COVID-19 Therapies - tixagevimab/cilgavimab (EVUSHELD™)

Guidance for healthcare providers May 25, 2022

Recently, Health Canada approved tixagevimab/cilgavimab (Evusheld™), a long-acting monoclonal antibody, for prevention of COVID-19 in individuals who are expected to have a reduced response to vaccination or who cannot receive a COVID-19 vaccine.

Please see the full guide developed by the B.C. COVID Therapeutics Committee for more information: Clinical Practice Guide for the Use of Tixagevimab/Cilgavimab

Who is the treatment currently being considered for?

Refer to: Clinical Practice Guide for the Use of Tixagevimab/Cilgavimab

The case-by-case use of tixagevimab/cilgavimab should be limited to patients who:

i. Are **severely immunocompromised** (categorized as Clinically Extremely Vulnerable Group 1); i.e.,
   - are solid organ transplant recipients,
   - in the past year have received active treatment (chemotherapy, targeted therapies including CAR-T, immunotherapy) for malignant hematologic conditions (e.g., leukemia, lymphoma, or myeloma),
   - have received a bone marrow transplant or stem cell transplant in the past 2 years or are taking immunosuppressants for graft vs. host disease (GVHD),
   - those who have taken anti-CD20 agents or B-cell depleting agents in the past 2 years,
   - or those with significant primary immunodeficiency affecting T-cells, immune dysregulation or type 1 interferon defects

AND

ii. Who have **no known cardiovascular disease** (i.e., known coronary artery disease, history of myocardial infarction, unstable angina, heart failure, arrhythmia)

AND

iii. Who have **additional risk factors** or exceptional circumstances that correlate with an extremely high risk of poor outcomes from COVID-19 (e.g., unable to receive COVID-19 vaccination, treatment of COVID-19 is contraindicated, transplant with poor lung graft function, severe GVHD)

Other risk factors may exist and can be determined on a case-by-case basis as per the clinician's discretion. The CTC does not recommend routinely offering tixagevimab/cilgavimab to patients in the CEV 1 category without additional risk factors for hospitalization from Omicron.

**THERAPY:** tixagevimab/cilgavimab (EVUSHELD™) - monoclonal antibody administered by gluteal intramuscular injection 300mg IM (150mg=1.5mL each tixagevimab and cilgavimab) every 6 months

**When to start:**
- Tixagavimab/cilgavimab can be administered at a pre-arranged time that is convenient to the patient and provider.
- It takes approximately 29 days to reach the maximum serum concentration of antibodies after a dose tixagevimab/cilgavimab and achieve the full effect of the drug.
- It should not be used if the patient has active COVID-19 or has been recently exposed to COVID-19 as tixagevimab/cilgavimab will not prevent the infection or be effective as treatment.
Tixagevimab/cilgavimab prescriptions should be faxed to 604-941-0532. Special Authority is not required.

Injections are delivered through:
- physician clinics (couriered to the location where it will be administered to the patient) OR
- hospital inpatient or a hospital-based clinic (where the order is processed through the hospital pharmacy).

Tixagevimab/cilgavimab is provided free of charge to patients.

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<tr>
<th>Contraindications and Cautions</th>
<th>Drug-to-Drug Interactions</th>
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<tr>
<td>Hypersensitivity reactions and infusion <strong>reactions are rare.</strong></td>
<td>Possesses <strong>no significant drug-drug interactions.</strong></td>
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<td>- Monoclonal antibodies have been shown to be associated with injection reactions and hypersensitivity reactions including anaphylaxis at rates similar to COVID-19 vaccines.</td>
<td>Tixagevimab/cilgavimab should not delay <strong>COVID-19 vaccinations.</strong></td>
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<td>- Patients receiving tixagevimab/cilgavimab should be observed for 15 minutes after their injections.</td>
<td>- Patients should have their vaccines up to date and should wait at least 14 days from their last COVID-19 vaccine dose before receiving tixagevimab/cilgavimab.</td>
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<td><strong>Cardiovascular disease:</strong> Patients taking tixagevimab/cilgavimab experienced more cardiovascular serious adverse events (SAEs) than those taking placebo (22 vs. 5).</td>
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<td>- All patients who experienced cardiac-related hospitalization or death who received tixagevimab/cilgavimab had cardiovascular risk factors; however not all had known cardiovascular disease.</td>
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<td>- The absolute risk of cardiovascular SAEs is low (approximately 0.56%); however, as the benefit of this drug in preventing hospitalization from COVID-19 is theoretical, the risk of tixagevimab/cilgavimab in those with cardiovascular diseases may not outweighed by this benefit.</td>
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<td><strong>Renal and liver disease:</strong> There are no dose adjustments or contraindications with renal or liver disease.</td>
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<td><strong>Pediatrics:</strong> Tixagevimab/cilgavimab has been approved for children 12 years and over weighing 40 kg or more. There were no individuals &lt; 18 years in clinical studies; dosing and safety has been inferred from pharmacokinetic and animal studies.</td>
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**Side Effects**

General side effects from tixagevimab/cilgavimab are mild and resolve quickly. As with vaccinations, patients can experience pain at the injection site, headache, malaise and fatigue.

**Laboratory Monitoring**

There is no laboratory monitoring required before or after the dose. Serology testing is not routinely recommended as it is not a useful predictor of clinical outcomes such as hospitalization from COVID-19 in vaccinated individuals.

This document provides guidance only; patients defined above are those who may benefit from treatment. Case-by-case assessment is still required, and the totality of risk factors needs to be considered when offering treatment. Expert consultation can assist with additional risk assessments.