DEPARTAMENTO DE SALUD

EMERGENCY USE AUTHORIZATION FOR EVUSHELD™

(tixagevimab co-packaged with cilgavimab)

Equipo de Tratamiento de Anticuerpos Monoclonales
Oficina del Principal Oficial Medico
Departamento de Salud de Puerto Rico

EVUSHELD (AstraZeneca)

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- The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARSCoV-2 and
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID19 vaccine component(s).

EVUSHELD

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EVUSHELD may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which EVUSHELD belongs (i.e., antiinfectives).

LIMITATIONS OF AUTHORIZED USE

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- EVUSHELD is not authorized for use in individuals:

  For treatment of COVID-19, or

  For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.

LIMITATIONS OF AUTHORIZED USE

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- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.
- Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

MEDICAL CONDITIONS OR TREATMENTS THAT MAY RESULT IN MODERATE TO SEVERE IMMUNE COMPROMISE

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- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts

- *For additional information please see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccinesus.html.Healthcare providers should consider the benefit-risk for an individual patient.*

DOSAGE AND ADMINISTRATION

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- The dosage of EVUSHELD for emergency use is 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular injections.
- Injection:
  - tixagevimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial.
  - cilgavimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial.

CONTRAINDICATIONS

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- EVUSHELD is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD.

WARNINGS AND PRECAUTIONS

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- Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour.
- Clinically Significant Bleeding Disorders: As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder.
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

ADVERSE REACTIONS

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- Most common adverse events (all grades, incidence ≥3%) are headache, fatigue, and cough.

ADVERSE EVENTS (ALL GRADES) REGARDLESS OF CAUSALITY OCCURRING IN AT LEAST 3% OF SUBJECTS RECEIVING EVUSHELD OR PLACEBO IN PRIMARY SAFETY ANALYSIS

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	EVUSHELD N= 3,461	**Placebo N= 1,736**
Headache	6%	5%
Fatigue	4%	3%
Cough	3%	3%

CARDIAC SERIOUS ADVERSE EVENTS

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- Through the additional data cut-off in PROVENT, a higher proportion of subjects who received EVUSHELD versus placebo in PROVENT reported myocardial infarction SAEs, one of which resulted in death, and cardiac failure SAEs.
- All subjects who experienced cardiac SAEs had cardiac risk factors and/or a prior history of cardiovascular disease at baseline.
- There was no clear temporal pattern, with events reported from several hours after EVUSHELD receipt through the end of the follow-up period.

REQUIRED REPORTING FOR SERIOUS ADVERSE EVENTS AND MEDICATION ERRORS

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- The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events* and medication errors potentially related to EVUSHELD within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500
- Submit adverse event and medication error reports, using Form 3500, to FDA MedWatch using one of the following methods:
  - Complete and submit the report online: www.fda.gov/medwatch/report.htm 10 | Page
  - Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
    - o Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787,
    - or o Fax to 1-800-FDA-0178, or
    - Call 1-800-FDA-1088 to request a reporting form

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

DRUG INTERACTIONS

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- Drug-drug interaction studies have not been performed.
- Tixagevimab and cilgavimab are not renally excreted or metabolized by cytochrome P450 (CYP) enzymes; therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of CYP enzymes are unlikely

PREGNANCY

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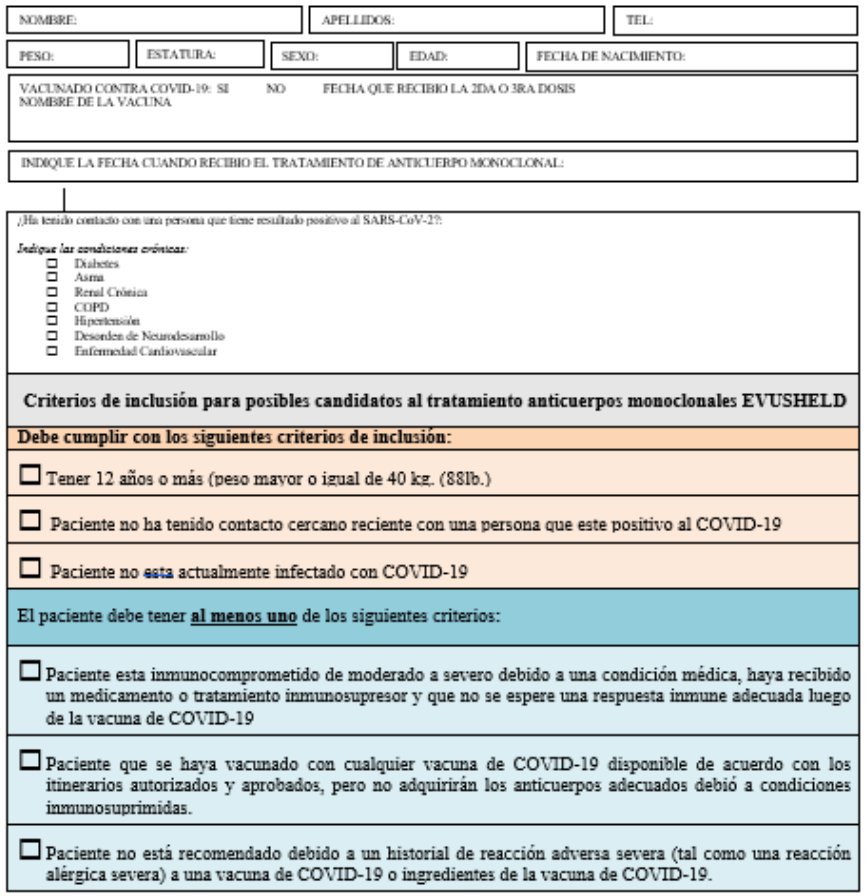
- Risk Summary

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. EVUSHELD should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

LISTA DE COTEJO DE CRITERIOS DE INCLUSIÓN

El Departamento de Salud ha estandarizado una lista de cotejo de criterios de Inclusión para facilitar el proceso de evaluar un paciente para el tratamiento de EVUSHELD bajo preexposición prevención a COVID-19

•Enlace para referir un paciente
•https://forms.office.com/g/LWQ9DFNnMt



GOBIERNO DE PUERTO RICO
Oficina del Oficial Principal Medico

DEPARTAMENTO DE SALUD

NOMBRE: | APELLIDOS: | TEL:

PESO: | ESTATURA: | SEXO: | EDAD: | FECHA DE NACIMIENTO:

VACUNADO CONTRA COVID-19: SI NO FECHA QUE RECIBIO LA 2DA O 3RA DOSIS
NOMBRE DE LA VACUNA

INDIQUE LA FECHA CUANDO RECIBIO EL TRATAMIENTO DE ANTICUERPO MONOCLONAL:

¿Ha tenido contacto con una persona que tiene resultado positivo al SARS-CoV-2?:

Indique las condiciones crónicas:
- ☐ Diabetes
- ☐ Asma
- ☐ Renal Crónica
- ☐ COPD
- ☐ Hipertensión
- ☐ Desorden de Neurodesarrollo
- ☐ Enfermedad Cardiovascular

Criterios de inclusión para posibles candidatos al tratamiento anticuerpos monoclonales EVUSHELD

Debe cumplir con los siguientes criterios de inclusión:

☐ Tener 12 años o más (peso mayor o igual de 40 kg. (88lb.)

☐ Paciente no ha tenido contacto cercano reciente con una persona que este positivo al COVID-19

☐ Paciente no ~~esta~~ actualmente infectado con COVID-19

El paciente debe tener **al menos uno** de los siguientes criterios:

☐ Paciente esta inmunocomprometido de moderado a severo debido a una condición médica, haya recibido un medicamento o tratamiento inmunosupresor y que no se espere una respuesta inmune adecuada luego de la vacuna de COVID-19

☐ Paciente que se haya vacunado con cualquier vacuna de COVID-19 disponible de acuerdo con los itinerarios autorizados y aprobados, pero no adquirirán los anticuerpos adecuados debió a condiciones inmunosuprimidas.

☐ Paciente no está recomendado debido a un historial de reacción adversa severa (tal como una reacción alérgica severa) a una vacuna de COVID-19 o ingredientes de la vacuna de COVID-19.

Fecha cuando se realizó la evaluación: ~~Evaluación~~ realizada por:

COMO UNIRSE A LAS FACILIDADES ADMINISTRANDO LOS TRATAMIENTOS EN PUERTO RICO

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Contactar al Equipo de Tratamiento de Anticuerpos Monoclonales del Departamento de Salud si desea Administrar EVUSHELD en su facilidad:

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