

Evusheld™ (fixagevimab co packaged w/ cilgavimab)
PATIENT INFORMATION
PROVIDER INFORMATION

 Name _____ DOB _____
 Address _____
 City _____ State _____ Zip _____
 Phone _____ Alt. Phone _____
 Email _____ Gender M F

 Name _____ NPI _____
 Address _____
 City _____ State _____ Zip _____
 Phone _____ Fax _____
 Office Contact _____ Phone _____

REQUIRED ✓Insurance Card Front/Back ✓Prescription Insurance Card Front/Back ✓Clinical Notes ✓Lab/Test Results

CLINICAL INFORMATION
 Dx(ICD-10): _____
 Drug Allergies: _____ Latex Allergy Yes No
 Height _____ (in) Weight _____ (lbs) Patient Provided with "Fact Sheet for Patients, Parents and Caregivers" Yes No

FDA EUA (Emergency Use Authorization) for COVID 19 PRE Exposure Prophylaxis

This EUA is for the use of the *unapproved products fixagevimab co-packaged with cilgavimab* for pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals 12 years of age and older weighing at least 40kg AND who are not currently infected with SARS-COV-2 and who have not had a known recent exposure to an individual infected with SARS-COV-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 COVID-19 vaccine component(s).

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination *include but are not limited to:*

- 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 <200/mm³, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥ 20mg prednisone or equivalent per day when administered for ≥ 2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g. B-cell depleting agents)

MEDICATION	DOSE/STRENGTH	DIRECTIONS	QTY	REFILLS
Evusheld™ (fixagevimab co-packaged with cilgavimab)	150mg (fixagevimab) + 150mg (cilgavimab)	Inject 150mg of fixagevimab and 150mg of cilgavimab IM as two separate injections in each of the gluteal muscles one after the other; may repeat in 6 months	1 Dose	1

My signature below certifies that (1) The above-named individual is my patient and the therapy identified has been deemed medically necessary. (2) All information provided is true and accurate to the best of my knowledge. (3) I authorize the use of BrookWell Health's Infusion and line access and flushing protocols. (4) I authorize BrookWell Health to perform any necessary emergency and/or anaphylaxis treatment as per BWH protocol (see reverse).

Provider Name: _____ **Provider Signature:** _____ **Date:** _____

Adverse Reaction Management Protocol

Hypersensitivity reaction including, but not limited to, fever, rash, itching, rigors, sneezing, nausea and vomiting

If reaction occurs:

- If indicated, stop infusion
- Maintain / establish vascular access
- May utilize the following PRN medications as follows:
 - * Allergies, hives, itching - Diphenhydramine 25-50mg PO/IV as a single dose, may repeat with either medication if needed
 - * Nausea, vomiting, heartburn - Ondansetron 4mg ODT (may repeat in 20 minutes if nausea continues) or Famotidine 20mg PO as a single dose; if severe - give Ondansetron 4mg slow IVP (may repeat in 20 minutes if nausea continues) or Famotidine 20mg slow IVP
 - * Headache, pain or fever > 100.4°F - Acetaminophen 500mg 1-2 tablets PO as a single dose or Ibuprofen 400mg PO as a single dose
 - * Hypotension (90/60) - place patient in reclined position, administer 0.9% NaCl IV 500ml, may repeat to keep BP > 90/60, monitor vital signs
 - * Hypertension (> 30mmHg above baseline or > 180mmHg SBP) - Clonidine 0.1mg and wait 45 minutes, may administer amlodipine 5mg if hypertension persists
 - * Chest pain/discomfort or shortness of breath - Oxygen 2-15 liters, titrate to keep SPO₂ ≥ 92%
 - * May give Famotidine 20mg IV or Methylprednisolone 125mg IV/IM - refractory to other treatments given
- May resume infusion when symptoms resolve at 50% previous rate and increase per manufacturer guidelines

Severe allergic/anaphylactic reaction management

- Obtain a thorough allergy and drug history, note any cross-sensitivity
- Identify risk factors for anaphylaxis including history of severe drug reactions and family history of same, when administering blood/blood components and the first dose of an infusion medication.
- Identify and respond to signs/symptoms of anaphylaxis which is the likely type of reaction when all of the following criteria are met:
 - * Sudden onset and progression of symptoms
 - * Life-threatening airway / breathing / circulatory symptoms, such as laryngeal edema, stridor, severe dyspnea / wheezing, confusion, signs of shock, tachycardia, hypotension, cardiac arrest
 - * Skin changes or changes in mucosa, such as flushing urticaria, angioedema
- Symptoms associated with less severe systemic reactions may include
 - * Neurological - dizziness, headache, weakness, syncope, seizures
 - * Psychiatric - anxiety
 - * Respiratory - dyspnea, wheezing, bronchospasm, tachypnea
 - * Cardiovascular - tachycardia, hypotension, arrhythmias
 - * Cutaneous - flushing erythema, pruritis, urticaria, angioedema
- Interventions
 - 1) Stop infusion immediately
 - 2) Discontinue any medication suspected of causing reaction
 - 3) Initiate basic life support as needed
 - * Initiate rapid response team, "Code"
 - 4) Utilize the 'Emergency Management of Anaphylaxis' in the Reaction Management Kit to follow steps for correct management of reaction.
 - 5) Perform interventions and treatments as ordered or according to organizational protocol
 - 6) Administer emergency medications - medications will include
 - * Epinephrine
 - * Corticosteroids - methylprednisolone 40mg or 125mg IV/IM
 - * Antihistamines - Diphenhydramine 25 - 50mg IV/IM
 - * IV fluids - 0.9% NaClResuscitation equipment will include
 - * Barrier mask for CPR
 - * Self-inflating bag for CPR maskBreathing support
 - * Oxygen and delivery system or device
 - 7) Monitor patient's vital signs. Monitor and observe patient for at least 6 hours
 - 8) Patient may require transfer to ER department for observation period
- Documentation - document in the patient's health record
 - * Presence of allergies/reactions
 - * Observations and patient assessment
 - * Licensed practitioner notification
 - * Interventions taken and outcome
 - * Patient condition and response to interventions