Bamlanivimab Infusion Treatment

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St. John's Well Child & Family Center
LEADING CHANGE THROUGH HEALTH

OPERATION WARP SPEED
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Why Monoclonal Antibody Infusion for COVID?

- U.S. Food and Drug Administration issued an emergency use authorization (EUA) for Monoclonal antibody usage on Nov 10th, 2020

- In clinical trials, bamlanivimab was effective for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing

- There is no adequate, approved, and available alternative to the emergency use of bamlanivimab for the treatment of Covid

- With so many positives at St. John’s, it was a natural step to start these treatments to prevent or reduce hospitalizations.
Licensing for Infusions

• If the Infusion center is within an existing licensed clinic, no separate licensing necessary
• verified with Pharmacy board and FTCA
• PAs and NPs may administer, furnish and order drugs—under physician supervision and pursuant to standardized procedures or protocols developed with their supervising physicians.
Infusion Room

- Sink is a requirement for the infusion room
- Rooms with comfortable chairs
- Each infusion takes place for one hour with observation for another hour
  - Patient intake, preparation of the infusion, starting the infusion and cleaning the room post infusion takes another 30 min
- Cannot administer more than 3 per chair in 8 hours
- One room for staff to change
### Equipment

#### PPE
- Negative pressure air filters for each room
- Head cap
- Face shield
- N-95 or K-95 mask
- Gown
- Gloves
- Shoe covers - for both patients and staff
- PPE disposing baskets (regular and biohazard)

#### Infusion
- Infusion pump (optional)
- IV needle and IV starter kit
- Vitals Machine - BP apparatus, Pulse oximeter, weighing scale, remote monitoring set of pulse Oximeter (RPM) & thermometer
- Normal saline infusion bags
- Polyvinylchloride infusion set containing 0.20/0.22 micron inline polyethersulfone filter
- Syringes - 20 ml & 2 ml syringes
- Antiseptic lotions

#### Supplies
- One comfortable chair for the patient
- Saline swabs, gauze pieces, sharp containers, water bottles for staff and patients
- Refrigerator
- Crash cart
- Cameras with remote monitoring
- TV for each room
- Emergency calling bell for the patients
- At least 3 working Computers at staff room and 3 working phones.
MEDICATIONS

• Ondansetron ODT 4 mg
• Ondansetron 4 mg IV for nausea
• Diphenhydramine 25 mg IV
• Albuterol inhaler
• Solu-Medrol injection
• 0.9% Sodium chloride flush (10 mL)
• 0.9% Sodium Chloride bag (500 mL)
• Epinephrine 0.3 mg IM
• Bamlanivimab 700 mg in 0.9% NaCl
• Famotidine
• Clonidine and Hydralazine
• Tylenol and Ibuprofen
Staffing

• One MD on-site
• One NP/PA
• RN
• One MA/BC
• Care-Coordinator
• Cleaning crew to clean the rooms after each infusion
• Pharmacy support for medication management (optional)
• IT support
• Remote Patient Monitoring (optional)
• Infusion therapy specialist/trainer, as needed
Patient Inclusion Criteria

- Treatment of Mild to Moderate COVID-19 positive patients
- Within 10 days of symptoms onset, the sooner the better
- 12 or older age group
- Weighing at least 40 Kgs
- At risk for progressing to severe COVID disease or potential to be hospitalized
- With the following high risk factors…
Exclusion criteria

• who are hospitalized due to COVID-19, OR

• who require oxygen therapy due to COVID-19, OR

• who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

• If the patient is pregnant or breastfeeding, discuss their options and specific situation

• Preferable to transfuse pregnant patients under OB/Gyn supervision in a hospital or hospital affiliated setting
Patient selection criteria

- High risk is defined as patients who meet at least one of the following criteria:
  - Have a body mass index (BMI) ≥35
  - Have chronic kidney disease
  - Have diabetes
  - Have immunosuppressive disease
  - Are currently receiving immunosuppressive treatment
  - Are ≥65 years of age

- Are ≥55 years of age AND have
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease
  - other chronic respiratory disease

- Are 12 – 17 years of age AND have
  - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR
  - neurodevelopmental disorders, for example, cerebral palsy, OR
  - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
Infusion Referring provider Workflow

- Verify indications, rule out exclusion criteria
- Explain about Bamlanivimab Medication and it’s EUA status
- How is it given?
- Possible side effects of BAM drug and the infusions
- Possible allergic reactions
- Arrange transportation
- Verify phone number, emergency contact, and their phone number
- Explain the duration of 3 hours
- Make sure to wear comfortable clothing and dress in layers
- Ask about pregnancy or breast feeding
Infusion center workflow

- Confirm the appointment
- Explain the procedure and take verbal consent
- Give the instructions of infusion process
- Give the patient fact sheets and verify understanding
- Explain the EUA status of the infusion
- Make the patient sign the consent form if available
- Complete all the documentation in the template
- Ensure everyone is trained on infusion process, documentation,
- Maintain logs, supplies and patient treatment data
- Explain RPM/Pulse Oximeter if included
- Give return to work letter if needed based on CDC guidelines
**EMR Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>CPT Short Descriptor</th>
<th>Labeler Name</th>
<th>Vaccine/Procedure Name</th>
<th>Payment Allowance</th>
<th>Effective Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q0239</td>
<td>bamlanivimab-xxxx</td>
<td>Eli Lilly</td>
<td>Injection, bamlanivimab, 700 mg</td>
<td>$0.010*</td>
<td>11/10/2020 – TBD</td>
</tr>
<tr>
<td>M0239</td>
<td>bamlanivimab-xxxx infusion</td>
<td>Eli Lilly</td>
<td>Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring</td>
<td>$309.600***</td>
<td>11/10/2020 – TBD</td>
</tr>
</tbody>
</table>

- For FQHCs, please submit **99215 or 99205** for maximum PPS rate (even with the new changes in 2021, based on the time spent, this visit can be coded for 99215 code)

- * Since we anticipate that providers, initially, will not incur a cost for the product, CMS will update the payment allowance at a later date. Providers should not bill for the product if they received it for free.

- *** **Medicare will pay a rate of $309.60** for many providers. These rates will also be geographically adjusted for many providers. For providers and suppliers with payments that are geographically adjusted by the methodology used by the Medicare Physician Fee Schedule (MPFS), files with the geographically adjusted payment rates for monoclonal antibody administration are included in the “Additional Resources” section. Certain settings utilize other payment methodologies, such as payment based on reasonable costs.***
Bamlanivimab Injection (700 mg/20 ml)

- **Manufacturer:** Eli Lilly
- **Product:** Single monoclonal antibody for outpatient infusion
- Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus and are intended to prevent progression of disease
- **Unit:** Supplied as one single-dose 20-ml vial per carton
- **Storage:** Unopened vials must be stored at refrigerated temperature (2°C–8°C / 36°F–46°F) until use
- Do not freeze, shake, or expose to direct light.
- **Dosage:** The dosage of bamlanivimab in adults and pediatric patients 12 years of age is 700 mg
- No dosage adjustment is recommended based on age, sex, race, body weight, renal or mild hepatic impairment, during pregnancy or while lactating, or for disease severity or inflammation. Not intended for children <12 years and weight <40kgs
Preparation and Administration

Bamlanivimab solution for infusion should be prepared by qualified HCP using aseptic technique:

- Remove the bamlanivimab vial from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. **Do not expose to direct heat**
- Inspect bamlanivimab visually for particulate matter and discoloration.
- Bamlanivimab is a clear to slightly opalescent and colorless to slightly yellow to slightly brown solution.
- Gently invert vial by hand approximately 10 times. Do not shake.
- Gently invert IV bag by hand approximately 10 times to mix. **Do not shake**
- This product is preservative-free and therefore, the diluted infusion solution should be administered immediately.
- If immediate patient infusion is not possible, store the diluted bamlanivimab solution at refrigerated temperature (2°C–8°C / 36°F–46°F) for no more than 24 hours and at room temperature for no more than 7 hours, including infusion time.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Number of Vials</th>
<th>Volume of Bamlanivimab</th>
<th>Volume of 0.9% Sodium Chloride</th>
<th>Total Volume for Infusion</th>
<th>Maximum Infusion Rate</th>
<th>Minimum Infusion Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bamlanivimab (700 mg/20 mL)</td>
<td>1 Vial</td>
<td>20 mL</td>
<td>250 mL</td>
<td>270 mL</td>
<td>270 mL/hr</td>
<td>60 Minutes</td>
</tr>
</tbody>
</table>
Infusion Workflow

**DOSE:** 700 mg infusion x1  
**Duration:** 60 minutes  
**Time of Tx:** As soon as diagnosed with COVID, within 10 days of symptom onset

**Use:** keep at room temperature for 20 minutes  
Do not expose to direct heat

**Storage:** Unopened vials must be stored at refrigerated temperature (2°C–8°C / 36°F–46°F) until use. Do not freeze, shake, or expose to direct light.

**Items needed:**  
Polyvinylchloride infusion set containing 0.20/0.22 micron inline polyethersulfone filter, 250 ml Normal saline bag, 20 cc syringe

Once mixed, administer immediately,  
If not possible, store the diluted medication in the fridge up to 24 hours, or 7 hours at room temp including infusion time

Remove 70 ml from 250-ml normal saline IV bag  
Inject 20 ml bamlanivimab into the bag to make it to final volume of 270 ml

Attach infusion set to IV bag, Prime the infusion set, administer via pump/gravity for 60 min  
**Infusion Rate - 270ml/hr**

Flush the infusion line once administration is complete, discard unused product

**Infusion Rate - 270ml/hr**

Patient should be monitored through infusion and at least one hour after  
**Total time: 2 hours (one hour for Infusion and one hour for observation)**
Duration
- Infusion time 60 minutes
- Post Infusion Check 60 minutes
- Total time for Visit: 2 hours

QVitals
- Check Vitals every 15 minutes
- Blood Pressure, O2 Saturation, Temp, Heart Rate

Reaction
- fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness

Anaphylaxis
- STOP infusion
- BLS protocol, IM Epinephrine

Mgmt
- if infusion reaction occurs: slow or stop the infusion immediately
- Supportive: consider Benadryl, epinephrine, Oxygen

Dose Adjust
- No dose adjustment needed for pregnant or lactating, pediatrics, renal impairment, mild hepatic impairment, geriatric
Reporting Side effects

As part of the EUA, FDA is requiring health care providers who prescribe Bamlanivimab to report-

- all medication errors and serious adverse events considered to be potentially related to bamlanivimab
- Use FDA’s MedWatch Adverse Event Reporting program.
- Providers can complete and submit the report online
- or download and complete the form, and fax at 1-800-FDA-0178.
- This requirement is outlined in the EUA’s health care provider Fact Sheet.
- FDA MedWatch forms should also be provided to Lilly
- please provide a copy of all FDA MedWatch forms to Eli Lily:
  Global Patient Safety Fax: 1-317-277-0853
  E-mail: mailindata_gsmindy@lilly.com
  Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events.
Documents on site & EMR

- Emergency contacts
- FDA-Approved Fact Sheet English/Spanish - For patients
- Policies and procedures on Infusion therapy and anaphylaxis
- Infusion Therapy Standard of Operating Procedure
- Reporting documents
- Patient and medication logs
Lessons Learned

- Staff can be reluctant to work in infusion center
- Many patients refuse treatment (50-60%)
  - Significant fear, lack of education about treatment
- Develop patient education materials and posters
- Ensure transportation before and after transfusion
- Advice to take their regular medicines on the day of infusion
- Verify the indications and day of onset of symptoms once again before transfusion
- Need a Care coordinator to sustain and maintain scheduling, if planning to schedule more cases
References

- https://www.covid19.lilly.com/bamlanivimab/hcp?gclid=EAIaIQobChMIi_ug8-P-7QIVUhx9Ch3AOQiSEAAAYASABEGKFOfD_BwE
Thank you

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St. John’s Infusion Video

https://drive.google.com/file/d/1kun9wKddC7MX76m_6jdP1GddAg3N62NI/view?usp=sharing