BlueCross BlueShield Arizona

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FAQs: BCBSAZ Monoclonal Antibody Treatment Program for High-Risk Members

12/30/21 UPDATE: In response to new FDA information about the Omicron variant, this program is **TEMPORARILY PAUSED** and is **NOT CURRENTLY ACCEPTING PATIENT REFERRALS** from providers. We hope to resume once the sotrovimab therapeutic is more widely available.

BACKGROUND Information

Blue Cross® Blue Shield® of Arizona (BCBSAZ) remains committed to partnering with providers to prevent unnecessary hospitalizations and deaths from COVID-19. Our monoclonal antibody (mAb) outpatient referral program targets high-risk members who have tested positive for COVID-19 and have mild to moderate symptoms. We are now accepting orders from network providers for treatment through the program. **The program has been paused and referrals are not accepted at this time.**

What prompted BCBSAZ to launch a monoclonal antibody treatment program for high-risk members?

The COVID-19 pandemic has had an immense impact on the state's health system, causing many hospitalizations and claiming the lives of over 23,000[1]Arizonans. Thousands of new cases continue to be reported each day, threatening the well-being and lives of many, especially those at high risk for serious illness and complications from the coronavirus. BCBSAZ recognizes the life-saving potential of monoclonal antibody treatment and is committed to increasing awareness about its value. We want to ensure our eligible high-risk members have access to the treatment.

New question 12/30/21: Why has BCBSAZ paused the monoclonal antibody treatment program?

With the rise of COVID-19 infections from the Omicron variant, the FDA and U.S. Department of Health and Human Services have paused the distribution of the monoclonal antibody drugs that have been effectively used against earlier strains of the virus. The following therapeutics are less effective against the Omicron variant:

- Bamlanivimab and etesevimab together
- Etesevimab alone
- REGEN-COV

For this reason, we are temporarily pausing the Blue Cross® Blue Shield® of Arizona (BCBSAZ) monoclonal antibody (mAb) treatment program and are no longer accepting orders from network providers for treatment.

The sotrovimab therapeutic is active against Omicron but is still very limited in supply. We are hopeful that we can resume our program once sotrovimab becomes more widely available.

1. ABCs of Monoclonal Antibodies

What are monoclonal antibodies?

Antibodies are proteins the body makes to fight infection. "Monoclonal" antibodies (mAbs) are made in a laboratory through a safe and effective cloning process using a single white blood cell. Monoclonal antibodies can help someone fight an infection like COVID-19 and reduce severe illness, hospitalization, and death. They can also help patients fight serious diseases like cancer and rheumatoid arthritis.

[1] ADHS - COVID-19 Deaths (azdhs.gov)

How does monoclonal antibody treatment for COVID-19 work?

Healthcare professionals infuse a specific type of monoclonal antibody into high-risk patients who have tested positive for COVID-19 and have been experiencing mild to moderate COVID-19 symptoms within the previous 10 days. The treatment can be done at home or in an infusion center. It takes approximately one hour to complete the infusion, followed by a one-hour monitoring period to watch for signs of rare side effects. The monoclonal antibodies help the immune system fight the COVID-19 infection.

2. ABOUT the BCBSAZ Monoclonal Antibody (mAb) Treatment Program for High-Risk Members

What is the purpose of this program?

BCBSAZ remains committed to partnering with providers to prevent unnecessary hospitalizations and deaths from COVID-19. Our monoclonal antibody (mAb) outpatient referral program targets our high-risk members who have tested positive for COVID-19 and have mild to moderate symptoms. Our goal is to help save lives and prevent unnecessary hospitalizations from COVID-19.

How does the program work? THE PROGRAM IS TEMPORARILY PAUSED as of 12/30/21

We accept orders from network providers who have identified high-risk BCBSAZ members who have had a positive COVID-19 PCR test within the past 10 days and are clinically eligible to receive mAb treatment. You must use the BCBSAZ therapy order form to refer patients into the program. We also use certain lab claim data to identify and reach out to high-risk members who have recently tested positive for COVID-19. To qualify for mAb treatment through this program, the patient meet all of the following criteria:

- Have had a positive COVID-19 PCR test within the last 10 days
- Have mild to moderate symptoms
- Be 5 years or older and considered high-risk for serious illness or hospitalization from COVID-19

For more information about mAb treatment and patient eligibility, see the NIH guidance for therapeutic management of non-hospitalized individuals.

Where do I find the order form to refer a patient into the program? REFERRALS ARE NOT ACCEPTED AT THIS TIME

You can find the BCBSAZ order form on our provider COVID-19 updates webpage. All fields on the form are required. When our BCBSAZ Care Management team receives your completed order, we'll work with certain mAb infusion providers to coordinate treatment scheduling.

Can I become a designated treatment provider for this program?

We are working with certain mAb infusion providers who have agreed to deliver timely outpatient treatment for our high-risk members. Although we are not partnering with other providers at this time, we will be tracking data and demand for treatment closely. This program may expand and include more treatment providers in the future.

Will referring providers be notified that their patients have received treatment through this program?

Yes. The BCBSAZ Care Management team and the designated treatment providers will coordinate care. Referring providers will be informed that their patients have received the treatment.

Is prior authorization required for this treatment?

No. The intake process will follow recommended clinical guidelines to determine the appropriateness of the treatment for the patient's condition.

Will patients receive information about monoclonal antibody treatment?

Yes. The infusion providers will answer any questions from patients. They will also share the mAb manufacturer's patient information at the time of treatment and offer a consultation with a pharmacist.

Does mAb treatment require follow-up care?

Yes. Seven days after the infusion, patients will receive a follow-up call from the infusion provider to check on symptoms and side effects.

Can I refer my patients to this program for mAb treatment? N/A at this time

Yes. We are now accepting treatment referrals from providers. If you have BCBSAZ patients (age 5 and older) who have tested positive for COVID-19 and have mild to moderate symptoms, use the BCBSAZ therapy order form to refer them into the program. For more information, see the NIH guidance for therapeutic management of non-hospitalized individuals.

Is this BCBSAZ program open to all members?

Our mAb treatment program targets members (age 5 and older) who are at high risk for severe COVID-19 illness, hospitalization, and death. It includes members with BCBSAZ fully insured plans, self-funded group plans, and Medicare Advantage plans. The program does not include members with Medicare Supplement plans, Federal Employee Program® (FEP®) plans, or those with BlueCard® plans issued by other BCBS Plans.

What service areas does the program cover?

The mAb treatment is offered across Arizona. Members living in more remote areas may be invited to travel to an outpatient infusion center for treatment.

How can I become an mAb treatment provider?

If you are interested in becoming an mAb treatment provider or requesting mAb products for COVID-19 treatment, please visit the ADHS mAb webpage for more information.

3. MORE ABOUT Monoclonal Antibody (mAb) Treatment

Is monoclonal antibody treatment for COVID-19 safe?

The Food and Drug Administration (FDA) has deemed certain monoclonal antibody treatments to be safe and effective for people with COVID-19 and has issued an emergency use authorization (EUA) for their use. The National Institutes of Health (NIH) has issued guidelines for the use of monoclonal antibody treatments for high-risk individuals of all ages, including newborns, who have tested positive for COVID-19 and have mild to moderate COVID-19 symptoms (within the previous 10 days).

What are the benefits?

The most significant benefit of receiving monoclonal antibody treatment for COVID-19 is the reduced likelihood of severe COVID-19 illness and complications, hospitalization, and death.

What are the possible side effects of this treatment?

The side effects of receiving any medication through infusion may include temporary pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the injection site. Allergic reactions may occur and can be life-threatening for some people. All patients receiving mAb treatment are

closely monitored during and at least one hour after the infusion. Other possible side effects can include nausea, vomiting, and itching.

Where can I find more information about monoclonal antibody treatment for COVID-19?

Monoclonal antibody treatment (for high-risk individuals of all ages who meet eligibility requirements) has received emergency use authorization from the FDA because it is proving to be effective in reducing severe COVID-19 illness and preventing hospitalization and death. For more information, visit the NIH (clinical guidance), HHS (logistics of mAb treatments distribution), and ADHS (Arizona state information) webpages about mAb therapeutics.

What if I have questions about your program?

If you have questions, contact our Care Management team at COVIDmabs@azblue.com or 602-544-8982.