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IMPORTANT PRESCRIBING INFORMATION

Subject: Temporary Alternative Packaging of Casirivimab and Imdevimab authorized to meet ongoing COVID-19 Public Health Demands

Dear Healthcare Provider:

The purpose of this notice is to make you aware of a new temporary alternative packaging for casirivimab and imdevimab (also known as REGEN-COV™). This alternative packaging contains individual antibody solutions of casirivimab and imdevimab in separate vials which are **co-packaged in a carton labeled as "casirivimab and imdevimab 120 mg/mL concentrate for solution for infusion" and manufactured by Roche**. Please be aware that the labels and labeling may cause some users to mistakenly believe that the vials contained within the carton are the co-formulated product and may contribute to confusion.

This co-packaged product will be distributed in addition to the current presentations of co-formulated REGEN-COV and dose packs of individual vial cartons of casirivimab and imdevimab. The co-packaged cartons were manufactured by Regeneron's development partner Roche Pharmaceuticals for distribution outside the United States; however, some will be distributed by Regeneron, to increase the available doses of casirivimab and imdevimab as we continue to combat the ongoing COVID-19 public health emergency. These casirivimab and imdevimab co-packaged cartons produced by Roche are available for pandemic use in the European Union. **The cartons include the same monoclonal antibodies that are authorized for use in the U.S. under REGEN-COV's Emergency Use Authorization (EUA)** and distributed as REGEN-COV co-formulated product or dose packaging of individual vial cartons. All other presentations of REGEN-COV may still be in inventory or distribution.

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Each Roche's co-packaged carton contains individual antibody solutions in separate vials as follows (shown in Figure 1 and Figure 2 below)**:**

- **One (1)** vial containing casirivimab; 300 mg/2.5 mL (120mg/mL) or 1,332 mg/11.1 mL (120 mg/mL)
- **One (1)** vial containing imdevimab; 300 mg/2.5 mL (120mg/mL) or 1,332 mg/11.1 mL (120 mg/mL)

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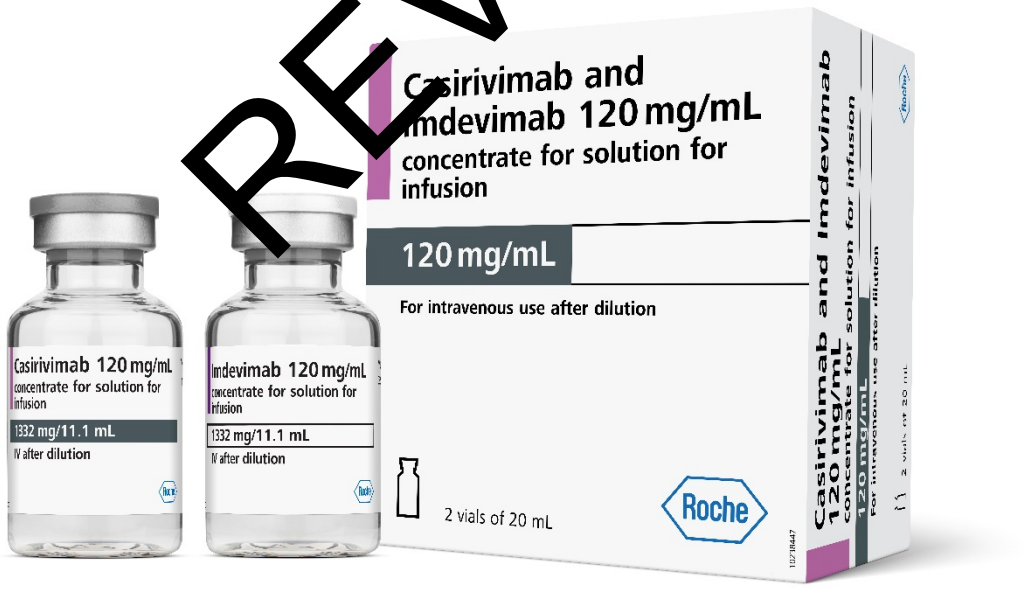
Figure 1. Roche-manufactured Co-packaged Casirivimab (300 mg/2.5mL) and Imdevimab (300mg/2.5mL)

Figure 2. Roche-manufactured Co-packaged Casirivimab (1332mg/11.1mL) and Imdevimab (1332mg/11.1mL)



Healthcare providers should be aware that the casirivimab and imdevimab formulations in individual vials in the co-packaged carton can be prepared and administered **the same** as the formulations in the individual vials in the REGEN-COV dose pack.

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The Healthcare Provider (HCP) Fact Sheet is enclosed with this letter for reference to the full prescribing information. Stay current with the latest Fact Sheet for Health Care Providers by visiting (https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf).

All formulations and presentations of casirivimab and imdevimab or REGEN-COV can be used to prepare treatment or post-exposure prophylaxis doses for intravenous infusion or subcutaneous injection. Under the EUA, more than one dose may be prepared from the vials, according to the specific instructions in the FDA-authorized EUA HCP Fact Sheet. Refer to the EUA HCP Fact Sheet for product preparation, administration and storage information.

Key Differences Between Roche's Co-packaged Vials of Casirivimab and Imdevimab and Other Presentations of REGEN-COV.

- The carton for Roche's co-packaged product is labeled as "casirivimab and imdevimab 120 mg/mL concentrate for solution for infusion". **Do not confuse this co-packaged carton with REGEN-COV (casirivimab and imdevimab) co-formulated solution.**
- The vials in the co-packaged carton may be used to prepare and administer intravenous infusions as well as subcutaneous injections despite having the statements such as "Concentrate for solution for infusion" or "For intravenous infusion after dilution".
- Inside the co-packaged carton there is a folded package leaflet which is not approved for US use. **Discard** the "package leaflet" included inside the carton and **refer to the EUA HCP Fact Sheet for current information.**
- Inside the shipment there is a one-page "Co-Packaged Product Quick Reference Guide" that provides a QR code that leads to the current U.S. HCP Fact Sheet and other key information related to the co-packaged presentation. A copy of the one-page document is appended to this letter.
- The carton and vial labels of co-packaged casirivimab and imdevimab do not include an NDC number. An NDC number is provided on the one page "Co-Packaged Product Quick Reference Guide" that is shipped with the product.
- **The barcode on the co-packaged carton labeling may not register with U.S. scanning systems and may not be functional for identifying the drug products.** There is no barcode on the co-packaged vial labels. Institutions should manually input the product information into their systems to confirm the barcode systems do not provide incorrect information when the product is scanned.
- Each co-packaged carton will be labeled with the names of the individual monoclonal antibodies only (i.e., casirivimab or imdevimab) and will not include the brand name "REGEN-COV".
- Roche is listed as the manufacturer instead of Regeneron.
- The cartons say "For pandemic use" instead of for EUA use.

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INVENTORY MANAGEMENT OF CO-PACKAGED CARTONS OF CASIRIVIMAB AND IMDEVIMAB

Barcodes

Linear barcodes on the co-packaged cartons may not register with U.S. scanning systems and may not be functional for identifying the drug products. Co-packaged vials do not have a barcode.

NDCs

NDCs are not printed on vials or carton for the Roche co-packaged presentation. An NDC number is provided on the one page "Co-Packaged Product Quick Reference Guide" that is shipped with the co-packaged product (also see Table 1 below). Be aware that the NDCs assigned for co-packaged carton are unique and should be added to appropriate systems for inventory management. Vial NDCs in the co-packaged cartons that are provided on the one page "Co-Packaged Product Quick Reference Guide" are the same NDCs as the individual vials of casirivimab and imdevimab included in the REGEN-COV dose packs.

Update your systems accordingly to reflect these NDCs.

Table 1: NDCs for Co-packaged Product

Co-Packaged Carton Contents	Co-Packaged Components	Concentration	Co-Packaged Carton NDC Number
2 Vials[1]	**1 vial of casirivimab** (NDC 61755-024-00)	1,332 mg/11.1 mL (120 mg/mL)	61755-042-02
	1 vial of imdevimab (NDC 61755-025-00)	1,332 mg/11.1 mL (120 mg/mL)	
2 Vials	**1 vial of casirivimab** (NDC 61755-026-00)	300 mg/2.5 mL (120 mg/mL)	61755-045-02
	1 vial of imdevimab (NDC 61755-027-00)	300 mg/2.5 mL (120 mg/mL)	

[1]More than one dose may be prepared from the vials, according to the instructions in the FDA-authorized EUA HCP Fact Sheet.

HEALTHCARE PROVIDER ACTION

- Stay current with the latest Fact Sheets for Health Care Providers (https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf)
- In light of the additional presentation, healthcare providers should update their Electronic Health Records (EHRs) with the new product information to allow for the use of available co-packaged cartons to prepare doses for intravenous infusion or subcutaneous injection for treatment or post-exposure prophylaxis.
- Create alerts, directed at healthcare providers, in the electronic health record (EHR) systems that if preparing an intravenous infusion with individual vials of casirivimab and imdevimab, they must be administered together after dilution.

- Create alerts, directed at healthcare providers, in the electronic health record (EHR) systems that if preparing subcutaneous injections that the individual syringes should be labeled to ensure the patient receives all syringes needed of each antibody for a single dose.
- Store REGEN-COV (casirivimab with imdevimab) co-packaged cartons in the refrigerator in the original carton and away from other COVID-19 vaccines and drug products. **Do not open co-packaged cartons until the time at which the intravenous infusion or the subcutaneous injections will be prepared.**
- Do not comingle co-formulated REGEN-COV cartons with co-packaged REGEN-COV cartons.
- **Due to multiple presentations of REGEN-COV (co-formulation in a single vial, dose-pack bags, and co-package cartons) it is important to educate staff on the different presentations and how to prepare doses appropriately with each presentation.**
- **The barcode on the co-packaged carton label may not register with U.S. scanning systems.** There is no barcode on the co-packaged vial labels. Institutions should manually input the product information into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures, including checking the label information manually and/or applying site-generated barcodes, should be instituted to assure that the correct drug product is being used for dose preparation.

Resources to help clarify dose preparation can be found on www.REGENCOV.com.

Reporting Adverse Events and Medication Errors

Under the EUA, all serious adverse events and all medication errors potentially related to casirivimab and imdevimab must be reported within 7 calendar days from the onset of the event. Serious adverse event reports and medication error reports should be submitted to FDA's MedWatch program using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
- Complete and submit a postage-paid Form FDA 3500 (https://www.fda.gov/media/76299/download) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 208529787, or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form.

Please provide a copy of all FDA MedWatch forms to Regeneron via fax (1-888-876-2736) or email (medical.information@regeneron.com).

Healthcare providers should direct questions about REGEN-COV (casirivimab with imdevimab) packaging or use to the Regeneron Medical Information Department at 1-844-734-6643 or to medical.information@regeneron.com.

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The EUA Fact Sheet for Healthcare Providers is included with this notice, available at www.REGENCOV.com, or available by scanning the QR Code below:

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Enclosure:

EUA Fact Sheet for Healthcare Providers

Co-Packaged Product Quick Reference Guide