Carta Trámite

23 de diciembre de 2020

A: Todos los Proveedores Contratados por First Medical Health Plan, Inc. para el Plan Vital, Región Única y Población Vital-X (Virtual)

Re: Carta Normativa 20-1218 relacionada a la Guía Clínica para la Administración de Bamlanivimab y REGN-COV2

Estimado(a) Proveedor(a):

Reciba un cordial saludo de parte de First Medical Health Plan, Inc.

Adjunto a este comunicado encontrará la Carta Normativa 20-1218 de la Administración de Seguros de Salud de Puerto Rico (ASES).

A través de esta Carta Normativa, la ASES informa que, recientemente la Administración de Alimentos y Drogas (FDA, por sus siglas en inglés) emitió una Autorización de Uso de Emergencia (EUA, por sus siglas en inglés) para varios medicamentos o combinaciones de medicamentos para el tratamiento del COVID-19.

Además, la ASES notifica que, cada uno de los medicamentos conlleva criterios y requisitos únicos disponibles en el documento *"Fact Sheet"*, el cual se encuentra adjunto a este comunicado. Se recomienda que, los proveedores que consideren recetar o administrar al menos uno de los medicamentos, se familiaricen con las recomendaciones realizadas por la FDA.

Esta Carta Normativa, además informa que, los Centros de Servicios de Medicare y Medicaid (CMS, por sus siglas en inglés) establecieron la siguiente codificación para los medicamentos de anticuerpos monoclonales y su administración:

Code	***CPT Short Descriptor***	***Labeler Name***	***Vaccine/Procedure Name***
Q0239	Bamlanivimab-xxxx	Eli Lilly	*Injection, Bamlanivimab 700 mg*
M0239	Bamlanivimab-xxxx Infusion	Eli Lilly	*Intrevenous infusion, Bamlanivimab-xxxx, includes infusion and post administration monitoring*
Q0243	Casirivimab and Imdevimab	Regeneron	*Injection, Casirivimab and Imdevimab, 2400 mg*
M0243	Casirivi and Indevi Infusion	Regeneron	*Intrevenous infusion, Casirivimab and Imdevimab includes infusion*

Para la administración de infusión de estos medicamentos, FMHP ha establecido una tarifa estándar de $200.00.

Para detalles específicos sobre la información provista por la ASES, le exhortamos a leer detenidamente la Carta Normativa 20-1218.

Si usted tiene alguna pregunta relacionada a este comunicado y/o necesita información adicional, siéntase en la libertad de comunicarse con nuestro Centro de Servicio al Proveedor al número libre de cargos 1-844-347-7802 de lunes a viernes de 7:00 a.m. a 7:00 p.m. También, puede acceder a nuestra página electrónica www.firstmedicalvital.com.

Cordialmente,

Departamento de Cumplimiento
First Medical Health Plan, Inc.

GOBIERNO DE PUERTO RICO
Administración de Seguros de Salud

Carta Normativa 20-1218

18 de diciembre de 2020

A: **ORGANIZACIONES DE MANEJO DE CUIDADO DIRIGIDO (MCOs POR LAS SIGLAS EN INGLES), GRUPOS MEDICOS, MEDICOS PRIMARIOS, FARMACIAS Y PROVEEDORES PARTICIPANTES DEL PLAN DE SALUD DEL GOBIERNO, PLAN VITAL**

RE: **GUIA CLINICA PARA LA ADMINISTRACION DE BAMLANIVIMAB Y REGN-COV2 (Regeneron Pharmaceutical, Inc.)**

Recientemente la administración de Drogas y Alimentos (FDA) por sus siglas en inglés, autorizó, bajo el mecanismo de uso de emergencias (EUA), varios medicamentos o combinaciones de medicamentos para el tratamiento del COVID-19.

Cada uno conlleva criterios y requerimientos únicos que procedemos a resumir, sin intención de ser exhaustivo, por lo que cada proveedor que considere recetar o administrar uno de estos productos debe familiarizarse con las recomendaciones del FDA, las cuales se encuentran en el denominado "factsheet".

BAMLANIVIMAB

La FDA el 9 de noviembre de 2020, emitió una autorización de uso de emergencia de la terapia de anticuerpos monoclonales *Bamlanivimab* para el tratamiento de la enfermedad por coronavirus leve a moderada 2019. Este fármaco está en la etapa de investigación y actualmente no está aprobado para ninguna indicación.

La Administración de Seguros de Salud (ASES), hace referencia a las indicaciones para el uso y administración de *Bamlanivimab* (EUA) disponibles en:
https://www.fda.gov/media/143602/download

- El uso de este medicamento es sólo para tratar COVID-19 leve o moderado en pacientes que tengan 12 años o más y pesen al menos 40 kg, con resultados positivos de la prueba viral directa del SARS-CoV-2 y que tienen **un alto riesgo de progresar a COVID-19 grave** y/u hospitalización.

Como alto riesgo la autorización en el EUA define lo siguiente:

- Alto riesgo de progresión de la enfermedad a severa y/o requerir hospitalización se define como aquellos pacientes que tengan al menos uno (1) de los siguientes criterios:
    - Obesidad, con un índice de masa corporal (BMI) igual o mayor de 35.
    - Padecen de enfermedad renal crónica.
    - Diabetes Mellitus
    - Presentan alguna condición o enfermedad inmunosupresora.
    - Se encuentran en tratamiento con medicamentos inmunosupresores.
    - 65 años o más de edad.
    - Pacientes de 55 años o más y que además presentan enfermedad cardiovascular, incluyendo Hipertensión, y/o enfermedad pulmonar obstructiva crónica u otra condición respiratoria.
- Tienen entre 12 -17 años y alguna de las siguientes condiciones:
    - Un BMI igual o mayor de la percentila 85 para su edad y sexo, según las tablas de crecimiento del CDC.
    - Drepanocitosis (sickle cell disease).
    - Enfermedad cardíaca congénita o adquirida.
    - Trastorno del desarrollo neural.
    - Dependencia de tecnología por condiciones médicas (traqueostomía, gastrostomía o dependiente de ventilación asistida no causada por enfermedad del COVID-19).
    - Asma o condición pulmonar crónica que requiera el uso diario de medicamentos para su control.

El uso de *Bamlanivimab* no está autorizado para las siguientes poblaciones de pacientes:

- Adultos o pacientes pediátricos que están hospitalizados debido a COVID-19, o
- Adultos o pacientes pediátricos que requieren oxigenoterapia debido a COVID-19, o
- Adultos o pacientes pediátricos que requieren un aumento en la tasa de flujo de oxígeno inicial debido a COVID-19 en aquellos pacientes en oxigenoterapia crónica debido a un subyacente no relacionado con COVID-19 comorbilidad.
- Pacientes que están hospitalizados con el COVID-19, o
- Adultos o pacientes pediátricos que requieren un aumento en la tasa de flujo de oxígeno inicial debido a COVID-19 en aquellos pacientes en oxigenoterapia crónica debido a un subyacente no relacionado con COVID-19 comorbilidad.

El Bamlanivimab sólo puede administrarse en entornos donde los proveedores de atención médica tengan acceso inmediato a medicamentos para tratar una reacción grave a la infusión, como anafilaxia y la capacidad de activar el sistema médico de emergencia (EMS), según sea necesario.

La autorización para distribución de este medicamento, a facilidades de salud y/o proveedores, estará según la dirección del Gobierno de los Estados Unidos en colaboración con las autoridades gubernamentales estatales. A su vez, este medicamento será provisto por el Gobierno Federal. No obstante, **los costos de administración son parte de la cubierta de beneficios del Plan Vital**. Por tanto, los proveedores de salud deben facturar a los MCOs los servicios asociados a la administración de este medicamento.

CODIFICACION ESTANDAR PARA LA FACTURACION DE SERVICIOS

El Centro de Medicare y Medicaid (CMS, con sus siglas en inglés) estableció la siguiente codificación para los productos o medicamentos de anticuerpos monoclonales y su administración:

Code	*CPT Short Descriptor*	*Labeler Name*	*Vaccine/Procedure Name*
Q0239	Bamlanivimab-xxxx	Eli Lilly	Injection, Bamlanivimab 700 mg
M0239	Bamlanivimab-xxxx Infusion	Eli Lilly	Intrevenous infusion, Balmlanivimab-xxxx, includes infusion and post administration monitoring
Q0243	Casirivimab and Imdevimab	Regeneron	Injection, Casirivimab and Imdevimab, 2400 mg.
M0243	Casirivi and Indevi Infusion	Regeneron	Intravenous infusion, Casirivimab and Imdevimab includes infusion

Incluimos como referencia los siguientes documentos sobre el Bamlanivimab:

Bamlanivimab Factsheet
Formulario para Solicitar Bamlanivimab
Carta Secretario de Salud

REGN-COV2 (Regeneron Pharmaceutical Inc. ROCHE)

El 21 de noviembre de 2020 el FDA emitió una autorización de uso de emergencia (EUA) para el Casirivimab y el Imdevimab, para ser administrados, ambos juntos en combinación, para pacientes adultos y pediátricos de 12 años o más, con un peso de 88 libras o más (40 kg.), que tengan una prueba viral para COVID-19 positiva con manifestaciones de la enfermedad leve a moderada y que sean pacientes de alto riesgo de progresar a una forma severa de la enfermedad que requiera hospitalización.

Es un medicamento de la categoría denominada anticuerpos monoclonales recombinantes al igual que el Bamlanivimab. La administración es por vía intravenosa en **una sola** infusión de 1200 mg./1200 mg.

LIMITACIONES DE USO

No está autorizado su uso en pacientes:

- Que se encuentren hospitalizados o
- Que requieran oxígeno suplementario o
- Que requieran uso de oxígeno basal suplementario por condiciones comórbidas y no relacionadas al COVID-19.

El EUA define los pacientes de alto riesgo son:

- Alto riesgo de progresión de la enfermedad a severa y/o requerir hospitalización se define como aquellos pacientes que tengan al menos uno (1) de los siguientes criterios.
- Obesidad, con un índice de masa corporal (BMI) igual o mayor de 35.
- Padecen de enfermedad renal crónica.
- Diabetes Mellitus
- Presentan alguna condición o enfermedad inmunosupresora.
- Se encuentran en tratamiento con medicamentos inmunosupresores.
- 65 años o más de edad.
- Pacientes de 55 años o más y que además presentan enfermedad
- cardiovascular, incluyendo Hipertensión, y/o enfermedad pulmonar obstructiva crónica u otra condición respiratoria.
- Tienen entre 12 -17 años y alguna de las siguientes condiciones:

- Un BMI igual o mayor de la percentila 85 para su edad y sexo, según las tablas de crecimiento del CDC.
- Drepanocitosis (sickle cell disease).
- Enfermedad cardíaca congénita o adquirida.
- Trastorno del desarrollo neural.
- Dependencia de tecnología por condiciones médicas (traqueostomía, gastrostomía o dependiente de ventilación asistida no causada por enfermedad del COVID-19.
- Asma o condición pulmonar crónica que requiera el uso diario de medicamentos para su control.

La ASES reconoce la importancia que los proveedores de salud tengan esta valiosa información y el fiel cumplimiento de los MCOs con estas directrices, que proveen el acceso al tratamiento adecuado a nuestros beneficiarios ya sea que estén hospitalizados o evitando su progresión a estadios graves.

Cordialmente,

Yolanda García Lugo, MS, MBA
Sub Directora ASES

Anejos (3)

Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19)

You are being given a medicine called **bamlanivimab** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab, which you may receive.

Receiving bamlanivimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about bamlanivimab. Talk to your healthcare provider if you have questions. It is your choice to receive bamlanivimab or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What is bamlanivimab?
Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Bamlanivimab is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab to treat people with COVID-19.

The FDA has authorized the emergency use of bamlanivimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section "**What is an Emergency Use Authorization (EUA)?**" at the end of this Fact Sheet.

What should I tell my healthcare provider before I receive bamlanivimab?
Tell your healthcare provider about all of your medical conditions, including if you:
- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How will I receive bamlanivimab?
- Bamlanivimab is given to you through a vein (intravenous or IV) for at least 1 hour.
- You will receive one dose of bamlanivimab by IV infusion.

What are the important possible side effects of bamlanivimab?
Possible side effects of bamlanivimab are:
- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever,

chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied so it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?
Like bamlanivimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with bamlanivimab. Should you decide not to receive bamlanivimab or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab. For a mother and unborn baby, the benefit of receiving bamlanivimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with bamlanivimab?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921).

How can I learn more?

- Ask your healthcare provider
- Visit www.bamlanivimab.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?
The United States FDA has made bamlanivimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Bamlanivimab has not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for bamlanivimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the product may no longer be used).

Literature issued November 2020

Eli Lilly and Company, Indianapolis, IN 46285, USA

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BAM-0001-EUA PAT-20201109

DEPARTAMENTO DE SALUD DE PUERTO RICO

BAMLANIVIMAB ORDER SET

Date:		Date of COVID PCR Test Positive:			
Patient Name:		DOB:		Age:	
Weight (Kg):		Height:		BMI:	
Phone Num:		Email:			
Address:					
Medical Insurance:		Contract:		Group:	
Physician Name:					
Specialty:		Lic. num:		NPI:	
Address					
Phone Num:		Email:			
Signature:					
Bamlanivimab Order:	**700 mg IV infusion in NSS over 60 minutes**	**Before this date:**			

PHYSICIAN GUIDANCE AND DRUG USE CRITERIA

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product **BAMLANIVIMAB** for the **treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.** Treatment with bamlanivimab should start as soon as possible after positive viral test for SARS-CoV- 2 and within 10 days of symptom onset.

- Providers are required to review **The Fact Sheet for Health Care Providers**: Emergency Use Authorization (EUA) of Bamlanivimab.
- As the health care provider, you must communicate to your patient or parent/caregiver information consistent with the "Fact Sheet for Patients and Parents/Caregivers" (and provide a copy of the Fact Sheet) prior to prescribing Bamlanivimab.
- 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:
  - ✓ Given the "**Fact Sheet for Patients, Parents and Caregivers**" (https://www.fda.gov/media/143604/download),
  - ✓ Informed of alternatives to receiving authorized bamlanivimab, AND
  - ✓ Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.

THIS GUIDANCE FOR USE IS BASED ON THE EMERGENCY USE AUTHORIZATION CLINICAL TRIALS DATA. THIS INFORMATION CAN CHANGE ON A DAILY BASE DURING THIS PANDEMIC AND SHOULD BE REVISED AS NEW INFORMATION BECOMES AVAILABLE.

EXCLUSION CRITERIA

- Bamlanivimab is **NOT AUTHORIZED** for use in patients:
  - ✓ who are hospitalized due to COVID-19, OR
  - ✓ who require oxygen therapy (SpO2 sat < 94%) 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 bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as Bamlanivimab, may be associated with **worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation**.

INCLUSION CRITERIA

Must meet all the following criteria:

- ☐ Positive result of direct SARS-CoV-2 viral testing
- ☐ 12 years of age and older
- ☐ Weight ≥40 kg
- ☐ Within 10 days of symptom onset
- ☐ High risk for progressing to severe COVID-19 and/or hospitalization (defined as patients **who meet at least one of the following criteria**:)
  - Have a body mass index (BMI) ≥35
  - Have chronic kidney disease
  - Have diabetes
  - Have immunosuppressive disease
  - Are currently receiving immunosuppressive treatment
  - Are ≥65 years of age
  - Are ≥55 years of age AND have
    - cardiovascular disease, OR
    - hypertension, OR
    - chronic obstructive pulmonary disease/other chronic respiratory disease.
  - Are 12 – 17 years of age AND have
    - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
    - sickle cell disease, OR
    - congenital or acquired heart disease, OR
    - neurodevelopmental disorders, for example, cerebral palsy, OR
    - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
    - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
- ☐ Bamlanivimab may **only be administered** 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.

DOSING, PREPARATION, ADMINISTRATION, STORAGE, AND MONITORING

- **Dosage**: Single intravenous (IV) infusion of **700 mg IV administered over at least 60 minutes.** Should be administered as soon as possible after positive viral test for SARS-CoV- 2 and within 10 days of symptom onset.
- **Preparation**
  - Remove bamlanivimab vial from refrigerator and allow the medication to reach room temperature (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 using a 250 mL prefilled 0.9% Sodium Chloride Injection bag for intravenous infusion following table instructions:

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

  - 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.
- **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 infusion bag over at least 60 minutes via pump or gravity.
- Once infusion is complete, flush the infusion line to ensure delivery of the required dose.
- Discard unused product.
- Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete.

- **Storage**
  - 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.
- **Monitoring**
  - **Before infusion**: Document vital signs (blood pressure, temperature, heart rate, respiration rate) and oximetry (SpO2). **If SpO2 ≤ 94% do not** administer bamlanivimab and refer patient to the Emergency Room for evaluation due to hypoxemia.
  - **During infusion**: Document vital signs, oximetry and infusion site evaluation every 20 minutes
  - **After infusion**: Document vital signs, oximetry, and infusion site evaluation for at least 1 hour after infusion is complete.
  - **The infusion center personnel are the designated health care providers to manage and document any adverse reaction.**
  - If the patient presents any adverse reaction, the infusion center personnel must provide immediate access to treatment for management and fill out the corresponding documentation in the adverse event section provided by the FDA (see link below) and notify physician after the event.
  - Instructions for self-isolation and infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) must be provided to the patient according to CDC guidelines.
- **Specific Populations**
  - No dosage adjustment is recommended in pregnant or lactating women. There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Bamlanivimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.
  - No dosage adjustment is recommended based on age, sex, race, body weight, renal or mild hepatic impairment, or for disease severity or inflammation.
  - **Patients with asthma** should have their inhaled medications readily available for use during and after infusion if deemed necessary. Also, the patient's physician should provide a written order with premedication drugs to use in case of an infusion related reaction.

STORAGE AND STABILITY

- Refrigerate unopened vials 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.
- 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 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.

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

- There are limited clinical data available for bamlanivimab. Serious and unexpected adverse events may occur that have not been previously reported with bamlanivimab use.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

- There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of bamlanivimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care.
- Infusion-related reactions have been observed 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 an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.**

ADVERSE DRUG EVENTS

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. 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, or
  - By using a postage-paid Form FDA 3500 (available at https://www.fda.gov/media/76299/download 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)"

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

REFERENCES

Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment. Available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19

Provider Fact Sheet. Available at http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf ; Accessed 11/17/2020

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GOBIERNO DE PUERTO RICO

Departamento de Salud

19 de noviembre de 2020

DIRECTORES EJECUTIVOS
ADMINISTRADORES
DIRECTORES MÉDICOS DE HOSPITALES
ASOCIACIÓN DE HOSPITALES

MEDICAMENTO *BAMLANIVIMAB* PARA PACIENTES COVID-19

El 9 de noviembre, Eli Lilly and Company recibió una Autorización de Uso de Emergencia (EUA, por sus datos) de la Administración de Alimentos y Medicamentos de los Estados Unidos (FDA, por sus siglas en inglés) para el tratamiento de anticuerpos monoclonales en investigación BAMLANIVIMAB. La EUA permite a los proveedores de atención médica administrar bamlanivimab a pacientes no hospitalizados con COVID-19 confirmado que presentan síntomas leves a moderados y tienen un alto riesgo de síntomas graves y hospitalización. En consonancia con los términos de la EUA para bamlanivimab, el Departamento de Salud y Servicios Humanos de los Estados Unidos, la Oficina del Subsecretario de Preparación y Respuesta (HHS/ASPR) supervisará la asignación del medicamento y coordinará su distribución. El tratamiento consiste de un anticuerpo monoclonal que se administra de manera intravenosa al paciente con COVID-19 confirmado. La facilidad de cuidado de la salud debe establecer qué tipo de especialista médico podrá referir un paciente COVID-19 positivo para que reciba el tratamiento Bamlanivimab.

Se recomienda que la administración del medicamento Bamlanivimab requiera que la institución de cuidado de la salud coordine una cita previa con el paciente. Es importante considerar que para la efectividad del tratamiento, es imprescindible que el medicamento se administre al paciente luego de tener una prueba positiva de COVID-19 y dentro de los primeros 10 días del comienzo de los síntomas. Es un proceso ambulatorio y el medicamento será libre de costo para el paciente. Sin embargo, la facilidad de cuidado de salud podría facturar al paciente un deducible por la administración del medicamento.

En Puerto Rico, el Departamento de Salud supervisará la asignación del medicamento y coordinará su distribución. En términos generales, el porcentaje del número total de pacientes COVID-19 confirmados y el número total de pacientes hospitalizados confirmados, durante un período de notificación de 7 días, equivaldrán al porcentaje de *Bamlanivimab* disponible para una semana de distribución determinada. Para Puerto Rico se han separados 820 frascos de una dosis cada una para la primeras dos semanas. El gobierno federal notificará semanalmente la cantidad asignada para nuestra jurisdicción.

OFICINA DE PREPARACIÓN Y COORDINACIÓN DE RESPUESTA EN SALUD PÚBLICA
Bo. Monacillos, Calle Casia #2
San Juan, PR 00921-3200
Tel.: (787) 773-0600 - Fax: (787) 773-0619

Toda solicitud y distribución de *Bamlanivimab* se llevará a cabo de la siguiente manera:

- Las facilidades de cuidado de la salud interesadas en adquirir el medicamento *Bamlanivimab* deberá enviar una notificación por escrito con la cantidad de viales que desean recibir en o antes de cada martes al siguiente correo electrónico: mvrosado@salud.pr.gov.

- El DSPR evaluará las solicitudes de *Bamlanivimab* enviadas semanalmente por las facilidades de cuidado de la salud.

- El gobierno federal determinará todo los miércoles la cantidad de *Bamlanivimab* asignada para las jurisdicciones.

- El DSPR adjudicará todos los jueves en el portal de *AmerisourceBergen* las cantidades del medicamento *Bamlanivimab* para las facilidades de cuidado de salud que hayan emitido solicitudes, basado en la asignación que otorgue el gobierno federal para nuestra jurisdicción.

- *AmerisourceBergen* coordinará entre jueves y viernes de cada semana, los detalles del envío con los hospitales/instituciones identificados por el DSPR para recibirlo.

- El DSPR proveerá un formulario que deberá formar parte del protocolo interno de cada facilidad de cuidado de la salud, el cual puede utilizarse como referido de un paciente para recibir el tratamiento *Bamlanivimab*. Dicho formulario deberá enviarse como evidencia del tratamiento provisto a cada paciente COVID-19 positivo al correo electrónico antes provisto.

El DSPR tendrá disponible a través de su página web el procedimiento para su solicitud. Sin embargo, si desean obtener más información sobre el *Bamlanivimab,* pueden acceder a: http://www.salud.gov.pr/Pages/COVID-19-ProfesionalesdelaSalud.aspx

Cordialmente,

Lorenzo González Feliciano, MD, MBA, DHA
Secretario de Salud

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