

**NM Outpatient Protocol: Emergency Use Authorization of Monoclonal Antibodies for Treating Mild to Moderate Coronavirus Disease 2019 (COVID-19)**

**BACKGROUND**

Investigational monoclonal antibodies have been authorized under an FDA Emergency Use Authorization (EUA) to be administered for the treatment of mild to moderate coronavirus disease 2019 (COVID-19). These are for use only in non-hospitalized adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

**Patients at High Risk of Progressing to Severe COVID-19 and/or Hospitalization** High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI)  $\geq 35$
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are  $\geq 65$  years of age
- Are  $\geq 55$  years of age AND have
  - o cardiovascular disease, OR
  - o hypertension, OR
  - o chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
  - o BMI  $\geq 85$ th percentile for their age and gender based on [CDC growth charts](#), OR
  - o sickle cell disease, OR
  - o congenital or acquired heart disease, OR
  - o neurodevelopmental disorders, for example, cerebral palsy, OR
  - o a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - o asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

**Monoclonal antibodies are 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 monoclonal antibodies has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19.

**Authorized Monoclonal Antibodies**

Bamlanivimab (LY-CoV555) and Casirivimab (REGN10933) with imdevimab (REGN10987) are available under an FDA Emergency Use Authorization (EUA).

**Efficacy:** The potential efficacy of bamlanivimab is based on interim data from one Phase 2 trial (BLAZE-1) on 465 ambulatory (non-hospitalized) adults with mild to moderate COVID-19 symptoms. More details on this can be found in Section 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA, within the [FACT SHEET FOR HEALTH CARE PROVIDERS: EMERGENCY USE AUTHORIZATION \(EUA\) OF BAMLANIVIMAB](#)

**Efficacy:** The potential efficacy of casirivimab with imdevimab is based on analysis of data from Phase 1/2 of the trial, R10933-10987-COV-2067, on 799 ambulatory (non-hospitalized) adults with mild to moderate COVID-19 symptoms. More details on this can be found in Section 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA within the [FACT SHEET FOR HEALTH CARE PROVIDERS: EMERGENCY USE AUTHORIZATION \(EUA\) OF CASIRIVIMAB AND IMDEVIMAB](#).

## **OBJECTIVE**

This protocol is intended to guide health providers in the therapeutic use of the monoclonal antibody treatments (1. bamlanivimab or 2. casirivimab with imdevimab) once a patient has been judged to be medically eligible for the treatment. Use must be in strict accordance with the following elements of the EUA labeling. Under this protocol, monoclonal antibody treatment may be ordered by NM nurses and pharmacists through Epic after this explicit order, “COVID MAB treatment per Protocol” is made by any NM-authorized prescriber: physicians (MDs or DOs) or advance practice providers (APPs). Selection of the specific MAB for a treatment order is therefore flexible, to permit adapting to actual product availability at the various NM treatment locations.

## **Monoclonal Antibodies and Details on Use:**

- For bamlanivimab see Appendix 1
- For casirivimab and imdevimab see Appendix 2

## **APPENDIX 1. Bamlanivimab**

### **Dosage**

Bamlanivimab should be administered as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset. The dosage of bamlanivimab in adults and pediatric patients 12 years of age and older weighing at least 40 kg is a single intravenous (IV) infusion of 700 mg bamlanivimab administered over at least 60 minutes. The 700mg dose is provided in a prepared IV solution with a final volume of 200 mL.

### **Dosage Adjustment in Specific Populations**

- **Pregnancy or Lactation:** No dosage adjustment is recommended in pregnant or lactating women.
- **Pediatric Use:** No dosage adjustment is recommended in pediatric patients who weigh at least 40 kg. Bamlanivimab is not authorized for patients weighing less than 40 kg.
  - Note: The safety and effectiveness have not been assessed in pediatric patients. The recommended dosing regimen is expected to result in comparable serum exposures of bamlanivimab in patients 12 years of age and older and weighing at least 40 kg as observed in adults, based on PK modeling
- **Geriatric Use:** No dosage adjustment is recommended in geriatric patients.
  - Note: Of the 309 patients receiving bamlanivimab in BLAZE-1, 11% were 65 years of age and older and 3% were 75 years of age and older. Based on population PK analyses, there is no difference in PK in geriatric patients compared to younger patients.
- **Renal Impairment:** No dosage adjustment is recommended in patients with renal impairment.
  - Note: Bamlanivimab is not eliminated intact in the urine, thus renal impairment is not expected to affect the exposure of bamlanivimab.

- **Hepatic Impairment:** No dosage adjustment is recommended in patients with mild hepatic impairment. Bamlanivimab has not been studied in patients with moderate or severe hepatic impairment.
  - Note: Based on population PK analysis, patients with mild hepatic impairment had approximately 20% higher clearance than patients with normal hepatic function. This effect is statistically significant, but not clinically meaningful.

### Administration

Bamlanivimab solution should be administered by a qualified healthcare professional.

- Gather the recommended materials for infusion:
  - Polyvinylchloride (PVC) infusion set containing a 0.20/0.22 micron in-line polyethersulfone (PES) filter.
- Attach the infusion set to the IV bag.
- Prime the infusion set.
- Administer the infusion solution via pump or gravity over at least 60 minutes (200 mL/hr).
- Once infusion is complete, flush the infusion line to ensure delivery of the required dose.
- Discard unused product.

### Monitoring

- Clinically monitor patients during the 60-minute infusion and observe patients for at least 1 hour after the infusion is complete.
- **Hypersensitivity including anaphylaxis and infusion-related reactions:** There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of bamlanivimab. Signs and symptoms of infusion related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.
- **If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care. The Epic order panel includes medications that may be administered for significant infusion reactions or hypersensitivity reactions including anaphylaxis.**

### Dose Form and Storage

Bamlanivimab injection, 700 mg/20 mL (35 mg/mL), is a sterile, preservative-free clear to slightly opalescent and colorless to slightly yellow to slightly brown solution supplied as one single-dose vial per carton.

Bamlanivimab is preservative-free. Discard unused portion. Store unopened vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. **DO NOT FREEZE, SHAKE, OR EXPOSE TO DIRECT LIGHT.** Solution in vial requires dilution prior to administration. The prepared infusion solution is intended to be used immediately. If immediate administration is not possible, store diluted bamlanivimab infusion solution in the refrigerator at 2°C to 8°C (36°F to 46°F) for up to 24 hours or at room temperature (20°C to 25°C [68°F to 77°F]) for up to 7 hours, including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature prior to administration.

### Dose Preparation

Bamlanivimab infusion solution should be prepared by a qualified healthcare professional using aseptic technique:

- Remove bamlanivimab vial from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. **Do not expose to direct heat.**
- Inspect bamlanivimab visually for particulate matter and discoloration.
  - Bamlanivimab is a clear to slightly opalescent and colorless to slightly yellow to slightly brown solution.
- Gently invert vial by hand approximately 10 times. **Do not shake.**

- Dilute bamlanivimab using a 250 mL prefilled 0.9% Sodium Chloride Injection bag for intravenous infusion according to the **Table below**.
  - Withdraw and discard required volume of 0.9% Sodium Chloride Injection from the infusion bag.
  - Withdraw required volume of bamlanivimab from the vial using an appropriately sized syringe.
  - Transfer bamlanivimab to the 0.9% Sodium Chloride Injection infusion bag.
  - Discard any product remaining in the vial.
- Gently invert IV bag by hand approximately 10 times to mix. **Do not shake.**
- This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted bamlanivimab infusion solution for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration.

**Table: Recommended Dilution and Administration Instructions for Bamlanivimab**

Treatment	Dose/Volume of Bamlanivimab (# of vials)	Volume of 0.9% sodium chloride to Discard from a 250 mL IV bag	Total Final Volume for Infusion	Minimum Infusion Rate	Minimum Infusion Time
Bamlanivimab 700 mg dose	700 mg/20 mL (1 vial)	70 mL	200 mL	200 mL/hr	60 minutes

### Safety

Contraindications: known hypersensitivity to any ingredient of bamlanivimab.

Adverse reactions: The most commonly reported adverse event in the Blaze 1 was nausea. Other possible side effects of bamlanivimab include anaphylaxis and infusion-related reactions, diarrhea, dizziness, headache, itching and vomiting. More details on this can be found in the Overall Safety Summary, Section 6.1 Clinical Trials Experience, within the [FACT SHEET FOR HEALTH CARE PROVIDERS: EMERGENCY USE AUTHORIZATION \(EUA\) OF BAMLANIVIMAB](#). Due to the limited number of patients who received bamlanivimab under controlled study conditions, the full range of possible adverse reactions, along with their frequency and severity remain uncertain. This emphasizes the importance of reporting reactions, as described in the following section.

Managing Anaphylaxis and Infusion-related reactions: The Epic order panel includes medications that may be administered for significant infusion reactions or hypersensitivity reactions including anaphylaxis.

### Reporting Requirements

The prescribing health care provider and/or the provider’s designee are/is responsible for mandatory reporting of all medication errors and serious adverse events\* potentially related to bamlanivimab treatment within 7 calendar days from the onset of the event.

\*Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;

- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

The reports should include unique identifiers and the words “Bamlanivimab treatment under Emergency Use Authorization (EUA)” in the description section of the report. Submit adverse event reports to FDA MedWatch using one of the following methods:

- Complete and submit the report online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm), or
- By using a postage-paid Form FDA 3500 (available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>) and returning by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or Call 1-800-FDA-1088 to request a reporting form
- Submitted reports should include in the field name, “Describe Event, Problem, or Product Use/Medication Error” the statement “Bamlanivimab treatment under Emergency Use Authorization (EUA)”

The prescribing health care provider and/or the provider’s designee are/is to provide mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of bamlanivimab.

#### OTHER REPORTING REQUIREMENTS

In addition, please provide a copy of all FDA MedWatch forms to:

Eli Lilly and Company, Global Patient Safety

Fax: 1-317-277-0853

E-mail: [mailindata\\_gsmtindy@lilly.com](mailto:mailindata_gsmtindy@lilly.com)

Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events.

Also refer to the [EUA labeling](#), section **8 ADVERSE REACTIONS AND MEDICATION ERRORS REPORTING REQUIREMENTS AND INSTRUCTIONS**

#### **INFORMATION FOR PATIENTS, PARENTS, OR CAREGIVERS**

Healthcare providers must communicate to each patient or parent/caregiver, as age appropriate, information consistent with the “Fact Sheet for Patients, Parents and Caregivers” (and provide a copy of the Fact Sheet) prior to the patient receiving bamlanivimab:

- [English Fact Sheet for Patients, Parents and Caregivers on Emergency Use Authorization \(EUA\) of Bamlanivimab for Coronavirus Disease 2019 \(COVID-19\). November, 2020.](#)
- [Spanish Fact Sheet for Patients, Parents and Caregivers on Emergency Use Authorization \(EUA\) of Bamlanivimab for Coronavirus Disease 2019 \(COVID-19\). November, 2020.](#)

Furthermore, Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient’s medical record that the patient/caregiver has been:

- a. Given the “Fact Sheet for Patients, Parents and Caregivers”,
- b. Informed of alternatives to receiving authorized bamlanivimab, and
- c. Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.

**This will be documented in the Epic Order Panel.**

#### **NM-SPECIFIC RESOURCES**

- For assistance specific to managing the care of a patient who is receiving or has received bamlanivimab, the prescribing health provider of record must be contacted.

- Medication Errors or adverse events associated with this medication should be entered as a NETS report as per standard procedure.

## **REFERENCES**

- [FACT SHEET FOR HEALTH CARE PROVIDERS: EMERGENCY USE AUTHORIZATION \(EUA\) OF BAMLANIVIMAB.](#) Note: This includes approved labeling for EUA use. November, 2020.
- [FDA letter. Emergency Use Authorization \(EUA\) for emergency use of bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 \(COVID-19\).](#) November, 2020.

## **APPENDIX 2. Casirivimab and Imdevimab**

### **DOSAGE AND ADMINISTRATION**

#### **Dosage**

Casirivimab and Imdevimab should be administered as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset. The dosage of casirivimab and Imdevimab in adults and pediatric patients 12 years of age and older weighing at least 40 kg is 1,200 mg of casirivimab and 1,200 mg of imdevimab administered together as a single intravenous (IV) infusion over at least 60 minutes. The dose is provided in a prepared IV solution with a final volume of 250 mL.

#### **Dosage Adjustment in Specific Populations**

- **Pregnancy or Lactation:** No dosage adjustment is recommended in pregnant or lactating women.
- **Renal Impairment:** No dosage adjustment is recommended in patients with renal impairment.
- **Pediatric Use:** No dosage adjustment is recommended in pediatric patients who weigh at least 40 kg.

#### **Administration**

Casirivimab and imdevimab infusion solution should be administered by a qualified healthcare professional using aseptic technique.

- Gather the recommended materials for infusion:
  - Polyvinyl chloride (PVC), Polyethylene (PE)-lined PVC, or Polyurethane (PU) infusion set
  - In-line or add-on 0.2 micron polyethersulfone (PES) filter
- Attach the infusion set to the IV bag.
- Prime the infusion set.
- Administer as an IV infusion via pump or gravity over at least 60 minutes through an intravenous line containing a sterile, in-line or add-on 0.2-micron polyethersulfone (PES) filter (see **Table 2**).
- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of casirivimab and imdevimab injection with IV solutions and medications other than 0.9% Sodium Chloride Injection is not known.
- After infusion is complete, flush with 0.9% Sodium Chloride Injection.
- Discard unused product.
- Clinically monitor patients during administration and observe patients for at least 1 hour after infusion is complete.

#### **Monitoring**

- Clinically monitor patients during the 60-minute infusion and observe patients for at least 1 hour after the infusion is complete.

- **Hypersensitivity including anaphylaxis and infusion-related reactions:** There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of casirivimab and imdevimab. Signs and symptoms of infusion related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.
- **If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care. The Epic order panel includes medications that may be administered for significant infusion reactions or hypersensitivity reactions including anaphylaxis.**

### Dose Form and Storage

Casirivimab and imdevimab are each supplied in individual single-dose vials. Casirivimab and imdevimab carton and vial labels may instead be labeled REGN10933 and REGN10987 respectively.

Casirivimab is a sterile, preservative-free, clear to slightly opalescent, colorless to pale yellow solution available as: Injection: 300 mg/2.5 mL (120 mg/mL) or 1,332 mg/11.1 mL (120 mg/mL) in a single-dose vial

Imdevimab is a sterile, preservative-free, clear to slightly opalescent, colorless to pale yellow solution available as: Injection: 300 mg/2.5 mL (120 mg/mL) or 1,332 mg/11.1 mL (120 mg/mL) in a single-dose vial

This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted casirivimab and imdevimab infusion solution in the refrigerator between 2°C to 8°C (36°F to 46°F) for no more than 36 hours and at room temperature up to 25°C (77°F) for no more than 4 hours, including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 30 minutes prior to administration

### Dose Preparation

Casirivimab and imdevimab are each supplied in individual single-dose vials. Casirivimab and imdevimab solutions must be diluted prior to administration.

Casirivimab and imdevimab solution for infusion should be prepared by a qualified healthcare professional using aseptic technique:

- Remove the casirivimab and imdevimab vials 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.**
- Inspect casirivimab and imdevimab vials visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded, and fresh solution prepared.
  - The solution for each vial should be clear to slightly opalescent, colorless to pale yellow.
- Obtain an IV infusion bag containing 250 mL of 0.9% Sodium Chloride Injection. Withdraw and discard 20 mL of 0.9% Sodium Chloride Injection from the infusion bag prior to adding casirivimab and imdevimab solutions according to the **Table below**.
- Withdraw 10 mL of casirivimab and 10 mL of imdevimab from each respective vial using two separate syringes and dilute together in the infusion bag containing 0.9% Sodium Chloride Injection, see **Table 2**. Discard any product remaining in the vial.
- Gently invert infusion bag by hand approximately 10 times to mix. **Do not shake**. This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted casirivimab and imdevimab infusion solution in the refrigerator between 2°C to 8°C (36°F to 46°F) for no more than 36 hours and at room temperature up to 25°C (77°F) for no more than 4 hours, including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 30 minutes prior to administration.

**IMPORTANT NOTE:** Casirivimab and imdevimab carton and vial labels may instead be labeled REGN10933 and REGN10987 respectively.

**Table: Recommended Dilution and Administration Instructions for Casirivimab and imdevimab**

Treatment	Antibody Dose	Volume to Withdraw from Vial	Number of Vials Needed (b)	Volume of 0.9% Sodium Chloride to Discard from a 250 mL Infusion Bag	Total Final Volume for Infusion	Minimum Infusion Rate	Minimum Infusion Time
Casirivimab and imdevimab  2,400 mg dose (a)	Casirivimab 1,200 mg	10 mL	1 vial of 11.1 mL OR 4 vials of 2.5 mL	20 mL	250 mL	250 mL/hr	60 minutes
	Imdevimab 1,200 mg	10 mL	1 vial of 11.1 mL OR 4 vials of 2.5 mL				

NOTE: casirivimab = REGN10933; imdevimab = REGN10987

a. 1,200 mg of Casirivimab and 1,200 mg of Imdevimab are to be administered together as a single intravenous infusion for a combined 2,400 mg dose.

b. One 11.1 mL vial of one antibody may be prepared with four 2.5 mL vials of the other antibody to create one treatment course.

### Safety (Medication Errors)

Error Potential: There are 2 important issues highlighted in the [Dear Healthcare Provider Letter: Preventing Medication Errors with Casirivimab and Imdevimab](#):

1. Casirivimab and imdevimab are authorized ONLY for intravenous Infusion after dilution. There may be cartons and vials of casirivimab and imdevimab that are labeled “for intravenous infusion or subcutaneous injection.” However, casirivimab and imdevimab MUST be administered by INTRAVENOUS (IV) INFUSION ONLY under this emergency use authorization, following the preparation instructions.
2. Casirivimab and imdevimab must be administered together although they are packaged separately. It is possible that the packaging may vary.

### Safety

Contraindications: known hypersensitivity to any ingredient of casirivimab and imdevimab.

Adverse reactions: Anaphylaxis and infusion-related reactions may be possible after casirivimab and imdevimab administration. More details can be found in the Overall Safety Summary, Section 6.1 Clinical Trials Experience, within the [FACT SHEET FOR HEALTH CARE PROVIDERS: EMERGENCY USE AUTHORIZATION \(EUA\) OF CASIRIVIMAB AND IMDEVIMAB](#). Due to the limited number of patients who received casirivimab and imdevimab under controlled study conditions, the full range of possible adverse reactions, along with their frequency and severity remain uncertain. This emphasizes the importance of reporting reactions, as described in the following section.



Managing Anaphylaxis and Infusion-related reactions: The Epic order panel includes medications that may be administered for significant infusion reactions or hypersensitivity reactions including anaphylaxis.

### **Reporting Requirements**

The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events\* potentially related to casirivimab and imdevimab treatment within 7 calendar days from the onset of the event.

\*Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

The reports should include unique identifiers and the words "Casirivimab and imdevimab treatment under Emergency Use Authorization (EUA)" in the description section of the report. Submit adverse event reports to FDA MedWatch using one of the following methods:

- Complete and submit the report online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm), or
- By using a postage-paid Form FDA 3500 (available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>) and returning by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or Call 1-800-FDA-1088 to request a reporting form
- Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" the statement "Casirivimab and imdevimab treatment under Emergency Use Authorization (EUA)"

The prescribing health care provider and/or the provider's designee are/is to provide mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of casirivimab and imdevimab.

### **OTHER REPORTING REQUIREMENTS**

In addition, please provide a copy of all FDA MedWatch forms to:

Regeneron Pharmaceuticals, Inc

Fax: 1-888-876-2736

E-mail: [medical.information@regeneron.com](mailto:medical.information@regeneron.com)

Or call Regeneron Pharmaceuticals at 1-844-734-6643 to report adverse events

Also refer to the [EUA labeling](#), section **8 ADVERSE REACTIONS AND MEDICATION ERRORS REPORTING REQUIREMENTS AND INSTRUCTIONS**

### **INFORMATION FOR PATIENTS, PARENTS, OR CAREGIVERS**

Healthcare providers must communicate to each patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving casirivimab and imdevimab:

- [FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION \(EUA\) OF CASIRIVIMAB AND IMDEVIMAB FOR CORONAVIRUS DISEASE 2019 \(COVID-19\). November, 2020.](#)

Furthermore, Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:

- a) Given the "Fact Sheet for Patients, Parents and Caregivers",
- b) Informed of alternatives to receiving authorized casirivimab and imdevimab, and
- c) Informed that casirivimab and imdevimab are unapproved drugs that are authorized for use under this Emergency Use Authorization.

**This will be documented in the Epic Order Panel.**

#### **NM-SPECIFIC RESOURCES**

- For assistance specific to managing the care of a patient who is receiving or has received casirivimab and imdevimab, the prescribing health provider of record must be contacted.
- Medication Errors or adverse events associated with this treatment should be entered as a NETS report as per standard procedure.

#### **REFERENCES**

- [FACT SHEET FOR HEALTH CARE PROVIDERS: EMERGENCY USE AUTHORIZATION \(EUA\) OF CASIRIVIMAB AND IMDEVIMAB](#) Note: This includes approved labeling for EUA use. November, 2020.
- [Information Sheet \("Fact Sheet Directions"\) on casirivimab and imdevimab](#). November, 2020.
- [Dear Healthcare Provider Letter: Preventing Medication Errors with Casirivimab and Imdevimab](#). November, 2020.
- [Frequently Asked Questions on the Emergency Use Authorization of Casirivimab + Imdevimab](#). November 21, 2020.
- [FDA letter, Emergency Use Authorization \(EUA\) for emergency use of casirivimab and imdevimab for the treatment of mild to moderate coronavirus disease 2019 \(COVID-19\)](#). November 21, 2020.
- [FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION \(EUA\) OF CASIRIVIMAB AND IMDEVIMAB FOR CORONAVIRUS DISEASE 2019 \(COVID-19\)](#). November, 2020.