Casirivimab-Imdevimab is now authorized for **post-exposure prophylaxis** in patients who meet the following criteria:

**Table 1: Casirivimab-Imdevimab Prophylaxis Criteria (must meet at least 1 from each box)**

|  |
| --- |
| Adult or pediatric patient (12 years of age and older weighing at least 40 kg) at high risk for progression to severe COVID-19\* |
| Asymptomatic resident with a positive SARS-CoV-2 test  **or**  Not fully vaccinated (defined as ≥2 weeks after final dose of vaccination)  **or**  Not expected to mount an adequate immune response to vaccination (see **Table 2**) |
| Have been exposed to an individual infected with SARS-CoV-2 consistent with CDC close contact criteria±  **or**  Are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (e.g., **nursing homes**, especially if a case of COVID-19 is identified in the same unit/area where the individual is residing) |

*\*Residence in LTCF can be considered a factor of high risk for progression to severe COVID-19. Other risk factors may include older age (for example, age ≥65 years of age), obesity or being overweight (for example, BMI >25 kg/m2), chronic kidney disease, diabetes, immunosuppressive disease or immunosuppressive treatment, cardiovascular disease or hypertension, chronic lung diseases, sickle cell disease, neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies), having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)). For other risk factors, see:* [*https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html*](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html)

*± Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). See this website for additional details:* [*https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*](https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html)

**Table 2: Examples of Patients Not Expected to Mount an Adequate Immune Response to Vaccination (check one if applicable)**

|  |
| --- |
| Immunocompromising condition (e.g., on chemotherapy for cancer, hematologic malignancies, recipient of a hematopoietic stem cell or solid organ transplant, untreated HIV with CD4+ count <200, combined primary immunodeficiency disorder)  Currently taking immunosuppressive medications (e.g., prednisone >20 mg [or equivalent] for >14 days, mycophenolate, cyclosporine, tacrolimus, sirolimus, everolimus, azathioprine, leflunomide, tofacitinib, biologics such as adalimumab, rituximab, or etanercept)  End-stage renal disease requiring hemodialysis  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

*Source:* [*https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html*](https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html)

**As the healthcare provider, you MUST communicate to your patient or parent/caregiver information consistent with the “Fact Sheet for Patients and Parents/Caregivers” prior to the patient receiving casirivimab-imdevimab AND MUST document in the patient’s medical record. This order form certifies that:**

* I have confirmed that this patient meets criteria for emergency use of casirivimab-imdevimab.
* I have reviewed with the patient/current medical decision maker information consistent with that provided by the FDA’s Emergency Use Authorization (EUA) *“Fact Sheet for Patients and Parents/Caregivers”* for casirivimab-imdevimab and have provided a copy of this fact sheet.
* Communication to the patient/caregiver included:
  + FDA has authorized the emergency use of casirivimab-imdevimab for the treatment of mild to moderate confirmed COVID-19 who are at high risk of progressing to severe COVID-19 and/or hospitalization.
  + FDA has authorized the emergency use of casirivimab-imdevimab for post-exposure prophylaxis in patients meeting the above criteria. Casirivimab-imdevimab is not authorized for pre-exposure prophylaxis for prevention of COVID-19.
  + The patient or parent/caregiver has the option to accept or refuse casirivimab-imdevimab.
  + The significant known and potential risks and benefits of casirivimab-imdevimab, and the extent to which such risks and benefits are unknown.
  + Information on available alternative treatments and the risks and benefits of those alternatives including clinical trials.
  + Patients treated with casirivimab-imdevimab should continue to self-isolate and use infection control measures according to CDC guidelines.
* I have discussed that this medication is an FDA unapproved drug authorized for emergency use only for patients with laboratory confirmed COVID-19.  I have communicated the risks, benefits, and alternatives to use as outlined in the fact sheet and have offered the opportunity for questions.
* The patient/current medical decision maker elected to proceed with treatment and has been Informed to report all adverse reactions to a healthcare provider1

1The prescribing health care provider and/or the provider’s designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to casirivimab-imdevimab treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words “REGEN-COV use for COVID-19 under Emergency Use Authorization (EUA)” in the description section of the report. Complete and submit the report here: www.fda.gov/medwatch/report.htm

**Order:**

**Casirivimab 600 mg and imdevimab 600 mg administered together as a single IV infusion given once peripherally over 21 minutes with a 0.2/0.22 micron in-line filter.**

**or**

**Casirivimab 600 mg and imdevimab 600 mg administered together as 4 subcutaneous injections administered consecutively, each at a different body site,** **into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.2**

**The infusion/injections are to be followed by 1 hour of patient monitoring for infusion reaction3, including vital sign checking every 15 minutes for that 1 hour.**

2When administering the subcutaneous injections, it is recommended that providers use different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of casirivimab and imdevimab. DO NOT inject into skin that is tender, damaged, bruised, or scarred.

3Signs and symptoms of infusion reaction can include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness

Prescriber signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Prescriber name (Please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_