



All Hands on Deck

Maximizing Resources to Support mAb
Administration in Utah's Long-Term Care Facilities

Michelle Hofmann MD, MPH, MHCDS, FAAP
Deputy Director, Executive Director's Office
Manager, Healthcare-Associated Infections and
Antibiotic Resistance Program

KEY POINTS



- A disproportionate share of COVID-19 deaths occur in Utahns residing in LTCFs
- A coordinated rapid response is essential in preventing disease and death from COVID-19 in Utah's LTCFs, including connecting LTCF residents to novel therapeutics
- Every partner plays a critical role in keeping Utah's LTCF residents safe

LONG-TERM CARE FACILITY RESPONSE



Rapid, coordinated outbreak response

- COVID-19 dedicated SNFs for outbreak containment
- On-call infection preventionists for assessment and response
- Onsite UHERT 'strike teams' for facility preparedness



Broad screening / outbreak testing

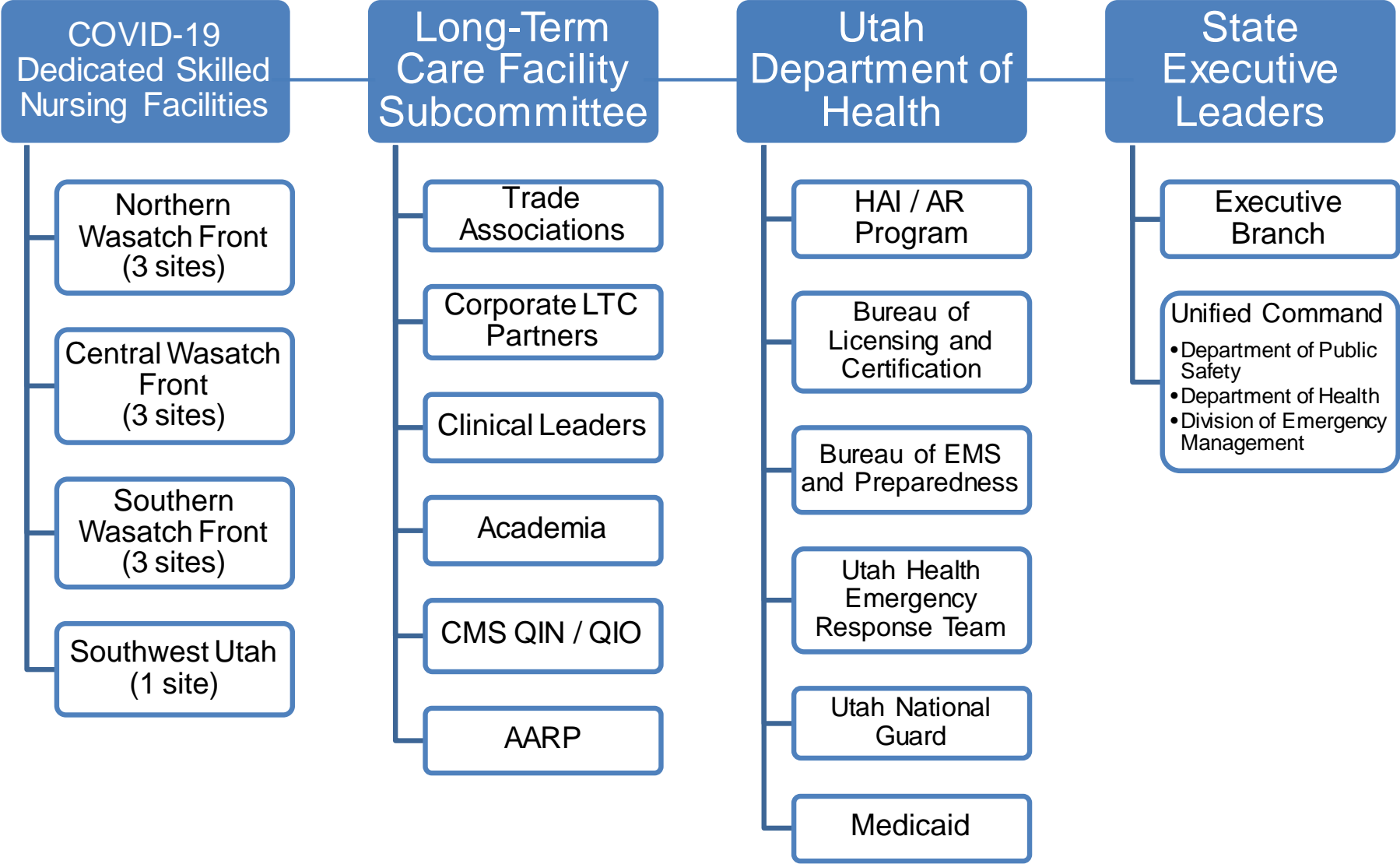
- UTNG mobile testing teams for weekly PCR testing during outbreaks
- Outbreak modeling to inform strategy
- Rapid ag tests for screening, symptomatic, exposure testing



Infection control / preparedness training

- LTCF-specific guidance on public website
- Train-the-trainer model
- Webinar series
- Infection prevention response plans
- Project ECHO
- Project Firstline

LEVERAGING PARTNERS



A CALL TO ACTION



Spencer J. Cox
Governor

EXECUTIVE ORDER
2021-02

- 7. Monoclonal antibodies.** The Utah Department of Health shall coordinate with local health departments to establish procedures to offer monoclonal antibodies to residents of long-term care facilities who have tested positive for COVID-19.

This Order is effective January 11, 2021, and shall remain in effect until modified, amended, rescinded, or superseded.



CLEAR ROLES AND RESPONSIBILITIES

Monoclonal Antibody Therapy in Long Term Care Facilities HAI, MIST, LTCF & MIF Responsibilities

PURPOSE: This document identifies the roles and responsibilities of the Healthcare Associated Infections (HAI) Team, Mobile Infusion Strike Team (MIST), Referring Long Term Care Facilities (LTCF), and designated MIST Infusion Facilities (MIF) requesting activation and deployment of the MIST. Please note this will be an evolving initiative and this document should be consulted regularly for changes.

RESPONSIBLE PARTY	ACTION REQUIRED
Pre-Activation Phase	
LTCF	Provide Flyer and Frequently Asked Questions documents to residents and staff to encourage identification of eligible recipients before contracting COVID-19. Support information sharing and communication with residents and/or surrogates, and medical directors / PCPs. Notify residents that receipt of MaB currently most likely requires transfer to a designated MIF or administration in an ambulatory site currently providing MaB: https://coronavirus.utah.gov/nowelltherapeutics/ .
LTCF	Provide staff with information on how and where to seek MaB treatment should they contract COVID-19: https://coronavirus.utah.gov/nowelltherapeutics/ .
Activation Phase	
HAI	Engage with facilities on a regular basis via facility-specific Infection Preventionist to identify outbreaks and potential need for MIST. Encourage facilities to initiate transfer of COVID-19 positive residents to a MIF as soon as resident is identified. There may be exceptions to the recommendation for transfer for outbreaks of sufficient size to mobilize the MIST, based on available resources.
LTCF	For questions about newly identified cases of COVID-19 that might benefit from MaB, contact facility-specific Infection Preventionist or email, HAI@utah.gov .
HAI	Request activation of the MIST through facility-specific Infection Preventionist or email, HAI@utah.gov .
HAI	Send MaB Facility Documentation Packet (includes Responsibilities, Flyer, FAQ, Screening Tool, Standardized Order Set, Consent Form, After Care Instructions) to MIF and notify MIST to schedule date and time for MIST arrival and infusion treatment.
Candidate Identification and Facility Preparation Phase	
MIF (in consultation with Referring Physician)	Pre-screen residents who may be eligible for infusion treatment using the Screening Tool in the Documentation Packet (including calculation of a Risk Score). Provide HAI a list of all pre-identified eligible residents to HAI@utah.gov within 24 hours of scheduled MIST arrival.
HAI	Provide list of eligible residents to MIST.
MIF	Ensure completion of Patient Consent Forms for all participating residents.
MIF	Identify appropriate common area to host all eligible residents and MIST for 2.5+ hours. Equip with chairs/beds for those receiving infusions.

Mobile Infusion Strike Team (MIST)
PATIENT SCREENING & REFERRAL - to be completed by the Facility in Consultation with the Referring Physician

Today's Date: _____ Referring Physician Information: _____
 Referring Physician Name: _____
 Referring Physician Office: _____
 Referring Physician Phone: _____
 Referring Physician Email: _____

Patient Information: _____
 Patient Name: _____
 Patient Address: _____
 Patient Phone: _____
 Patient Email: _____

Check all symptoms that are present:
 Fever Cough Sore Throat Fatigue Headache Muscle Pain Loss of Taste/Smell Shortness of Breath Diarrhea or Nausea

Check all symptoms that are NOT present:
 Fever Cough Sore Throat Fatigue Headache Muscle Pain Loss of Taste/Smell Shortness of Breath Diarrhea or Nausea

INFORMED PATIENT CONSENT
Bambanibab / Casirivimab/Imevismab (Evanesco)

I hereby certify that I have read and understood the risks, benefits, alternatives, and possible modes of treatment to the patient. We have already arrived at the decision to proceed with the administration of the selected monoclonal antibody (Bambanibab, Casirivimab, and Imevismab) which is currently authorized for emergency use by the Food & Drug Administration (FDA) and made available through the State of Utah COVID-19 Response.

Signature of Physician: _____ Date: _____
 Signature of Patient: _____ Date: _____

Monoclonal Antibodies for Treatment of COVID-19

In September, the Food and Drug Administration issued an Emergency Use Authorization (EUA) to allow the use of monoclonal antibodies for the treatment of mild to moderate symptoms of COVID-19 in specific patients.

Antibodies are proteins our bodies make to fight viruses, such as the virus that causes COVID-19. Antibodies made in a laboratory are a like a natural antibodies to fight the amount of virus in your body. They are called monoclonal antibodies.

Who can get this treatment?

- Adults 18 years old or older
 - At least 88 pounds (40kg)
 - Laboratory confirmed COVID-19 (PCR or antigen)
 - Symptomatic, with no more than 10 days from symptom onset
 - Symptomatic, with no more than 10 days from symptom onset
 - Not pregnant
 - Not on immunosuppressive therapy or acquired (e.g., rheumatoid therapy, certain types of cancer treatment that will suppress the immune system)
- Children 2-17 years old or older
 - Laboratory confirmed COVID-19 (PCR or antigen)
 - Symptomatic, with no more than 10 days from symptom onset
 - Not pregnant
 - Not on immunosuppressive therapy or acquired (e.g., rheumatoid therapy, certain types of cancer treatment that will suppress the immune system)

Who can't get it?
 The Utah Department of Health has included a list of participating providers on the coronavirus.utah.gov website. This list can be found, along with additional information on coronavirus.utah.gov.

The Utah Long Term Care Facilities. Please contact your assigned Utah Department of Health Healthcare Associated Infections Infection Preventionist, or if you are unsure who your Infection Preventionist is, please email LIIP@utah.gov.

The most common reported side effects with bambanibab are nausea, diarrhea, dizziness, headache, itching, and vomiting. The most common reported side effects with casirivimab/imevismab are nausea and vomiting, hypotension, and arrhythmia. The side effects of getting any medicine by vein may include local pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. More information can be found in the fact sheet from the FDA, found at <https://www.fda.gov/oc/ohrt/covid-19-antibodies>.



HAI / AR, MIST, MIFs

- MIST Activation and Response
- Physician Orders
- Data Collection

MOBILE INFUSION STRIKE TEAM (MIST) INFUSION TREATMENT ROLES & RESPONSIBILITIES

Pre-Infusion Preparation

STEP #	RESPONSIBLE PARTY	ACTIONS REQUIRED
1	MIF (MIST)	Identify recipient to be infused, with assistance from the assigned facility POC.
2	MIF (MIST)	Verify patient eligibility and preparation status.
3	MIF (MIST)	Obtain Patient Consent Form.
4	MIST Team Member	Verify correct procedure and equipment to be used for the volume.
5	MIST Team Member	Obtain labative data.
6	MIST Team Member	If patient meets criteria on the eligibility form for MIF infusion.
7	MIST Team Member	Set up infusion equipment as applicable, with a MIST monitoring equipment.

Infusion Treatment

STEP #	RESPONSIBLE PARTY	ACTIONS REQUIRED
1	MIF (MIST)	<ul style="list-style-type: none"> Infusion medication Administer 10 mL of Bambanibab, Casirivimab, and Imevismab (Evanesco) over 10 to 15 minutes. Administer Bambanibab (Evanesco) over 10 to 15 minutes.
2	MIST Team Member	<ul style="list-style-type: none"> Monitor patient vitals and symptoms. Obtain labative patient assessment. Yield and/or use as applicable.
3	MIF (MIST)	<ul style="list-style-type: none"> After 10 minutes, withdraw all of the BMM (Evanesco) and/or Evanesco. Flush line with 100 mL NS. Spoke MIF bag with MIST bagging with labative data. Spoke MIF bag with MIST bagging with labative data. Spoke MIF bag with MIST bagging with labative data. Spoke MIF bag with MIST bagging with labative data. Spoke MIF bag with MIST bagging with labative data.
4	MIST Team Member	<ul style="list-style-type: none"> Remove Bambanibab, Casirivimab, and Imevismab (Evanesco) from the patient's arm. Apply pressure to the site. Apply and remove full size of patient care.

Post Infusion

STEP #	RESPONSIBLE PARTY	ACTIONS REQUIRED
1	MIST Team Member	After the infusion is complete, document all vital signs.
2	MIST Team Member	After vital signs are documented, document all vital signs.
3	MIST Team Member	Remove patient from the room and ensure patient is safe.
4	MIST Team Member	Spoke MIF bag with MIST bagging with labative data.
5	MIST Team Member	Spoke MIF bag with MIST bagging with labative data.
6	MIF (MIST)	Spoke MIF bag with MIST bagging with labative data.
7	MIF (MIST)	Spoke MIF bag with MIST bagging with labative data.

Mobile Infusion Strike Team (MIST) Physician Order Set

Patient Name: _____ DOB: _____
 Facility Name: _____ Referring Physician: _____

ELIGIBILITY VERIFICATION & TREATMENT - to be completed and signed by MIST RN and LIIP

Patient is not symptomatic and has mild to moderate illness as noted by all of the following:
 • Not hospitalized due to COVID-19 OR
 • Does not require oral or intravenous supplemental oxygen due to COVID-19, and/or has a saturation of oxygen (SpO2) > 92% on room air.

Patient is not:
 • Greater than 10 days since symptom onset
 • If pregnant, not treated with O2/CPAP/Physician
 • Received COVID-19 testing in the past 10 days (both dates)

On-Site MIST Required Nurse Name: _____
 MIST Required Nurse (RN) Signature: _____
 MIST Licensed Independent Practitioner (LIP) Name: _____ Date: _____
 MIST Licensed Independent Practitioner (LIP) Signature: _____
 Telephone Order

Treatment to be Given:
 Bambanibab Expiration Date: _____ Lot: _____
 Bambanibab Expiration Date: _____ Lot: _____

PHYSICIAN ORDER SET - to be completed and signed by HAI Program Manager

Infusion Treatment to be Given for Available Monoclonal Antibody

IMPORTANT NOTE: Both Bambanibab and Casirivimab/Imevismab options must be checked to avoid liability to infuse your patient due to inadequate monoclonal antibody supply.

If Bambanibab is the available monoclonal antibody available, infuse 10 mL of Bambanibab and 10 mL of Imevismab from each vial using two separate syringes and dilute together in a 250 mL 0.9% NS total volume (270 mL) and proceed. If you are in-line or add-on 0.200/0.2 micron polyethersulfone (PES) filter taking over 60 minutes, flush the line to ensure delivery of the required dose at infusion.

If Bambanibab is the available monoclonal antibody available, infuse 700 mg of Bambanibab mixed as 1 vial 700 mg Bambanibab (200 mg) in 250 mL 0.9% NS total volume 270 mL in an in-line or add-on 0.200/0.2 micron polyethersulfone (PES) filter taking over 15 minutes. Flush the infusion line to ensure delivery of the required dose at infusion.

Patients with adverse reaction for any adverse response (hypotension, SPO2<90, tachycardia (HR >100 or fever, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, diarrhea).

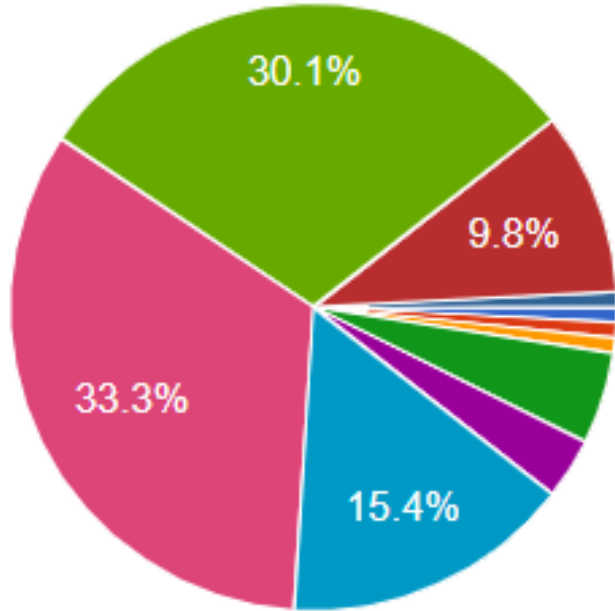
Stop infusion for any adverse response.
 Notify Referring Physician and Licensed Independent Practitioner of any adverse response.
 Call 911 any severe adverse response (hypotension, bronchospasm, angioedema, severe bronchospasm).

Physician Order Set Continued, Next Page

Referring LTCFs / Monoclonal Infusion Facilities (MIFs)

- Patient Education
- Screening and Consent
- Coordination with HAI / AR
- MIF Site Preparation / Service Terms & Conditions

OUTCOMES

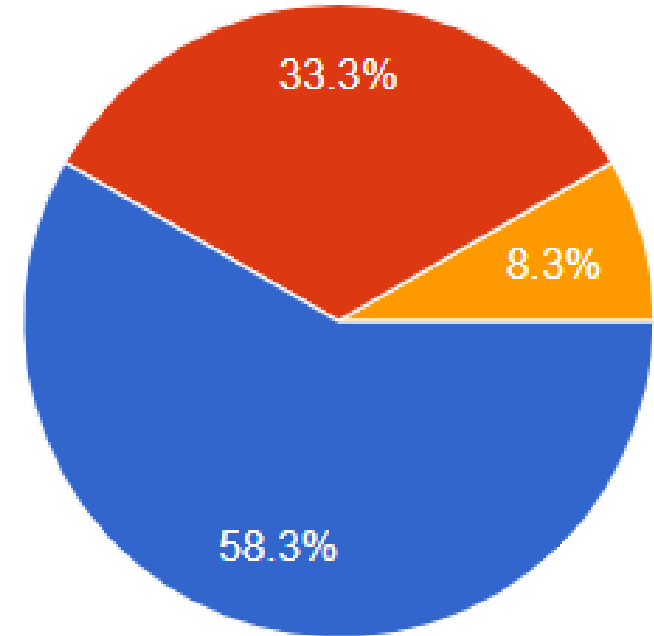


Age Breakdown

- 18-20
- 21-30
- 31-40
- 41-50
- 51-60
- 61-70
- 71-80
- 81-90

Post-Infusion Symptoms

- Improved
- Stayed the same
- Worsened



To date, we have completed 125 infusions to date in 13 facilities since 1/16/21 launch

- 2 ineligible due to increased oxygen need
- 2 with nausea / vomiting treated onsite
- 1 with difficult IV access
- 1 hospitalization post-treatment (25% reporting)
- No deaths (25% reporting)