



Standard Operating Procedure

Procedure Title:	Monoclonal Treatment Ordering/Documentation Process
Date:	9/22/21
Version:	1.0
Department:	CIC
Approved By:	Brooke Gregory

Purpose:

The purpose of this SOP is to provide guidance for ordering Outpatient Infusion for COVID Treatment or SUB Q Injections (Monoclonal Treatment) through Asante and how to properly document.

Procedure:

Patients who have a recent diagnosis of mild to moderate coronavirus disease 2019 (COVID-19) and are at high risk for progressing to severe COVID-19 and/or hospitalization may be a candidate for Monoclonal Treatment at Asante.

1. **If a patient's COVID-19 result comes back positive** and it is within the 10-day window, the ordering Provider may feel that they would benefit from the Monoclonal Treatment at Asante due to their risk for progressing to severe COVID-19 and/or hospitalization.
 - a. The provider will send a note to the Medical Assistant to initiate the FDA authorized emergency use of Monoclonal Treatment order.
 - b. The Medical Assistant will fill out the "Casirivimab and Imdevimab Order Set Outpatient Infusion for COVID treatment" order form (3 pages) in its entirety and attach the facesheet/updated demographics, H&P or most recent progress note indicating medical necessity and reason for patient classified as high-risk and copy of laboratory Positive SARS-CoV-2 test results.
 - c. Once completed, the Medical Assistant will give paperwork to Provider to complete and sign.

2. **If a patient calls in requesting Monoclonal Treatment**, a Medical Assistant will screen the patient over the phone and send documentation to provider requesting approval for order.
 - a. The Medical Assistant will confirm we have record of a positive COVID-19 test within the last 10 days.

- b. The Medical Assistant is to document all symptoms, timing and request for order and send to the Provider for guidance on if patient qualifies for Monoclonal Treatment.
 - c. If the order is approved by the Provider, the Medical Assistant will fill out the “Casirivimab and Imdevimab Order Set Outpatient Infusion for COVID treatment” order form (3 pages) in its entirety and attach the facesheet/updated demographics, H&P or most recent progress note indicating medical necessity and reason for patient classified as high-risk and copy of laboratory Positive SARS-CoV-2 test results.
 - d. Once completed, the Medical Assistant will give paperwork to Provider to complete and sign.
- 3. Once the order has been approved by Provider, the Medical Assistant will contact the patient.**
- a. Medical Assistant to call patient and state “Your provider has recommended monoclonal treatment for you by either infusion or subcutaneous injection. This treatment is given under the conditions of emergency use authorization and there are some risks involved that I would like to make sure you are aware of. These risks include allergic reactions, worsening symptoms after treatment, pain, bruising of skin at the site, soreness, swelling and possible infection at the site. With your verbal consent for treatment, we can start the order process for you. Asante will have you sign the consent when you arrive and will be able to provide you with a copy so that you can read it in more detail.”
 - b. The Medical Assistant is to document above understanding by using text macro “.euaconsent”:
“Patient gave verbal consent to treatment with casirivimab and imdevimab and understands the conditions of Emergency Use Authorization (including risks, benefits, & alternatives to casirivimab and imdevimab). Risks include allergic reactions, worsening symptoms after treatment, pain, bruising of skin at the site, soreness, swelling and possible infection at the site. Patient is also aware that it may interfere with their ability to fight off a future COVID-19 infection and may reduce the body’s immune response to a COVID vaccine.”
 - c. The Medical Assistant will inform the patient that they will need to sign the consent for treatment: “Casirivimab and Imdevimab Emergency Use Authorization (EUA)” once they arrive at the treatment facility.
- 4. Once above has been properly documented in a patient case and signed ordered received from the Provider:**
- a. Medical Assistant will fax order form along with pertinent information to “Asante COVID Infusion Clinic” at 541-201-4192.

- b. Medical Assistant will inform patient that order has been faxed and they will receive a call from the Asante COVID Infusion Clinic to schedule their appointment.

Casirivimab & Imdevimab has been authorized for Emergency Use by the FDA to permit the emergency use of the unapproved medication for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in patients who are at high risk for progressing to severe COVID-19 and/or hospitalization.