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Confirm the Coronavirus 2019 (COVID-19) Diagnosis. Confirm that your patient:

- has received positive results of direct SARS-CoV-2 viral testing
- is an adult or a pediatric patient (12 years of age and older weighing at least 40 kg)
- has mild to moderate COVID-19
- is at high risk for progression to severe COVID-19, (as defined below) including hospitalization or death

2

Confirm that the patient is at high risk. The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progressing to severe COVID-19:

- Older age (for example, age ≥ 65 years of age)
- Obesity or being overweight (for example, BMI > 25 kg/m², or if age 12-17, have BMI ≥ 85 th percentile for their age and gender based on [CDC growth charts](#))
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- 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))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above.

For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the [CDC website](#). Healthcare providers should consider the benefit-risk for an individual patient.

REGEN-COV, (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab) supplied as individual vials to be administered together, is authorized for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. [see Limitations of Authorized Use]

- REGEN-COV has not been approved, but has been authorized for emergency use by FDA
- This use is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner
- Healthcare providers should review the [Fact Sheet for Healthcare Providers](#) for information on the authorized use of REGEN-COV and mandatory requirements of the EUA and must comply with the requirements of the EUA. [The FDA Letter of Authorization](#) is available for reference, as well as the [Dear Healthcare Provider Letter](#) and [Patient Fact Sheet](#)

3 Select the most appropriate route of administration for your patient to receive REGEN-COV.

REGEN-COV may be administered by intravenous infusion (strongly recommended) or subcutaneous injection (when intravenous (IV) infusion is not feasible and would lead to delay in treatment).

- For IV infusion, find an infusion center near your patient. You can either:
 - Contact Regeneron Medical Information at 1-844-734-6643, explain that you are a healthcare provider and want to prescribe REGEN-COV, and ask for information regarding infusion sites that are near your patient, or
 - Refer to either of the following infusion site locators:
 - [National Infusion Center Association \(NICA\) Infusion Center Locator](#)
 - [HHS Office of the Assistant Secretary for Preparedness and Response \(ASPR\) Infusion Center Locator](#)
- For subcutaneous injection, follow the preparation and administration instructions in the fact sheet for healthcare providers (also available on www.regencov.com), and/or assist your patient in finding an appropriate treatment site

4 Write the order for REGEN-COV.

- For IV infusion, you may reference the [National Infusion Center Association \(NICA\) intravenous infusion order form](#), or you can contact the infusion site to understand their preferred process at the site level for prescribing REGEN-COV
- For subcutaneous injection, you may reference the [NICA subcutaneous injection order form](#).
- Counsel your patient about where and how they will receive the medication, and that they should receive it as soon as possible

5 Share the following educational resources with your patient:

- Refer the patient to www.regencov.com where they can find the [Patient Fact Sheet](#) and other information
- Have your patient contact Regeneron Medical Information at 1-844-734-6643, or medical.information@regeneron.com if they have any questions about the medication
- Refer your patient to the [HHS resource](#) for more information on COVID-19 monoclonal antibody treatments

AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

REGEN-COV has not been approved, but has been authorized for emergency use by FDA

These uses are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner

Healthcare providers should review the [Fact Sheet for Healthcare Providers](#) for information on the authorized uses of REGEN-COV and mandatory requirements of the EUA and must comply with the requirements of the EUA. The [FDA Letter of Authorization](#) is available for reference, as well as the [Dear Healthcare Provider Letter](#) and [Patient Fact Sheet](#).

Authorized Use and Important Safety Information (continued)

Treatment:

REGEN-COV is authorized for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death

Limitations of Authorized Use (Treatment)

- REGEN-COV is 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 flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity
- Monoclonal antibodies, such as REGEN-COV, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high-flow oxygen or mechanical ventilation

Criteria for Identifying High Risk Individuals

Please refer to the [Fact Sheet for Healthcare Providers](#) for criteria for identifying high risk individuals

SARS-CoV-2 Viral Variants

Circulating SARS-CoV-2 viral variants may be associated with resistance to monoclonal antibodies. Healthcare providers should review the Antiviral Resistance information in Section 15 of the Fact Sheet for details regarding specific variants and resistance, and refer to the CDC website (<https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html>) as well as information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

Important Safety Information

REGEN-COV (casirivimab and imdevimab) is an unapproved investigational therapy, and there are limited clinical data available. Serious and unexpected adverse events may occur that have not been previously reported with REGEN-COV use.

- **Contraindication:**

REGEN-COV is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to REGEN-COV

- **Warnings and Precautions:**

- **Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of REGEN-COV. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Hypersensitivity reactions occurring more than 24 hours after the infusion have also been reported with the use of REGEN-COV under EUA. Infusion-related reactions, occurring during the infusion and up to 24 hours after the infusion, have been observed with administration of REGEN-COV. These reactions may be severe or life threatening

- **Signs and symptoms of infusion-related reactions**

may include: fever, difficulty breathing, reduced oxygen saturation, chills, nausea, arrhythmia (e.g., atrial fibrillation, tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions (e.g., pre-syncope, syncope), dizziness, fatigue and diaphoresis. Consider slowing or stopping the infusion and administer appropriate medications and/or supportive care if an infusion-related reaction occurs

- **Clinical Worsening After REGEN-COV Administration:** Clinical worsening of COVID-19 after administration of REGEN-COV has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (e.g., atrial fibrillation, tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to REGEN-COV use or were due to progression of COVID-19

Authorized Use and Important Safety Information (continued)

- **Limitations of Benefit and Potential for Risk in Patients with Severe COVID-19:** Benefit of treatment with REGEN-COV has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as REGEN-COV, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high-flow oxygen or mechanical ventilation. Therefore, REGEN-COV is 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 flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity
- **Adverse Reactions:**
 - **COV-2067 (Treatment):** Infusion-related reactions (adverse event assessed as causally related by the investigator) of grade 2 or higher severity have been observed in 10/4,206 (0.2%) of those who received REGEN-COV at the authorized dose or a higher dose. Three subjects receiving the 8,000 mg dose of REGEN-COV, and one subject receiving the 1,200 mg casirivimab and 1,200 mg imdevimab, had infusion-related reactions (urticaria, pruritus, flushing, pyrexia, shortness of breath, chest tightness, nausea, vomiting, rash) which resulted in permanent discontinuation of the infusion. All events resolved. Anaphylactic reactions have been reported in the clinical program in subjects receiving REGEN-COV. The events began within 1 hour of completion of the infusion, and in at least one case required treatment including epinephrine. The events resolved
 - **COV-2093 (Subcutaneous Dosing):** Injection site reactions occurred in 12% and 4% of subjects following single dose administration in the REGEN-COV and placebo groups, respectively. Remaining safety finding following subcutaneous administration in the REGEN-COV group were similar to the safety findings observed with intravenous administration in COV-2067. With repeat dosing, injection site reactions occurred in 252 subjects (35%) in the REGEN-COV group and 38 subjects (16%) in the placebo group; all injection site reactions were grade 1 or 2 in severity. Hypersensitivity reactions occurred in 8 subjects (1%) in the REGEN-COV group; and all hypersensitivity reactions were grade 1 or 2 in severity. There were no cases of anaphylaxis
- **Patient Monitoring Recommendations:** Clinically monitor patients during dose administration and observe patients for at least 1 hour after intravenous infusion or subcutaneous dosing is complete
- **Use in Specific Populations:**
 - **Pregnancy:** There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. REGEN-COV should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus
 - **Lactation:** There are no available data on the presence of casirivimab and/or imdevimab in human milk or animal milk, the effects on the breastfed infant, or the effects of the drug on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for REGEN-COV and any potential adverse effects on the breastfed child from REGEN-COV or from the underlying maternal condition

Reporting Adverse Events

- The prescribing healthcare provider and/or the provider's designee are responsible for mandatory reporting of all medication errors and **ALL SERIOUS ADVERSE EVENTS** potentially related to REGEN-COV. These adverse events must be reported within 7 calendar days from the onset of the event
- Healthcare facilities and providers must report therapeutics information and demonstrate adequate utilization via data reported through HHS Protect, Teletracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services
- **MedWatch adverse event reports can be submitted to the FDA [here](#), by submitting a postage-paid Form [FDA 3500](#) and returning by mail/fax, or by calling 1-800-FDA-1088 to request a reporting form.** In addition, please provide a copy of all FDA MedWatch forms to Regeneron Pharmaceuticals, Inc via fax (1-888-876-2736) or email (medical.information@regeneron.com)

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Please see additional Important Safety Information on the following pages.

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