REGEN-COV coding and reimbursement guide

How to use this guide

The REGEN-COV Coding and Reimbursement Guide provides an overview of the relevant codes, current as of May 2021, that may support reimbursement of the administration of REGEN-COV in outpatient settings.

The Centers for Medicare and Medicaid Services (CMS) has issued specific coding guidance for REGEN-COV and its administration. In addition, please note that there is comprehensive documentation and guidance, as published by CMS for other aspects of COVID-19-diagnostic laboratory services and treatment, which are not outlined in this information.

The information presented in this guide is for informational purposes only and is not intended to guarantee or provide reimbursement or legal advice. Regeneron and its agents make no warranties or guarantees concerning the accuracy or appropriateness of this information for your particular use. The information in this guide is gathered from multiple resources and subject to change without notice. Payer coding requirements may vary or change over time, so it is important to regularly check with each payer to confirm payer-specific requirements.

The following information pertains to REGEN-COV therapy and administration:

- Review of relevant codes
  - International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes
  - Level II Healthcare Common Procedure Coding System (HCPCS)
    - Administration code
    - Product code
  - National Drug Code (NDC)
  - Revenue Coding for Hospital Administration
- Additional considerations

AUTHORIZED USE

REGEN-COV, (casirivimab with imdevimab 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 progressing to severe COVID-19 and/or hospitalization. [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**

LIMITATIONS OF AUTHORIZED USE

- REGEN-COV (casirivimab with imdevimab) 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
- 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

Review of relevant codes

Codes should be confirmed with each respective payer, as there may be variability in both coding and documentation requirements.

INTERNATIONAL CLASSIFICATION OF DISEASES, TENTH REVISION, CLINICAL MODIFICATION (ICD-10-CM) DIAGNOSIS CODES

Code[1]	Description	Notes
Z23	Encounter for immunization	Required by Medicare as primary diagnosis. Other payers may have different requirements
U07.1	COVID-19	For discharges on or after April 1, 2020, through the duration of the COVID-19 public health emergency period

Effective January 1, 2021, the Centers for Disease Control and Prevention (CDC), under the National Emergencies Act Sections 201 and 301, announced further additions to ICD-10-CM Classification related to COVID-19. These additions can be viewed here: https://www.cdc.gov/nchs/data/icd/Announcement-New-ICD-code-for-coronavirus-19-508.pdf

Healthcare providers should refer to individual payer policies on COVID-19 billing and coding as appropriate.

LEVEL II HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) ADMINISTRATION CODES

REGEN-COV will be administered via a single intravenous (IV) infusion.[2]

Code[3,4]	Description
M0243	IV infusion, casirivimab and imdevimab, includes infusion and post administration monitoring
M0244	IV infusion, casirivimab and imdevimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency

LEVEL II HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) PRODUCT CODE

The following HCPCS code may be used to identify REGEN-COV.

Code[3]	Description
Q0243	Injection, casirivimab and imdevimab 2,400 mg

Select payers may require further claims documentation to better identify both casirivimab (REGN10933) and imdevimab (REGN10987), which could include but not be limited to:

- National Drug Codes (NDCs)
- Descriptor of monoclonal antibody name(s)
- Mode of administration

Review of relevant codes *(cont'd)*

CASIRIVIMAB AND IMDEVIMAB NATIONAL DRUG CODE (NDC)[2]

Antibody	Concentration	Packaging size	NDCs for Billing[a]
Casirivimab	1,332 mg/11.1 mL (120 mg/mL)	1 vial per carton	61755-**0**024-01
	300 mg/2.5 mL (120 mg/mL)	1 vial per carton	61755-**0**026-01
Imdevimab	1,332 mg/11.1 mL (120 mg/mL)	1 vial per carton	61755-**0**025-01
	300 mg/2.5 mL (120 mg/mL)	1 vial per carton	61755-**0**027-01

DOSE PACK PROVIDING 1 TREATMENT DOSE OF 2,400 MG (1,200 MG CASIRIVIMAB AND 1,200 MG IMDEVIMAB)[2]

Dose-Pack Size	Dose-Pack Components	Concentration	Dose-Pack NDCs for Billing[a]
2 Cartons	**1 casirivimab REGN10933** (NDC 61755-024-01)	1,332 mg/11.1 mL (120 mg/mL)	61755-**0**035-02
	1 imdevimab REGN10987 (NDC 61755-025-01)	1,332 mg/11.1 mL (120 mg/mL)	
8 Cartons	**4 casirivimab REGN10933** (NDC 61755-026-01)	300 mg/2.5 mL (120 mg/mL)	61755-**0**036-08
	4 imdevimab REGN10987 (NDC 61755-027-01)	300 mg/2.5 mL (120 mg/mL)	
5 Cartons	**1 casirivimab REGN10933** (NDC 61755-024-01)	1,332 mg/11.1 mL (120 mg/mL)	61755-**0**037-05
	4 imdevimab REGN10987 (NDC 61755-027-01)	300 mg/2.5 mL (120 mg/mL)	
5 Cartons	**4 casirivimab REGN10933** (NDC 61755-026-01)	300 mg/2.5 mL (120 mg/mL)	61755-**0**038-05
	1 imdevimab REGN10987 (NDC 61755-025-01)	1,332 mg/11.1 mL (120 mg/mL)	

Note: casirivimab = REGN10933; imdevimab = REGN10987.
[a]Product NDC numbers are 10 digits, however proper billing requires an 11-digit number in a 5-4-2 format. Converting NDCs from a 10-digit to an 11-digit format for billing requires an additional zero and is indicated in the table above in bold font.[5]

Review of relevant codes *(cont'd)*

REVENUE CODING FOR HOSPITAL ADMINISTRATION[4]

Revenue codes allow hospitals to capture cost data for billing of services provided.

Revenue Code	Description
Administration	
0771	Preventive care services, vaccine administration
Drug	
0636	Pharmacy, drugs requiring detailed coding

Additional Considerations

Since REGEN-COV will be made available by the government to providers at no cost during the initial EUA period, providers may not receive third-party payer reimbursement for the therapy when delivered in the hospital outpatient setting of care. However, providers may be able to obtain payment for the drug administration service. Providers should clarify claim submission requirements by payer, as the documentation may vary.

Since COVID-19 monoclonal antibody doses are provided by the government without charge, providers should only bill for the administration. Healthcare providers should not include the COVID-19 monoclonal antibody codes on the claim when the product is provided for free. However, CMS recognizes that many provider billing systems require a charge to be submitted, even when a product is provided for free or without charge. In this instance, physicians and non-physician practitioners bill the monoclonal antibody or COVID-19 immunization vaccine with a token charge of $0.01 (one penny). Providers should clarify all requirements by payer, as guidelines may vary by payer.

Healthcare personnel who provide these services to enrollees in a Medicare Advantage Plan should submit claims for monoclonal antibodies to treat COVID-19 that are covered by Part B in accordance with Section 3713 of the CARES Act to traditional Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.

Authorized Use and Important Safety Information

REGEN-COV, (casirivimab with imdevimab 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 progressing to severe COVID-19 and/or hospitalization. [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**

DEFINITION OF HIGH RISK PATIENTS

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/m^2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm
- 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 progressing 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: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient.

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.

Authorized Use and Important Safety Information *(cont'd)*

ADDITIONAL INFORMATION FOR HEALTHCARE PROVIDERS:

- Casirivimab and imdevimab are each provided in a separate carton and vial. **Casirivimab** and **imdevimab** vial labels and carton labeling may instead be labeled **REGN10933** and **REGN10987**, respectively
- Each REGEN-COV dose pack contains sufficient number of vials of casirivimab (REGN10933) and imdevimab (REGN10987) to prepare one treatment dose
- You may receive cartons and vials of casirivimab and imdevimab that are labeled "for intravenous infusion or subcutaneous injection." **However, casirivimab and imdevimab must be administered together after dilution by intravenous (IV) infusion only**
- Store casirivimab and imdevimab together in inventory. See regencov.com/hcp/dosing/packaging for images of packaging
- REGEN-COV may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary
- **The authorized dosage is 1200 mg of casirivimab with 1200 mg of imdevimab administered together as a single intravenous (IV) infusion as soon as possible after a positive viral test for SARS-CoV-2 and within 10 days of symptom onset.** Since the optimal dosing regimen has not yet been established, it might be updated as data become available. See the **Fact Sheet for Healthcare Providers** for complete dosage, preparation, and administration instructions

- 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)

Authorized Use and Important Safety Information *(cont'd)*

Important Safety Information

REGEN-COV (casirivimab with 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.

- **Warnings and Precautions:**
  - **Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of REGEN-COV (casirivimab with imdevimab). If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care. Infusion-related reactions 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, arrythmia (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, dizziness, fatigue and diaphoresis. If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care
  - **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, arrythmia (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
  - **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:**
  - None of the SAEs were considered to be related to study drug. SAEs that were reported as Grade 3 or 4 adverse events were pneumonia, hyperglycemia, nausea and vomiting (2,400 mg REGEN-COV), intestinal obstruction and dyspnea (8,000 mg REGEN-COV) and COVID-19, pneumonia and hypoxia (placebo). REGEN-COV **is not authorized at the 8,000-mg dose (4,000 mg casirivimab and 4,000 mg imdevimab)**
  - One anaphylactic reaction was reported in the clinical program. The event began within 1 hour of completion of the infusion, and required treatment including epinephrine. The event resolved. Infusion-related reactions, of Grade 2 or higher severity, were reported in 4 subjects (1.5%) in the 8,000-mg (4,000 mg casirivimab and 4,000 mg imdevimab) arm. These infusion-related reactions events were moderate in severity; and included pyrexia, chills, urticaria, pruritus, abdominal pain, and flushing. One infusion-related reaction (nausea) was reported in the placebo arm, and none were reported in the 2,400-mg (1,200 mg casirivimab and 1,200 mg imdevimab) arm. In two subjects receiving the 8,000-mg dose of REGEN-COV, the infusion-related reactions (urticaria, pruritus, flushing, pyrexia, shortness of breath, chest tightness, nausea, vomiting) resulted in permanent discontinuation of the infusion. All events resolved

Authorized Use and Important Safety Information *(cont'd)*

- **Patient Monitoring Recommendations:** Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete
- **Use in Specific Populations:**
  - **Pregnancy:** There is currently limited clinical experience in the use of REGEN-COV in COVID-19 patients who are pregnant. REGEN-COV therapy should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus
  - **Lactation:** There is currently no clinical experience in the use of REGEN-COV in COVID-19 patients who are breastfeeding. 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

References:

1. Data on file. Regeneron.
2. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab with imdevimab). Regeneron Pharmaceuticals, Inc. May 2021. https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf. Accessed May 18, 2021.
3. Centers for Medicare & Medicaid Services. Medicare monoclonal antibody COVID-19 infusion program instruction. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies. Updated December 3, 2020. Accessed May 18, 2021.
4. Centers for Medicare & Medicaid Services. COVID-19 frequently asked questions (FAQs) on Medicare fee-for-service (FFS) billing. https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf. Updated May 6, 2021. Accessed May 18, 2021.
5. US Food and Drug Administration. National Drug Code database background information. https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information. Accessed May 18, 2021.

Refer to the Fact Sheet for Healthcare Providers and visit regencov.com for more information.