REGEN-COV Now Available for Subcutaneous Injections & Administration in Physician Offices

The FDA has issued an EUA to permit the emergency use of REGEN-COV supplied as individual vials to be administered in individuals 12 years of age and older (weighing at least 40 kg) for post-exposure prophylaxis of COVID-19.

Available Dosage Forms

- A single vial that contains two antibodies co-formulated in a 1:1 ratio of casirivimab and imdevimab or
- Individual antibody solutions in separate vials, which may be supplied in separate cartons or in a dose pack.

TREATMENT DOSAGE

The authorized dosage is 600 mg of casirivimab and 600 mg of imdevimab administered by 4 subcutaneous injections as soon as possible after positive SARS-CoV-2 viral testing and within 10 days of symptom onset.

POST-EXPOSURE PROPHYLAXIS DOSAGE

The authorized dosage is 600 mg of casirivimab and 600 mg of imdevimab administered by 4 subcutaneous injections as soon as possible following exposure to SARS-CoV-2.

For Subcutaneous Injection

• Administer casirivimab and imdevimab using the co-formulated vial or using the individual vials by subcutaneous injection.

• Clinically monitor patients after injections and observe patients for at least 1 hour.

Preparation for Subcutaneous Injection

Remove the vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. **Do not expose to direct heat. Do not shake the vials.** This product is preservative-free and therefore, the prepared syringes should be administered immediately.

For treatment, subcutaneous injection is an alternative route of administration when intravenous administration is not feasible and would lead to delay in treatment. For post-exposure prophylaxis, either subcutaneous injection or intravenous infusion can be administered.

MEDICAL ASSOCIATION OF THE STATE OF ALABAMA®

Preparation & Administration

Prepare 600 mg of casirivimab and 600 mg of imdevimab	Preparation of four syringes
Using casirivimab and imdevimab co-formulated vial	• Withdraw 2.5 mL solution per syringe into FOUR separate syringes
Using casirivimab and imdevimab individual vials	**Casirivimab:** Withdraw 2.5 mL solution per syringe into TWO separate syringes. May use: • Two vials of 2.5 mL **OR** • One vial of 11.1 mL (approximately half of the vial) **AND** **Imdevimab:** Withdraw 2.5 mL solution per syringe into TWO separate syringes. May use: • Two vials of 2.5 mL **OR** • One vial of 11.1 mL (approximately half of the vial) For a total of four syringes

Administration for Subcutaneous Injection

- For the administration of 600 mg of casirivimab and 600 mg of imdevimab, gather four syringes and prepared for subcutaneous injections
- Administer the subcutaneous injections consecutively, each at a different injection 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.
- When 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
- Clinically monitor patients after injections and observe patients for at least 1 hour.

If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriatemedications and/or supportive therapy.

MEDICAL ASSOCIATION OF THE STATE OF ALABAMA®

Eligibility Information

To be eligible for the outpatient treatment, individuals must have at least one condition that puts them at high risk for major complications or death from COVID-19. The high-risk categories include:

- Older age (for example 65 years and older)
- Obesity or being overweight
- Pregnancy
- Chronic Kidney Disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease or high blood pressure
- Chronic lung diseases
- Sickle cell disease
- Neurodevelopmental disorders
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation – not related to COVID-19)
- Other medical conditions of factors that place patients at high risk for progressing to severe COVID-19

MEDICAL ASSOCIATION OF THE STATE OF ALABAMA®

Ordering and Coding

AmerisourceBergen is the sole distributor for REGEN-COV. Amerisource asks that facilities order a two-week supply. an account can be set up here.

The form must be completed even if the facility has an existing Amerisource account.

Questions regarding ordering can also be addressed to:

- HHS: COVID19Therapeutics@hhs.gov
- Amerisource: C19therapies@Amerisoucebergen.com

Coverage & Reimbursement

All providers, including physician practices, need to follow the coding and payment information on the technical coding website here, and toolkit here. Medicare is paying for monoclonals under the vaccine benefit during the Public Health Emergency. During the PHE, the services to administer monoclonals are not technically physician services and they are paying for them consistent with how they pay for other vaccines (like the flu vaccine).

REIMBURSEMENT FOR POST-EXPOSURE PROPHYLAXIS (PEP) UNDER MEDICARE

If a private MD gives REGEN-COV SQ in their office, how much will the MD be reimbursed?
A: $450

If a nursing home provides REGEN-COV (either IV or SQ) for treatment or PEP, how much will nursing home be reimbursed?
A: If the patient's permanent residence is the nursing home, reimbursement is $750. If not permanent residence, then $450.

If a home health company provides REGEN-COV for treatment or PEP at patient's home, what is the reimbursement?
A: $750 at home

If a nursing home doesn't have sufficient staff and hires home health to provide REGEN-COV for treatment or PEP in a nursing home, what is the reimbursement?
A: If the patient's permanent residence is the nursing home, reimbursement is $750. If not permanent residence, then $450.

Are the reimbursement amounts for IV and SQ the same?
A: yes

MEDICAL ASSOCIATION OF THE STATE OF ALABAMA®

Coverage & Reimbursement

HCPCS CODE	MEDICARE	BCBS
M0243 CASIRIVIMAB & IMDEVIMAB INFUSION OR INJECTIONS & POST-ADMINISTRATION MONITORING	$450	$309
M0244 CASIRIVIMAB & IMDEVIMAB INFUSION OR INJECTIONS & POST-ADMINISTRATION MONITORING IN THE HOME OR RESIDENCE	$750	$750
M0240 CASIRIVIMAB & IMDEVIMAB INFUSION OR INJECTIONS & POST-ADMINISTRATION MONITORING, SUBSEQUENT REPEAT DOSES	$450	$309
M0241 CASIRIVIMAB & IMDEVIMAB INFUSION OR INJECTIONS & POST-ADMINISTRATION MONITORING IN THE HOME OR RESIDENCE, SUBSEQUENT REPEAT DOSES	$750	$750

Dose pack size	Dose pack components	Concentration	Dose pack NDCs for billing[a]
2 cartons	1 casirivimab REGN10933 (NDC 61755-024-01)	1,322 mg/11.1 mL (120 mg/mL)	61755-0035-02
	1 imdevimab REGN10987 (NDC 61755-025-01)	1,322 mg/11.1 mL (120 mg/mL)	
8 cartons	4 casirivimab REGN10933 (NDC 61755-026-01)	300 mg/2.5 mL (120 mg/mL)	61755-0036-08
	4 imdevimab REGN10987 (NDC 61755-027-01)	300 mg/2.5 mL (120 mg/mL)	

Antibody	Concentration	Package 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	61755-0039-01
Casirivimab	1332 mg/11.1 mL (120 mg/mL)	1 vial per carton	61755-0024-01
	300 mg/2.5 mL (120 mg/mL)	1 vial per carton	61755-0026-01
Imdevimab	1332 mg/11.1 mL (120 mg/mL)	1 vial per carton	61755-0025-01
	300 mg/2.5 mL (120 mg/mL)	1 vial per carton	61755-0027-01