Allergy & Asthma Network
Upcoming & Recorded Webinars

Sleep Issues: The Effect of Allergies, Asthma & Related Conditions
- February 25, 2021 – 4:00 PM ET
- Dr. Brian Robertson

Addressing COVID-19 Vaccine Hesitancy in High Risk Communities
- March 4, 2021 – 4:00 PM ET

How to Be an Advocate
- Free recorded webinar – watch at your convenience
- On website: Advocacy ▶ Become a Patient Advocate

Look for more information at Allergyasthmanetwork.org

Allergy & Asthma NETWORK

COVID-19:
New Approaches to Prevention & Treatment for Allergy & Asthma Patients

February 17, 2021

OUR SPEAKERS

Ronald Rideman, PharmD

- Director, Medical Affairs
  Regeneron Pharmaceuticals

Tonya Winders

- President & CEO, Allergy & Asthma Network
- President, Global Allergy & Airways Patient Platform

PROGRAM OUTLINE

- Current State of COVID-19
- Antibody Therapy for COVID-19
- Caring for COVID-19 at Home

Poll Question

- **We'd like to know who is with us today!**
- **What category best describes you? (we have a limited number of answers or would offer more!)**

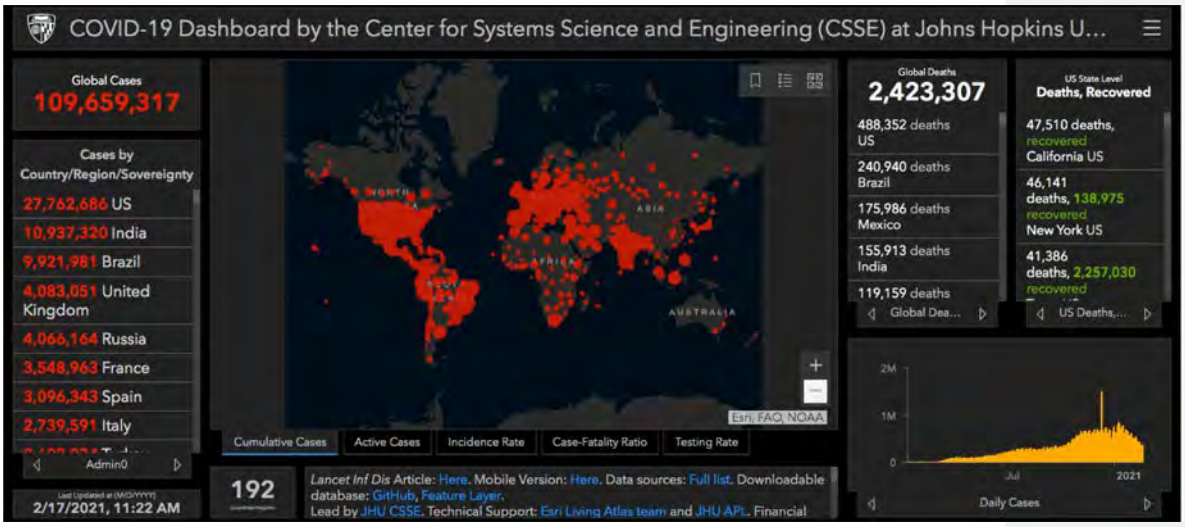
Current State of COVID-19

February 2021

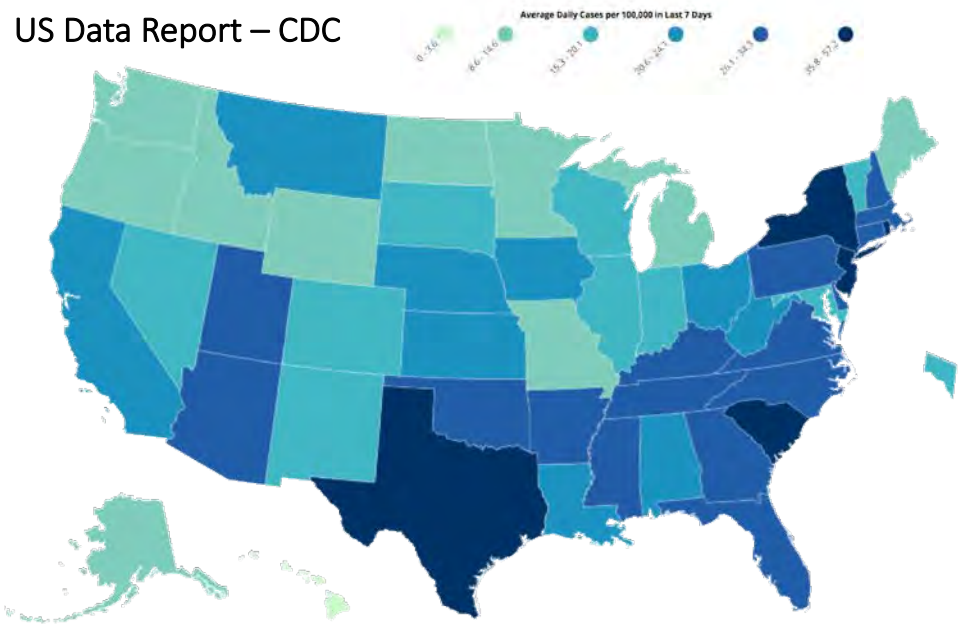
Tonya Winders

Johns Hopkins Global Map

February 17th – 11:22 AM



US Data Report – CDC



TOTAL CASES
27,542,421
+56,384 New Cases

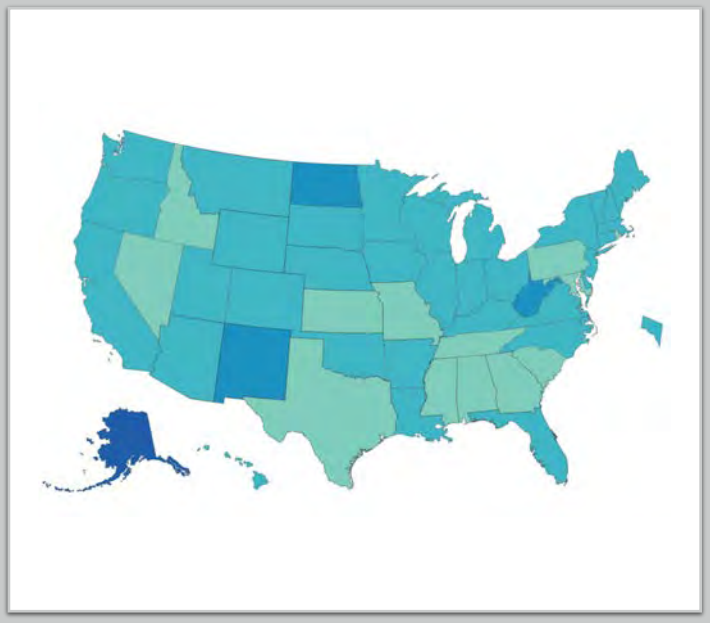
AVERAGE DAILY CASES PER 100K IN LAST 7 DAYS
25.9

TOTAL DEATHS
485,070
+1,217 New Deaths

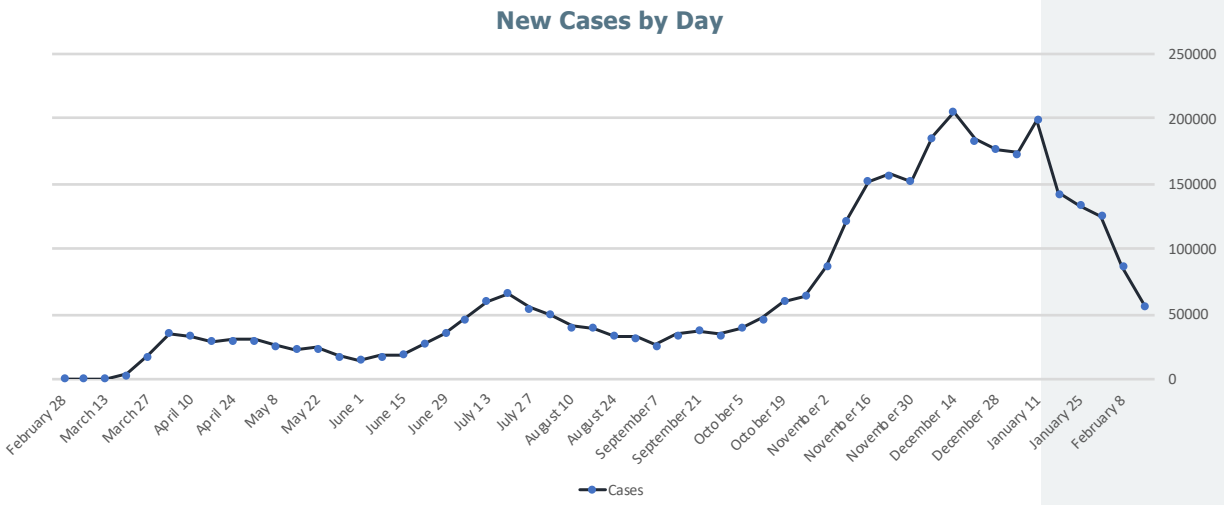
CDC | Updated: Feb 16 2021 12:28PM

In the News

- State are expanding access to vaccines
  - The supplies aren't keeping up
- Widespread vaccinations won't come until the summer
- Israel study on Pfizer vaccine indicates 94% drop in symptomatic COVID-19 cases
- Seven coronavirus variants have been detected in U.S.

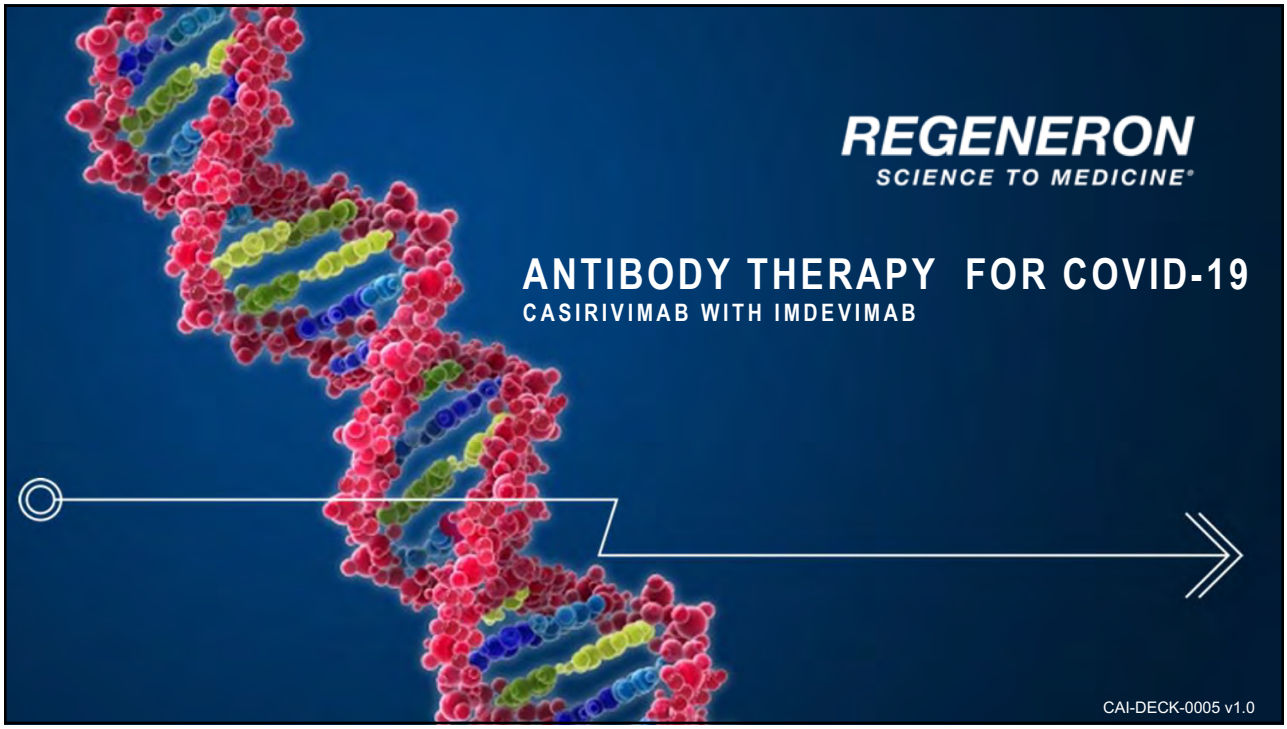


COVID-19 Cases in US by Date Reported



Poll Question

- **What do you think is the early estimate for the COVID-19 recovery rate?**



US COVID-19 INFECTION AND DEATH RATES ARE HIGH

Coronavirus in the US: Latest Map and Case Count[1]

Updated February 3, 2021, 12:30 PM ET

	TOTAL REPORTED	ON FEB. 2	14-DAY CHANGE
Cases	26.4 million+	114,234	-30%

Cases from January 20, 2021 to February 3, 2021[2]

As of February 3, 2021, the US is experiencing the highest case count and daily deaths (4,100/day) since the beginning of the pandemic

1. New York Times. Coronavirus Outbreak. https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html. Accessed February e, 2021. 2. Google News. Coronavirus (COVID-19). https://news.google.com/covid19/map?hl=en-US&mid=%2Fm%2F06mz5&gl=US&ceid=US%3Aen. Accessed February 3, 2021.

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TOOLS TO FIGHT THE PANDEMIC

1 **Vaccinations to prevent new infections**

2 **Other available therapies**

Hospitalized patients requiring supplemental oxygen	Mild/moderate hospitalized patients (at high risk, hospitalization not due to COVID-19, not requiring supplemental O_2)	Ambulatory patients (mild/moderate patients at high risk)
Remdesivir (+ baricitinib [EUA]), dexamethasone	Monoclonal antibodies (casirivimab and imdevimab; bamlanivimab; bamlanivimab and etesevimab [EUA])	Monoclonal antibodies (casirivimab and imdevimab; bamlanivimab; bamlanivimab and etesevimab [EUA])

Adapted from: NIH. COVID-19 Treatment Guidelines. https://www.covid19treatmentguidelines.nih.gov/therapeutic-management. Accessed January 29, 2021.
https://www.prnewswire.com/news-releases/lillys-bamlanivimab-iv-cov555-administered-with-etesevimab-iv-cov016-receives-fda-emergency-use-authorization-for-covid-19-301225460.html Accessed February 9, 2021

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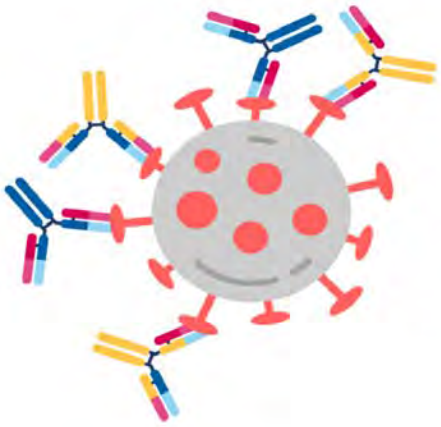
WHAT ARE ANTIBODIES?



When the human body encounters **pathogens** like SARS-CoV-2, the virus that causes COVID-19, the body's immune system naturally produces **antibodies** to recognize and kill or neutralize the dangerous invaders.

The immune system typically remembers its reaction to a pathogen and can produce the same protective antibodies again in the future. This is called **IMMUNOLOGICAL MEMORY**.

https://www.usatoday.com/pages/interactives/sponsor-story/How-antibodies-fight-pathogens-like-coronavirus/

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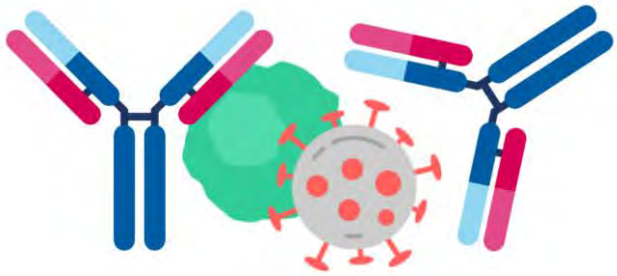
INNATE AND ADAPTIVE IMMUNITY



Innate immunity is the immunity you're born with. But the immunity you gain during your lifetime is called **adaptive immunity**, and it has two types: **passive and active. Both use protective antibodies**.

People who recover from **COVID-19** are believed to acquire at least some lasting immunity against the disease, as their bodies produce **protective antibodies and immune system memory** but evidence remains limited. [1]

https://www.usatoday.com/pages/interactives/sponsor-story/How-antibodies-fight-pathogens-like-coronavirus/

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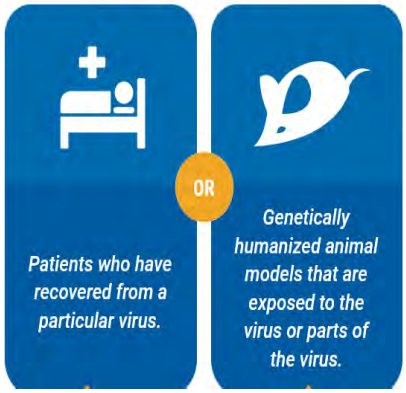
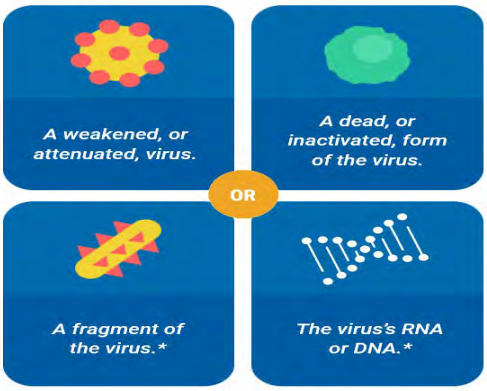
CREATION OF ANTIBODY MEDICINES AND VACCINES

ANTIBODY MEDICINES ARE DERIVED FROM:



VACCINES ARE CREATED USING ANTIGENS, WHICH CAN BE:



*These two approaches are primarily being explored for COVID-19. [2]

https://www.usatoday.com/pages/interactives/sponsor-story/How-antibodies-fight-pathogens-like-coronavirus/

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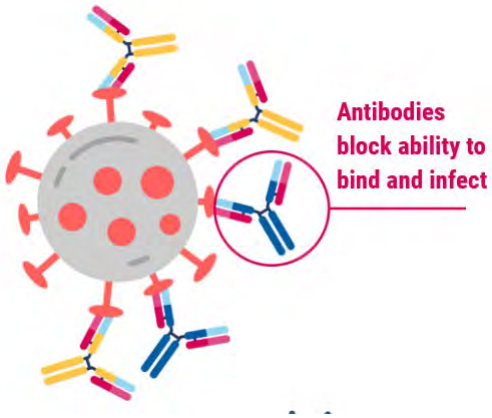
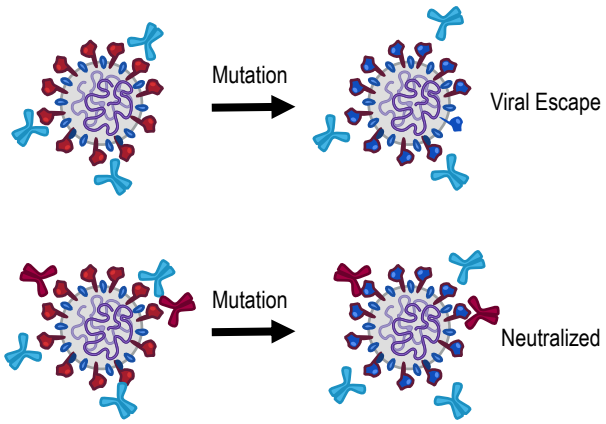
ANTIBODIES



https://www.usatoday.com/pages/interactives/sponsor-story/How-antibodies-fight-pathogens-like-coronavirus/

SARS-COV-2 HAS THE POTENTIAL TO MUTATE, DECREASING THE NEUTRALIZATION ABILITY OF THERAPEUTIC ANTIBODIES

- RNA viruses are known to mutate[1-3]
- Mutations in Spike RBD can decrease the neutralization ability of the antibody[1,4,5]
- New variant may replace the wild-type virus[1,4,6]
- The probability of mutation at multiple binding sites is lower than a single binding site[1,4,7]
- Using more than one antibody may minimize the risk of SARS-CoV-2 escape variants[1]



1. Baum A et al. *Science*. 2020;369:1014-1018. 2. Smith EC et al. *PLoS Pathog*. 2017;13:e1006254. doi.org/10.1371/journal.ppat.1006254. 3. Sanjuán R et al. *Cell Mol Life Sci*. 2016;73:4433-4448. 4. Tai W et al. *J Virol*. 2016;91:e01651-16. doi:10.1128/JVI.01651-16. 5. Sui J et al. *J Virol*. 2014;88:13769-13780. 6. Kim Y-S et al. *Emerg Infect Dis*. 2019;25:1161-1168. 7. Coughlin MM et al. *Virology*. 2009;394:39-46.

ONGOING CLINICAL DEVELOPMENT PROGRAM FOR CASIRIVIMAB AND IMDEVIMAB

STUDY 2067[1]
Nonhospitalized (IV)
Seamless Phase 1/2/3

STUDY 2066[2]
Hospitalized (IV)
Seamless Phase 1/2/3

STUDY 2069[2]
Household contact prophylaxis (SC)
Phase 3

Other ongoing trials[2]

- STUDY 2093: healthy volunteer, multidose, PK/safety (SC)
- RECOVERY trial: hospitalized patient, Phase 3 study (IV)
- Study 20145: different dose regimens in nonhospitalized patients (IV and SC)

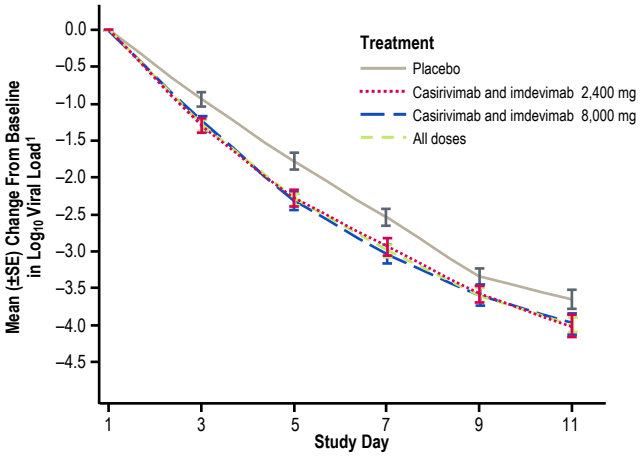
Number of currently enrolled patients: 12,710 (January 28, 2021)[3]

IV, intravenous; SC, subcutaneous.
1. Weinreich DM et al. *N Engl J Med*. 2020. doi:10.1056/NEJMoa2035002. 2. Clinicaltrials.gov. Accessed January 25, 2021. 3. Data on file; Regeneron.

REGENERON 21

BOTH TESTED DOSES OF CASIRIVIMAB AND IMDEVIMAB REDUCED VIRAL LOAD FROM BASELINE (STUDY 2067)

EUA Analysis Study 2067 Nov 2020



- At baseline, the largest reductions in viral load relative to placebo occurred in patients with[1]
  - High viral load (–0.78 $\log_{10}$ copies/mL)
  - Serum antibody-negative (–0.69 $\log_{10}$ copies/mL)
- In the mFAS for the Phase 1/2 analysis (n=665), the difference in TWA from Day 1–7 for the pooled doses of casirivimab and imdevimab was –0.36 $\log_{10}$ copies/mL (*P*<0.0001) compared with placebo[1]

The largest viral reductions were seen in patients with the highest viral loads at baseline

The authorized dosage in adults and in pediatric patients (12 years of age and older weighing at least 40 kg) is 1,200 mg of casirivimab and 1,200 mg of imdevimab administered together as a single IV infusion over at least 60 minutes.
The mFAS includes all randomized patients with positive RT-qPCR in NP swab samples at randomization.
1. Regeneron. Casirivimab and imdevimab EUA fact sheet for HCPs. 2020. https://www.regeneroneua.com/.

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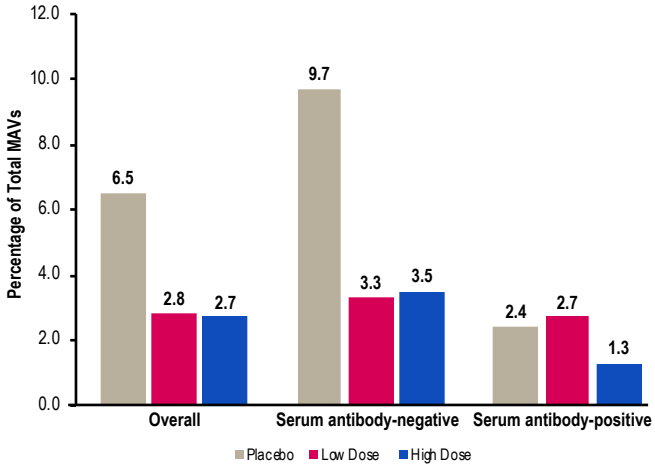
CASIRIVIMAB AND IMDEVIMAB REDUCED MEDICALLY ATTENDED VISITS (MAVs)

Prospective Analysis Study 2067 Data On File

- Overall population (mFAS, n=665)
  - 57% reduction in the low dose (6.5% vs 2.8%)
- Serum antibody-negative (mFAS, n=360)
  - 65% reduction in the low dose (9.7% vs 3.3%)
- Serum antibody-positive (mFAS, n=236)
  - No effect in the low dose (2.4% vs 2.7%)
  - 46% reduction in the high dose (2.4% vs 1.3%)



The authorized dosage in adults and in pediatric patients (12 years of age and older weighing at least 40 kg) is 1,200 mg of casirivimab and 1,200 mg of imdevimab administered together as a single IV infusion over at least 60 minutes.
Total MAVs include hospitalizations, ER and urgent care visits, and physician/telemedicine visits.

Data on file; Regeneron

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SAFETY PROFILE OBSERVED IN THE CASIRIVIMAB AND IMDEVIMAB CLINICAL TRIAL PROGRAM (STUDY 2067)

EUA Analysis Study 2067 Nov 2020

SAEs

Patients with:	Placebo (N=262)	Casirivimab and Imdevimab Low Dose (2,400 mg IV) (N=258)	Casirivimab and Imdevimab High Dose (8,000 mg IV) (N=518)
SAEs	6 (2.3%)	4 (1.6%)	2 (0.8%)

Hypersensitivity Reactions

- One anaphylactic reaction was reported in the casirivimab and imdevimab clinical program within 1 hour of the completion of the infusion
  - Patient was treated with epinephrine, leading to event resolution

	Placebo (N=262)	Casirivimab and Imdevimab Low Dose (2,400 mg IV) (N=258)	Casirivimab and Imdevimab High Dose (8,000 mg IV) (N=518)
Infusion-related reaction Grade ≥2, number of patients (%)	1 (0.4%)*	0	4 (1.5%)†
Treatment discontinuation due to infusion-related reaction	0	0	2 (0.8%)‡

Casirivimab and imdevimab is not authorized at the 8,000 mg dose (4,000 mg casirivimab and 4,000 mg imdevimab).
*Infusion-related event reported was nausea. †Moderate infusion-related events reported were pyrexia, chills, urticaria, pruritus, abdominal pain, and flushing. ‡Infusion-related events reported were urticaria, pruritus, flushing, pyrexia, shortness of breath, chest tightness, nausea, and vomiting. All events resolved.
Regeneron. Casirivimab and imdevimab EUA fact sheet for HCPs. 2020. https://www.regeneroneua.com/. Accessed January 29, 2021.

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SUMMARY: PROSPECTIVE AND EMERGENCY USE AUTHORIZATIONS ANALYSES

- Results from the placebo group demonstrated that nonhospitalized patients were more likely to have ≥1 MAV if they[1]
  - Were baseline serum antibody-negative
  - Had a baseline viral load of >10^4 copies/mL
  - Had ≥1 risk factor
- Casirivimab and imdevimab reduced the number of MAVs in all groups versus placebo, with the greatest reduction in the serum antibody-negative group[1]
- Casirivimab and imdevimab had an incidence of SAEs of 1.6% in the low-dose and 0.8% in the high-dose groups[2]

1. Data on file; Regeneron. 2. Regeneron. Casirivimab and imdevimab EUA fact sheet for HCPs. 2020. https://www.regeneroneua.com/. Accessed January 29, 2021.

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PATIENTS ELIGIBLE FOR MONOCLONAL ANTIBODIES UNDER EMERGENCY USE AUTHORIZATION (EUA)

Adults and children ≥12 years (≥40 kg)

+

Positive SARS-CoV-2 viral test

+

At high risk for progressing to severe COVID-19 and/or hospitalization (see Risk Factors)*

*Risk Factors

- Overweight (BMI >35), or
- Chronic kidney disease, or
- Diabetes, or
- Chemotherapy, or
- Suppressed immune system due to disease or medicine (e.g., for rheumatoid arthritis), or
- 65 years of age of older

OR

Over 55 years of age and
- Cardiovascular disease, or
- Hypertension, or
- Chronic obstructive pulmonary disease (COPD)/other chronic respiratory disease

12–17 years of age and
- BMI >85th percentile, or
- Sickle cell disease, or
- Congenital or acquired heart disease, or
- Neurodevelopmental disorders, or
- Chronic respiratory disease daily requiring medication

NOT authorized for patients who are hospitalized or require oxygen therapy due to COVID-19 or who require increased oxygen flow for non-COVID–related reasons.

1. Regeneron. Casirivimab and imdevimab EUA fact sheet for HCPs. 2020. https://www.regeneroneua.com/. Accessed January 29, 2021. 2. Eli Lilly. Bamlanivimab EUA fact sheet for HCPs. 2020. https://www.fda.gov/media/143603/download. Accessed January 21, 2021.

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CURRENT CHALLENGES AND MECHANISMS TO IMPROVE mAb UPTAKE

CHALLENGES	MECHANISMS TO IMPROVE/FACILITATE EDUCATION AND PATIENT ACCESS
Patients unaware of mAbs (unaware of option/"vaccine noise"/differentiation)	Website, webinars, television
HCPs unaware of mAbs	Physician education, website, webinars
HCP logistics (lack of protocols, obtaining therapy)	Coordinate partnerships and best practices; promote best practice sessions
Patient logistics (access to care after positive diagnosis)	Website, webinars, television; provide best practice for physician referrals
Facility/outpatient/home infusion logistics (establishing infusion center/safe location for infusion)	Coordinate partnerships between hospitals, infusion centers, and home infusion
Confusion over packaging and dosing	Physician education, website, webinars,; promote necessary updates

REGENERON 27

REGENERONEUA.COM/PATIENTS

REGENERON 28

Antibody medicines could serve as an important bridge to a vaccine, and may have utility beyond for certain people, such as those who are immuno-compromised or do not respond to a vaccine. Both approaches are important and necessary to hopefully end the COVID-19 pandemic.

https://www.usatoday.com/pages/interactives/sponsor-story/How-antibodies-fight-pathogens-like-coronavirus/

Caring for COVID-19 at Home

Tonya Winders

CDC

If you have a fever, cough or other symptoms:

- You might have COVID-19.
- Most people have mild illness and are able to recover at home.
- If you think you may have been exposed to COVID-19, contact your healthcare provider

Some with COVID-19 may go to the hospital & many manage at home.

CDC – Caring for COVID-19 at Home

- Stay home except to get medical care
- **Stay home.** Most people with COVID-19 have mild illness and can recover at home without medical care. Do not leave your home, except to get medical care. Do not visit public areas.
- **Take care of yourself.** Get rest and stay hydrated. Take over-the-counter medicines, such as acetaminophen, to help you feel better.
- **Stay in touch with your doctor.** Call before you get medical care. Be sure to get care if you have trouble breathing, or have any other emergency warning signs, or if you think it is an emergency.
- **Avoid public transportation**, ride-sharing, or taxis.

Tips for Staying Hydrated

Things to Drink

- Decaf tea
- Water with lemon
- Soup
- Ice chips

Drinks to Avoid

- Sports Drinks
- Coffee
- Fruit Juice
- Ginger ale
- Alcohol

CDC – Caring for COVID-19 at Home

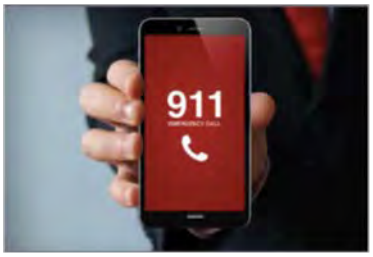
- Separate yourself from other people
- **As much as possible, stay in a specific room** and away from other people and pets in your home. If possible, you should use a separate bathroom. If you need to be around other people or animals in or outside of the home, wear a mask.
- **Tell your close contacts** that they may have been exposed to COVID-19. An infected person can spread COVID-19 starting 48 hours (or 2 days) before the person has any symptoms or tests positive. By letting your close contacts know they may have been exposed to COVID-19, you are helping to protect everyone.
- Additional guidance is available for those living in close quarters and shared housing.
- If you are diagnosed with COVID-19, someone from the health department may call you. Answer the call to slow the spread.

CDC – Caring for COVID-19 at Home

- Monitor your symptoms
- **Symptoms of COVID-19 include fever, cough, or other symptoms**.
- **Follow care instructions from your healthcare provider and local health department.** Your local health authorities may give instructions on checking your symptoms and reporting information.

When COVID-19 is an Emergency - CDC

- Look for **emergency warning signs** for COVID-19. If someone is showing any of these signs, **seek emergency medical care immediately:**
- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face
- *This list is not all possible symptoms. Please call your medical provider for any other symptoms that are severe or concerning to you.
- **Call 911 or call ahead to your local emergency facility:** Notify the operator that you are seeking care for someone who has or may have COVID-19.



The 3 W's

10 Things to Manage COVID -19 Symptoms at Home

Poll Question

- **Which of these actions do NOT belong in the 3W's for reducing COVID-19 risk?**

TIME FOR QUESTIONS

Record your questions in the question box

We'll get to as many as we can!

JOIN US FOR OUR
NEXT COVID-19 WEBINAR

- Addressing COVID-19 Vaccine Hesitancy in High Risk Communities
- February 17th
- 4:00 PM ET

Allergy & Asthma NETWORK

COVID-19:
New Approaches to Prevention & Treatment for Allergy & Asthma Patients
Allergyasthmanetwork.org