

Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (XXXX-XXXX). Do not return the completed form to this address.

A 60-Minute Online Bulletin Board Forum
MODERATOR'S GUIDE FOR CONSUMER AND HEALTHCARE PROVIDER (HCP)
AUDIENCE FEEDBACK TEAMS
Month 01, 202X

BACKGROUND AND INSTRUCTIONS

[MONTH 1 ONLY: Thank you for your participation in this project! This project is sponsored by the Federal COVID Response Team (FCR). The FCR is a cross-agency partnership that includes the U.S. Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the U.S. Department of Defense (DOD).

The NIH has set up a partnership among government, industry, and university researchers to identify drugs and other treatments that are most promising. These are called ACTIV trials-- Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

The purpose of this Bulletin Board Forum is to discuss your thoughts and feelings about some topics related to COVID-19 and clinical trials. We also want to hear your suggestions on how to best reach you with important information on what's available for people who get exposed to or get sick with COVID-19. Your feedback will help us share this important information in the most effective way.]

[SUBSEQUENT MONTHS: Thank you for your participation in this project! As a reminder, or if this is your first month joining us, this project is sponsored by the Federal COVID Response Team (FCR). The FCR is a cross-agency partnership that includes the U.S. Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the U.S. Department of Defense (DOD).

The NIH has set up a partnership among government, industry, and university researchers to identify drugs and other treatments that are most promising. These are called ACTIV trials-- Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

The purpose of this Bulletin Board Forum is to discuss your thoughts and feelings about some topics related to COVID-19 and clinical trials. We also want to hear your suggestions on how to best reach you with important information on what's available for people who get exposed to or get sick with COVID-19. Your feedback will help us share this important information in the most effective way.]

During the course of this 2-day discussion forum, please keep in mind the following:

- Your **total time** spent on this Bulletin Board Forum will be approximately **60 minutes** (across 2 days). It is up to you how you spend your time answering questions, but we encourage to you check in on Day 1 and Day 2 to respond to any follow-up questions from our moderator and to see what others have posted.
- A group of participants will take part in this Bulletin Board Forum. You will be asked a set number of questions each day. *After* you answer each question, you will be able to see how others in the forum answered the same question. You will be able to react to comments from other participants in the Bulletin Board Forum as well as interact with the moderator. We want to hear all opinions and perspectives. Please be respectful of all opinions and perspectives.
- There are no right or wrong answers to the questions we ask.
- This activity can be completed on a computer (desktop or laptop) or using the smartphone/tablet app, whichever you prefer. At the end of the discussion, we will download everyone's feedback for the purposes of our report. Please note that there will be NO audio or video recording of this Bulletin Board Forum.
- All information and opinions you give us will be kept **private**. Your identity will not be revealed to anyone outside of this discussion group. Please do not share any information which could be used to identify someone, such as someone's full name. This information will be used for research purposes only and will *not* be shared with any third parties.
- We are *not* here to influence you or your behaviors in any way. What we seek is your honest feedback. You will *not* be targeted for any sales or promotional activities as a result of taking part in this discussion.
- Your participation is voluntary. What this means is that you are free to decline to answer any questions and you are free to withdraw from the Bulletin Board Forum at any time without penalty.
- Feel free to move through the questions at your leisure (at any time during the day). As your moderator, I may contact you on this Bulletin Board Forum to ask a follow-up question about something you wrote.
- Project staff may be viewing the Bulletin Board Forum, but the participants and the moderator will be the only ones communicating during the 2-day discussion.

Thank you. Now, let's get started!

INTRODUCTIONS

[MONTH 1 ONLY: Please introduce yourself using your first name only (no last names) and let us know (a) what state you live in and (b) one thing you like to do for fun.]

[SUBSEQUENT MONTHS: If this is your first time joining, please introduce yourself using your first name only (no last names). If you are returning feedback team member, welcome back! Please share your first name for any new members in this bulletin board activity.

As let us know: (a) what state you live in and (b) [INSERT INTRO QUESTION].]

[Intro questions include:

- Favorite seasonal activity
- Something you are looking forward to this month
- Favorite vacation]

[MONTH 1 ONLY: HEALTHCARE ACCESS AND COVID EXPERIENCE

[CONSUMERS]

1. **POLL: Do you currently have someone you consider a primary care provider? This is someone whom you see for check-ups or common medical problems.**
 - 1) Yes
 - 2) No
 - i. If no, where do you usually go when you are sick and need care or treatment?
2. **POLL. First, we'd like to know more about your personal experience with COVID-19. Please select any of the following that apply to you:**
 - 1) I have not had COVID-19.
 - 2) I was exposed to COVID-19 at home, at work, or somewhere else, but I did not feel sick.
 - 3) I was tested for COVID-19 and told my test result was positive.
 - 4) I had COVID-19 myself.
 - 5) Someone in my household who I provide care for when they are sick (like a parent, spouse or partner, or child) had COVID-19, and I helped care for them.
 - 6) Someone who I provide care for but lives outside of my house had COVID-19, and I helped care for them when they were sick.
 - 7) Someone I knew but do not live with (a friend, other family members) had COVID-19.
 - 8) I personally stayed overnight in the hospital for COVID-19 treatment.
 - 9) Someone who I provide care for stayed overnight in the hospital for COVID-19 treatment.
3. **In your own words, briefly walk us through your personal experience being sick with COVID-19. If you did not have COVID-19 personally, tell us about the experience of someone else you know.**
 - a. If you had COVID-19:
 - i. What care or treatments for COVID-19 did you do at home?
 - ii. If you needed medical care, where did you go?

- iii. What care or treatments have you done since your COVID-19 symptoms ended? If you are still having COVID-19 symptoms, what care or treatment have you gotten to help manage those symptoms?
 - b. If you provided care for a loved one who had COVID:
 - i. What care or treatments for COVID-19 did they do at home?
 - ii. If they needed medical care, where did you go first?
 - iii. What care or treatments has your loved one done since their COVID-19 symptoms ended? If they are still having COVID-19 symptoms, what care or treatment have they gotten to help manage those symptoms?
4. **If you have not had COVID-19 personally: What preventive steps or care did you look for to help protect your health?**

[HCPs]

1. **Tell me about your experiences treating patients with COVID-19.**
2. **What treatments are you aware of for COVID-19, and what is your experience with those treatments in your practice?**
3. **How do you learn about new treatments or therapies for COVID-19?**
4. What kinds of questions do your patients have about treatments for COVID-19?
 - a. What information would be helpful for conversations with patients?
 - b. What information do you feel you are missing, right now, when it comes to treatments for COVID-19?

[MONTH 1 ONLY: CLINICAL TRIAL KNOWLEDGE AND EXPERIENCE]

[CONSUMERS]

1. **POLL. Have you or someone you know ever participated in a clinical trial?**
 - 1) Yes
 - 2) No
2. If you or someone you know have personally taken part in a clinical trial, how did you/they find out about it and what made you/them decide to participate?
3. If you haven't participated in a clinical trial, tell me more about your thoughts on participating in a clinical trial.
4. Tell me about any clinical trials you have heard of for COVID-19, and your thoughts about participating or not participating in one.

[HCPs]

1. Describe your familiarity with clinical trials, and what your professional experience with them has been.

2. Have you ever referred a patient to a clinical trial? Why or why not?
3. What would change your mind (positively or negatively) about referring patients to a clinical trial?
4. How familiar are you with any clinical trials for COVID-19?
 - a. Would you be more or less likely to share information with a patient about trials for COVID-19 treatment, compared to other kinds of clinical trials? What considerations would you have?

[MONTH 1 ONLY]: TRUSTED SOURCES OF INFORMATION

Next, we are interested in hearing about your preferences looking for information about COVID-19 treatments.

Below is a list of sources people might use for COVID-19 treatment information. Please select the top three you trust the most to give you information about COVID-19 treatments and let us know why you picked these:

PROFESSIONAL ASSOCIATIONS/ORGANIZATIONS/INSTITUTIONS

- Association (Specify which one: _____)
- Hospital/health clinic
- Non-profit organization (Specify which one: _____)
- Government agency (Specify which one: _____)

HEALTH PROFESSIONALS

- Doctor (primary care doctor or specialist doctor) (Specify which one: _____)
- Nurse
- Physician assistant
- Social worker
- COVID-19 testing site staff

COMPLEMENTARY AND INTEGRATIVE MEDICINE PROVIDERS

- Acupuncturist
- Chiropractor
- Herbalist/natural medicine practitioner

ACQUAINTANCES/LOVED ONES

- Co-worker/colleague
- Family member/spouse/partner
- Friend/peer
- Support group
- Someone else in your local community, school, or faith organization

MEDIA

- Magazine (Specify which one: _____)
- Newspaper (Specify which one: _____)
- Radio station (Specify which one: _____)
- Television station (Specify which one: _____)
- Podcast (Specify which one: _____)
- Scientific journal (Specify which one: _____)

INTERNET/SOCIAL MEDIA

- Online search (Specify which ones: Google, Bing, etc.: _____)
- Online discussion group (Specify which one: _____)
- Social media (Specify which ones: Facebook, Instagram, Snapchat, Twitter, LinkedIn, etc.: _____)
- Websites (Specify which ones: _____)
- Website of medication manufacturer (Specify which ones: _____)

OTHER, please specify: _____: (1) _____ ,
(2) _____ and (3) _____.

Of the following, how do you prefer to receive information about COVID-19 treatments? Please select your top two preferred formats and let us know why you picked them:

- Brochure
- Email
- Infographic
- In-person conversation
- Fact sheet
- Podcast
- Poster
- Social media post (e.g., Facebook, Instagram, Snapchat, Twitter, LinkedIn)
- Regular mail
- Video
- Webinar
- Website
- Other, please specify: _____: (1) _____ and
(2) _____.

If you only had the following two options, do you prefer reviewing health information in print form or in digital/electronic form? PICK ONLY ONE.

_____ Print form
_____ Digital/electronic form

MESSAGE TESTING

MESSAGE OR AD CONCEPT QUESTIONS TO REMAIN THE SAME ACROSS MONTHS; HOWEVER NEW AD MESSAGES/CONCEPTS WILL BE PRESENTED TO PARTICIPANTS BASED ON EACH UNIQUE TOPIC

Please review each of the following communication materials and respond to the review prompts. Thank you in advance for responding to these prompts about the test communication materials!

[REVIEW PROMPTS]

1. **One thing in this [test communication material] that grabbed your attention and why (for example, what was something surprising or new to you?).**
2. **How clear and easy to understand is this [test communication material]? If there was something confusing to you, let us know what it was, why, and any suggestions you might have for wording it more clearly.**
3. **POLL. To what degree do you feel like this [test communication material] is speaking directly to you, like the [test communication material] understands you and your situation?**

1 to 7 scale, 1 is "Not at all relatable" and 7 is "Extremely relatable."

4. **How did reading [test communication material] change your thoughts about clinical trials for COVID-19 treatments? What, if anything, might you do differently after reading this [test communication material] (this includes learning more about this topic)?**

[CONSUMERS]

1. Available COVID-19 Treatment Options [CLICK HERE TO REVIEW]




Page 1 of 2



AVAILABLE COVID-19 TREATMENT OPTIONS

If you or a loved one test positive for COVID-19, you may now have treatment options. COVID-19 treatment options are available for patients with mild to moderate symptoms and for hospitalized patients. Mild symptoms may include fever, cough, sore throat, malaise (feeling unwell), headache, muscle pain, nausea, vomiting, diarrhea, and loss of taste and smell. Moderate symptoms may also include shortness of breath.

The U.S. Food and Drug Administration (FDA) has authorized treatments for emergency use. Talk to your healthcare provider about treatment options. Your healthcare provider will know the best option for you, based on your symptoms and your health history. If you do not have a healthcare provider, call 1-877-332-6585 to find out who to talk with about your symptoms and treatment.

TREATMENT FOR NON-HOSPITALIZED COVID-19-POSITIVE PATIENTS	
 Monoclonal antibodies attack the virus	
 SYMPTOMS	Mild to moderate
 REQUIREMENTS	Healthcare provider's referral, receiving treatment within 10 days of having the first symptoms of COVID-19, 12 years of age or older, high risk status* including obesity, diabetes, chronic kidney disease, weakened immune system, or taking a medicine that weakens the immune system.

*Click [here](#) to learn more about high risk status.

OUT-OF-HOSPITAL TREATMENT OPTIONS FOR PATIENTS WITH MILD TO MODERATE COVID-19 ILLNESS

The following treatments have been authorized for emergency use by the FDA for non-hospitalized patients with mild to moderate cases of COVID-19. The FDA has determined that the known and potential benefits of these treatments for non-hospitalized patients are greater than the treatments' known and potential risks.

Monoclonal antibody treatments: The FDA has issued Emergency Use Authorization for two investigational monoclonal antibody treatments that can attach to SARS-CoV-2, the coronavirus that causes COVID-19. These antibodies could help your immune system recognize and respond more effectively to the virus.

These treatments have been authorized for patients with mild to moderate cases. This includes those who have had symptoms for 10 days or less, who are 12 years of age and older, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. It also includes people who are 65 years old or older, and for people who have certain chronic medical conditions. Learn more about antibody treatments with: [etesevimab and bamlanivimab](#) or [casirivimab and imdevimab](#).

There is no cost for the antibodies themselves, but the facility may charge for the infusion (giving the treatment by IV). Medicare covers the IV treatment costs, but Medicaid coverage is different in each state. Many large private insurance plans cover all costs, but you should check with yours to find out for sure. If you do not have insurance, ask the treatment facility if there are any fees.

Learn what monoclonal antibodies are and how they can help

HOSPITAL TREATMENTS FOR PATIENTS WITH SEVERE COVID-19 ILLNESS

The following treatments for hospitalized patients with severe cases of COVID-19 have been approved or authorized for emergency use by the FDA.

Remdesivir: This is the first drug approved by the FDA for the treatment of COVID-19 in hospitalized adults and hospitalized pediatric patients at least 12 years of age. Remdesivir, also known as Veklury®, is in a class of treatments called antivirals. It works by stopping SARS-CoV-2 from spreading in the body.

Other available COVID-19 treatments: Other drugs and treatments are used to slow or reduce the virus' growth and spread in the body, as well as to enhance breathing, provide disease-fighting antibodies developed in labs, and help with other symptoms.

TREATMENT OPTIONS FOR HOSPITALIZED COVID-19 PATIENTS			
TREATMENT	SYMPTOMS	INTERVENTIONS	REQUIREMENTS
Remdesivir attacks the virus	Moderate to severe	May be on oxygen, high-flow oxygen, or non-invasive ventilation	Healthcare provider's recommendation
Convalescent plasma attacks the virus and reduces some inflammation	Moderate to severe	May be on oxygen, high-flow oxygen, or non-invasive ventilation	Healthcare provider's recommendation
Baricitinib reduces inflammation (immune response)	Moderate to severe	On oxygen, high-flow oxygen, or non-invasive or invasive ventilation	Healthcare provider's recommendation
Corticosteroids reduce inflammation (immune response)	Moderate to severe	On oxygen, high-flow oxygen, or non-invasive or invasive ventilation	Healthcare provider's recommendation

CLINICAL TRIALS FOR NEW COVID-19 TREATMENTS

Because the coronavirus that causes COVID-19 is a novel or new virus, we are still learning about it. Hundreds of clinical studies (also known as [clinical trials](#)) for COVID-19 treatments are underway now, and many other clinical trials are looking for volunteers.

The participation of patients with COVID-19 in clinical trials is critical to finding effective treatments. One of the largest needs is for a diverse population of individuals from all backgrounds. Scientists need to test treatments and vaccines in all populations, including Black, Hispanic, and Native American communities, to be sure the treatments and vaccines work in all people affected by COVID-19.

[Find a clinical trial](#)



2. **I've Never Had COVID-19 [CLICK HERE TO REVIEW]**

Page 1 of 2



I'VE NEVER HAD COVID-19

Information on COVID-19 risks and how you can help prevent the disease.

AM I AT RISK?

COVID-19 spreads easily and is mainly transmitted from person to person when respiratory droplets are expelled as a person talks, coughs, or sneezes. It can also be spread when people come into contact with droplets containing the virus by touching the surface where the droplets are, then touching their faces. People of any age can get COVID-19. Older adults and people with underlying conditions are at increased risk for severe illness from COVID-19.

Underlying Conditions

Older adults and people with underlying conditions, such as cancer, heart and lung conditions, type 2 diabetes, kidney disease, obesity, sickle cell, or compromised immune systems are known to have increased risks for severe cases of COVID-19.



Find out how you can participate in a vaccine or other prevention trial.

ENROLL NOW [↗](#)

How Can I Participate in a Clinical Trial for a New Vaccine and Other Preventions?

Clinical trials help advance our understanding of diseases and find new ways to prevent, diagnose, and treat illnesses such as COVID-19. Multiple agencies and institutions are recruiting participants for COVID-19 vaccine and other prevention trials. Safe and effective vaccines and other preventions that work for most people are only possible when volunteers from all walks of life participate in the development of those vaccines and other preventions by joining clinical trials.

If you would like to participate in a prevention clinical trial, visit preventcovid.org [↗](#)



WHEN CAN I GET A COVID-19 VACCINE?

Vaccines are an important strategy to prevent illness and are very effective. Diseases that were once commonplace and deadly have been eliminated or significantly diminished thanks to vaccines. Keep in touch with your healthcare providers to find out when a vaccine will be available to you.

HOW DO VACCINES WORK?

Simply put, a vaccine trains the immune system to recognize certain pathogens such as viruses and bacteria. The human body produces proteins called antibodies to fight the pathogens. By introducing weakened or killed strains (or parts) of viruses, bacteria, fungi, or parasites, the body can safely develop antibodies that can recognize and fight a full-scale infection caused when the pathogens multiply and affect normal processes in the body.



ARE VACCINES SAFE? WHAT ARE THE RISKS AND SIDE EFFECTS?

Safety is the top priority in the development of vaccines, from beginning to end. FDA-approved vaccines are safer than the diseases they are meant to prevent. Side effects from vaccines are usually mild and don't last long. Common side effects are discomfort where the injection is given, tiredness, headaches, chills, mild fever, and muscle or joint aches. More serious side effects are very rare and include allergic reaction in one or two people per million. Vaccines go through three phases of rigorous testing and the United States requires that side effects be tracked and monitored to ensure continued safety even after vaccines have been thoroughly tested and reviewed before approval by the Food and Drug Administration (FDA).

Rigorous Testing

Vaccines go through rigorous laboratory testing before being tested on humans. If the FDA determines that a vaccine candidate is safe to use in people, clinical trials commence with about 20 to 100 volunteers. Depending on the results with these initial volunteers, the testing is expanded to include thousands of people before the safety and effectiveness data about the vaccine are submitted to the FDA for review.



HOW GETTING YOUR FLU SHOT CAN HELP

Getting your flu vaccination reduces the number of people who get the flu. This reduces the demand on healthcare resources as many healthcare systems are stressed by the number of COVID-19 patients they are treating.

Influenza

The flu is a contagious viral respiratory illness caused by influenza viruses. According to the Centers for Disease Control and Prevention, it kills between 12,000 and 61,000 annually. Young children, older adults, pregnant women, and people with chronic health conditions are most at risk from developing serious complications. The best way to protect yourself and others is to get your flu shot.

SYMPTOMS OF COVID-19 AND FLU

Many early symptoms of COVID-19 and the flu are similar and testing may be needed to confirm a diagnosis:

COVID-19

- Cough
- Congestion or runny nose
- Difficulty breathing or shortness of breath
- Fatigue
- Fever or chills
- Headache
- Muscle or body aches
- Nausea or vomiting
- Diarrhea
- Sore throat
- Loss of taste or smell

Influenza


- Cough
- Congestion or runny nose
- Difficulty breathing or shortness of breath
- Fatigue
- Fever or chills
- Headache
- Muscle or body aches
- Nausea or vomiting (more common in children)
- Diarrhea
- Sore throat

^ Top

[HCPs]

1. **High-Risk COVID-19 Patients May Avoid Hospitalization with Monoclonal Antibody Treatment [CLICK HERE TO REVIEW]**

Page 1 of 2



High-Risk COVID-19 Patients May Avoid Hospitalization with Monoclonal Antibody Treatment

Is My Patient Eligible for Treatment?

On May 14, 2021, the FDA updated the Emergency Use Authorizations for COVID-19 monoclonal antibodies. These updates expand the definition of "high-risk" patients who are eligible for treatment and provide greater latitude to healthcare providers to exercise their clinical judgment.

- Clinicians may now refer any adult or pediatric (age 12 years and older and ≥ 40 kg) patient if they have a medical condition or other factor, including race/ethnicity, that puts them at higher risk for progressing to severe COVID-19.
- Eligibility is not limited to the medical conditions and factors listed below.
- For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>


Your patient may be eligible for monoclonal antibody treatment if they meet the following criteria¹:

- Are an adult or pediatric (≥ 12 years of age and weighing at least 40 kg) patient
- Experienced the **onset in the last 10 days** of mild to moderate symptoms of COVID-19
- Have a positive test for COVID-19
- Are at high risk for progressing to severe COVID-19 and/or hospitalization; high-risk factors include but are not limited to:
 - Age ≥ 65 years of age
 - Obesity or being overweight based on CDC clinical growth charts²
 - Pregnancy
 - Chronic kidney disease
 - Diabetes
 - Immunosuppressive disease or immunosuppressive treatment
 - Cardiovascular disease or hypertension
 - Chronic lung diseases
 - Sickle cell disease
 - Neurodevelopmental disorders
 - Having a medical-related technological dependence (for example: tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19)

For more detail on the eligibility criteria for the authorized treatments, see the Fact Sheets on the FDA website.¹

To guide treatment decisions, you should:

- Review the antiviral resistance information in Section 15 of the authorized fact sheets¹ for each monoclonal antibody therapy available under EUA for details on specific variants and resistance, and
- Refer to the CDC website, as well as information from state and local health authorities, for reports of viral variants in their region.²



M02.51E English: [CombatCOVID.hhs.gov](https://www.combatcovid.hhs.gov) • 1-877-332-6585 Spanish: [CombateCOVID.hhs.gov](https://www.combatecovid.hhs.gov) • 1-877-366-0310 05/18/21
1



Early Action Is Vital

Early testing, identification, and referral are vital to access to monoclonal antibody treatment. So, consider:

- Discussing monoclonal antibodies, the importance of reporting symptoms, and COVID-19 testing with your high-risk patients during routine care appointments
- Pre-identifying patients who may be eligible for monoclonal antibody treatment

Your patient is **not** eligible for treatment if they:

- 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 for those on chronic oxygen therapy due to an underlying non-COVID-19 related comorbidity.

How to Find Infusion Locations

You can find infusion locations in your area:

- by visiting <https://protect-public.hhs.gov/pages/therapeutics-distribution>, OR
- by calling **1-877-332-6585** for English, or **1-877-366-0310** for Spanish

Contact the infusion location(s) to learn their referral procedures and whether they are accepting new patients.

For more information, visit
CombatCOVID.hhs.gov

English: 1-877-332-6585 • Spanish: 1-877-366-0310



COMBATCOVID




References

1. FACT SHEETS FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB AND ETESEVIMAB (revised March 14, 2021) and CASIRIVIMAB AND IMDEVIMAB
<https://www.fda.gov/media/145802/download>
<https://www.fda.gov/media/145611/download>
2. CLINICAL GROWTH CHARTS. Centers for Disease Control and Prevention.
https://www.cdc.gov/growthcharts/clinical_charts.htm
3. Variant Proportions in the U.S. (May 11, 2021). Centers for Disease Control and Prevention.
<http://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html>

2. **Talking with Patients about Monoclonal Antibodies for COVID-19: Tips and Frequently Asked Questions [CLICK HERE TO REVIEW]**

Page 1 of 3



Talking with Patients about Monoclonal Antibodies for COVID-19: Tips and Frequently Asked Questions

Early treatment with monoclonal antibodies may prevent your high-risk COVID-19 patients from progressing to more severe disease or hospitalization.

Tips for Talking with High-Risk Patients about Monoclonal Antibody Treatment

- Talk with your patients about receiving the treatment quickly after COVID-19 symptoms appear.
- Ensure your patients know that monoclonal antibody treatment may help increase their chances of recuperating at home and avoid hospitalization.
- Discuss the availability and potential benefits of monoclonal antibody treatment during routine in-person or telehealth visits with high-risk patients. This allows patients to learn about the treatment prior to potential COVID-19 infection, when they may be under stress and ill.
- Share key facts:
 - Monoclonal antibody treatments are authorized by the FDA.
 - Data from clinical trials indicates that treatments may reduce hospitalizations for high-risk patients.
 - Treatments are generally available at little or no cost to eligible patients.

Frequently Asked Patient Questions

Q: Why should I seriously consider monoclonal antibody treatment?

A: If you are high risk, develop mild to moderate symptoms, and test positive for COVID-19, early treatment with monoclonal antibodies may prevent progressing to more severe disease and hospitalization.

Q: Why am I eligible for the treatment?

A: Monoclonal antibody treatments may help people who:

- Have mild to moderate symptoms of COVID-19, and
- Have tested positive for COVID-19, and
- Have had symptoms for 10 days or less, and
- Are at high risk of getting more serious symptoms


You can learn more about treatment eligibility at: <https://combatcovid.hhs.gov/i-have-covid-19/how-do-i-know-if-im-high-risk>

Q: What are monoclonal antibodies?

A: Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful viruses like SARS-CoV-2. Monoclonal antibodies attack the virus and reduce its ability to spread through your body.

M06.51E English: [CombatCOVID.hhs.gov](https://combatcovid.hhs.gov) • 1-877-332-6585 Spanish: [CombateCOVID.hhs.gov](https://combatecovid.hhs.gov) • 1-877-366-0310 05/24/21

1




Talking with Patients about Monoclonal Antibodies for COVID-19: Tips and Frequently Asked Questions

Q: How do I get treatment?

A: If you have had symptoms for 10 days or less and have tested positive for COVID-19 and you are high risk, I can refer you to receive treatment. The infusion itself will take from about 15 minutes to an hour, and you will be at the facility for two to three hours.

Q: Where can I get treatment?

A: We can locate the nearest treatment site by using the information provided by the U.S. Department of Health and Human Services, which is carefully tracking distribution on their website at: <https://protect-public.hhs.gov/pages/therapeutics-distribution>. You can also reach them over the phone at 1-877-332-6585 (for English) or 1-877-366-0310 (for Spanish).



Q: Are there side effects?

A: Some side effects are possible.^{1,2} An infusion of any medicine may cause brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. Allergic reactions may happen during and after an antibody infusion. Trained healthcare staff will monitor you for allergic reactions. While side effects are possible, antibody treatments do not contain any live virus. There is no risk you will get COVID-19 from monoclonal antibody treatments.

Q: What are the chances it will work?

A: Patient data from clinical trials showed that high-risk COVID-19 patients treated with monoclonal antibodies had a 70% reduction in relative risk of progression to severe disease or hospitalization compared to patients who did not receive monoclonal antibodies.³ The treatment is most effective when given shortly after symptoms appear, so it is important to get tested and treated as soon as possible.

Q: If I receive monoclonal antibodies, do I have to isolate?

A: Yes. You must still follow isolation requirements to protect yourself and others.

Q: Can I still get the COVID-19 vaccine if I receive monoclonal antibodies?

A: Yes, but you should wait 90 days after treatment to get the vaccine.

M06.51E English: [CombatCOVID.hhs.gov](https://combatCOVID.hhs.gov) • 1-877-332-6585 Spanish: [CombateCOVID.hhs.gov](https://combateCOVID.hhs.gov) • 1-877-366-0310 05/24/21
2



Talking with Patients about Monoclonal Antibodies for COVID-19: Tips and Frequently Asked Questions

Q: If I have received the vaccine, can I still receive the monoclonal antibody treatment?

A: Yes. Patients who develop COVID-19 infection despite vaccination may receive monoclonal antibody treatment.

Q: How much will the treatment cost? Is it covered by insurance?

A: Because the federal government has purchased a supply of monoclonal antibody treatments, there is no cost to the patient for the antibody product itself. Depending on your insurance coverage, you may or may not need to pay for a provider to administer the infusion. For many, infusion administration will have no cost. In particular:

- Medicare is covering all infusion costs. Learn more about Medicare coverage of the treatment at: <https://www.cms.gov/files/document/covid-infographic-coverage-mono-clonal-antibody-products-treat-covid-19.pdf>
- Medicaid coverage of infusion cost varies by state.
- For patients covered under commercial insurance plans, costs of infusion may vary, but many large insurers are waiving all costs. Check with your health plan.
- If you do not have insurance, you should ask the treatment facility if there are charges.

For more information, visit
CombatCOVID.hhs.gov

English: 1-877-332-6585 • Spanish: 1-877-366-0310



COMBATCOVID

References

1. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV™ (Casirivimab with Imdevimab) (Revised version, May 14, 2021) <https://www.fda.gov/media/145611/download>
2. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab (Revised version, May 14, 2021) <https://www.fda.gov/media/145802/download>
3. Center for Drug Evaluation and Research (CDER). (2021). Emergency Use Authorization (EUA) for Bamlanivimab 700 mg and Etesevimab 1400 mg IV Administered Together, Center for Drug Evaluation and Research (CDER) Review. U.S. Food and Drug Administration. <https://www.fda.gov/media/146255/download>



INFORMATION RECALL

Which ONE piece of information do you remember MOST clearly?

- a. What was it about that information that made it stand out to you?
- b. What do you remember about the wording/text/visuals/images of that information?
- c. What do you feel the main idea of that information was trying to communicate?
- d. What is one new thing you learned from that information?

CLOSING POLL :

[CONSUMERS]

[MONTH 1:]

1. **How likely are you to find out more about clinical trials for COVID-19 treatments?**
2. **If you or a loved one had COVID-19, how likely are you to participate in a trial for COVID-19 treatments?**

1 to 7 scale, 1 is "Not at all likely" and 7 is "Extremely likely."

Why did you rate this question in this manner?
Where would you go for more information?

[SUBSEQUENT MONTHS:]

1. **Since our last discussion, have you taken any action to find out more about clinical trials for COVID-19 treatments?**

Yes/No

If yes, what action did you take?
If no, why did you choose not to take action?

2. **Compared to a few months ago, how likely are to consider a clinical trial for COVID-19 treatment for yourself?**

More likely, no change, less likely

Why did you choose your answer?

3. **Compared to a few months ago, how likely are to consider a clinical trial for COVID-19 treatment for a loved one?**

More likely, no change, less likely

Why did you choose your answer?

[HCPs]

[MONTH 1:

1. **How likely are you to find out more about clinical trials for COVID-19 treatments?**

1 to 7 scale, 1 is “Not at all likely” and 7 is “Extremely likely.”

Why did you rate this question in this manner?
Where would you go for more information?

2. **How well-prepared do you feel to answer patients’ questions about clinical trials for COVID-19 treatments?**

1 to 7 scale, 1 is “Not at all prepared” and 7 is “Extremely prepared.”

Why did you rate this question in this manner?
Where would you go for more information?]

[SUBSEQUENT MONTHS:

1. **Compared to a few months ago, how likely are you to share information about clinical trials for COVID-19 treatments with patients?**

More likely, no change, less likely

Why did you choose your answer?

2. **Compared to a few months ago, how likely are you to share information about clinical trials for COVID-19 treatments with other providers?**

More likely, no change, less likely

Why did you choose your answer?]

Finally, please share any additional questions you have about clinical trials to find new, better treatments for COVID-19.

CLOSE

Those are all the questions we have. Thank you very much, again, for participating and be well!