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 September 2021, that may support reimbursement of the administration of REGEN-COV.

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.

For the most up-to-date information regarding Medicare coverage, coding, payment for administration, and billing of monoclonal antibody products to treat COVID-19, visit the Centers for Medicare & Medicaid Services website **here**.

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 Code
  - Level II Healthcare Common Procedure Coding System (HCPCS)
    - Administration code
    - Product codes
  - National Drug Code (NDC)
  - Revenue Coding for Hospital Administration
- Additional considerations

AUTHORIZED USES AND IMPORTANT SAFETY INFORMATION

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

REGEN-COV coding and reimbursement guide *(cont'd)*

Post-Exposure Prophylaxis:

REGEN-COV is authorized in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:

- not fully vaccinated **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) **and**
  - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC) **or**
  - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)

Limitations of Authorized Use (Post-Exposure Prophylaxis)

- Post-exposure prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19
- REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19

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**

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

Review of relevant codes

Codes should be confirmed with each 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[1,2]	Description	Notes
U07.1	COVID-19	For discharges on or after April 1, 2020, through the duration of the COVID-19 public health emergency period
Z20.822	Contact with and (suspected) exposure to COVID-19	N/A

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 the 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

Code[3]	Site of care	Description
M0243	Outpatient (not including the home)	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring
M0244	Home or residence	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, 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.
M0240	Outpatient (not including the home)	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, **subsequent repeat doses**
M0241	Home or residence	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, 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, **subsequent repeat doses**

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

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

Code[3]	Description
Q0244	Injection, casirivimab and imdevimab, 1,200 mg
Q0240	Injection, casirivimab and imdevimab, 600 mg

Prior to June 3rd, 2021, the HCPCS code Q0243 (injection, casirivimab and imdevimab, 2,400 mg) was used to identify REGEN-COV. Providers may submit claims for patients given REGEN-COV prior to June 3rd using this code if appropriate/needed.

Review of relevant codes *(cont'd)*

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

CASIRIVIMAB AND IMDEVIMAB NATIONAL DRUG CODE (NDC)[4]

Antibody	Concentration	Packaging size	NDCs for Billing[a]
Co-Formulated Casirivimab and Imdevimab	600 mg/600 mg per 10 mL (60 mg/60 mg per mL)	1 vial per carton	61755-**0**039-01
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 1,200 MG CASIRIVIMAB AND 1,200 MG IMDEVIMAB[4]

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)	

[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)*

CASIRIVIMAB AND IMDEVIMAB CO-PACKAGED CARTON[4]

Co-Packaged Carton Size	Co-Packaged Components	Concentration	Co-Packaged Carton NDCs for Billing[a]
2 vials	1 casirivimab (NDC 61755-024-00)	1,332 mg/11.1 mL (120 mg/mL)	61755-**0**042-02
	1 imdevimab (NDC 61755-025-00)	1,332 mg/11.1 mL (120 mg/mL)	
2 vials	1 casirivimab (NDC 61755-026-00)	300 mg/2.5 mL (120 mg/mL)	61755-**0**045-02
	1 imdevimab (NDC 61755-027-00)	300 mg/2.5 mL (120 mg/mL)	

[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]

REVENUE CODING FOR HOSPITAL ADMINISTRATION[6]

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

Authorized Uses and Important Safety Information

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

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

IMPORTANT SAFETY INFORMATION (CONT'D)

- **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
  - **Limitations of Benefit and Potential for Risk in Patients with Severe 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

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

IMPORTANT SAFETY INFORMATION (cont'd)

- **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-2069 (Post-exposure prophylaxis):** In subjects who were SARS-CoV-2 negative at baseline (Cohort A), injection site reactions (all grade 1 and 2) occurred in 55 subjects (4%) in the REGEN-COV group and 19 subjects (2%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV group were erythema and pruritus. Hypersensitivity reactions occurred in 2 subjects (0.2%) in the REGEN-COV group and all hypersensitivity reactions were grade 1 in severity. In subjects who were SARS-CoV-2 positive at baseline (Cohort B), injection site reactions, all of which were grade 1 or 2, occurred in 6 subjects (4%) in the REGEN-COV group and 1 subject (1%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV group were ecchymosis and erythema
  - **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

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

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)

References:

1. ICD-10-CM official guidelines for coding and reporting FY 2021. https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2021.pdf. Accessed August 19, 2021.
2. New ICD-10-CM code for the 2019 novel coronavirus (COVID-19). https://www.cdc.gov/nchs/data/icd/Announcement-New-ICD-code-for-coronavirus-19-508.pdf. Accessed August 19, 2021.
3. Centers for Medicare & Medicaid Services. COVID-19 vaccines and monoclonal antibodies. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies. Updated August 19, 2021. Accessed August 19, 2021.
4. Fact sheet for health care providers. Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab and imdevimab). Regeneron Pharmaceuticals, Inc. September 2021. https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf.
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 August 19, 2021.
6. 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 July 2, 2021. Accessed August 19, 2021.

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

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REGEN-COV™ (casirivimab and imdevimab)