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ALLIANT HEALTH SOLUTIONS

Monoclonal Antibody Therapy for High Risk COVID Patients

Welcome!

- All lines are muted, so please ask your questions in Q&A
- For technical issues, chat to the 'Technical Support' Panelist
- Please actively participate in polling questions that pop up on the lower right-hand side of your screen

We will get started shortly!

Monoclonal Antibody Therapy for High Risk COVID Patients

June 22, 2021

Tim Davis, PharmD
Eastern Region Pharmacist, North Carolina Public Health Preparedness and Response
HPP COVID-19 Vaccine and Therapeutics Planning Lead

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Making Health Care Better *Together*

Collaborators:

- Alabama Hospital Association
- Alliant Quality
- Comagine Health
- Georgia Hospital Association
- KFMC Health Improvement Partners
- Konza

Hospital Quality Improvement

Welcome from all of us!

kfmc Health Improvement Partners

KONZA

Alabama Hospital Association

Comagine Health
Formerly HealthInsight

GHA Georgia Hospital Association

Alliant Quality
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Tim Davis

EASTERN REGION PHARMACIST

NC PUBLIC HEALTH PREPAREDNESS AND RESPONSE

Contact: tim.davis@dhhs.nc.gov

Disclaimer

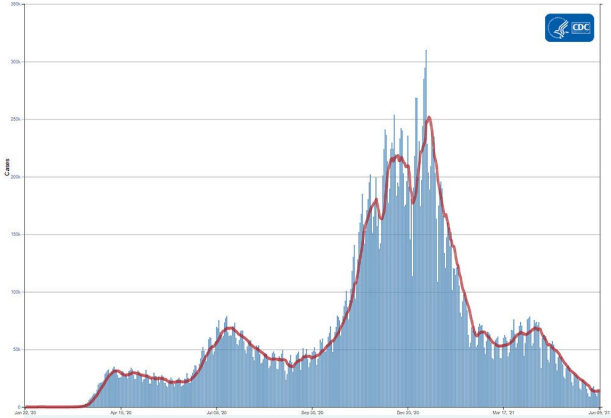
I have no financial interests to disclose, or conflicts of interest associated with the material discussed in this presentation.

Learning Objectives

- Learn Today:
  - Identify and review the currently authorized COVID-19 monoclonal antibody therapies and the requirements associated with their emergency use
  - Demonstrate how the use of monoclonal antibodies can reduce hospitalization and death in those at highest risk for negative outcomes from COVID-19
- Use Tomorrow:
  - Share tools and resources available to providers and patients interested in monoclonal antibody therapy

CDC COVID Statistics as of June 9, 2021

COVID Data Tracker

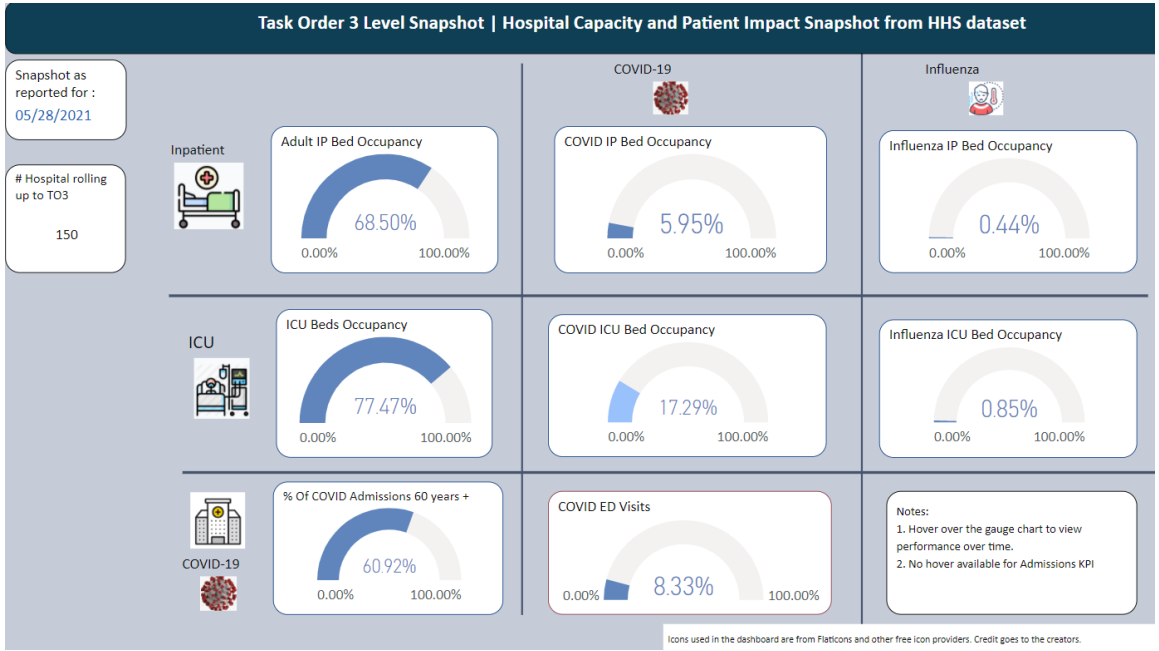


Daily Trends in COVID-19 Cases in the United States Reported to CDC

7-Day moving average

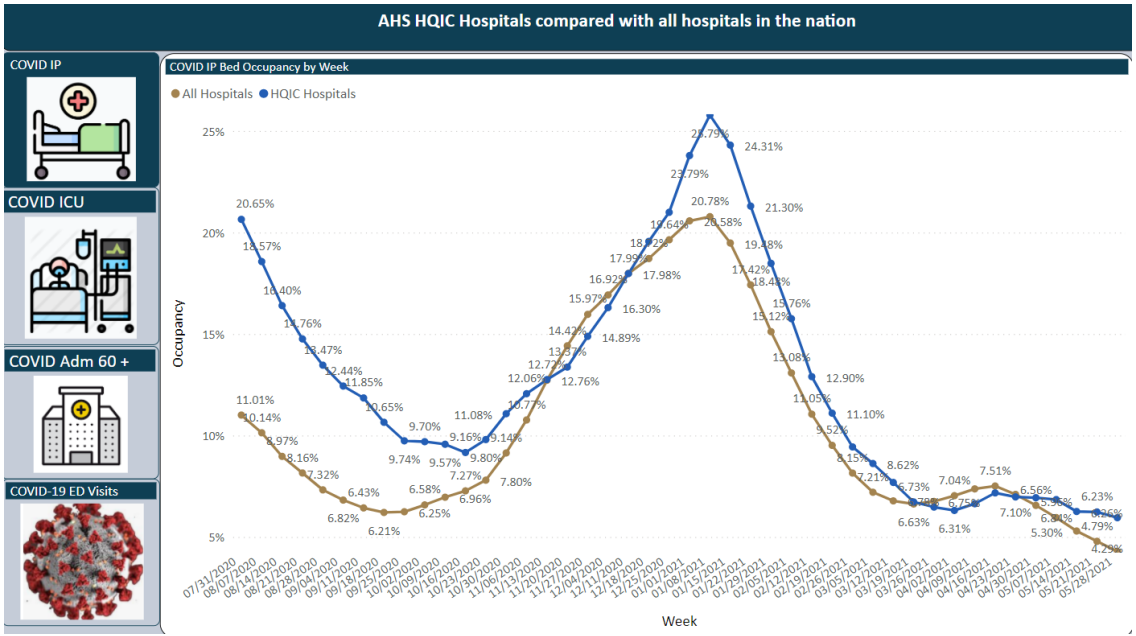
Cases in US	33,246,578	**Cases in US** Last 30 Days	
Deaths in US	596,059	**Deaths in US** Last 30 Days	
% Adults with At Least One Vaccination	64.0%		

Hospital Capacity and Patient Impact for 150 Alliant HQIC Hospitals



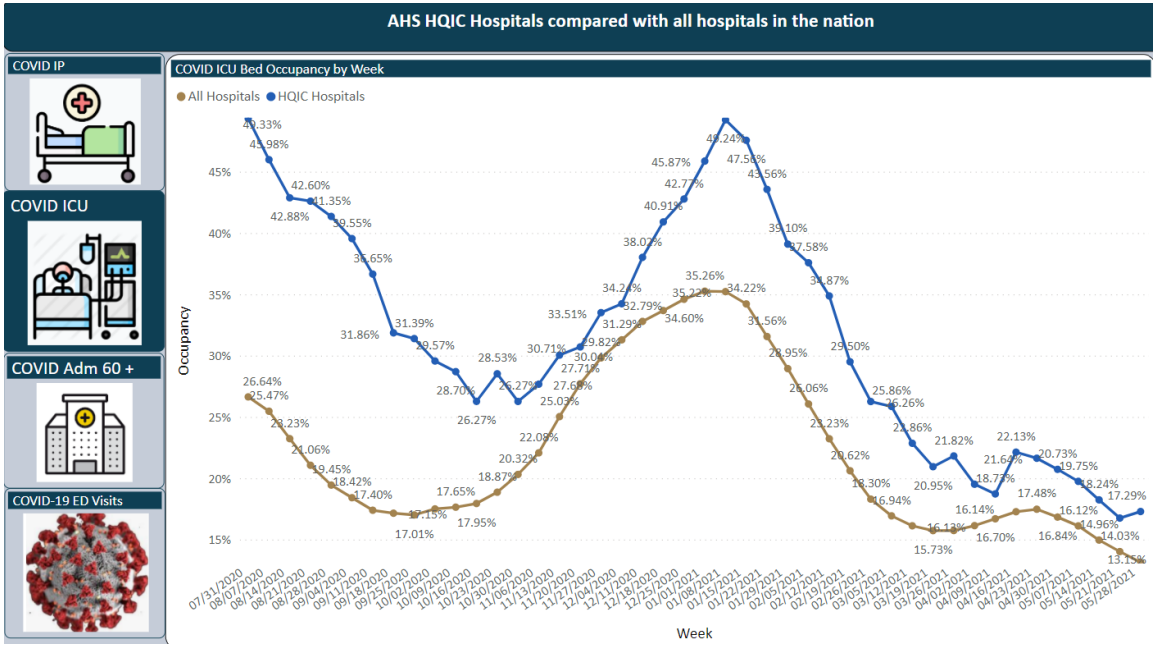
Source: HHS Protect Data

COVID IP Bed Occupancy by Week for 150 Alliant HQIC Hospitals



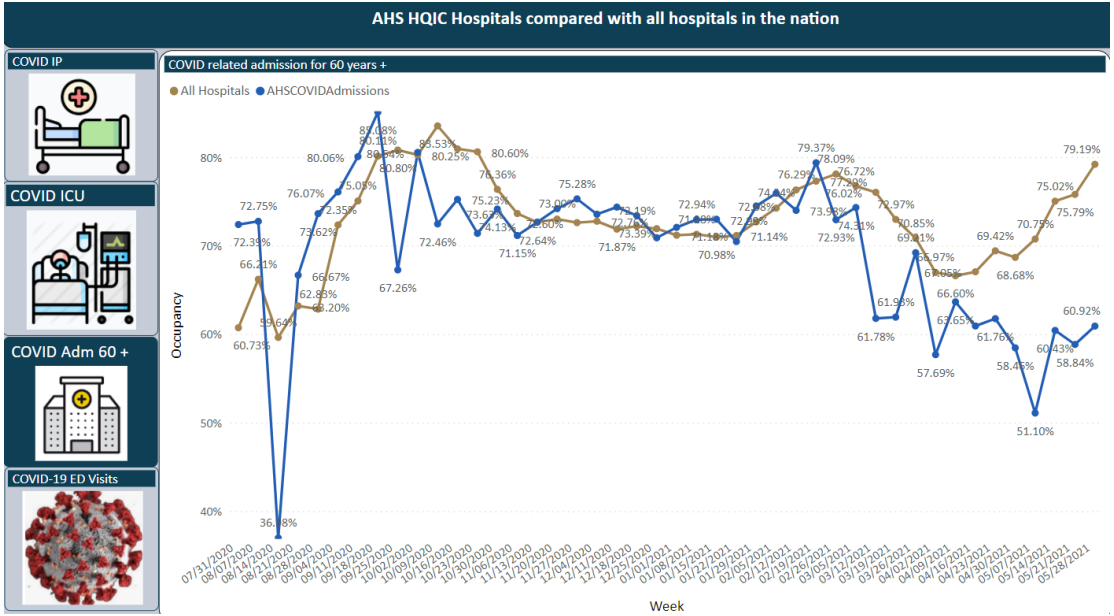
Source: HHS Protect Data

COVID ICU Bed Occupancy by Week for 150 Alliant HQIC Hospitals



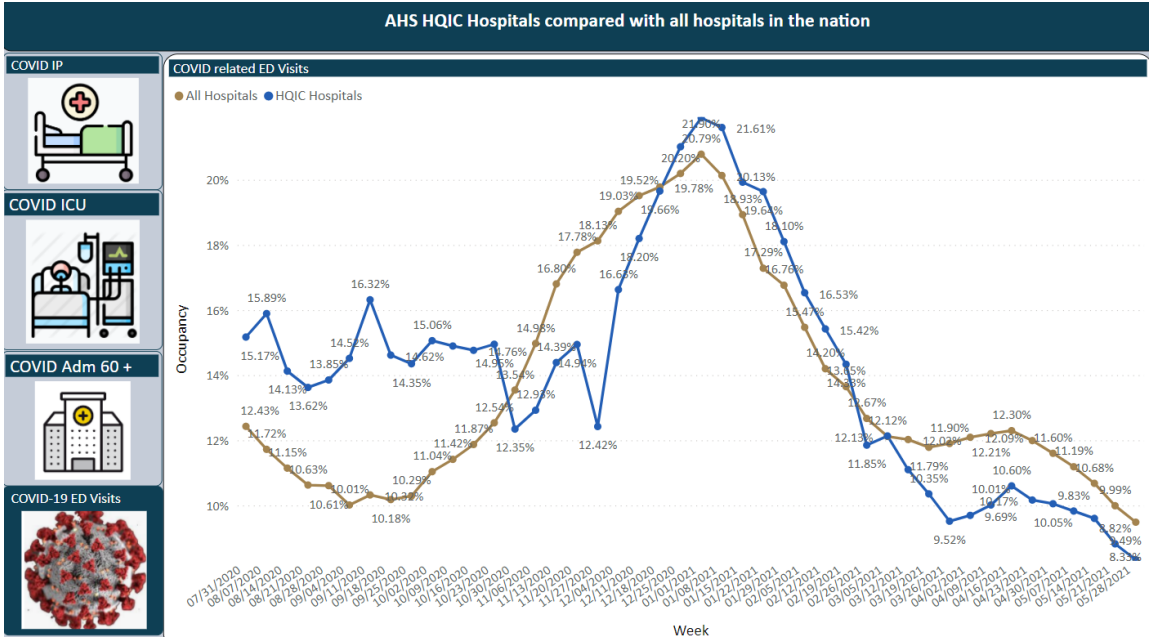
Source: HHS Protect Data

COVID Related Admission for 60 years+ for 150 Alliant HQIC Hospitals



Source: HHS Protect Data

COVID Related ED Visits for 150 Alliant HQIC Hospitals



Source: HHS Protect Data

About Monoclonal Antibodies

- Laboratory created antibodies that mimic the body's immune response
  - Over 100 mAbs currently FDA approved for variety conditions
- Directly neutralize the SARS-CoV-2 virus
- Most effective when given early in infection
- Three products currently under EUA
  - Casirivimab/imdevimab (REGEN-COV)
  - Bamlanivimab/etesevimab
  - Sotrovimab

Indications for Use

- Treatment of mild to moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg)
- Eligibility criteria
  - Positive SARS-CoV-2 viral test
  - High risk for progression to severe COVID-19
    - Recently expanded to allow physician discretion
  - Administered within 10 days of symptom onset
- Patients must also have no known hypersensitivity to any ingredients in the chosen therapy.

Additional EUA Requirements

- Healthcare providers must document that the patient/caregiver has been:
  - Given the appropriate "Fact Sheet for Patients, Parents, and Caregivers"
  - Informed of the alternatives to receiving mAb therapy
  - Informed that these mAbs are unapproved drugs that are authorized for use under an EUA
- Healthcare providers are responsible for mandatory reporting of all medication errors and serious adverse events to FDA MedWatch within 7 calendar days.
- Administration locations must have immediate access to medications to treat severe infusion reactions and the ability to activate the EMS system as necessary.

Product Comparison

	Casirivimab/ Imdevimab	Bamlanivimab/ Etesevimab	Sotrovimab
Manufacturer	Regeneron	Eli Lilly	GSK/VIR Biotech
EUA Granted	Nov. 2020	Feb. 2021	May 2021
Primary Clinical Trial	Phase 1/2/3 COV-2067 Trial (NCT04425629)	Phase 2/3 BLAZE 1 trial (NCT04427501)	Phase 1/2/3 COMET-ICE trial (NCT04545060)
Study Population	Mild to moderate COVID-19 (symptoms, not hospitalized)	Mild to moderate COVID-19 (symptoms, not hospitalized)	Mild to moderate COVID-19 (symptoms, not hospitalized)
Primary Endpoint	COVID-19 hospitalization or all-cause death through Day 29	COVID-19 hospitalization or death by any cause by day 29	Progression of COVID-19 at day 29
Outcome	70% reduction in hospitalization/death	87% reduction in hospitalization/death	85% reduction in hospitalization/death
Median Time to Symptom Resolution	10 days vs. 14 days in placebo group	8 days vs. 10 days in placebo group	Not yet available

For full trial details used to gain EUA, please see section 18 of the respective EUA factsheets for casirivimab/imdevimab, bamlanivimab/etesevimab and sotrovimab.

Product Comparison Cont.

	Casirivimab/ Imdevimab	Bamlanivimab/ Etesevimab	Sotrovimab
Authorized Dose	600mg/600mg	700mg/1400mg	500mg
Administration Route(s)	IV Infusion (20-50 mins) -OR- Subcutaneous Injection	IV Infusion (21-70 mins)	IV Infusion (30 mins)
Post-Admin Monitoring	1 hour	1 hour	1 hour
Storage Requirements	2-8°C	2-8°C	2-8°C
How Supplied	Co-formulated vial Individual vials (2.5 or 11.1mL)* Dose Packs*	Individual vials	Individual vial
How to Purchase	Free AmerisourceBergen	Free AmerisourceBergen	Not yet available

NIH treatment guidelines strongly recommend (AIIa) the use of casirivimab/imdevimab or bamlanivimab/etesevimab in non-hospitalized COVID-19 patients that meet EUA eligibility.

Note: NIH recommendations have not been updated since sotrovimab gained EUA.

Monoclonal Antibodies & Variants

Variant	Fold Reduction in Susceptibility		
	Casirivimab/ Imdevimab	Bamlanivimab/ Etesevimab	Sotrovimab
B.1.1.7 (Alpha) (UK)	No change	No change	No change
B.1.351 (Beta) (S. Africa)	No change	215	No change
P.1 (Gamma) (Brazil)	No change	>46	No change
B.1.427/429 (Epsilon) (CA)	No change	9	No change
B.1.526 (Iota) (NY)	No change	31	No change
B.1.617.2 (Delta) (India)	No change	No data avail.	No change

This data compiled from section 15 of the respective EUA factsheets for casirivimab/imdevimab, bamlanivimab/etesevimab and sotrovimab.

Due to the reduced effectiveness against the Beta and Gamma variants HHS/ ASPR has paused distribution of Bamlanivimab/Etesevimab in states where combined prevalence of those variants is >10%.
As of 6/16 that includes AZ, CA, FL, IL, IN, MA, OR, RI, and WA.

Real World Evidence

mAb Manuscript Pre-prints

- Real-World Effect of Monoclonal Antibody Treatment in COVID-19 Patients in a Diverse Population in the United States
- Implementation of SARS-CoV-2 monoclonal antibody infusion sites at three medical centers in the United States: Strengths and challenges assessment to inform COVID-19 pandemic and future public health emergency use

Planning Considerations

- Federal Response to COVID-19: Monoclonal Antibody Playbook
  - Administration locations
  - Staffing
  - Ancillary Supplies
  - PPE
  - Product storage/preparation
- Reimbursement
  - CMS Toolkit for COVID-19 Monoclonal Antibody Infusion

Additional Resources

FDA EUA Website

Project ECHO Outpatient Therapeutics Mini-Series

NICA Infusion Center Locator

NICA COVID-19 Antibody Therapy Resource Center

ASPR COVID-19: Monoclonal Antibody Therapeutics

Eli Lilly Bamlanivimab/Etesevimab Website

Regeneron REGEN-COV Website

GSK Sotrovimab Website

Additional Resources

1. Implementation of the Comprehensive Hospital Preparedness Checklist for the Coronavirus disease-2019 which is a CDC developed checklist that outlines important considerations for preparing for a surge in patient capacity.

2. Combat COVID

Key Takeaways

- Learn Today:
  - Monoclonal antibodies are a powerful and important tool in our COVID-19 toolbox that when used early in patients with mild to moderate COVID-19 can significantly reduce hospitalization/death in high-risk patients.
  - There are currently 3 monoclonal antibody products authorized for emergency use in the United States. Two of which are currently available at no cost to the provider.
- Use Tomorrow:
  - Leverage resources provided to consider providing monoclonal antibody therapy or at least refer patients to existing infusion centers.

How will this change what you do? Please tell us in the poll…

Questions?

Email us at HospitalQuality@AlliantQuality.org or call us 678-527-3681

HQIC Goals

Behavioral Health Outcomes & Opioid Misuse

- ✓ Promote opioid best practices
- ✓ Decrease high dose opioid prescribing and opioid adverse events in all settings
- ✓ Increase access to behavioral health services

Patient Safety

- ✓ Reduce risky medication combinations
- ✓ Reduce adverse drug events
- ✓ Reduce *C. diff* in all settings

Quality of Care Transitions

- ✓ Convene community coalitions
- ✓ Identify and promote optical care for super utilizers
- ✓ Reduce community-based adverse drug events

Upcoming Events

July 27, 2021 2:00 p.m. EST

Establishing a Robust Pain Management Initiative Within Your Hospital

Phyllis Hendry, MD, FAAP, FACEP & Brittany Johnson, PharmD, CPh

Event registration and information:

https://www.alliantquality.org/topic/hospital-quality-improvement/

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Thank you for joining us!

How did we do today?

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Hospital Quality Improvement

This material was prepared by Alliant Quality, the quality improvement group of Alliant Health Solutions (AHS), the Hospital Quality Improvement Contractor (HQIC) under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. AHSHQIC-TO3H-21-717

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