Preparing Health Centers to Administer Outpatient COVID-19 Monoclonal Antibodies

Bureau of Primary Health Care (BPHC)
Tuesday, December 22, 2020
Session Overview

AGENDA

- Opening Remarks
  Jim Macrae, Associate Administrator
  Bureau of Primary Health Care (BPHC)

- COVID-19 Response mAb
  CAPT David Wong, MD
  Operation Warp Speed - Therapeutics

- Health Center Experience
  Rebecca Hanratty, MD, Denver Health
  Sarah Rall, PharmD. Marshfield Clinic Health System

- Q&A

- Final Comments and Close
Opening Remarks

James Macrae
Associate Administrator
Bureau of Primary Health Care (BPHC)
COVID-19 Response - mAb

CAPT David Wong, MD
Operation Warp Speed (OWS)
Therapeutics
COVID-19 Outpatient Therapeutics: Monoclonal Antibodies

CAPT DAVID WONG, MD
DECEMBER 22, 2020
Context

- EUAs issued for bamlanivimab (Eli Lilly and Company) on Nov 9, 2020
- EUA issued for casirivimab/imdevimab (Regeneron Pharmaceuticals) on Nov 21, 2020
- Health equity implications
  - Product access
  - Capacity of healthcare facilities to administer monoclonal antibodies (mAbs)

Topics for today

- **Overview** of monoclonal antibodies (mAbs)
  - Focus on bamlanivimab
- **Preparing HCs** for administering mAbs
- **Allocation and distribution**
  - State-based allocation
  - Special Projects for Equitable and Efficient Distribution (SPEED)
- **Reimbursement**
Therapeutics Depend on Stage of COVID-19 Illness

Objective: Optimize therapeutic use to prevent or shorten hospitalizations

<table>
<thead>
<tr>
<th>No Illness</th>
<th>Exposed/Asymptomatic Infected</th>
<th>Early Symptomatic</th>
<th>Hospital Admission</th>
<th>ICU Admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy, no infection</td>
<td>Not hospitalized, no limitations</td>
<td>Not hospitalized, no new oxygen requirement</td>
<td>Hospitalized, no active medical problems</td>
<td>Hospitalized, high flow oxygen/non invasive ventilation</td>
</tr>
<tr>
<td>Antiviral therapies</td>
<td>Monoclonal Antibodies</td>
<td>Remdesivir</td>
<td>Convalescent Plasma</td>
<td></td>
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<tr>
<td>Immune modulator therapies</td>
<td></td>
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</tr>
</tbody>
</table>

- Hospitalized, not on oxygen
  - Antiviral therapies
  - Remdesivir
  - Convalescent Plasma

- Hospitalized, on oxygen
  - Antiviral therapies
  - Remdesivir
  - Convalescent Plasma
  - Immune modulator therapies
  - Dexamethasone
  - Baricitinib (with Remdesivir)

- Hospitalized, mechanical ventilation/ECMO
  - Immune modulator therapies
  - Dexamethasone
  - Baricitinib (with Remdesivir)

Phase 2 Trial Results: Bamlanivimab in Outpatients with Covid-19

All study-patients, Hospitalization or ED visit within 29 days of administration
- Treatment group (n=309), 1.6%
- Placebo group (n=143), 6.3%
- Number needed to treat (NNT) to avoid hospitalization/ED = 21.3

Study-patients with BMI ≥35 or Age ≥65, Hospitalization/ED within 29 days
- Treatment group (n=95), 4.2%
- Placebo group (n=48), 14.6%
- NNT = 9.6

SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19

Bamlanivimab EUA – Eligibility Criteria

- **All Patients (who meet at least 1 of the following criteria):**
  - BMI ≥35
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease
  - Receiving immunosuppressive treatment
  - Age ≥ 65 years
  - Age ≥ 55 years AND have any of the following
    - Cardiovascular disease
    - Hypertension
    - COPD/other chronic respiratory disease

- **Adolescents (Age 12-17 years) who meet at least 1 of the following criteria:**
  - BMI ≥85th percentile for age/gender
  - Sickle cell disease
  - Congenital or acquired heart disease
  - Neurodevelopmental disorders (e.g. cerebral palsy)
  - Medical-related technological dependence [e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)]
  - Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control
About Bamlanivimab

EUA authorizes use of Bamlanivimab for treatment of high-risk COVID-19 outpatients (ages ≥12 y/o, weight ≥40 kg) with mild-to-moderate symptoms at risk for progressing to severe disease/hospitalization

1. Direct SARS-CoV-2 test (e.g., PCR, rapid antigen test) must be positive
2. Administer as soon as possible after positive test result and within 10 days of symptom onset
3. Provider reviews Fact Sheet for Healthcare Providers
4. Discuss and provide copy of Fact Sheet for Patients, Parents, and Caregivers
5. Administer in setting where HCPs have immediate access to meds to treat severe infusion reactions (e.g., anaphylaxis) and ability to activate EMS
   - Infusion time: At least 60 minutes
   - Post-infusion monitoring: 60 minutes, visual observation and symptom check
# Bamlanivimab
## Dosing and Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>700mg in 270mL 0.9% NaCl IVPB over at least 60 minutes (PVC infusion set with 0.20/0.22 micron filter)</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Monitor during infusion (no specified interval) and for 1 hour after completion</td>
</tr>
<tr>
<td>Storage Requirements</td>
<td>700mg/20mL vial – store in original carton to protect from light at 2-8°C; do not freeze, shake, or expose to direct light or heat</td>
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<tr>
<td>Stability Once Reconstituted</td>
<td>24 hours at 2-8°C OR up to 7 hours (including infusion time) at room temperature</td>
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<tr>
<td>Required Chart Documentation</td>
<td>- That patient/caregiver has been given fact sheet</td>
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<tr>
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<td>- Informed patient of treatment alternatives to bamlanivimab</td>
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<tr>
<td></td>
<td>- Inform patient that bamlanivimab is an unapproved drug used under the auspices of EUA</td>
</tr>
<tr>
<td>Adverse Effects (in ≤3% of pts)</td>
<td>Hypersensitivity reactions, nausea, diarrhea, dizziness, headache, pruritis, vomiting</td>
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</table>
Infusion Supplies

- 250 ml 0.9% NaCl
- IV Infusion Tubing
- 0.2/0.22 µm Filter
- 20 ml Syringe x2
- 18g Sterile Needle x2
- Alcohol Wipes
- IV Insertion Supplies

Infusion Supplies

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Infusion Setup

- Infusion with IV Pump
- 0.2/0.22 µm filter

Gravity Infusion
- Utilize flow limiting device or
- Calculate drip rate (see p. 18 of Lilly playbook)

Solution Stability
- 7 hours at room temperature, including infusion time
- 24 hours at 2-8°C
Key Resources:

Preparing and Planning to Administer mAbs

**OWS Playbook:**

**Lilly Playbook:**

**Fact Sheet for Healthcare Providers:**
https://www.fda.gov/media/143603/download

**Bamlanivimab Baseball Card (a.k.a. Pocket Resource Card):**
State-Based Allocation System for mAbs

1. Maximize use of existing infrastructure within USG, as well as manufacturer and distributor channels
   - Eli Lilly (manufacturer) and AmerisourceBergen (distributor)

2. Allocations must ensure both temporal and geographic equity

3. USG to allocate to state and territorial health departments based on:
   - Confirmed Hospitalizations (7-Day Incident)
   - Confirmed Cases (7-Day Incident)

4. States/Territories responsible for allocation to final points of care

www.phe.gov/bamlanivimab
Special Projects for Equitable and Efficient Distribution (SPEED)

- Launched week of 12/14/20
- **Goal:** Assist states with identifying and allocating mAbs to healthcare facilities that serve priority populations
  - Long-term care facilities
  - FQHCs
  - Dialysis centers
  - Correctional facilities
- **HHS intends to provide 100% of mAb requests (2 weeks’ anticipated need) to SPEED sites via direct federal allocations**
  - SPEED allocations can include partnerships between FQHCs and medical centers/infusion centers
  - FQHC SPEED program being coordinated with State Primary Care Associations

https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx
mAbs have been purchased by USG and currently are provided to healthcare facilities at no cost

CMS has set a fully-loaded Medicare reimbursement rate (national average of $309.60) to cover administration costs in all settings


Thank you!
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Health Center Experience

Rebecca Hanratty, MD
Director of General Internal Medicine, Denver Health
Associate Professor of Medicine, Division of General Internal Medicine
University of Colorado School of Medicine
Health Center Experience

Sarah Rall, PharmD
Marshfield Clinic Health System,
Director of Pharmacy Operations,
Purchasing & Supply
QUESTIONS
Resources


Casirivimab + Imdevimab
Baseball Cards

Bamlanivimab
Baseball Card
Thank You

James Macrae, Associate Administrator, HRSA
Bureau of Primary Health Care

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Ayanna Williams, Public Health Advisor
Toria Reaves, Epidemiologist
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Thank You & Contacts

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Operation Warp Speed – Therapeutics/ASPR
Allocation and Distribution Team - Detailed to HHS
COVID 19 Response

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