

HMH_151i

COVID mAb Infusion Pathway

Patient Pathways

Key

Alert	Short-form notifications designed for more time-sensitive information. Patients receive via either: <ol style="list-style-type: none">1. App notification2. Text message/phone call
Education	Longer-form, less time sensitive Information. Patients receive via either: <ol style="list-style-type: none">1. App notification2. Email
Monitoring Survey	Specialized alerts that ask patients a specific question and depending on the response, a notification will be sent to Care Navigator dashboard

Pathway Content

Anchor: Day patient is scheduled to receive bamlanivimab infusion

Day: 0 (Day of Sign Up)

Group: ALL PATIENTS SCHEDULED TO bamlanivimab infusion

Good day from Houston Methodist! You are receiving this message because you already received or are going to receive a therapy in one of our Houston Methodist facilities. If you have an upcoming appointment for the therapy, you can view it in MyChart, located [here](#). If you do not have a MyChart account, you can register as a new user [here](#).

You do NOT need an authentication code to sign up. The site tells you how to access without a code. If you have any technical issues while trying to get into MyChart, please contact our customer service team at 832-667-5694. Please do not call the Emergency Department or Laboratory for your test results. These departments cannot access or communicate your results with you.

We will be sending you some important information about this medication. Please save us in your phone as "Houston Methodist." To stop receiving messages, text "STOP" at any time.



Anchor: Day patient is scheduled to receive bamlanivimab infusion

Day: 0 (Day of Sign Up)

Group: ALL PATIENTS SCHEDULED TO receive bamlanivimab infusion

Attachments:

Good day from Houston Methodist! We would like to take a minute to confirm some of your contact information.

- No Email
 - It looks like we don't have your email address on file. We use emails to provide you with important FAQs about your upcoming appointment. Would you like to provide it?
 - Yes
 1. What is your email address?
 - No
- Has Email
 - The following is the current email address we have on file for you: <patient's email.> Would you like to update this information? We use emails to provide you with important FAQs about your upcoming appointment.
 - Yes
 - What is your email address?
 - No
- Thank you for your response.

Anchor: Day patient is scheduled to receive bamlanivimab infusion

Day: -3 days prior to appointment

Group: ALL PATIENTS SCHEDULED TO RECEIVE DRUG

Subject: Houston Methodist: Important Information for COVID-19 Monoclonal Antibody Infusion Body:

Good day from Houston Methodist! We're contacting you through this method because your preferences indicate that you are comfortable receiving text messages and emails from Houston Methodist. Please be mindful that these texts and emails are not secure and pose some risks for disclosure, and by continuing, you are accepting these risks.

You are receiving this message because you are scheduled to receive a therapy in one of our Houston Methodist outpatient infusion clinics. Below you will find important information regarding the medication you will be receiving.

Below are some common questions related to the use of monoclonal antibody infusions.

Q: What are monoclonal antibody infusions, such as bamlanivimab and casirivimab/ imdevimab?

A: These are investigational medicines used in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. These are investigational drugs because they are still being studied.

The FDA has authorized the emergency use of antibody infusions for the treatment of COVID-19 under an Emergency Use Authorization (EUA).

Q: What is an Emergency Use Authorization (EUA)?

A: In an emergency, like a pandemic, the Food and Drug Administration (FDA) can make a judgment that it's worth releasing a product for use even without the typical timeline for a new vaccine or treatment. If there's evidence that strongly suggests that people have benefited from the therapy, the FDA can issue an emergency use authorization (EUA) to make it available to the public. Current studies strongly indicate that the infusion therapies are safe and effective in reducing hospitalizations related to COVID-19 and an EUA was given for them. The infusion therapies will continue to be studied.

Q: Are monoclonal antibody infusions such as bamlanivimab and casirivimab/ imdevimab safe and will they work?

A: This medication may help prevent patients from requiring hospitalization, reduce viral load, and minimize symptoms associated with COVID-19. However, there is currently limited evidence as studies remain ongoing. Serious and unexpected results may happen. These drugs are still being studied so it is possible that all of the risks are not known at this time.

Q: How will I receive monoclonal antibody infusions?

A: These are given to you through a vein (intravenous or IV) for at least 1 hour. You will receive one dose of IV infusion.

Q: What are the important possible side effects of or issues in having these therapies?

A: Possible side effects of bamlanivimab and casirivimab/ imdevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion.
- Tell your primary care physician (PCP) right away if you get any of the following signs and symptoms of allergic reactions: fever; chills; nausea; headache; shortness of breath; low blood pressure; wheezing; swelling of your lips, face, or throat; rash including hives; itching; muscle aches; and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

It is possible that antibody therapies could interfere with your body's own ability to fight off a future infection of COVID-19. Similarly, these therapies may reduce your body's immune response to a vaccine for COVID-19. Specific studies have not been conducted to address these possible risks. Talk to your primary care physician (PCP) if you have any questions.

Q: What other treatment choices are there?

A: The FDA may allow for the emergency use of other medicines. Go to <https://www.covid19treatmentguidelines.nih.gov/> for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19.

It is your choice to be treated or not to be treated with infusions. If you decide not to receive monoclonal antibody infusions or stop them at any time, it will not change the other medical care you receive.

Q: What if I am pregnant or breastfeeding?

A: There is limited experience treating pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving infusions may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

Q: How do I report side effects (or medical issues) with infusion therapies?

A: Tell your primary care physician right away if you have any medical issues that bother you or side effects that do not go away.

Q: I'm now feeling much better as a result of the infusion. Can I cut my isolation short & go back to work or resume activities as before?

A: No, unfortunately. Continue to limit exposure to other individuals for 10 days after your symptoms first appeared, your symptoms are improving, and you have had 24 hours fever free

without using fever reducing medicine. To remain in isolation means staying in your home, washing your hands, disinfecting commonly-shared hard surfaces, and staying at least 6-feet apart from others. You can return to work after you have met all of the requirements to end isolation.

Q: I feel better, and my employer wants me to get a new COVID-19 test before coming back in. Should I be retested?

A: It probably will not help you to be retested at this time. Studies show that many people who test positive will continue to test positive for up to three months. At any rate, you should stay in isolation for 10 days after your symptoms first appeared, symptoms are improving, and you have had 24 hours fever free without using fever reducing medications, after which you can return to work.

Q: I have COVID, but I'm not feeling that bad. Should I wait until my symptoms get worse before receiving the monoclonal antibody infusion?

A: It is recommended to receive treatment as soon as possible. In high-risk patients, receiving treatment earlier when symptoms are less severe may prevent progression of disease that would require hospitalization.

Q: Can I receive the COVID vaccine after having a monoclonal antibody infusion?

A: It is recommended that patients wait 90 days after receiving a COVID-19 monoclonal antibody treatment before taking the COVID-19 vaccine.

How can I learn more?

- Ask your primary care physician (PCP).
- Visit <https://www.covid19treatmentguidelines.nih.gov/>.
- Contact your local or state public health department.

Anchor: Infusion Appointment Date

Day: -1

Time:

Group: ALL PATIENTS SCHEDULED TO RECEIVE DRUG

Attachment:

Good day from Houston Methodist Hospital! With your upcoming appointment, we wanted to check in on your current symptoms.

When did your symptoms begin?

- 1-2 days ago
- 3-4 days ago

- c. 5-6 days ago
- d. 7-8 days ago
- e. 9+ days ago
- f. No symptoms present (asymptomatic)

1. As of today, how would you describe your symptoms?
 1. Improved
 2. Worsening
 3. No change

If the answer is “a. Improved” or “c. No change”, then respond with “That is good news! We will see you at your upcoming appointment.”

If the answer is “b. Worsening”, proceed to Question 2

2. Is it becoming more difficult to breathe?

If “YES”: Please contact your provider to discuss your worsening symptoms or consider going to the closest Houston Methodist Emergency Department.

If “NO”: Please consider contacting your provider to discuss your current symptoms.

Then close out the survey by saying: “Thanks so much for your time! If you need more information on COVID-19, please visit <https://www.houstonmethodist.org/coronavirus/>.”

Anchor: Day after infusion

Day: +1

Group:

Attachments:

Good day from Houston Methodist! We just wanted to check in on you. Are you feeling OK?

- Yes “Great! That’s wonderful to hear” [Then go to next question]
 - No: If they answer no, then say: Can you tell us more about what you’re experiencing?
 - Swelling in your face or throat [automatically respond to the patient: Contact your primary care provider or call 911 or go to the nearest ER]
 - Shortness of breath [automatically respond to the patient: If you have shortness of breath that you find concerning or persistent pain in your chest, please call 911 or go to your nearest ER.]
 - Fatigue, chills, nausea etc. [then move to next question]
 - Stress, fear, anxiety, or other mental health issues. [move to next question]
2. Would you like a phone call from a nurse to answer any COVID related questions?
 - Yes -- You just indicated that you want to speak to a nurse for COVID related issues. Is that what you intended?
 - If they press yes again, then we say: “Please expect a call back from Houston Methodist during work hours, which may come in as an unrecognized number on your

phone. We hope you try to take our call. Note that, due to patient volume, it could take us several business days for us to reach you. If you'd like to speak to someone sooner, please call your primary care physician. If you do not have one, call 713-790-3333, and they can direct you to a physician." [trigger alert to our nurses]

Anchor: Day after infusion

Day: +2

Group:

Attachments:

Subject: Houston Methodist: Important Information for COVID-19 Monoclonal Antibody Infusion

Body:

Good day from Houston Methodist! We might have already sent you this email previously. We're sending it again just to help refresh your memory. We're contacting you through this method because your preferences indicate that you are comfortable receiving text messages and emails from Houston Methodist. Please be mindful that these texts and emails are not secure and pose some risks for disclosure, and by continuing, you are accepting these risks.

You are receiving this message because you are scheduled or have already received therapy in one of our Houston Methodist outpatient infusion clinics. Below you will find important information regarding the medication you will be receiving.

Below are some common questions related to the use of monoclonal antibody infusions.

What are monoclonal antibody infusions, such as bamlanivimab and casirivimab/ imdevimab?

These are investigational medicines used in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. These are investigational drugs because they are still being studied.

The FDA has authorized the emergency use of antibody infusions for the treatment of COVID-19 under an Emergency Use Authorization (EUA).

What is an Emergency Use Authorization (EUA)?

In an emergency, like a pandemic, the Food and Drug Administration (FDA) can make a judgment that it's worth releasing a product for use even without the typical timeline for a new vaccine or treatment. If there's evidence that strongly suggests that people have benefited from the therapy, the FDA can issue an emergency use authorization (EUA) to make it available to the public. Current studies strongly indicate that the infusion therapies are safe and effective in reducing hospitalizations related to COVID-19 and an EUA was given for them. The infusion therapies will continue to be studied.

Are monoclonal antibody infusions such as bamlanivimab and casirivimab/ imdevimab safe and will

they work?

This medication may help prevent patients from requiring hospitalization, reduce viral load, and minimize symptoms associated with COVID-19. However, there is currently limited evidence as studies remain ongoing. Serious and unexpected results may happen. These drugs are still being studied so it is possible that all of the risks are not known at this time.

How will I receive monoclonal antibody infusions?

These are given to you through a vein (intravenous or IV) for at least 1 hour. You will receive one dose of IV infusion.

What are the important possible side effects of or issues in having these therapies?

Possible side effects of bamlanivimab and casirivimab/ imdevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion.
- Tell your primary care physician (PCP) right away if you get any of the following signs and symptoms of allergic reactions: fever; chills; nausea; headache; shortness of breath; low blood pressure; wheezing; swelling of your lips, face, or throat; rash including hives; itching; muscle aches; and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

It is possible that antibody therapies could interfere with your body's own ability to fight off a future infection of COVID-19. Similarly, these therapies may reduce your body's immune response to a vaccine for COVID-19. Specific studies have not been conducted to address these possible risks. Talk to your primary care physician (PCP) if you have any questions.

What other treatment choices are there?

The FDA may allow for the emergency use of other medicines. Go to <https://www.covid19treatmentguidelines.nih.gov/> for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19.

It is your choice to be treated or not to be treated with infusions. If you decide not to receive monoclonal antibody infusions or stop them at any time, it will not change the other medical care you receive.

What if I am pregnant or breastfeeding?

There is limited experience treating pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving infusions may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects (or medical issues) with infusion therapies?

Tell your primary care physician right away if you have any medical issues that bother you or side effects that do not go away.

I'm now feeling much better as a result of the infusion. Can I cut my isolation short & go back to work or resume activities as before?

No, unfortunately. Continue to limit exposure to other individuals for 10 days after your symptoms first appeared, your symptoms are improving, and you have had 24 hours fever free without using fever reducing medicine.. To remain in isolation means staying in your home, washing your hands, disinfecting commonly-shared hard surfaces, and staying at least 6-feet apart from others. You can return to work after you have met all of the requirements to end isolation..

I feel better, and my employer wants me to get a new COVID-19 test before coming back in. Should I be retested?

It probably will not help you to be retested at this time. Studies show that many people who test positive will continue to test positive for up to three months. At any rate, you should stay in isolation for 10 days after your symptoms first appeared, your symptoms are improving, and you have had 24 hours fever free without using fever reducing medications, after which you can return to work.

I have COVID, but I'm not feeling that bad. Should I wait until my symptoms get worse before receiving the monoclonal antibody infusion?

It is recommended to receive treatment as soon as possible. In high-risk patients, receiving treatment earlier when symptoms are less severe may prevent progression of disease that would require hospitalization.

Can I receive the COVID vaccine after having a monoclonal antibody infusion?

It is recommended that patients wait 90 days after receiving a COVID-19 monoclonal antibody treatment before taking the COVID-19 vaccine.

How can I learn more?

- Ask your primary care physician (PCP).
- Visit <https://www.covid19treatmentguidelines.nih.gov/>.
- Contact your local or state public health department.

Anchor: Continued follow-up after infusion

Day: +7

Group:

Good day from Houston Methodist! We just wanted to check in on you. Are you feeling OK?

- Yes "Great! That's wonderful to hear" [Then go to next question]
- No: If they answer no, then say: Can you tell us more about what you're experiencing?
 - Swelling in your face or throat [automatically respond to the patient: Contact your primary care provider or call 911 or go to the nearest ER]
 - Shortness of breath [automatically respond to the patient: If you have shortness of breath that you find concerning or persistent pain in your chest, please call 911 or go to your nearest ER.]
 - fatigue, chills, nausea etc. [then move to next question]
 - Stress, fear, anxiety, or other mental health issues [then move to next question]

Would you like a phone call from a nurse to answer any COVID related questions?"

- Yes -- You just indicated that you want to speak to a nurse for COVID related issues. Is that what you intended?
 - If they press yes again, then we say: "Please expect a call back from Houston Methodist during work hours, which may come in as an unrecognized number on your phone. We hope you try to take our call. Note that, due to patient volume, it could take us several business days for us to reach you. If you'd like to speak to someone sooner, please call your primary care physician. If you do not have one, call 713-790-3333, and they can direct you to a physician." [\[trigger alert to our nurses\]](#)

Anchor: Continued follow-up after infusion

Day: +8

Group:

Good day from Houston Methodist! It was our pleasure taking care of you! We will be slowing our messages now that we know you're on the road to recovery. You should expect a few more check-ins with you over the course of the next few months.

We'd like to get your assessment of us. How much do you agree or disagree with the following statement? It was helpful to me to receive texts, reminders and emails from this program.

1. Strongly agree
2. Agree
3. Undecided
4. Disagree
5. Strongly disagree.

We'd also like to ask you a few quick questions about your experience at the hospital for the infusion processes.

1. Was there good communication between the different providers and nurses providing you care?
 1. Press 1 for Yes, definitely
 2. Press 2 for Yes, mostly
 3. Press 3 for Yes, somewhat
 4. Press 4 for No.

2. As a result of your experience with the therapy, how likely would you be to recommend this facility to your friends and family?
 1. Press 1 for yes, definitely recommend
 2. Press 2 for most likely would recommend
 3. Press 4 for most likely would not recommend
 4. Press 5 for no, will not recommend

3. What else would you like to say about your infusion therapy experience? [free text]

Anchor: Continued follow-up after infusion

Day: +26

Group:

Good day from Houston Methodist! We just wanted to check in on you. Are you feeling OK?

- Yes “Great! That’s wonderful to hear” [Then go to next question]
- No: If they answer no, then say: Can you tell us more about what you’re experiencing?
 - Swelling in your face or throat [automatically respond to the patient: Contact your primary care provider or call 911 or go to the nearest ER]
 - Shortness of breath [automatically respond to the patient: If you have shortness of breath that you find concerning or persistent pain in your chest, please call 911 or go to your nearest ER.]
 - fatigue, chills, nausea etc. [then move to next question]
 - Stress, fear, anxiety, or other mental health issues [then move to next question]

Have your symptoms ever worsened to the point of needing to be hospitalized? [regardless of their response on this, move to the next question afterwards]

If “YES”, then ask:

- a) When were you hospitalized?
 - a. Free text date, if possible
- b) How long were you hospitalized?
 - b. Free text number in days, if possible

If “NO”: “That is great!”

Would you like a phone call from a nurse to answer any COVID related questions?”

- Yes -- You just indicated that you want to speak to a nurse for COVID related issues. Is that what you intended?
 - If they press yes again, then we say: “Please expect a call back from Houston Methodist during work hours, which may come in as an unrecognized number on your phone. We hope you try to take our call. Note that, due to patient volume, it could take us several business days for us to reach you. If you’d like to speak to someone sooner, please call your primary care physician. If you do not have one, call 713-790-3333, and they can direct you to a physician.” [trigger alert to our nurses]

Anchor: Continued follow-up after infusion

Day: +30

Time: 12 pm

Group:

Houston Methodist here. It was such a pleasure caring for you. If you ever have any questions or concerns, please share them with your primary care physician. If you do not have one, please call 713-790-3333 so we can direct you to a physician.