Bamlanivimab and Etesevimab Executive Summary and Guidelines for Use
Presented by Drs Shahzad Mustafa and Will Carroll
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Indication for Use:
- Bamlanivimab and Etesevimab is a combination of investigational monoclonal antibodies that have been recently authorized by the FDA for emergency use for the treatment of **mild to moderate** COVID-19
- For use in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization

Mechanism of Action:
- Bamlanivimab and Etesevimab are recombinant neutralizing human IgG1κ monoclonal antibodies (mAb) that target the viral spike protein that SARS-CoV-2 uses to enter host cells. Designed to block viral attachment and entry of SARS-CoV-2 into human cells thus potentially neutralizing the virus and treating COVID-19
- Using both antibodies together is expected to reduce the risk of viral resistance

Clinical Evidence Review:
- Clinical evidence was reviewed by a team of RRH medical and pharmacy providers
- In summary, Bamlanivimab and Etesevimab demonstrated a reduction in COVID-19 viral load at day 11 and a subsequent reduction in hospitalization at day 29 post-administration

Safety:
- Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of bamlanivimab with and without etesevimab
- Infusion-related reactions have been observed with administration of bamlanivimab and etesevimab together. Most common were nausea, pruritus, pyrexia, dizziness, and rash.
- Provider obtains written consent
- Completion of FDA MedWatch Form for all medication errors and serious events within 7 days

Emergency Use Authorization Restrictions:
- For outpatient use (May be used for patients hospitalized for non-COVID reasons who later test positive for COVID-19 and have symptom onset during their hospitalization)
- Administration site must be able to provide immediate access to medications to treat a severe infusion reaction such as anaphylaxis and able to activate the EMS as necessary.
- Must receive medication within 10 days of testing + for COVID-19
- **Exclusion Criteria:**
  - Patients who are hospitalized due to COVID-19 (unless positive test occurs and symptom onset begins during hospitalization)
  - Patients who require oxygen therapy due to COVID-19
  - Patients who are on chronic oxygen therapy due to underlying non-COVID-19 related
comorbidity

- Patients who do not meet the specified requirements for age, weight, or risk stratification
**RRH Guidelines for Use:**

- Allow for use in inpatient setting beginning April 19, 2021
- Allow for use in outpatient setting beginning April 19, 2021

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<th>Should We Use This Medication At RRH?</th>
<th>Yes</th>
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| **Who Can Prescribe?**               | - Open to all providers without restriction  
- Providers must review EUA Provider Fact Sheet (attached) |
| **Who Can Receive?**                 | - Outpatient COVID-19 + patients identified in the ED and/or PCP (must have tested + within 10 days of receiving med)  
- Inpatients who test positive and symptom onset begins during hospitalization (must have tested + within 10 days of receiving med) |
| **How Is It Ordered?**               | - **Option 1:** Inpatient Providers complete attached screening tool and order in CareConnect  
- **Option 2:** Referral to Clinic – Referring provider screens, if eligible, refer to clinic. Infusion location provider Screens again and orders in CareConnect  
- Schedule 2-3 days prior |
| **Is this Reimbursable?**             | Only for administration and monitoring |
| **Where Will They Receive?**         | - **Outpatient:** Wilson Health Center  
[MD- Darren Houtt, MD]  
M-F: 8:30AM – 3:30PM (Max Capacity 15 patients/day)  
Sat-Sun: As needed if someone may miss the window  
- **RRH Inpatient Setting** |
| **How Will Medication Be Provided?** | - RGH Inpatient Pharmacy for Wilson  
- Local Inpatient Pharmacy |
| **Administration & Monitoring Instructions:** | - Provide patient with EUA Patient Fact Sheet (attached)  
- Administer together 700 mg bamlanivimab and 1,400 mg etesevimab as a single intravenous infusion dose over 31 minutes (for a prefilled 100mL NaCl bag)  
- Monitor for 1 hour post-infusion |

**References:**