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CLL Society's Webinar: Is There Good News Ahead? Update on Omicron and Beyond / Available Therapies for COVID-19

Friday, March 18, 2022

Audience Questions and Answers

COVID-19 DISEASE AND RESOURCES

1. Where can I find the COVID-19 Action Plan on the CLL Society website?

Here is the direct link: <https://cllsociety.org/2021/07/covid-19-plan-checklists-for-chronic-lymphocytic-leukemia-cll-preparing-for-pre-and-post-covid-19-exposure/>

2. Any suggestions for making dental care safer for those of us at high risk for severe disease (other than vaccination and boosting)? Is there any benefit to wearing nose-only masks during procedures where having an un-masked mouth is necessary?

Dental care is very important, but does not carry zero risk. Some suggestions for lowering that risk would be to: 1) Make sure you are up to date on all recommended COVID-19 vaccines 2) Obtain Evusheld 3) Call the Dental office and make sure that all staff who will be in direct contact with are up-to-date with their vaccines 4) Ask that all staff in direct contact with you (especially dentist and dental assistant) wear an N-95 mask while they are in your room at all times 5) You can wear goggles or glasses as an extra layer of protection and 5) Ask for an extra early appointment (perhaps 30 mins or so) before the office opens so you can be seen before many other people are coming into the office for their appointments as well. And lastly, no the nose mask is not going to protect your respiratory tract so it would not be very useful.

3. What is your advice to patients regarding whether friends or family members should wear masks if indoors with CLL patients?

If congregating indoors, both those with CLL and those without should all wear KN95 or N95 masks when possible. And ideally, all should be up-to-date on their COVID-19 vaccination series. It also helps to increase ventilation (such as opening windows or doors) when possible.

4. So, is this Doctor telling us that if you're 50 and over and have CLL you have co-morbidities?

You are considered high-risk.



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5. Where does someone with CLL on watch-and-wait for 16 years with no symptoms or treatments fall on the risk framework for immunosuppressed category?

Everyone with CLL/SLL is considered moderately to severely compromised, regardless of treatment status.

COVID-19 POLICIES

1. With Congress not passing a new covid relief bill, how will this affect CLL patients in future vaccine and therapeutic developments like Evusheld and oral medications. Will they continue to develop new therapies without funding for new variants? What can we do to help advocate for ourselves? I live in CT and fortunately my elected officials believe in passing this bill while other states do not.

This is a valid concern. CLL Society is working hard behind the scenes contacting government officials and collaborating with other immunosuppressed organizations who are fighting for this same issue. If further funding is not provided, the biggest concern for the CLL community is that there will not be "additional" doses of Evusheld purchased, as well as doses of vaccines and monoclonal antibodies. You can write your state legislators if you would like to make your voice known on this issue. Stay tuned to our website, as we are in the process of extending our advocacy efforts in the near future.

COVID-19 VACCINE

1. Please talk about waning immunity and when we need more boosters.

According to the CDC guidance on vaccine dosing, everyone who is immunocompromised should receive three doses of their primary COVID-19 vaccination series, followed by an additional "booster" dose three months after the third dose of the primary COVID-19 vaccine series. As of right now, there are no further recommendations for additional doses.

2. I had 3 Moderna vaccines. Can I get Pfizer if that's the only one available?

Yes, absolutely. You can mix and match vaccines according to the CDC guidance.

EVUSHELD

1. I'm interested in Evusheld by AstraZeneca.

You must first obtain a prescription from any healthcare provider. You can use the Evusheld locator tool found here to locate a dose:

https://rrelyea.github.io/evusheld/?campaign_id=9&emc=edit_nn_20220214&instance_id=53116&nl=the-morning®i_id=128578288&segment_id=82663&te=1&user_id=b43acd396c37217284e3aec398516a68



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2. Does Evusheld work well against BA2?

Yes. It retains its neutralizing capability very well against BA.2.

3. This is the first time I have heard of Evusheld. Any specific recommendations for a reference besides "internet search"?

Please read through the instructions document in CLL Society's COVID-19 Action Plan. There are multiple links throughout that document that provide "therapeutic locator tools" where you can find where all the COVID-19 therapeutics are currently available. <https://cillsociety.org/2021/07/covid-19-plan-checklists-for-chronic-lymphocytic-leukemia-cll-preparing-for-pre-and-post-covid-19-exposure/>

4. Individuals that have had the Evusheld are asking if they should get a blood test to determine effectiveness. What is the recommended test and is there a benefit in doing so?

If you get Evusheld, you instantly have the antibodies present within your system. There is no need to obtain an antibody test right after Evusheld as there is no test available to the general public that differentiates between the antibodies that your body has produced and the antibodies that Evusheld provides as soon as the injection has been received.

5. Is Evusheld considered to "prevent" COVID or only to lessen the severity of COVID?

It both helps to prevent infection, reduces the risk of developing severe COVID-19 or death.

6. Are the Evusheld antibodies effective for everyone with CLL. (On therapy or not)

Yes. Evusheld is indicated for all those who are moderately to severely immunocompromised. Since CLL is a cancer of the immune system, everyone (regardless of treatment status) is considered eligible under the moderately to severely immunocompromised criteria.

7. Is there any test for the Evusheld antibodies?

The semi-quantitative COVID-19 spike antibody level will tell you your antibody level, but it does not differentiate between antibodies created by one's own immune system and the antibodies provided by the Evusheld injection.



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- 8. 21 years w CLL vaccines not beneficial even w booster, though a second follow up on antibodies show 1325. My docs recommend Evusheld I'm currently on 200 mg Venclexta daily. In good health and active. Anything I should know?**

Evusheld is recommended/indicated for everyone who is moderately to severely immunocompromised. This includes all of those with CLL/SLL, regardless of treatment status.

- 9. Does the Evusheld make your immune system stronger so that a person can venture out more.**

It does not make your immune system stronger. However, it directly provides the COVID-19 antibodies into your system-even if your body hasn't produced antibodies to previous COVID-19 vaccinations.

- 10. How effective is Evusheld for immunocompromised? Availability of Evusheld seems very limited, especially after CDC said we should get two doses. Will this get better soon?**

We are hoping so. The department of Health and Human Services claim that there are "doses of Evusheld sitting on shelves" in many places. You might try looking at the Evusheld locator tool within the COVID-19 plan on our website and see if you can find a dose that is available a bit further away from you. Many are finding success in driving 30 mins to an hour to locations that are more rural and the doses are not in as much demand.

- 11. If I have gotten Evusheld, should I still wear a mask and practice social distance outside?**

It is a personal decision after you have weighed all of the factors surrounding where you will be outside. For instance will you be at a crowded outdoor concert, or will you be in your back yard with 1-2 guests. That being said, it is always safer to wear a quality N95 or KN95 mask whenever possible when you know you will be around others.

- 12. Why did the CDC decide to cancel the 6 month repeat Evusheld injections? I just received the first injections a few weeks ago and was scheduled for the repeat in 6 months. My hospital called this morning and said the CDC notified them there will not be any 6 month repeat injections.**

Because the repeat doses most probably will need to be sooner than 6 months now with the rise of the Omicron subvariants. At this time the FDA will not say if another dose is needed in 2,3 or 6 months. We simply do not know. They are awaiting to see what subvariant of Omicron becomes the most prevalent in the US, as one will require additional dosing and the other may due to Evusheld having better neutralization against one over the other. Stay tuned to our website



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as we will share any news as soon as we become aware of it. You can also keep an eye on www.Evusheld.com for updates.

13. At this time my medical system only gives Evusheld to people who do not test positive for COVID antibodies. I have CLL, should I get Evusheld and where?

Unfortunately, each medical system has put their own criteria in place as to what patients are being prioritized for the doses. A couple have put this criteria in place, but it is not a criteria that was suggested by the FDA or AstraZeneca. Evusheld is indicated for all of those who are moderately to severely immunocompromised. You can also speak with your primary care provider to write you a prescription if they are outside of your medical system. They can write a prescription for you wherever you find a dose available.

14. If someone has had a strong antibody response to the covid vaccine, should they still consider Evusheld?

Evusheld is indicated for all who are moderately to severely immunocompromised (including those with CLL/SLL). Antibody levels are not a recommended determinant according to the FDA and AstraZeneca.

15. Are gammagobullin infusions effective and how would they compare to Evusheld protection (if an untreated CLL patient would like to travel)?

There are no data indicating that IgG infusions provide enough COVID-19 antibodies to provide adequate protection.

16. Are there any considerations after receiving EVUSHELD and then receiving ongoing maintenance of Rituximab? Does Rituximab reduce the effectiveness of EVUSHELD.

Since Evusheld is not dependent upon your immune system to "create" antibodies, Rituximab would not reduce the effectiveness.

17. Evusheld has a side effect of heart infarctions. How rare is it? I understand the shots are investigational.

Very rare. Although if you have any cardiac history, please discuss your situation with your treating CLL physician to weigh the risk versus benefits.

18. Any hopes that Evusheld will be covered under Medicare. Or the price come down?

Currently, there is no cost for the medication as it is not yet been approved for commercial use. However, the facility may charge a facility fee and/or fee for the nurse to provide the injection.



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19. If you received Regeneron, post COVID, is Evusheld still an option for protection? Or is it not necessary, or is one no longer eligible?

Evusheld is absolutely still an option. The antibodies from Regeneron are short acting and since they have not been used much since the rise of Omicron, those antibodies are most likely not still present in high quantities.

20. How should we feel comfortable with Evusheld injections when we were informed over a month after initial injections that the dosage was not adequate? I was ready to resume regular activity after the first dose, but when the second FDA advisory came out, and my caregivers could provide me with a second dose, but not what the extent or the time of possible coverage would be, but now wonder about Evusheld's efficacy. My care providers did not have enough information to reassure us. They weren't even clear if and when an additional COVID vaccination would be needed. What advice can the panel give?

In February, the FDA revised Evusheld's emergency use authorization to increase its initial dosing regimen from 150 mg to 300 mg. According to FDA, this change in dosing was made based on new data suggesting a higher dose might be needed to prevent infection from two of the newer (rapidly rising) Omicron subvariants.

21. In Ann Arbor, MI, I asked my hematologist for Evusheld and she said that was a question for my pcp. My pcp said he couldn't prescribe anything unless I have Covid, and if I get Covid I should go to an urgent care for an antiviral. These kinds of issues with docs are almost more stress-inducing as the prospect of getting Covid itself.

There are many who have had the same experience. Any healthcare provider can prescribe Evusheld. You might consider going to www.Evusheld.com and printing off the FDA Fact Sheet. As for where to get antivirals, it might be quicker to go to one of the "Test to Treat" locations who have the antivirals on hand and can give them to you right there with your report of a positive test (you do not need to wait for retesting to obtain it per the government's guidelines). Here is the link to the Test to Treat website:

<https://aspr.hhs.gov/TestToTreat/Pages/default.aspx>

22. I was lucky to receive Evusheld very early in its distribution. It is a real "get out of jail free card". I wanted to make people aware that there was an update from FDA regarding the Evusheld dosage. I was contacted about a week ago to come in and have a second 1,500 unit treatment. When I went to get the treatment, I was told that the FDA had updated the dosage to 3,000 units from its original 1,500 unit dosage and they were contacting all of the initial recipients to come in for the additional 1,500 unit treatment. It



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would be wise to let people know so if they haven't been contacted they can follow up on this.

You are correct. If you received a dose of Evusheld prior to February, you will need a second dose right away. In February, the FDA revised Evusheld's emergency use authorization to increase its initial dosing regimen from 150 mg to 300 mg. According to FDA, this change in dosing was made based on new data suggesting a higher dose might be needed to prevent infection from two of the newer omicron subvariants.

23. When can one get Evusheld after having Covid and mAb infusion?

The guidelines were recently updated by the CDC to indicate there is no longer a waiting period required.

24. Can't people who are Exposed get Evusheld? Isn't it still effective in that case?

Evusheld is not indicated for treatment or known exposure.

25. I have had a double dose of Evusheld. Should I attempt another double dose in six months?

Stay tuned to our website. As soon as the FDA guidance comes out regarding when additional doses of Evusheld are needed, we will be announcing that information immediately.

EVUSHELD AND COVID-19 VACCINE

1. I have CLL and on Imbruvica. I had two vaccines and a booster. Tests showed that I developed no antibodies to the spike protein. I have received the full doses of Evusheld. Should I get a second booster and when should I get it in relation to when I got the Evusheld?

According to the CDC guidance on vaccine dosing, everyone who is immunocompromised should receive three doses of their primary COVID-19 vaccination series, followed by an additional "booster" dose three months after the third dose of the primary COVID-19 vaccine series. Ideally, you should get the 4th "booster" dose first, wait two weeks, then obtain Evusheld. But if you have already received Evusheld, please talk with your treating CLL physician regarding timing. There are no data yet on ideal timing of additional vaccine doses AFTER Evusheld. Although we expect for there to be information coming out within the next month. Stay tuned to our website as we will let everyone know as soon as the data is made available.

2. I've heard you should wait 2 weeks time between receiving Evusheld and a booster. My travel plans are such that I'd rather not wait 2 weeks after



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Evusheld to get my 4th booster. What's the worst that can happen? I am CLL - watch and wait.

The two weeks comes from the minimum time period you should wait after getting a dose of the vaccine before obtaining Evusheld. Not the other way around. We would encourage you to speak to your treating CLL physician, as some are recommending waiting anywhere from 1-3 months. But there are no data just yet regarding best timing of receiving Evusheld AFTER vaccination, however we expect for there to be data and recommendations surrounding that very soon. Please stay tuned to the website as we will announce it as soon as the information becomes available.

3. If you have had 3 vaccine shots (ending in August) and got the Evusheld shots as well recently, do you need a 4th vaccine booster and if so, how long after the Evusheld injections?

According to the CDC guidance on vaccine dosing, everyone who is immunocompromised should receive three doses of their primary COVID-19 vaccination series, followed by an additional "booster" dose three months after the third dose of the primary COVID-19 vaccine series. Please speak to your treating CLL physician regarding recommended timing of the 4th dose after Evusheld. Currently, there are no data that points to best timing. Although we expect that information to be published very soon within the next month.

4. I've had 3 shots of vaccine but tested as no detectable antibodies. Last shot 9/3/21. Finished rix infusions 5/14/21, I'm on list to get Evusheld but availability is limited, Should I in the meantime get a 4th booster shot while I wait for Evusheld?

According to the CDC guidance for the immunocompromised, you should get the fourth "booster" dose. Then ideally wait two weeks after the vaccine dose to obtain Evusheld.

OTHER COVID-19 TREATMENTS (PRE AND POST EXPOSURE)

1. Which mAb do you would you prefer to get at this time? Bebtelovimab or Sotrovimab? Which is currently more effective?

Both are effective at this current time. However, as the Omicron subvariant, BA.2, is rapidly rising in the US Sotrovimab is going to start being used much less as it is not as effective against BA.2. Sotrovimab is the best for BA.2, but the difficulty in obtaining Sotrovimab at this time is that it is still in short supply in many areas of the country.

2. Test and treat is a very good idea. However, for those of us that might not be able to do antivirals due to contraindications of other medications we



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are on, what would be the first line of offense, with therapy, monoclonal antibody infusion?

Talk to your treating physicians. The medications you are on may mean that you can still take Paxlovid, but just require additional close monitoring while you are on it. Remdesivir and monoclonal antibodies are also good options. And a last option would be Molnupiravir, which is still effective-it is just much less effective when compared to Paxlovid.

3. This last answer is contradictory. Is Sotrovimab better or worse than Bebtelovimab for BA.2?

The neutralizing capacity of Bebtelovimab is higher against BA.2. However, Sotrovimab is still effective at this time while the original Omicron variant is still the most prevalent.