalized due to COVID-19, OR
  - o who require oxygen therapy due to COVID-19, OR
  - o who require 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.
- Benefit of treatment with bamlanivimab or **casirivimab and imdevimab** has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab or **casirivimab and imdevimab** may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

BAMLANIVIMAB/ CASIRIVIMAB AND IMDEVIMAB CRITERIA:

Date of positive viral test for SARS-CoV-2 _____ administration of Bamlanivimab or **casirivimab and imdevimab** to be administered as soon as possible after positive test within 10 days of symptom onset. If positive SARS-CoV-2 was completed outside of the NCH Healthcare System, please attach confirmation of positive SARS-CoV-2 test with this order.
Optimal infusion date(s) between _____ and _____.

This EUA is for the use of the unapproved product bamlanivimab or **casirivimab and imdevimab** for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Check high risk criteria. High risk is defined as patients who meet at least one of the following criteria:

- ❑ Body mass index (BMI) ≥ 35
- ❑ Chronic kidney disease- indicate stage _____
- ❑ Diabetes
- ❑ Immunosuppressive disease
- ❑ Currently receiving immunosuppressive treatment
- ❑ ≥ 65 years of age with additional risk factors/comorbitities: _____
- ❑ Patient is ≥ 55 years of age AND have must have one of the comorbitities below:
  - ❑ Cardiovascular disease OR
    - ❑ hypertension OR
    - ❑ chronic obstructive pulmonary disease/other chronic respiratory disease
- ❑ Patient is 12-17 years of age AND
  - ❑ BMI ≥ 85th percentile for their age and gender based on CDC growth charts https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
  - ❑ sickle cell disease OR
  - ❑ congenital or acquired heart disease OR

❑ neurodevelopmental disorders, for example, cerebral palsy OR

❑ a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COIVD-19) OR

❑ asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

INFUSIONS:

1. Ensure the patient is provided with the Emergency Use Authorization fact sheet.
2. 0.9% Sodium Chloride IV **250 ml bag** @ 20ml/hr to keep vein open. Flush with 10ml – 30ml before and after medication administration and as needed.
3. Monitor patient including vital signs and oxygenation pre-infusion; q 30 minutes during infusion; and for at least one hour after infusion.
4. Once infusion is complete, flush the infusion line to ensure delivery of the required dose.

***Pharmacy may substitute infusion product based allocated product availability.

❑ **BAMLANIVIMAB INFUSION ORDERS:**

1. Bamlanivimab 700 mg IV in NS 200ml; infuse over at least 60 minutes via pump or gravity. Use polyvinylchloride infusion set containing a 0.2-0.22 micron in-line polyethersulfone filter.

-OR-

❑ **CASIRIVIMAB & IMDEVIMAB INFUSION ORDERS**

2. casirivimab 1,200 mg and imdevimab 1,200 mg administered together as an intravenous infusion over at least 60 minutes via pump or gravity. Use polyvinylchloride infusion set containing a 0.2-0.22 micron in-line polyethersulfone filter.

❑ **ADVERSE REACTION ORDERS**

The following orders should be followed if a patient experiences the following:

A) A sudden drop in Systolic BP less than 90 mm Hg
B) Pulse Rate less than 50 beats per minute
C) Shortness of breath
D) Any signs or symptoms of a transfusion reaction
   1) Stop the Infusion
   2) Sodium Chloride 0.9% at 100 ml/hr
   3) Start Oxygen @ 2 liters/nasal cannula to keep O2 sat >90%
   4) Call SWAT
   5) Call Physician for follow-up orders
   6) Notify pharmacy for FDA MedWatch submission

ADDITIONAL REACTION ORDERS (attn: must be reviewed / ordered prior to infusion being scheduled)

❑ Give Diphenhydramine (Benadryl) 25 mg IVP x 1 dose
❑ Acetaminophen 650 mg po (if not given as a premedication)
❑ Give Methylprednisolone (Solu-Medrol) 125 mg IV x 1 dose

PHYSICIAN SIGNATURE _____ **DATE/TIME**_____

PHYSICIAN NAME PRINTED_____(Ordering physician must have NCH privileges)

By signing, physician attests to personally reviewing risks, benefits and alternative therapy options with the patient regarding the emergency use authorization for Bamlanivimab/ CASIRIVIMAB & IMDEVIMAB.
Scheduling will be completed based on availability of the allocated product (Bamlanivimab or CASIRIVIMAB & IMDEVIMAB)
References:
CMS guide: https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

Fact sheet for health care providers: http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf

Fact sheet for health care providers: Fact Sheet for Heatlh Care Providers: Emergency Use Authorization (EUA) of Casirivimab and Emdevimab (fda.gov)