Bebtelovimab Executive Summary & Guidelines for Use

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Indication for Use:

- Bebtelovimab is an investigational monoclonal antibody that has been authorized by the FDA for emergency use for the ***treatment*** of COVID-19 in patients at risk for progression to severe COVID-19 including hospitalization.
- Lab data indicates effectiveness against Omicron sub-variant BA.2.
- For use in adults and pediatric patients who are 12 years of age and older weighing at least 40 kg with laboratory confirmed SARS-CoV-2 infection at high risk for progression to severe COVID-19 (as defined by the CDC). Patients are ineligible for treatment if they are hospitalized due to COVID-19, require oxygen due to COVID-19 or require an increase in their baseline oxygen requirements due to COVID-19.
- To be administered as soon as possible ***within 7 days*** of symptom onset.
- Product is not a substitution for vaccination in patients eligible to receive vaccination

Mechanism of Action:

- Bebtelovimab binds to the spike protein receptor binding domain of SARS-CoV-2. This binding is thought to inhibit fusion of the virus to human cell membranes preventing virus attachment.

Clinical Evidence Review:

- Clinical evidence was reviewed by a team of RRH medical and pharmacy providers
- In summary, bebtelovimab reduced the risk of progression of COVID-19 by 34% at day 7 compared to placebo. There was no clinically significant difference in relative risk reduction, hospitalization rate or deaths between patients who received bebtelovimab alone or in combination with bamlanivimab/etesevimab.

Safety:

- Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of monoclonal antibodies.
- Common adverse events include nausea, vomiting, rash, pruritus and infusion-related reactions. All adverse events were noted at a rate of <1% in clinical trials.
- Provider must obtain written consent
- Completion of FDA MedWatch Form for all medication errors and serious events within 7 days of onset of event

Emergency Use Authorization Restrictions:

- Administration site must be able to provide immediate access to medications to treat a severe adverse reaction such as anaphylaxis and able to activate the EMS as necessary.
- ***Exclusion Criteria:***
    - Patients hospitalized due to COVID-19
    - Patients requiring oxygen due to COVID-19
    - Patients requiring an increase in baseline oxygen flow rate due to COVID-19
    - Patients who do not meet the specified requirements for age, weight, or risk stratification

RRH Guidelines for Use:

Should We Use This Medication At RRH?	Yes
Who Can Prescribe?	• Open to (all) providers without restriction • Providers must review EUA Provider Fact Sheet (attached)
Who Can Receive?	• Select outpatient treatment for positive SARS-CoV-2
How Is It Ordered?	• ***Outpatient- injection*** • Bebtelovimab 175 mg/2 mL IV Push injection over 30 seconds
Is this Reimbursable?	• HCPCS code M0222 bebtelovimab injection $350.50 per dose
Where Will They Receive?	• **WICC/St Mary's campus** • **Wilson Health Centre/ RGH campus**
How Will Medication Be Provided?	• Bebtelovimab 175 mg/2 mL IV Push injection
Administration & Monitoring Instructions:	• Provide patient with EUA Patient Fact Sheet (attached) • Prepare the injection per manufacturer's guidelines. Allow medication to come to room temperature for 20 minutes, **do not shake vial**. Withdraw 2 mL bebtelovimab from vial and attach syringe to IV hub. • **Inject entire contents of syringe over at least 30 seconds**. • Flush IV hub with 10 mL of Sodium Chloride 0.9% after completion of injection to ensure full dose delivered. • Monitor for 1 hour post-injection.

References:

1. Bebtelovimab [package insert]. Indianapolis, IN: Eli Lilly and Co; 2022.