# Monoclonal Antibody Treatment and Post-Exposure Prophylaxis (PEP) Order Form for Patients ≥ 12 Years Old

| PATIENT NAME: | DOB: |
|---|---|
| ALLERGIES: | POSITIVE COVID-19 TEST ON*: |
| FDA PATIENT FACT SHEET PROVIDED ON:<br>* Not applicable for post-exposure prophylaxis use<br>** Per FDA EUA, patient education and patient fact sheet must be provided to the patient prior to administration. | |

## PATIENT SCREENING

- ☐ Age (≥ 12 y.o.): _____ (Required)
- ☐ Weight (≥ 40 kg): _____ (Required)
- ☐ **Mild to moderate COVID-19**; high-risk for progressing to severe COVID-19 and/or hospitalization (see below), positive test (antigen or PCR), within 10 days of symptom onset **OR**
- ☐ **Post-Exposure Prophylaxis (PEP)**, patient meets all of the following:
  - ☐ High-risk for progressing to severe COVID-19 and/or hospitalization (see below) **AND**
  - ☐ Vaccination status (one of the following) **AND**
    - ☐ Not fully vaccinated **OR**
    - ☐ Not expected to mount an adequate immune response to complete vaccination
  - ☐ Exposure risk
    - ☐ Exposure to COVID-19 positive individual as defined in CDC close contact criteria **OR**
    - ☐ At high risk of exposure to infected individuals in a residential setting

**Patient meets at least one of the following high-risk criteria:**

- ☐ Is ≥ 65 years of age
- ☐ Has a body mass index (BMI) ≥ 25
- ☐ Pregnancy
- ☐ Has chronic kidney disease
- ☐ Has diabetes
- ☐ Has immunosuppressive disease
- ☐ Is currently receiving immunosuppressive treatment
- ☐ Cardiovascular disease or hypertension
- ☐ Chronic lung diseases
- ☐ Neurodevelopmental disorders or other conditions that confer medical complexity
- ☐ Sickle cell disease
- ☐ Having a medical-related technological dependence not related to COVID-19 (e.g., tracheostomy, gastrostomy)
- ☐ Is 12-17 years of age and has: BMI ≥ 85th percentile for their age and gender based on CDC growth charts; sickle cell disease; congenital or acquired heart disease; neurodevelopmental disorders; medical related technological dependence; OR asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
- ☐ Other medical conditions or factors that place the patient at high risk for progressing to severe COVID-19
  Describe: _____

**Monoclonal Antibodies are NOT AUTHORIZED for use in patients** who are hospitalized due to COVID-19, OR who require oxygen therapy due to COVID-19, OR who require an increase in baseline oxygen flowrate due to COVID-19 for those on chronic oxygen therapy due to an underlying non-COVID-19 condition.

- ☐ Patient does not meet any of the above contraindications

**Monoclonal Antibody Therapy is NOT AUTHORIZED for pre-exposure prophylaxis. Only REGEN-COV (casirivimab + imdevimab) and bamlanivimab + etesevimab have Emergency Use Authorization for post-exposure prophylaxis, sotrovimab does not. Administration of monoclonal antibody for post-exposure prophylaxis is NOT A SUBSTITUTE for COVID-19 vaccination.**



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## DRUG AND ADMINISTRATION FOR TREATMENT OF MILD TO MODERATE COVID-19

☐ **REGEN-COV Treatment:** 600 mg casirivimab and 600 mg imdevimab. Per EUA, add 10 mL of co-formulated casirivimab and imdevimab OR add 5 mL of casirivimab and imdevimab to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet. Alternatively, may administer subcutaneously (SC) using four 2.5 mL injections as instructed in Health Care Providers Fact Sheet.

[a] Using individual vials, add 5 mL of casirivimab and 5 mL of imdevimab to a prefilled infusion bag.

[b] For treatment, IV infusion is strongly recommended. SC injection is an alternative route when IV infusion is not clinically or operationally feasible and would lead to delay in treatment.

☐ **Bamlanivimab/etesevimab Treatment:** 700 mg bamlanivimab and 1,400 mg of etesevimab. Per EUA, bamlanivimab and etesevimab must be diluted together as a single intravenous infusion. Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet.

[a] The minimum infusion time for patients weighing between 40 and 50 kg who are administered bamlanivimab and etesevimab together using the 250 mL prefilled 0.9% Sodium Chloride infusion bag must be extended to at least 70 minutes to ensure safe use (endotoxin load).

☐ **Sotrovimab Treatment:** 500 mg sotrovimab. Per EUA, remove one vial of sotrovimab from refrigerator and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes. Gently swirl vial (DO NOT SHAKE) before use without creating air bubbles. Add 8mL of sotrovimab (1 vial) to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Provider Fact Sheet.

[a] Sotrovimab is a clear, colorless, or yellow to brown solution. Discard if particulate matter or discoloration is observed prior to administration.

[b] Prior to infusion, gently rock the infusion bag back and forth by hand for 3 to 5 minutes. Avoid forming air bubbles.

## DRUG AND ADMINISTRATION FOR POST-EXPOSURE PROPHYLAXIS (PEP)

☐ **REGEN-COV, initial PEP:** 600 mg casirivimab and 600 mg imdevimab. Per EUA, add 10 mL of co-formulated casirivimab and imdevimab OR add 5 mL of casirivimab and imdevimab to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet. Alternatively, may administer subcutaneously (SC) using four 2.5 mL injections as instructed in Health Care Providers Fact Sheet.

[a] Using individual vials, add 5 mL of casirivimab and 5 mL of imdevimab to a prefilled infusion bag.

[b] For post-exposure prophylaxis, either SC injection or IV infusion can be used per Health Care Providers Fact Sheet.

☐ **REGEN-COV, repeat dose PEP:** 300 mg casirivimab and 300 mg imdevimab. Per EUA, add 5 mL of co-formulated casirivimab and imdevimab OR dilute individual vials of casirivimab and imdevimab (see below) to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet. Alternatively, may administer subcutaneously (SC) using two 2.5 mL injections as instructed in Health Care Providers Fact Sheet.

[a] Using individual vials, add 2.5 mL of casirivimab and 2.5 mL of imdevimab for a total of 5 mL to a prefilled infusion bag

[b] Subsequent repeat dosing every 4 weeks after initial 600 mg casirivimab and 600 mg imdevimab dosing for the duration of ongoing exposure

[c] For post-exposure prophylaxis, either SC injection or IV infusion can be used per Health Care Provider Fact Sheet.

☐ **Bamlanivimab/etesevimab PEP:** 700 mg bamlanivimab and 1,400 mg of etesevimab. Per EUA, bamlanivimab and etesevimab must be diluted together as a single intravenous infusion. Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as a single intravenous infusion (IV) as instructed in Health Care Providers Fact Sheet.

[a] The minimum infusion time for patients weighing less than 50 kg who are administered bamlanivimab and etesevimab together using the 250 mL prefilled 0.9% Sodium Chloride infusion bag must be extended to at least 70 minutes to ensure safe use (endotoxin load).

*To be documented at time of administration:*

**Casirivimab LOT Number:** _____ **Expiration Date:** _____

**Imdevimab LOT Number:** _____ **Expiration Date:** _____

**Bamlanivimab LOT Number:** _____ **Expiration Date:** _____

**Etesevimab LOT Number:** _____ **Expiration Date:** _____

**Sotrovimab Lot Number:** _____ **Expiration Date** _____

_____

**Administering Provider** **Signature** **Date**



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## 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 patient for hypersensitivity reaction for a period of 60 minutes following infusion.
- ☐ Send record of treatment and post infusion summary (page 3) to prescriber at fax number below

## MANAGEMENT OF HYPERSENSITIVITY

Patients must be clinically monitored during infusion and observed for at least one hour after infusion is complete. Vital signs must be measure before infusion and ≤ q 30 minutes, and when indicated until conclusion of observation period.

| **Management of Minor Infusion-Related Symptoms** | |
|---|---|
| Nausea/Vomiting | ☐ Ondansetron (Zofran): 4 mg ODT (oral dissolving tablet) or 4 mg IV |
| Headache/Fever | ☐ Acetaminophen: 650-1,000 mg PO |
| *** Minor infusion related symptoms such as nausea, headache, fever, and dizziness can often improve with slowing infusion rate. For minor symptoms early in the infusion, decrease infusion rate by 25-50%. | |
| **Management of Severe (anaphylactic and non-anaphylactic) Administration-Related Symptoms** | |
| *** Immediately stop infusion, obtain vital signs, initiate supplemental oxygen, as indicated. Activate the emergency medical system (EMS; e.g., call 911 if applicable) and notify the patient's physician/clinician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient and initiates treatment, as appropriate. | |
| **Management of Anaphylactic Symptoms** | |
| Anaphylaxis | ☐ **Epinephrine 0.3 mg IM (includes autoinjector); if signs of hypotension and/or respiratory distress with wheezes or stridor are present, repeat dose every 5 to 15 minutes for up to two doses and diphenhydramine as described below.**<br>☐ Diphenhydramine 50 mg IM or IV (administer alone for moderatesymptoms) |
| *** Immediately stop infusion, obtain vital signs, initiate supplemental oxygen as indicated, administer medications as above, limit epinephrine to shock or severe respiratory distress. Call EMS and continue supportive care, while monitoring patient closely until arrival. Notify the prescribing physician/clinician as soon as able. | |

## ADDITIONAL ORDERS

## ORDERING PRESCRIBER

**Prescriber Name:** _____

**Prescriber Signature:** _____

**As the ordering prescriber, I allow for product selection and authorize the administering practitioner to substitute for another monoclonal antibody identified on this order form, unless the box below is checked.**

- ☐ **Dispense as written (DAW) *** checking DAW could result in significant delays in treatment based on availability of medication supplies *****

**Direct Contact Number:** (___) ___–_____ **Fax Number:** (___) ___–_____

**Order date:** _____ ☐ **Check if administered under a standing order**



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| REPORTING REQUIREMENTS |
| --- |
| In accordance with the Michigan Public Health Code (MCL 331.531), the following survey must be completed for each patient treated with monoclonal antibody (MAB) therapy supplied through the State of Michigan: https://forms.office.com/Pages/ResponsePage.aspx?id=sgF4Zzdipk67RItjfx6ergRINfmr3E1Njq-ZF3K4vsBUMjRaVE43VjM1MFJRTllCVzBMMk9HWVVBTiQlQCN0PWcu. |

| POST ADMINISTRATION SUMMARY |
| --- |
| ☐ No administration related problems<br><br>**Additional Comments:** |

**Patients, Parents and Caregivers EUA Resources:**

- ☐ Fact Sheet For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Casirivimab and Imdevimab for Coronavirus Disease 2019 (COIV-19): **https://www.fda.gov/media/145612/download**.
- ☐ Fact Sheet For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab for Coronavirus Disease 2019 (COVID-19): **https://www.fda.gov/media/145803/download**.
- ☐ Fact Sheet For Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Sotrovimab for Coronavirus Disease 2019 (COVID-19): **https://www.fda.gov/media/149533/download.**

**Patient Consent:** by signing this I attest to have read, or had explained to me, the patient fact sheet for the monoclonal antibody that I am receiving and have been provided an opportunity to ask questions, which have been answered to my satisfaction. I understand the potential risks and benefits associated with monoclonal antibody therapy and agree to receive the administration of this medication.

| Form Completed by/Relationship to Patient | Signature | Date |
| --- | --- | --- |

**Standing Orders:** Note if administration is done under a standing order issued by an authorized prescriber, the administering clinician should complete all applicable sections of this form in accordance with the Standing Order. The name of the prescriber issuing the Standing Order should be documented and the Standing Order box checked on Page 3.