COVID-19 Monoclonal Antibodies

Thursday, February 11, 2021
Outline

Introduction (IDPH) - 5 minutes

Experiences from hospitals:
- CHI Health Missouri Valley (Kathy Stone) - 20 minutes
- University of Iowa Health Care (Lisa Mascardo) - 20 minutes

Question and Answer Panel - 15 minutes
- Kathy Stone, PharmD, RPh, BCSCP (CHI Health Missouri Valley)
- Lisa Mascardo, PharmD, FASHP (University of Iowa Health Care)
- Alexis Beyer, PharmD, MPH, CPH (U.S. Department of Health and Human Services)
- Ronald Rideman, PharmD (Regeneron)
Disclosures

Lisa Mascardo, Kathy Stone, and Alexis Beyer report no actual or potential conflicts of interest in relation to this continuing pharmacy education activity.

Ronald Rideman reports he is employed by Regeneron. CEImpact has taken appropriate action for conflict resolution, including external peer review.
Objectives

- Discuss how to implement an outpatient monoclonal antibody infusion service within an established healthcare organization.
- Describe how to access bamlanivimab and/or casirivimab/imdevimab and identify the appropriate contact(s) who can assist with the process.
- List strategies to increase provider awareness and patient acceptance of COVID-19 monoclonal antibody therapies.
- Identify anecdotal treatment trends and outcomes realized by sites that have already implemented infusion services for monoclonal antibodies.
- Discuss opportunities for treating long-term care residents with COVID-19 monoclonal antibodies.
Monoclonal Antibodies (mAbs)

- Bamlanivimab (Eli Lilly) and casirivimab/imdevimab (Regeneron) are available under EUA
- mAbs directly neutralize the COVID-19 virus and are intended to prevent progression of disease
- Likely most effective when given early in infection
- Product delivered via single administration (i.e., IV infusion)
  - 16 to 60-minute administration duration
  - 60-minute observation period
Monoclonal Antibody Patients

- Not authorized for use in patients:
  - 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.

- EUAs for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg):
  - with positive results of direct SARS-CoV-2 viral testing, and
  - who are at high risk of progressing to severe COVID-19 and/or hospitalization.

See EUAs for additional information, including high risk definitions.
### Allocation Processes for Existing Sites

<table>
<thead>
<tr>
<th>Hospitals and clinics</th>
<th>USG</th>
<th>IDPH</th>
<th>Distributor</th>
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</thead>
<tbody>
<tr>
<td>via State allocations every two weeks</td>
<td>Determines state allocations based on confirmed cases and hospitalizations</td>
<td>Determines allocations for sites based on usage and on-hand information</td>
<td>Ships directly to sites identified by IDPH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Long-term care facilities, FQHCs, dialysis centers, home infusion providers, and correctional facilities</th>
<th>USG/USG Partner Organizations</th>
<th>Distributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>via Special Projects for Equitable and Efficient Distribution (SPEED)</td>
<td>Receive requests directly or via IDPH and place orders to distributor</td>
<td>Ships directly to sites. SPEED currently only receive bamlanivimab.</td>
</tr>
</tbody>
</table>
New Sites

- Direct ordering option available for “new” sites, including infusion centers, dialysis care centers, physician’s offices, etc.
- Sites required to:
  - Provide AmerisourceBergen with board of pharmacy license or physician letter of authorization
  - Attest to their designated class of trade and that they will administer authorized product according to the EUA
  - Provide utilization data via Teletracking or NHSN
- To submit a direct order:
  [https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8](https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8)
Monoclonal Antibody Locator Tools

HHS Locator

National Infusion Center Association Locator
Monoclonal Antibodies and Long-Term Care

Administering monoclonal antibodies to long-term care patients:
- At a hospital
- At long-term care facility by hospital staff
- At long-term care facility by long-term care facility staff

For more information, see the recording for the long-term care webinar from January 25, 2021:
- Webinar
- Slides

Lilly's neutralizing antibody bamlanivimab (LY-CoV555) prevented COVID-19 at nursing homes in the BLAZE-2 trial, reducing risk by up to 80 percent for residents

January 21, 2021

INDIANAPOLIS, Jan. 21, 2021 /PRNewswire/ -- Bamlanivimab (LY-CoV555) significantly reduced the risk of contracting symptomatic COVID-19 among residents and staff of long-term care facilities, Eli Lilly and Company (NYSE: LLY) announced. The Phase 3 BLAZE-2 COVID-19 prevention trial — conducted in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the COVID-19 Prevention Network (CoVPN) — enrolled residents and staff at skilled nursing and assisted living facilities, commonly referred to as nursing homes, across the U.S.

The 965 participants who tested negative for the SARS-CoV-2 virus at baseline (299 residents and 666 staff) were included in the analysis of primary and key secondary endpoints for assessing prevention, while the 132 participants (41 residents and 91 staff) who tested positive for the virus at baseline were included in exploratory analyses for assessing treatment, adding to the growing body of evidence for treatment with bamlanivimab. All participants were randomized to receive either 4,200 mg of bamlanivimab or placebo.

After all participants reached 8 weeks of follow-up, there was a significantly lower frequency of symptomatic COVID-19 (the primary endpoint) in the bamlanivimab treatment arm versus placebo (odds ratio 0.43, p=0.00021). Results for all key secondary endpoints also reached statistical significance in both the overall and resident populations.

For the pre-specified subgroup of nursing home residents, there was also a significantly lower frequency of symptomatic COVID-19 in those treated with bamlanivimab versus placebo in this important population (odds ratio 0.20; p=0.00026). These results suggest that residents randomized to bamlanivimab have up to an 80 percent lower risk of contracting COVID-19 versus residents in the same facility randomized to placebo.

Results from exploratory analyses of viral load in the treatment group were consistent with previously disclosed data from BLAZE-1 evaluating bamlanivimab as an outpatient treatment for recently diagnosed COVID-19.
COVID-19 Monoclonal Antibodies

CHI Health Missouri Valley

Kathy Stone, PharmD, RPh, BCSCP

February 11, 2021
• Critical Access Hospital located in Harrison County in Southwest Iowa
• Pharmacy Services provided:
  • Drug regimen reviews and medication reconciliation
  • Renal dosing
  • Anticoagulation monitoring
  • Ambulatory Infusion Center, which includes Oncology
  • Drug information for the hospital and rural clinics
  • Medical Surgical, Outpatient Surgery, and Emergency Services
  • Therapeutic Medication Decision Support
Monoclonal Antibody Planning

• Multi-discipline approach:
  • Pharmacy
  • Nursing – Surgery, Quality, Infusion
  • Registration
  • Provider service line for Primary Care and Emergency Services

• IT Services
  • “Covid” infusion space separate from “well” infusion space with separate entrance from well patients
  • IT Build
  • Pharmacy – drug build with universal ordering capabilities in Electronic Medical Record (EMR) and infusion pumps
  • Registration – mAb “chair” additions
  • Updates as the Emergency Use Authorization (EUA) total volume changed
• Available through Iowa Department of Public Health (IDPH) weekly or biweekly allocations.
• Provided at no cost to the facility at this time, however, this means no patient charge for the drug. Only charge is for the administration fee.
• In January, direct ordering became available for additional doses.
• Refrigerated single-dose vials require significant space.
• Resource allocation while simultaneously rolling out Covid vaccine to Tier 1A with the same staff.
Provider Education

• Created a presentation and spent 1+ hours going over the process with our MedStaff.
  • Highlights:
    • Symptom onset documentation – must be given within 10 days of SYMPTOMS.
    • Date of positive test documentation if not within our system.
    • Providing Emergency Use Authorization info to the patient/caregiver and documenting the education and CONSENT.
    • Provider decision to offer at testing visit pending positive or when resulted.
    • Once positive and patient consents, contact scheduling/MAC office for them to contact the patient with an appointment time.
    • Place Referral to Ambulatory Infusion for bamlanivimab. At our site, pharmacy then placed the order set on the infusion encounter.
Bamlanivimab Infusions

• The majority given in the infusion center with a 3-hour encounter planned
  • 30 minutes for vitals, IV start, and medication preparation
  • 1 hour for infusion
  • 1 hour for monitoring
  • 30 minutes built in for any delays
• Few given in ED at our location, but some locations do give in ED if nursing and beds available
• Average weekly infusions: 12
• Nursing contacts ED provider to evaluate patients with O2 below 92% or out of range vitals prior to giving the infusion in the case that the patient condition may have deteriorated to needing hospitalization.
Challenges

• Administration understanding of the process at some locations
• Weekend/after-hours nursing and pharmacy availability
• Complexity of original EUA preparation instructions
  • Vial must sit for 20 minutes prior to preparation to come to room temp
  • Withdraw 70ml from 250ml bag - largest available syringe is 50ml
  • Add 20ml of medication for total volume of 200ml
• 1 FT pharmacist and 1 PT pharmacist
  • We did not want to further burden nursing by having them have to prepare the infusion also
  • Maintain work/life balance with 24/7 calls
Outcome Trends

- As of January 25, 2021, CHI Health Missouri Valley has given 98 bamlanivimab infusions. Positive case count for the county from November 19, 2020 through January 25, 2021 = 733. ~13% of positive cases during that time received the monoclonal antibody.
- 1 reaction – hive on face and systemic itching. The infusion was stopped.
- 6 have been admitted – 2 of those were within 72 hours of symptoms (1 of the 2 unrelated to Covid) – 4 were ~1 week from symptom onset.
- 2 have passed away (to my knowledge).
Long Term Care Patients

• With our nursing home outbreak, after bamlanivimab was available, we coordinated with the facility to schedule residents as they tested positive.
• The facility brought patients to our hospital for the infusions in groups.
• The facility relied on CHI Health Missouri Valley for expertise and experience for infusions and care for these patients.
Takeaways & Future Planning

- Multidisciplinary Support (nursing, provider, administration, pharmacy)
- Infection control and planning
- Patient scheduling vs given in ED

Future planning:
- With the leveling off of case counts anticipated with vaccinations, we are planning to continue to offer on an as needed basis. Nursing leadership continues to assign a nurse each day to be available.
- Weekend doses for those who are able to travel may be offered a sister location that has 24/7 pharmacy staffing with nursing staff already allocated.
- Possibly more infusions in the ED vs dedicated staff/unit due to less complex compounding.
- Clinical research review of impact of mAb therapy versus those who did not receive.
COVID-19 Monoclonal Antibodies – UIHC Experience

Lisa Mascardo, PharmD, FASHP
Director, Ambulatory Pharmacy Services, UIHC
February 11, 2021
University of Iowa Health Care

Academic medical center serving patients from all 99 counties.

- 845-bed Hospital
- 56,000 Emergency Department visits
- 200+ Outpatient Clinics accommodate more than 1 million clinic visits annually
Space Evaluation

• 4 potential locations
• Considerations:
  – Air handling
  – Transport of patients (distance, amount of contact with others)
  – Staffing (nursing, provider oversight)
  – Emergency response
  – Patient drop-off/parking
  – Drug prep/delivery/storage
  – EHR build
  – Power/data/infrastructure
  – Patient scheduling
  – Capacity/number of patients who could be infused daily
Patient Evaluation for Therapy

• EHR report built that identified COVID-19+ patients who met EUA criteria

• Leveraged workflows built by Influenza-Like-Illness (ILI) and Home Treatment Team (HTT) groups to identify eligible patients

• Expert panel evaluated literature and approved process
  – Limited to patients 18 and older
  – Available to pregnant patients after consult with OB

• Originally concerned that Demand >> Supply, so added additional qualifying criteria

• Pharmacists called qualifying patients to offer Ab therapy
COVID Risk Score Criteria and Stratification

ADULT (18+) COVID RISK SCORE CRITERIA AND STRATIFICATION

Medical History

- Immunosuppression (2 points)
- Currently receiving chemotherapy, history of bone marrow or solid-organ transplant, HIV
- Active cancer/malignancy (1 point)
- Cognitive Impairment or Developmental Disability (1 point)
- Age (2 points possible)
  - <25 (-1 point)
  - 25-55 (0 points)
  - 55-69 (1 point)
  - >70 (2 points)
- Congestive heart failure (1 point)
- Coronary artery disease (1 point)
- Hypertension (1 point)
- Nursing home resident (1 point)
- Chronic kidney disease (CKD) (2 points)
- Cirrhosis (1 point)
- Pregnancy (2 points)
- Chronic pulmonary disease (2 points possible)
  - Asthma (1 point)
  - Chronic obstructive pulmonary disease, interstitial lung disease, cystic fibrosis, other chronic pulmonary diseases (2 points)
- Diabetes (1 point)
- Active tobacco use disorder (1 point)
- Congenital hematologic disorders (2 points possible)
  - Sickle cell disease (2 points)
  - Thalassemia and others (1 point)
- Cerebrovascular disease (1 point)
- Obesity with a BMI (body mass index) >35 (2 points possible)
  - BMI 30-39.9 (1 point)
  - BMI 40+ (2 points)
- Race/Ethnicity = Hispanic or Latino, Black or African American, American Indian or Alaskan Native, and Native Hawaiian and other Pacific Islander people (1 point)

Score 0-2: ILI Respiratory Teledermcare Team
Score 3+: Home Treatment Team (HTT)
Patient Conversations

• Early experience – most patients wanted to discuss with family before calling back to be scheduled

• Reasons for hesitation:
  – Mild symptoms
  – Young (18-40 yrs/old)
  – Few antibody qualifiers (often only BMI > 35)
  – Concerns about adverse effects
  – Cost
  – Not wanting an “experimental” drug
Increasing Awareness and Uptake

- All patients with positive COVID-19 tests who meet criteria are offered therapy
- Information created for employee website and sent directly to providers from CMO
- Article in local newspaper
- As numbers of positive cases declined, the minimum COVID-19 risk score was lowered to increase uptake
Infusion Data to Date (2/2/21)

- Patients infused: 368
- Average patient age: 57.7yrs
- Average # days from symptom onset to infusion: 4.77
- # admissions post infusion: 13 (not necessarily COVID related)
- Infusion stopped for 1 patient for possible reaction (later deemed unrelated to infusion)
- Average # days from infusion to admission: 6.23
- Infusions by COVID risk score (graph on next slide)
Infusions by COVID risk score
Administrations per Week

Doses Administered

Week

Doses
Challenges and Responses

• Differences in preparation requirements of products (requested more bamlanivimab)

• Availability of transportation for patients
• Ability to predict number of infusions (and staffing needs)
• Outside referrals/test results (including LTC patients) – route through ILI clinic/telemedicine process for referral for infusion
Planning and Management Teams

Providers:
- Dr. Rami Boutros, Executive Medical Director, Offsite Ambulatory Programs
- Dr. Andy Bryant, Director – COVID-19 Home Treatment Team
- Dr. Katie Imborek, Medical Director – Influenza Like Illness (ILI) Telemedicine and Respiratory Clinic
- Dr. Dilek Ince, Clinical Associate Professor of Internal Medicine – Infectious Diseases

Iowa River Landing Management Team:
- Dr. Rami Boutros, Executive Medical Director, Offsite Ambulatory Programs
- Heather Day, Nurse Manager, Iowa River Landing
- Michelle Turner, Associate Director, Nursing Services, Iowa River Landing
- Steve Woodward, Director, Clinical Services, Iowa River Landing

Pharmacy Team:
- Mike Brownlee, Chief Pharmacy Officer
- Angela Hunter, IRL Pharmacy Practice Specialist
- Lisa Mascardo, Director, Ambulatory Pharmacy
- Heidi Wood, Interim Ambulatory Clinical Pharmacy Manager

Health Care Information Systems Team:
- Nathanael Adam, Assistant Director, Administrative Applications, Health Care Information Systems
- Sarah Hacker, Lead Application Developer, Health Care Information Systems
- Keri Semrau, Associate Director, Ambulatory Care Services
Q & A Session
Kathy Stone, PharmD, RPh, BCSCP (CHI Health Missouri Valley)
Lisa Mascado, PharmD, FASHP (University of Iowa Health Care)
Alexis Beyer, PharmD, MPH, CPH (U.S. Department of Health and Human Services)
Ronald Rideman, PharmD (Regeneron)
Helpful Links

General Resources
- Operation Warp Speed Monoclonal Antibody Playbook
- National Infusion Center Association COVID-19 Antibody Treatment Resource Center
- IDPH Monoclonal Antibodies
- HHS ASPR Outpatient Therapeutics Mini-Series

Bamlanivimab (Eli Lilly)
- Bamlanivimab Letter of Authorization (EUA)
- Bamlanivimab Provider Fact Sheet
- FDA Frequently Asked Questions on the EUA for Bamlanivimab
- Lilly Bamlanivimab Information
- Lilly Bamlanivimab Antibody Playbook
- Bamlanivimab Pocket Resource Card
- Bamlanivimab Overview, Allocation, and Distribution

Casirivimab/Imdevimab (Regeneron)
- Casirivimab/imdevimab Letter of Authorization (EUA)
- Casirivimab/imdevimab Provider Fact Sheet
- FDA Frequently Asked Questions on the EUA for Casirivimab + Imdevimab
- Important Prescribing Information: A Letter from Regeneron to Healthcare Providers on Preventing Medication Errors
- Regeneron Casirivimab/imdevimab Information
- Regeneron Casirivimab/imdevimab Guidebook
- Casirivimab/imdevimab Overview, Allocation and Distribution

Billing and Coding
- COVID-19 Frequently Asked Questions on Medicare Fee-for-Service Billing
- CMS Monoclonal Antibody COVID-19 Infusion Insurance Coverage of Monoclonal Antibody Treatment
- Drug Supply Chain Security Act (DSCSA)
Continuing Education

Continuing Pharmacy Education (CPE) for “COVID-19 Monoclonal Antibodies” has been accredited by CEimpact, an ACPE-accredited provider of continuing pharmacy education.

Although you attended the live session, you MUST complete the online requirements to obtain your CPE Credit. The deadline for obtaining your CPE credit is March 11, 2021.

Login at CEimpact.com. Complete the Course Exam and Evaluation, then follow the instructions to access your completion certificate or your CPE Statement of Credit on CPE Monitor.

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<th>Practice Role</th>
<th>Access Code</th>
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<tr>
<td>Emergency and Trauma Services</td>
<td>wPdNgv</td>
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<tr>
<td>Nurses</td>
<td>FEcSKc</td>
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For questions, please contact Cassie Kennedy at cassie.kennedy@idph.iowa.gov or (515) 330-5755.