

Monoclonal Antibody Treatment for COVID 19

Provider Scripting

12/9/2020

A SUGGESTED APPROACH TO DISCUSSING MONOCLONAL ANTIBODY THERAPY WITH A COVID POSITIVE PATIENT.

This discussion presupposes the following:

- The patient's presentation is suspicious for COVID 19
- The patient is mildly to moderately ill
- The patient does not require hospitalization currently.

Subsequently, the patient would need to be proven to be COVID positive; have no history of difficulties with antibody therapy and passes inclusion/exclusion criteria screening as enclosed.

Voice is that of the Doctor:

I'm concerned that you may have contracted COVID. It could be the flu or other illnesses, but COVID is high on the list.

I would like you to be tested right away for COVID and for Flu

I see that you are over 65, and I know that you have chronic health problems such as diabetes, and you are overweight.

These are factors that raise the chances that you might be at risk for hospitalization for worsening infection if you do indeed have COVID.

What are the options?

*There are some new therapies that just recently became available to us. They are still considered **experimental**.*

You are under no obligation to accept the treatment; it isn't guaranteed to prevent progression, but early reports suggest it can be highly effective at preventing disease progression. In other words, they reduce your chances of getting sicker, requiring hospitalization, and requiring the use of breathing machines

Would you be interested in learning more, or having this kind of treatment?

Yes? Ok, then let's review your record again.

I see no reason why you shouldn't be a possible candidate for this treatment.

Here's how it happens

It is given by an infusion through the veins, so it means a needle stick.

It's done at the Hospital, but as an outpatient.

It takes about an hour to give the medication, but we watch you for at least an hour afterwards.

Most people can drive themselves home.

Does it work?

Yes, according to preliminary reports. But I can't guarantee it, and remember, it is still in the testing stage.

What are the risks?

There is always a chance of a problem with your IV, but these are rare. It's possible that you might react to the drug itself. Some people may develop rash, swelling, nausea, difficulty breathing- things usually associated with an allergic reaction. However, these appear so far to be very rare with these medications. I must tell you, though, that because this is so new and experimental, we simply don't know of all the potential and even delayed side effects.

One thing that might help you to decide, if you are still interested to this point, is to use the Cleveland Clinic calculator to tell you about your risk of disease progression (PERFORM)

OK, here's what comes next.

We need to be sure that your questions have been answered, and that you have been given or will be receiving these patient information materials about the experimental COVID treatment we just discussed. We need you to read them since, if your test is positive, you will have to provide consent before we can order the treatment.

Test for COVID is positive

You are mildly sick right now, and I don't think that you need to go to the Hospital- provided you don't become sicker. I would be worried if you developed headaches, slurred speech, fevers that don't come down, severe intestinal problems, leg swelling, chest pain or difficulty breathing, among other COVID-related symptoms.

If any of those things happen to you, don't wait. Go right to the Hospital.

Still interested in treatment for COVID?

Let's review things to make sure you still qualify for treatment. Do you have any questions about the treatment? If you feel all of your questions have been answered, we need you to either sign this form in front of me and other witnesses, or engage in a further telephone or video conversation with me whereby you say that you:

- *Agree to accept monoclonal antibody therapy for treatment of COVID 19*
- *That we have discussed risks and benefits*
- *That we have discussed options including no therapy*
- *That this is experimental treatment*
- *That even with treatment you will still be required to mask and isolate according to health department rules.*

We will ask to have two witnesses; one may be from your family or household who will witness your verbal consent; and one or more from my office who will do the same.

What happens now?

First and foremost, you are to rest and take good care of yourself!

I will contact the hospital to see if we can get you on the list for treatment. Remember, we don't have much of this to dispense yet, so the answer may be that we can't get you treated before ten days have passed from the day you first became ill. If we hit ten days- the drug can't be given.

If there IS drug available for you, you will be contacted by the infusion center, who will take it from there. If there is no drug available but a chance that more will be delivered prior to your ten-day mark, we will place you on a waiting list.

Please review the paperwork, and reach out to me should you have any questions or concerns