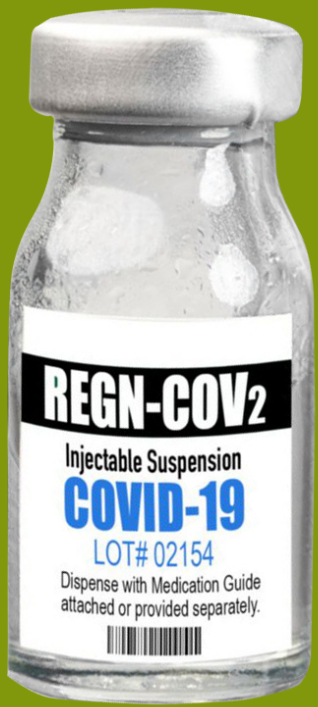
COVID-19:
TREATMENT BILLING GUIDE
Regeneron EUA
(Casirivimab + Imdevimab)

DEC 11th UPDATE

November 23, 2020.
On November 21, 2020, the Federal Drug Administration (FDA) granted Emergency Use Authorization (EUA) to Regeneron Pharmaceuticals for its Regeneron infusion for COVID-19 treatment. Regeneron is a combination of two monoclonal antibodies, casirivimab and imdevimab, to be given together to treat mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older and weighing at least 40 kilograms, or approximately 88 pounds) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19. This includes those who are 65 years of age or older or who have certain chronic medical conditions.

The company states the intravenous infusion should be administered as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of COVID-19 symptom onset. Administration may only be done in settings in which health care 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. To review the fact sheet for Health Care Providers EUA of Casirivimab and Imdevimab regarding the limitations of authorized use, visit https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf



The monoclonal antibody combination is not authorized for patients who are hospitalized for COVID-19 or require oxygen. Clinical trials have not shown benefits for using the treatment in hospitalized patients, and in fact, it may lead to worse outcomes for those who need oxygen or ventilation, the FDA says. Possible side effects include a sudden allergic reaction called anaphylaxis and IV-related reactions, fever, chills, hives, itching, and skin reddening or blotching.

COVID-19: Treatment Billing Guide, Regeneron EUA

Enrollment

- Health care providers will follow the same enrollment process when administering Regeneron infusion as those administering the other COVID-19 vaccines.
- To review the provider enrollment information, visit https://www.cms.gov/medicare/covid-19/enrollment.

Payment for Product

- During the COVID-19 public health emergency (PHE), ***Medicare will cover and pay for these infusions the same way it covers and pays for COVID-19 vaccines (when furnished consistent with the EUA)***. This in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).
- Medicare will not provide payment for the monoclonal antibody products that health care providers receive for free, as will be the case for the product's initial availability in response to the COVID-19 PHE.
- IF, health care providers begin to purchase these monoclonal antibody products (after the initial offering), CMS anticipates setting payment rates the same as it does for COVID-19 vaccines. Example: Medicare will pay 95% of the average wholesale price (AWP) for COVID-19 vaccines provided/furnished in physician office settings and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines.
- Medicare Beneficiaries pay no cost sharing for these monoclonal antibody infusion:
    - o No co-payment/coinsurance
    - o No deductible

Payment for Infusion

- Initial payment rate for Regeneron product infusion/administration is inclusive of the preparation time, one (1) hour infusion time and post-administration monitoring while in the hospital OP setting.
- Rates will be geographically adjusted. Currently, rate of payment is $309.60.

Billing for Infusion Administration

- Health care providers can bill for the administration of the monoclonal antibody infusion on a single claim for COVID-19, or, submit claims on roster bill according to the FDA EUA.
- Health care providers are expected to maintain appropriate and supportive documentation attesting to the medical necessity of the service. This to include:
    - o Support of the terms of the EUA are met,
    - o For the treatment of mild to moderate COVID-19, with positive viral test of direct SARS-CoV-2
    - o Patient is at high risk for progression to severe COVID-19, and/or hospitalization
    - o Name of the practitioner who ordered or made the decision to administer (this is also the case where claims are submitted on roster bills)
- Health care providers can only bill for the administration of the monoclonal antibody infusion when doses are provided by the government without charge.
- Health care providers should not include the monoclonal antibody codes on the claim when the product is provided for free.
- Health care providers participating in a Medicare Advantage Plan should submit claims for Regeneron infusion administration to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021.
- M0243 Intravenous infusion, Casirivimab and Imdevimab includes infusion and post administration monitoring.

COVID-19: Treatment Billing Guide, Regeneron EUA

Guidelines

- Regeneron EUA is a combination monoclonal antibody (casirivimab + imdevimab); under CMS guidelines this drug falls under the Chemotherapy Hierarchy for administration:
  - o These patients present a high-risk population with mild to moderate symptomology for COVID-19
  - o Patients must be 12-years of age or older and weigh at least 40 kg (approximately 88 pounds) with positive viral test of direct SARS-CoV-2
  - o High risk for progressing to severe COVID-19 and/or hospitalization
  - o Administer Regeneron infusion within 10 days of symptom onset
  - o These patients cannot be serviced in the same area with any other immunocompromised patients receiving Chemotherapy, due to the high potential of cross contamination of the environment regardless of the distance and life expectancy of the virus itself on surfaces
  - o The administration of Regeneron infusion must be done under direct physician supervision
    - ·This does not mean the physician administers the drug, however, must be present and immediately available to furnish assistance and direction throughout the performance of the procedure. The physician does not need to be present in the actual room. This is due to the high adverse reaction to the drug in the form of anaphylaxis.
  - o Generally, an emergency kit is available with the required medications to mitigate the reaction of anaphylaxis
  - o Any adverse reaction during the administration or observation period following must be reported to the FDA-SRP web page or via the FAERS Electronic Submissions web page. Either report must state **"Use of Casirivimab and Imdevimab was under an EUA"**; and in accordance with the Fact Sheet for Healthcare Providers: www.fda.gov/medwatch/report.htm OR complete and submit the FDA Form 3500 (Health Professional) by fax at 1-800-FDA-0178
  - o Patients treated with Regeneron (casirivimab and imdevimab) should continue to self-isolate and use infection control measures according to the CDC guidelines (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing).

Charging

Facility with FREE drug: HCPC M0243 Infusion and Monitoring	Facility: If adverse reactions occur, can utilize CPT 96366, 96375 and 96376
Facility + Drug Cost: HCPC M0243 Infusion and Monitoring	Facility: if adverse reactions occur, can utilize CPT 96366, 96375 and 96376

Professional:
E&M New 99201 - 99205 | OR | E&M Est 99211 - 99215

E&Ms are based on intensity of service to severity of illness and are for either New or Established patients

CPT 99070 abd 99072 are a possible for supplies and time of staff to mitigate infection/disease transmission during the evaluation, treatment or procedural services. NOTE: These CPTs cannot be billed along with an E&M Level.

References

- FDA Letter of Authorization
- Regeneron Fact Sheet Information /Patient Fact Sheet (English + Spanish)
- Emergency Use Authorization
- Fact Sheet for Health Care Providers

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