COVID-19 Impact: Monoclonal Antibody Use in PALTC

This meeting will be recorded and will be available at www.fmda.org/journalclub.php
FMDA Journal Club

February 24, 2021
Corinne Bishop, RN, CRRN, CRNI; Christopher Lemelle, MD, MBA – Special Guests
Diane Sanders-Cepeda, DO, CMD – Host
• COVID-19 State of the State
• Monoclonal Antibody Use in PALTC
• Open Discussion
Florida's COVID-19 Data and Surveillance Dashboard

Florida Department of Health, Division of Disease Control and Health Protection

Total Cases
1,878,533

Cumulative Data for Florida Residents:

Positive Residents
1,844,228

Resident Hospitalizations
78,212

Florida Resident Deaths
30,213

Non-Resident Deaths
536

Data updated Daily
Comparison of counties is not possible because case data are not adjusted by population.

Click here to access and download data

Recent Data for Florida Residents (Last 30 Days):

New Cases of Residents by Day

Resident Deaths by Date of Death

The Deaths by Day chart shows the total number of Florida residents with confirmed COVID-19 that died on each calendar day (12:00 AM - 11:59 PM). Death data often has significant delays in reporting, so data within the past two weeks will be updated.
Monoclonal Antibody Use in PALTC

Corinne Bishop, RN, CRRN, CRNI
Infusion Nurse Specialist, Omnicare Pharmacy Services

Christopher Lemelle, MD, MBA
Strategy and Clinical Innovation, CVS/Omnicare
Monoclonal Antibody Update
Today’s Objectives

I. Review current perspective and current research related to the use of Monoclonal antibodies

II. Discuss operational considerations when starting this treatment program in PALTC facilities

III. Describe the challenges and opportunities seen statewide and nationally with the delivery of this treatment in PALTC facilities

IV. Open Discussion
What are MONOCLONAL ANTIBODIES?

Monoclonal antibodies (mAbs) are antibodies developed in a laboratory to help our bodies fight infection.

Nearly 100 mAbs are FDA approved to treat health conditions including cancers and autoimmune diseases.

mAbs are also being studied for the treatment and prevention of COVID-19.
Current COVID monoclonal antibody research is sparsely focused and largely focuses on Bamlanivimab +/- Etesevimab.

The Blaze studies are a progressive series of studies with the latest, Blaze-4, focused on comparing efficacy of mono, combination, or placebo in patients diagnosed with mild to moderate SARS-CoV-2.

**Blaze 4 Summary**

**Design:** Randomized, placebo-controlled phase 2/3 trial at 49 US centers and 577 patients

**Interventions:** Bamlanivimab, Bamlanivimab + Etesevimab, or placebo IV infusions

**Outcomes Measured:**
- Main- Viral load change at day 11
- Secondary- Symptoms, need for hospital assessment, or death

**Conclusions:**
- Main- Statistically significant reduction in viral load for combination (not for solo and placebo)
- Secondary- Hospital readmission for placebo 5.8% vs average 1.5% in treated groups
  - Only 9 mild reactions and no deaths.

Source: [https://jamanetwork.com/journals/jama/fullarticle/2775647](https://jamanetwork.com/journals/jama/fullarticle/2775647)
Operational Considerations
Monoclonal Antibody Allocation
Federal SPEED Program through ASCP

SPEED – Special Projects for Equitable and Efficient Distribution for the allocation of monoclonal antibodies

Direct allocation to long-term care pharmacies

Partners: American Society of Consultant Pharmacists and AMDA-The Society for Post-Acute and Long-Term Care Medicine

- Website: https://www.ascp.com/page/mab
Bamlanivimab and Casirivimab/Imdevimab—Emergency Use Authorization (EUA)

• Patients categorizing as high risk must have at least one of the following criteria:
  – Body mass index (BMI) ≥ 35
  – Chronic kidney disease
  – Diabetes
  – Immunosuppressive disease
  – 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
Emergency Use Authorization (EUA)- Patient Criteria

• Are 12 – 17 years of age **AND** have
  – BMI ≥ 85th percentile for their age and gender based on CDC growth charts
  – Sickle cell disease
  – Congenital or acquired heart disease
  – Neurodevelopmental disorders, for example, cerebral palsy
  – A medical-related technological dependence, for example, 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
Monoclonal Antibody – Restrictions

- Monoclonal antibodies are **not** authorized for use in patients:
  - Who are hospitalized due to COVID-19
  - Who require oxygen therapy due to COVID-19
  - Oxygen dependent patients who require an increase in oxygen flow rate due to COVID-19 complications

Monoclonal Antibody and COVID-19 Vaccines

- If the patient has received monoclonal antibodies, they should not receive the COVID-19 vaccine for 90 days
- If the patient has received the COVID-19 vaccine(s) and subsequently tests positive for COVID-19, they can receive monoclonal antibodies

**Bamlanivimab (Lilly)**

**Dose** - 700 mg given as a one-time infusion

* EUA change: 100 ml/over 30 minutes

**Casirivimab/Imdevimab (Regeneron)**

**Dose** - 1200 mg of Casirivimab with 1200mg of Imdevimab combined in one infusion bag given as a one time infusion over a minimum of 60 minutes.

**Monoclonal Antibodies should be administered** as soon as possible after a positive COVID-19 test, and within 10 days of symptom onset
Bamlanivimab and Etesevimab Combination

Emergency Use Authorization (EUA)

The authorized dosage is 700 mg bamlanivimab and 1,400 mg of etesevimab administered together as a single intravenous (IV) infusion as soon as possible after positive viral test for SARS-CoV-2 and within ten days of symptom onset.

Per the FDA: *Lilly and authorized distributor(s) will ensure that the authorized bamlanivimab and etesevimab are distributed, as directed by the U.S. government*
Bamlanivimab -Updated EUA

• Updated Patient Friendly Guide

• Updated HCP EUA - Mixing

100 mL NS to infuse over 30 minutes.

Rationale:

1. Concerns with a rapid infusion using the 16 minutes, as the nursing staff is more accustomed to infusing at a minimum of 30 minutes.

2. Using 30 minutes would require VS at the 1/2 point to identify potential infusion reactions before the entire dose is infused.

3. If mixed in 50 ml and they fail to infuse the chaser bag the patient would lose 50% of the dose.
Clinical and Operational Considerations

- Anaphylaxis Treatment
- Nursing Time- IV Access and Monitoring
- Exclusion Criteria
- Vaccination Timing
- Order Toolkit

This program has specific requirements which are largely constrained by facility labor capacity and capability, as well as provider hesitancy.
Monoclonal Antibody – IV Access, Anaphylaxis and Infusion-Related Reactions

• Ensure peripheral IV before ordering

• There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of monoclonal antibodies

• Anaphylaxis and infusion-related reaction orders must be obtained prior to infusion

• Anaphylaxis kit/medications must be readily available and will be supplied by the pharmacy

• If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care per prescriber’s orders
Monoclonal Antibody – Monitoring

• Monitor patient during administration and for at least one hour post infusion. Signs and symptoms of infusion-related reactions may include:

  – Fever
  – Chills
  – Nausea
  – Headache
  – Bronchospasm
  – Hypotension/Hypertension
  – Angioedema
  – Throat irritation
  – Rash including urticarial
  – Pruritus
  – Myalgia
  – Dizziness
  – Diaphoresis
  – Difficulty breathing
  – Reduced oxygen saturation
  – Fatigue/weakness
  – Arrhythmia (e.g., atrial fib, sinus tachycardia, bradycardia)
  – Chest pain or discomfort
  – Altered mental status

• Monitor vital signs:
  – Prior to initiating infusion
  – Every 15 minutes during infusion
  – Every 15 minutes for one hour post infusion

• Resume COVID monitoring per facility protocol
Monoclonal Antibody Tool Kit

- Monoclonal Administration Algorithm
- Intake Prescriber Order Form
- Nursing Care Plan
- Sample Consent Form
- Administration Flowsheet
- Facility Preparation Checklist
- Administration Procedure
- Skills Competency Checklist
- EUA Patient Fact Sheet
- EUA HCP Fact Sheet

***Operation WARP SPEED***
Program Options
Three possible models

Infusion On-Site

Pro
• Complete control
• Infusion reimbursed at acute care rate ($358)

Con
• 2 hours of nursing time
• Need infusion capable staff

Transport to off-site infusion

Pro
• Relieves labor/capability constraints

Con
• Complex logistics
• Patient transport safety
• Loss of revenue/reimbursement

Infusion On-Site with external partner

Pro
• End to end on site service

Con
• Variable cost (a few federal/state programs are free)
• Reliant on third party scheduling
Best Practices

Education via live webexes for facility staff

Pre-educating Patients and Families on admission

Contract Infusion Nurse support (limited markets)

Vascular Access Support

Multiple infusions - grouping patients reduces labor constraint

- Create an Infusion Room on COVID unit
- No more than 3 patients at a time infused per RN
- Provide CNA to complete q 15-minute VS
- Identify 1 or 2 RNs in close geographic proximity to become mAb team
Questions?
Open Discussion
This meeting has been recorded and will be available at www.fmda.org/journalclub.php