Report on Monoclonal Antibody Therapy

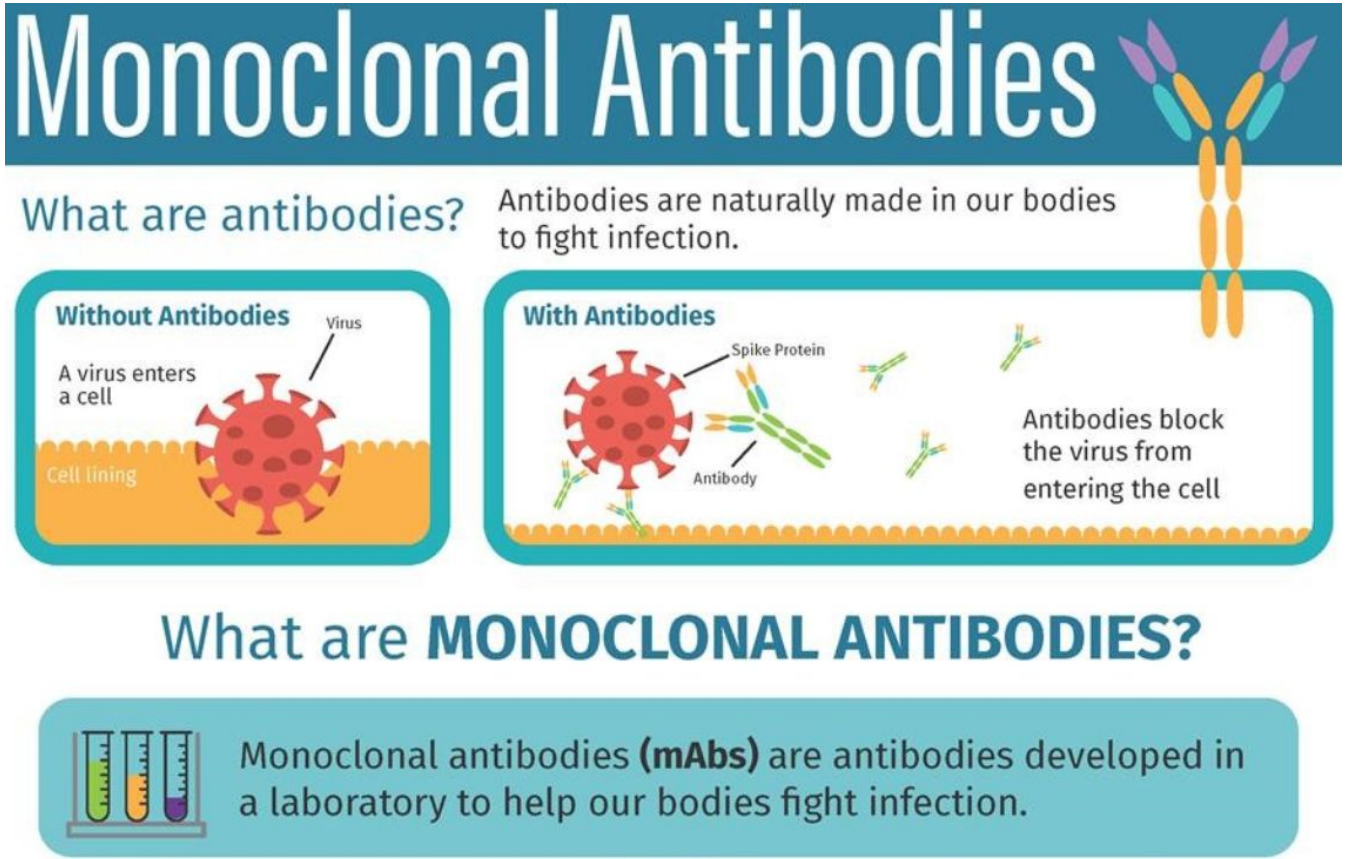
Health and Human Services Interim Committee

October 20, 2021

What are Monoclonal Antibodies & Who Can Get Them?

Based on EUA, monoclonal antibody infusion is <u>NOT</u> authorized for:

- Hospitalized due to COVID-19
- On oxygen due to COVID-19
- Symptom onset ≥ 10 days (Clinical trials show most benefit in 7 days)



Innovation in Utah: Prioritizing a Scarce Resource

Intermountain Healthcare: Equitable Risk-Adapted Strategy for Monoclonal Antibody Treatments

Recommendations for Health Systems

RECOMMENDATIONS

The following section provides key recommendations based on Intermountain Healthcare's experience.

Implement a Risk Adapted Strategy for Prioritizing Scarce Resources

- ✓ Leverage a publicly available, standardized, and validated risk score, such as the Utah COVID-19 Risk Score[1], to identify high-risk patients who are statistically more likely to benefit from treatment.
- ✓ Provide a quantifiable and adaptable approach to supply demand matching for managing limited infusion resources.
- ✓ Develop risk models with an equity focus by including race, ethnicity, and gender, and social determinants of health (e.g., environment, community, and individual economic stability) in data analysis[1] to identify patients who will benefit the most from treatment.
- ✓ Set a risk threshold for hospitalization based on the maximum number of patients that could be safely infused and the number of high-risk patients who are mathematically more likely to benefit from treatment.
  - Use this threshold to understand how many patients need to be treated to maintain a certain hospitalization rate.
  - Use the output of the risk models to prioritize limited infusion capacity to patients for whom prevention of hospitalization was most likely.
  - Adjust risk threshold estimates as capacity and eligibility criteria expand.

Simple Scoring Tool to Estimate Risk of Hospitalization and Mortality in Ambulatory and Emergency Department Patients with COVID-19

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Utah Crisis Standards of Care Monoclonal Antibody Allocation Guidelines

September 1, 2021

Produced in cooperation with

UHA

UTAH DEPARTMENT OF HEALTH

Current Allocation vs. Utilization

MONOCLONAL ANTIBODIES ALLOCATION, UTILIZATION, AND ORDERED AMOUNT			
Program Week	Allocation to Utah	Ordered Amount	Utilization Reported
Wed-Tue 9/22 – 9/28	1,608	1,608	503 (incl. 40 UDOH)
Wed-Tue 9/29 – 10/5	1,740	1,740	458 (incl. 54 UDOH)
Wed-Tue 10/6 – 10/12	1,896	624	552 (incl. 102 UDOH)
Wed-Tue 10/13 – 10/19	2,134	744	Due 10/20
Wed-Tue 10/20 – 10/26	2,050	Due 10/22	Due 10/27

Constraints in the system have changed over time. Initially, supply was scarce and led to creation of the risk score to drive appropriate utilization. Today, the human resources to administer monoclonal antibody therapy are the constraint <u>not</u> available doses.

Capacity, Reporting Week of October 6-12

97% capacity

Healthcare Systems
420 infusions / week

Providing MAb since November 2020, in 57 sites across Utah, including ERs, urgent cares, clinics, and infusion centers

- Intermountain Healthcare
- University of Utah Health
- HCA MountainStar
- Steward Healthcare
- Rural 9 Hospitals

56% capacity

UDOH Mobile Mission
100 infusions / week

Operating since January 2021 after EO to provide mobile MAb services in nursing homes across Utah

- Recent addition of new UTNG staff doubling capacity
- Post-exposure prophylaxis to contain outbreaks
- Training to self-administer

25% capacity

New Sites
750 infusions / week

Standing up high throughput fixed sites to rapidly expand capacity using standing orders and coordinated scheduling

- UDOH Murray
- Davis Hospital
- Nomi Health Orem (contract pending)

Total system capacity: 1270 infusions / week

Reporting week, Oct 6-12: 552 doses (43% capacity)


If you build it,
they will come?
they

Problems and Solutions to Optimize New Capacity

01	Healthcare systems at capacity and need to be shielded from any increases in demand	• Revamped website to allow patients to self-screen (risk calculator) • Poison Control hotline staff to support education, wayfinding, and connecting to treatment
02	Lack of awareness by providers and patients that a viable treatment option exists for COVID-19	• Provider letter to targeted DOPL list • Trade association outreach (UMA, UHA, UHCA, UALA, HHUA) • Media campaign, including billboards and social media
03	Patients commonly present after 7-day eligibility window from symptom onset has closed	• Educate public before they get COVID-19 / early testing • Rapid coordinated scheduling • MaB messaging with test results • Standing physician orders • Expand to 10-day eligibility window

Risk Calculator

Do I qualify for monoclonal antibody therapy?

People who are older or have underlying medical conditions are the most likely to benefit from mAb. Talk to your doctor or use our risk score calculator to find out if you would benefit from mAb. The risk score calculator will tell you if you qualify for mAb treatment and how to schedule an appointment at an infusion site near you.

Risk score calculator

¿Califico para el tratamiento con anticuerpos monoclonales?

Las personas de mayor edad o con enfermedades subyacentes son las que tienen más probabilidades de beneficiarse de los mAb. Hable con su médico o utilice nuestra herramienta de cálculo de riesgo para saber si puede beneficiarse de los mAb. La herramienta de cálculo de riesgo le indicará si puede recibir el tratamiento con mAb y cómo solicitar una cita en un centro de infusión cercano a usted.

Herramienta de cálculo de riesgo

Monoclonal Antibodies:

- If you test positive for COVID-19
- At high-risk
- Symptoms less than 7 days

CORONAVIRUS
UTAH.GOV

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Deputy Director

10/7/2021

Dear Provider,

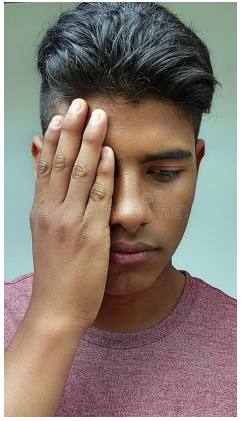
Since November 2020, Utah providers have administered approximately 7,100 monoclonal antibody infusions (mAb), preventing an estimated 900 hospitalizations. However, our state's current mAb capacity exceeds the number of patient referrals being received for this treatment. I am writing to ask for your help referring patients who may benefit from this life-saving treatment.

Patients who benefit most from mAb treatment are those most likely to be hospitalized or die from COVID-19. These patients are typically older or have complex underlying medical conditions. Patients who qualify for mAb must:

- Test positive for SARS-CoV-2.
- Currently have symptoms of COVID-19.
- Be within the first 7 days of symptom onset.
- Be at high risk for severe illness from COVID-19 due to things like age and underlying

Proposed Adjustments to Utah COVID-19 Risk Score

- Lower unvaccinated Risk Score threshold from 5 to 4
- Lower vaccinated Risk Score threshold from 8.5 to 7
- Extend the duration of eligibility from 7 days to 10 days



Hispanic male, 16+, unvaccinated

Vaccinated, 16+, with obesity, diabetes, shortness of breath

61+, vaccinated, diabetes and high blood pressure

Female, 30+, unvaccinated, high blood pressure shortness of breath

Next Steps

1. Execute Nomi Health Orem site contract and open this infusion center
2. Operationalize coordinated scheduling model for Wasatch Front high throughput sites using Poison Control hotline staff
3. Execute standard language on test result reporting with large testing partners
4. Monitor public traffic of website, social media, and hotline to assess public awareness and interest / evaluate need for additional communications
5. Pursue strategies for increasing capacity in the southwest region
6. Explore a statewide informatics solution using UHIN that models the patient identification processes in place within the Intermountain and U of U Health systems to support more proactive identification of eligible patients

APPENDIX

Adjustments to Utah COVID-19 Risk Score

The Utah Scarce Medications Allocation subcommittee of the Utah Crisis Standards of Care committee met to determine adjustments in the Utah COVID-19 Risk Score, based on the desired expansion to a broader eligible population and the expanded capacity brought about by the activation of state supported missions and locations.

This group is composed of clinical physician and pharmacy representatives from all hospital systems (including rural hospital representation) who have been actively supporting this response from the beginning by developing scarce resources guidance, adopted by all through consensus to ensure an equitable and standardized approach to access. Previous guidance has included: The Utah Crisis Standards of Care Guidelines (framework for allocation of scarce critical care/ICU resources), Criteria for Remdesivir Use when in Scarce Supply, Extracorporeal Membrane Oxygenation Scarce Resource Guideline, and multiple iterations of the Monoclonal Antibody Allocation Guidelines

Adjustments to Utah COVID-19 Risk Score

Suggested modifications to Utah COVID-19 Risk Score
-Lowering unvaccinated Risk Score threshold from 5 to 4 (which does …….)
-Lowering vaccinated Risk Score threshold from 8 to 7 (which does ……) or severely immunocompromised
-Extending the duration of eligibility from 7 days to 10

All eligible patients must meet the EUA criteria per Federal law:

Age ≥ 16 yo; Test confirmed COVID-19 (PCR or Antigen; home or lab); Symptomatic, with no more than 10 days from symptom onset; NO new hypoxemia (SpO2<90% on room air or receiving new/increased supplemental oxygen); NOT being admitted or already admitted to an acute care hospital for COVID-19 specifically, or for COVID-19 related complications

IF meeting above inclusion criteria AND pregnant, then the patient is eligible.

Adjustments to Utah COVID-19 Risk Score

Examples of eligible patients >/= 4 for unvaccinated

Male age 51 or older;

Hispanic male age 16 or older

Female age 71 or older;

Black female age 31 or older

Anyone age 31 and up with either diabetes or obesity

Any male age 16 or older with hypertension and new shortness of breath

Any female age 31 or older with hypertension and new shortness of breath

Any person of any age (16+) with obesity and diabetes

Any person of any age (16+) with obesity, any high risk comorbidity, and new shortness of breath.

Adjustments to Utah COVID-19 Risk Score

Examples of eligible patients >/= 7 for vaccinated

Male age 71 or older with either diabetes, immunocompromised, or obesity

Male age 61 or older with diabetes and hypertension

Male age 61 or older who is obese and has new shortness of breath

Hispanic male age 61 or older with any single comorbidity (HTN, CAD, CHF, kidney disease, liver disease, CVD. etc)

Hispanic female age 71 or older with hypertension

Female age 61 or older with diabetes, hypertension, and new shortness of breath

Female age 51 or older with diabetes and any 2 high risk comorbidities

Anyone age 31 or older with diabetes, obesity, and new shortness of breath

Monoclonal Antibody Therapy

For high risk individuals | For medical providers

https://coronavirus.utah.gov/noveltherapeutics/

For high risk individuals

If you've tested positive for COVID-19, are at high risk for severe illness, and it has been 7 days or less since your symptoms first started, you may benefit from monoclonal antibody treatment (mAb).

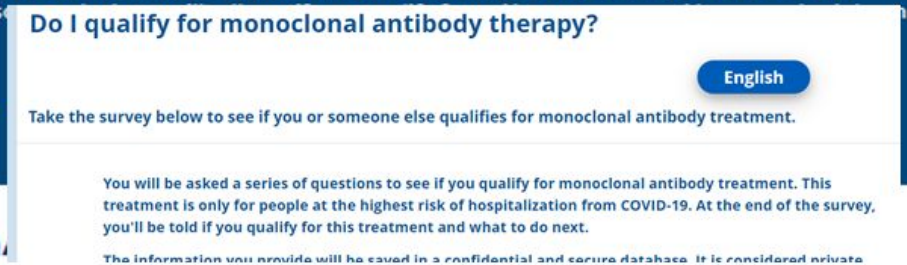
Getting vaccinated is the best way to prevent COVID-19. Monoclonal antibody treatment should NOT be used to prevent or treat mild symptoms of COVID-19. People who benefit the most from this treatment are those who are most likely to be hospitalized or die from COVID-19.

Where can I get vaccinated? | Where can I get tested? | Will mAb therapy benefit me?

Do I qualify for monoclonal antibody therapy?

People who are older or have underlying medical conditions are the most likely to benefit from mAb. Talk to your doctor or use our risk score calculator to find out if you would benefit from mAb. The risk s… appointment at an infusion site near you.

Risk score calculator



What is monoclonal antibody therapy (m…

Our bodies naturally make antibodies to fight infection. Monoclonal antibodies are like the antibodies your body makes to fight other viruses, but they are made in a lab and are designed to target the coronavirus spike protein. When the antibodies bind to the spike protein, they block the virus from entering your