

Long-Term Care: Providing Monoclonal Antibody Therapy Safely

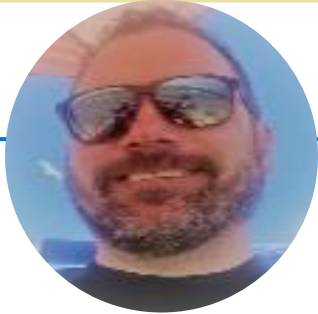
June 16, 2021



Polling Question



Meet your Speakers:



**Rick Mancini, RPH,
Pharmacy Director,
PharMerica**

Rick has 27 years of experience in long-term care pharmacy, including consulting pharmacy and management positions.



**Linda Walker, BSN, RN,
Chief Nursing Officer,
Trauma Coordinator**

Linda is currently working at Three Rivers Health in Basin, Wyoming, as the chief nursing officer and trauma coordinator.



**Jesse Kinsey, BS, RN,
Pharmacy Nurse
Consultant**

Jesse serves as a long-term care pharmacy nurse consultant for customers throughout Montana and Wyoming for PharMerica.

Monoclonal Antibodies (mAbs)

- There are currently four mAbs given FDA authorization for emergency use in early stage, high risk COVID-19 patients
 - bamlanivimab and etesevimab (Eli Lilly)
 - casirivimab and imdevimab (Regeneron)
- mAbs are laboratory produced antibodies that are specific for a designated antigen
 - Monoclonal Antibodies can aid in the bodies immune response to fight the COVID-19 virus
- Authorized use:
 - The treatment of mild to moderate coronavirus disease 2019 (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 for progressing to severe COVID-19 and/or hospitalization

Limitation of Authorized Use

- Not to be used in patients who
- Are hospitalized due to COVID-19, OR
 - Require oxygen therapy due to COVID-19, OR
 - 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.

Source: mAbs Evolving Evidence (DUKE)

Monoclonal Antibodies (mAbs)

The FDA's definition of high-risk is based on age and meeting 1 of the following defined criteria:

Ages 18 and older	Ages 12-17
<ul style="list-style-type: none">• 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<ul style="list-style-type: none">○ cardiovascular disease, OR○ hypertension, OR○ chronic obstructive pulmonary disease/other chronic respiratory disease.	<ul style="list-style-type: none">• Are 12 – 17 years of age AND have<ul style="list-style-type: none">○ 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<ul style="list-style-type: none">▪ asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Monoclonal Antibodies (mAbs) continued

March 24th Update on Variants

- Avoid the use of bamlanivimab monotherapy and to instead consider using the alternative monoclonal antibody therapies (bamlanivimab/etesevimab, casirivimab/imdevimab), which are expected to maintain activity against circulating COVID-19 variants.
- This will lower the risk of treatment failure if patients become infected with a SARS-CoV-2 viral variant resistant to bamlanivimab alone.

Table 3: Pseudovirus Neutralization Data for SARS-CoV-2 Variant Substitutions with Bamlanivimab Alone

Lineage with Spike Protein Substitution	Key Substitutions Tested ^a	Fold Reduction in Susceptibility
B.1.1.7 (UK origin)	N501Y	no change ^b
B.1.351 (South Africa origin)	E484K	>2,360 ^c
P.1 (Brazil origin)	E484K	>2,360 ^c
B.1.427/B.1.429 (California origin)	L452R	>1,020 ^c
B.1.526 (New York origin) ^d	E484K	>2,360 ^c

**BAM
monotherapy
no longer
effective**

Source: HHS March 24
Advisory

Monoclonal Antibodies (mAbs)

Emerging safety and efficacy data

- BLAZE-1 demonstrated that bamlanivimab and etesevimab in combination reduced the need for hospitalization or death by approximately 70%
- BLAZE-3, studying bamlanivimab for post-exposure prophylaxis for nursing home residents and workers, has 2 significant topline findings;
 - A significant reduction of symptomatic COVID-19 infection 8 weeks post mAb treatment
 - An 80% reduction in risk of contracting COVID-19 vs placebo
- Per a Regeneron interim analysis: casirivimab and imdevimab given prophylactically after exposure to a COVID-19 patient in the household demonstrated:
 - A complete reduction in symptomatic infections (8 cases in placebo and 0 in treatment)
 - A 50% reduction in asymptomatic infections (23 cases in placebo and 8 in treatment)
 - Viral load was cut by 100-fold

This data helps to support use of mAbs in early stage, high-risk patients before serious symptoms occur

Monoclonal Antibodies (mAbs)

- **Number Needed to Treat (NNT)**

- Bamlanivimab
 - NNT = 10 to 25 residents
 - 4-10% absolute risk reduction

- **For some context**

- Warfarin for Atrial Fibrillation
 - In patients without a prior history of stroke, the NNT to prevent one case of stroke with warfarin is **25**
- Statins
 - In patients without known heart disease receiving daily statin therapy over 5 years, the NNT for heart attack prevention is **104**. Additionally, the NNT for stroke prevention is **154**
- Antihypertensives for Cardiovascular Disease
 - In patients receiving antihypertensive therapy for 5 years, the NNT to prevent 1 death is **125**
 - The NNT to prevent heart attack is **100**, and to prevent stroke, **67**

Monoclonal Antibodies (mAbs)

- **Challenges of administration in Long-Term Care Facilities (LTCFs)**
 - Vascular Access
 - Timing
 - Within 10 days of diagnosis
 - Short beyond-use-dating
 - 4-7 hours window at room temperature once compounded
 - 24-36 hours stored at refrigerated temperatures once compounded
 - Need to account for infusion time as well
 - Infusion time
 - bamlanivimab and etesevimab (Eli Lilly)
 - Combination therapy – Options for 21 to 70 minute infusions depending on volume
 - casirivimab and imdevimab (Regeneron)
 - 1 hour infusion time
 - Post Administration Monitoring – 1 hour



Bonnie Bluejacket Memorial Nursing Home

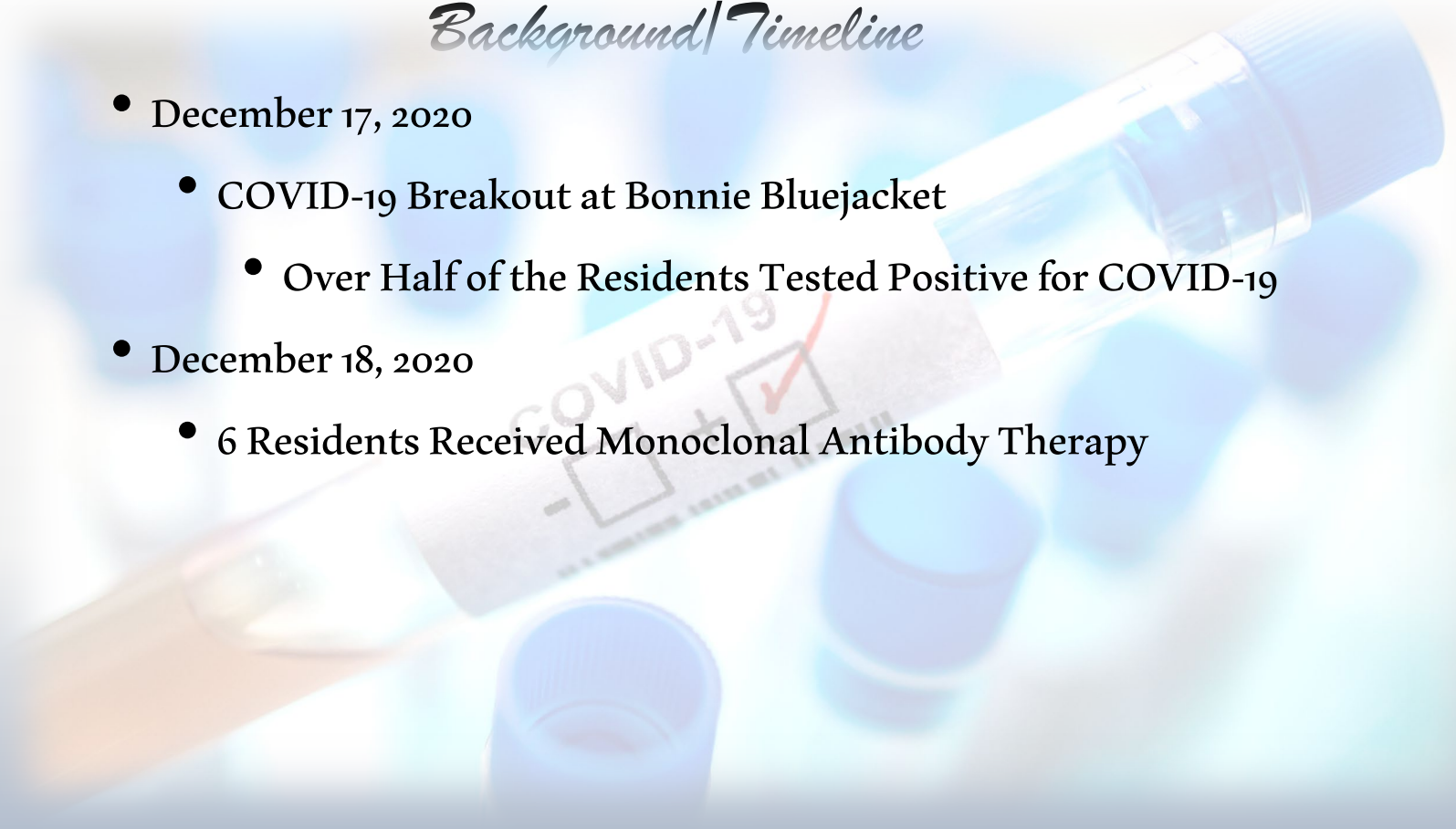
- Bonnie Bluejacket Memorial Nursing Home is located in beautiful Big Horn County in Basin, Wyoming.
- The facility has 37 beds for long-term care and offers skilled nursing care.
- The Care Center is affiliated with Three Rivers Health/South Horn County Hospital District and is on the same campus as the Hospital and Midway Clinic.





Background/Timeline

- December 17, 2020
 - COVID-19 Breakout at Bonnie Bluejacket
 - Over Half of the Residents Tested Positive for COVID-19
- December 18, 2020
 - 6 Residents Received Monoclonal Antibody Therapy

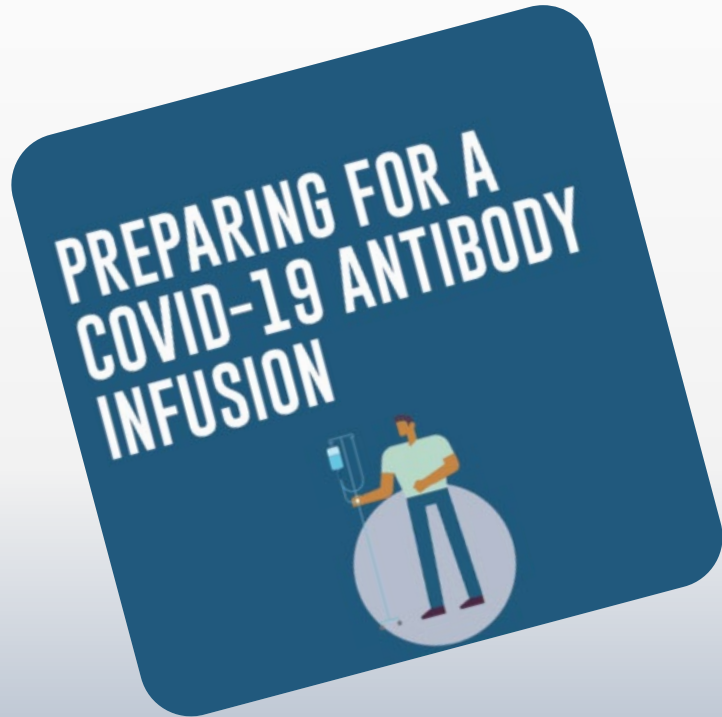


Polling Question





Adult Bamlanivimab Referral Pack/Resident Consents



Adult Monoclonal Antibody Referral Packet

- Engage Patients or DPOA in Shared Decision Making
- Explaining the Meaning of EUA Status
- Educate on Potential Risks and Benefits
- Discuss Alternative Treatment Options
- Provide Fact Sheet for Patients, Parents and Caregivers
- Obtain Informed Consent for Treatment



Checklists

Criteria Met Under EUA for Monoclonal Antibody Therapy Administration as Defined Below:

Patients must meet at least one of the following criteria:

- Body Mass Index ≥ 35**
- Chronic Kidney Disease**
- Have Immunosuppressive Disease, Specify _____**
- Currently Receiving Immunosuppressive Treatment, Specify _____**
- Are ≥ 65 years of Age**
- Are ≥ 55 years of Age AND have**
 - Cardiovascular Disease, or Chronic Obstructive Pulmonary Disease/Other Chronic Respiratory Disease**

Documentation of shared Decision Making Regarding EUA Status and Consent

The following have been discussed and understood by the patient or caregiver

- Monoclonal Antibody Therapy is an unapproved drug by the FDA that is authorized for use under Emergency Use Authorization**
- Alternatives to receiving authorized Monoclonal Antibody Therapy**
- Provided “Fact Sheet for Patients, Parents and Caregivers” and all questions answered to their satisfaction**
- Signed “Informed Consent to Treatment with EUA, Bamlanivimab for Mild to Moderate COVID-19”**



Vital Signs

- Vital Signs Including Pulse Oximetry upon initiation of Monoclonal Therapy infusion: Pre-infusion, every 15 min x1 hour; then every 30 min x2 after infusion has been completed**
- Notify Provider of Vital Signs**
Changes in vital signs (+/-10%) during and immediately following Monoclonal Therapy infusion, T >100.5
- Notify Provider and Stop Infusion**
Observe for infusion reaction which may include fever, chills, nausea, headache, bronchospasms, hypotension, angioedema, throat irritation, rash include urticaria, pruritis, myalgia, dizziness during and immediately following infusion

Standing Orders



Medication Standing Orders

Premedications

If ordered must be administered at least 30 min prior to starting Infusion

- Diphenhydramine 25mg, PO X1; Indication: Allergy Prophylaxis
- Diphenhydramine 50mg, PO X1; Indication: Allergy Prophylaxis
- Acetaminophen 650 mg, PO X1; Indication: Allergy Prophylaxis
- Ondansetron 4mg, ODT X1; Indication: Nausea Prophylaxis
- Ondansetron 4mg, IV Push x1: Nausea Prophylaxis

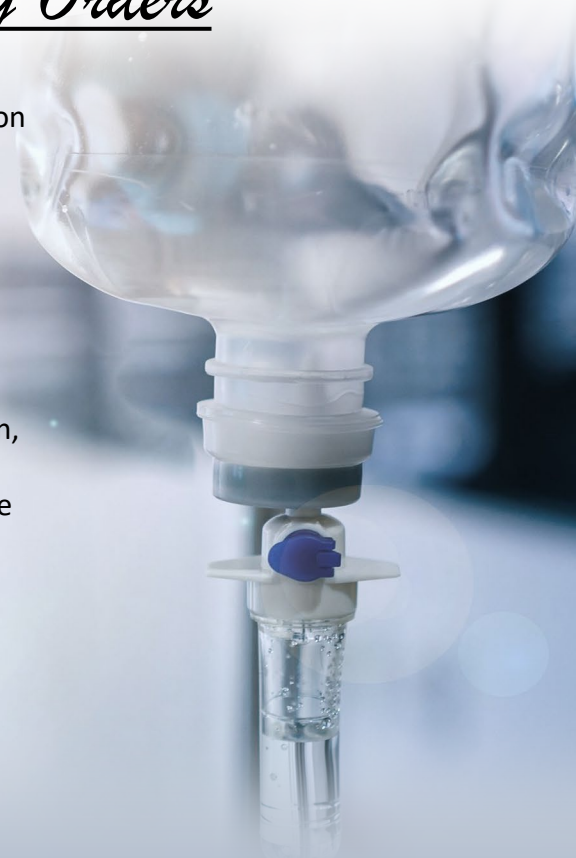
Emergency Allergic Reaction Medications

If patient develops any signs of hypersensitivity reaction, **STOP** infusion, contact provider

- Methylprednisolone (SOLU-Medrol) 40mg, IV Push, X1 PRN; Max Dose 125mg
- Diphenhydramine (Benadryl) 50mg, IV Push, X1
- Epinephrine 1mg/mL solution, 0.3mg IM, X1 PRN

Infusion

- Bamlanivimab 700mg/20mL, IV x1
Use 0.2-micron filter, infuse at 270mL/hr





Equipment

- Appropriate PPE
- IV Supplies
- IV Pump
- Vital Signs Monitor
- Emergency Kit
 - Contains Standard Anaphylaxis Therapy
 - Prepared by Pharmacist
- Comfortable Seating for Resident

Support Staff

- Registered Nurse
 - 3:1 Ratio
- CNA
 - Assist with VS Monitoring
- Social Worker
 - Consents
 - Phone Calls to Family Members





Barriers

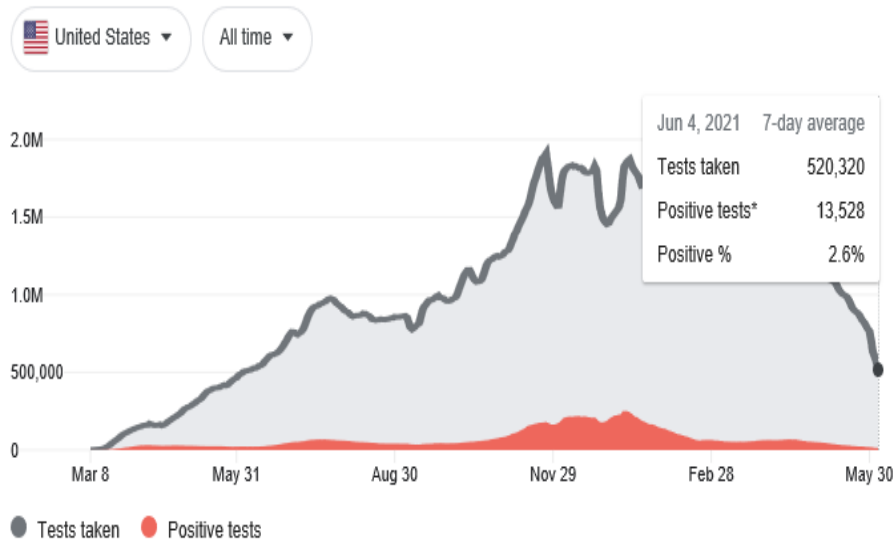
- **Supply of Monoclonal Antibody**
 - **Limited Due to State Allocation**
- **Specialized 0.2-micron filter**
- **Time and Resources**
 - **Total of 5 hours**
 - **Resident Education/Consents**
 - **Prep**
 - **IV Starts**
 - **Infusion Time**
 - **Post Infusion Monitoring**
 - **Availability of Staffing**
 - **Short Staffing Due To COVID + Employees**

Successes

- **6 Residents Received the Monoclonal Antibody**
- **All Infusions Were Completed Successfully**
- **None of These Residents Were Hospitalized Related to COVID-19**
- **Built Teamwork and Confidence in Nursing**

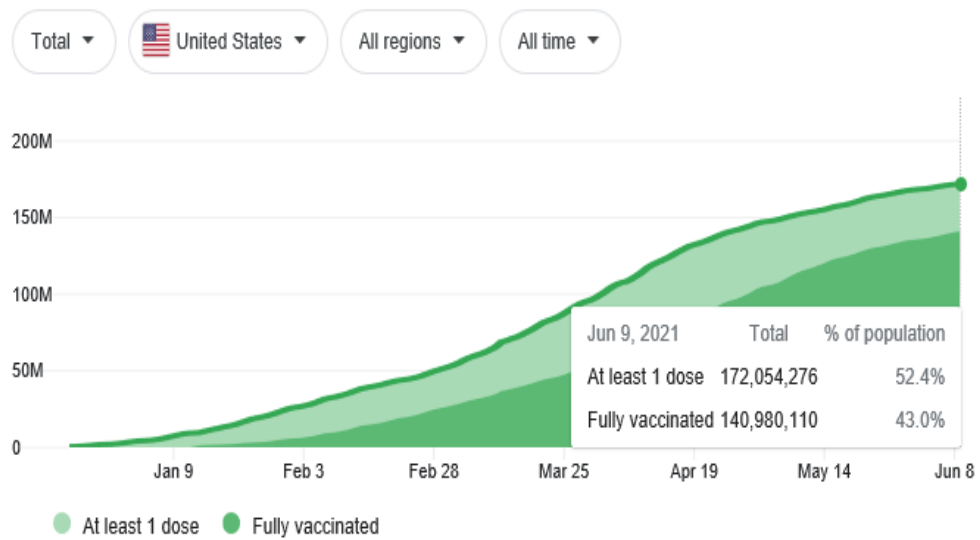
COVID-19 (+) cases versus Vaccination Rates

From [Our World in Data](#) · Last updated: 17 hours ago · Based on 7-day average



* Positive tests are estimated by multiplying tests taken by the positivity rate. Positive tests may not be equal to positive cases because of reporting differences and people taking multiple tests. · [About this data](#)

From [Our World in Data](#) · Last updated: 2 days ago



This data shows how many people have received at least 1 dose of a vaccine. People who are fully vaccinated may have received more than 1 dose. · [About this data](#)

Monoclonal Antibodies Are Not New

- Nearly 100 mAbs are FDA approved to treat health conditions including cancers and autoimmune diseases.
- In April, nearly a million doses of monoclonal antibody had been purchased by the government and made available across the country.
- SPEED (Special Projects and Equitable and Efficient Distribution)



Underused

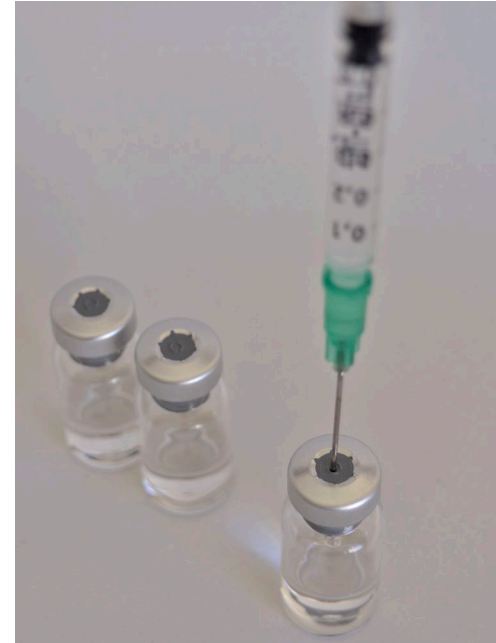
- Unfamiliar
- Narrow window
- Underestimated/unknown
- Hesitancy related to environment



Build Your Knowledge

Importance of understanding your partners and resources:

- IV nursing support services
- Infusion therapy education and competency
- Assessment confidence
- Order forms and templates
- Policy and procedure guidance



Polling Question



Q & A

Thank you for attending today's session!

For questions, please contact
Linda Walker linda.walker@trhealth.com or
Jill Hult jhult@mpqhf.org.

Polling Question

