Covid-19 Pre-exposure prophylaxis
1/31/22

Background:
On December 8, 2021, the FDA granted emergency use authorization (EUA) of tixagevimab/cilgavimab for the prevention of Covid-19 infection for specific high-risk groups. The primary data supporting this EUA came from the PROVENT study, a double blind randomized clinical trial that enrolled adults ages 59 or older with a prespecified chronic medical condition and at increased risk of SARS-CoV2 infection who had not been vaccinated or had a prior or current history of infection. In the primary analysis, those who received tixagevimab/cilgavimab had a 77% reduction in incident infection and this reduction was maintained for 6 months.

The EUA has emphasized the following groups should be prioritized:

Individuals 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).

Per the NIH Covid Treatment Panel, in times of scarcity, individuals with severe immune compromise should be prioritized.

Medical conditions that result in severe immune compromise include:

- Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)
- Patients receiving Bruton tyrosine kinase inhibitors
- Chimeric antigen receptor T cell recipients
- Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication
- Patients with hematologic malignancies who are on active therapy
- Lung transplant recipients at any time post transplantation
- Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)
- Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents or are currently on a second signal inhibitor such as belatacept
- Patients with severe combined immunodeficiencies
- Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm^3

Medical conditions that result in moderate immune compromise include:

- Receiving active cancer treatment for non-hematologic malignancies (e.g. myelosuppressive chemotherapy)
- Solid organ transplant on immunosuppression (>1 year)
- HSCT <2 years (without GVHD/not taking immunosuppressive meds for another indication)
- Moderate primary immunodeficiency on treatment
- Untreated/advanced HIV, CD4 count <200 but >50 cells/mm3
- Active treatment with high-dose corticosteroids (>20mg daily for at least 2 weeks) or other drugs that may suppress your immune response (active, within the last month)

A phased allocation process will take place

Phase 1.

The UCLA Health will consider the following initial approach for risk stratification:

*on occasion a serology will be requested if patient does not fall under traditional immunosuppressive conditions

Serostatus is emphasized in part because of prior data on monoclonal antibodies (Weinrich, and colleagues NEJM Jan 21, 2021 and Recovery Collaborative group) and in part based on the primary endpoint of the study.

Phase 1. Initial Allocation Process:

A team of pharmacists and physicians (Evusheld Team) will review a database of all patients who have had 1 primary care visit or 2 subspecialty visits in the last 3 years.

The primary MD on record will be contacted to discuss the medication with patients who meet criteria. The primary MD on record shall share the EUA fact sheet (English and Spanish).

Once patient agrees, the Evusheld admin team will reach out to patient to schedule at CTRC, Bowyer, Allergy and Immunology Clinic or Connie Frank. MD from team will place order.

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Phase 2. (Start date 1/24/22)

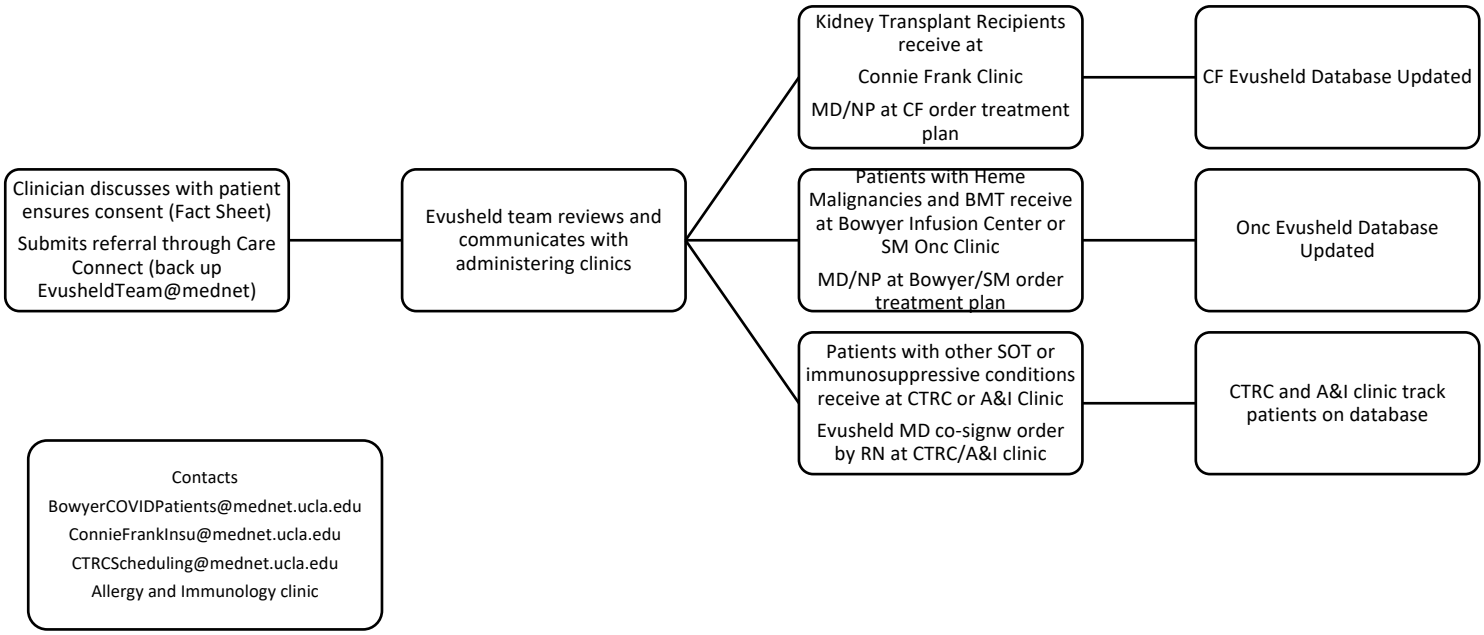
Individuals who meet EUA criteria inpatient and have no hx of exposure, no symptoms or are not positive can be considered for inpatient administration of tixagevimab/cilgavimab. Teams caring for these patients should give patient fact sheet and obtain verbal consent before placing order.

Select groups will be prioritized (patients who have received full vaccination):

- Any solid organ transplant recipient
- Any patient on myelosuppressive chemotherapy
- Any patient receiving other immunosuppressive therapy including B cell depleting agents, Bruton's tyrosine kinase inhibitors, TNF alpha inhibitors, steroids >20mg for > 4 weeks or equivalent
- HIV with CD4 ≤200

Phase 3 (start date 1/31/22)
Will open to referrals to all patients who are fully vaccinated who meet moderate-severe immunosuppressive conditions listed above. Referral will be reviewed by Evusheld Team and if appropriate patients will be scheduled at select sites. Clinicians should review fact sheet with patients before placing order

Workflow for referrals



Database maintenance:

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Each administering clinic will update individual databases within Evusheld Box folder
Evidence of Evusheld administration will be visible on Covid-19 Snapshot on Care Connect (in addition to medication history)

Referral Outcomes

1. Meets criteria, will schedule
2. Does not meet EUA criteria
3. Meets criteria, but defer scheduling due to recent vaccination or for other reasons.