Is There Good News Ahead? Update on Omicron and Beyond Available Therapies for COVID-19

March 18, 2022

10 AM PT, 11 AM MT
12 PM CT, 1 PM ET
This program was made possible by grant support from:

- Regeneron
- Janssen
- Pharmacyclics®
Speakers

Welcome
Robyn Brumble, MSN, RN
Director of Scientific Affairs and Research
CLL Society

Speaker
Joshua A. Hill, MD
Assistant Professor
Vaccine and Infectious Disease Division and Clinical Research Division
Fred Hutch

Moderator
Brian Koffman, MDCM (retired)
MS Ed
Executive Vice President and Chief Medical Officer
CLL Society

Speaker
Sameer Parikh, MD, MBBS
Assistant Professor of Medicine, Hematology
Consultant, Division of Hematology
Mayo Clinic
Poll Questions
Where to Find the COVID-19 Action Plan
On CLL Society’s Website
Recent Updates to the COVID-19 Action Plan
Include Links To:

• The CDC guidance for those who are immunocompromised to remain up-to-date on recommended COVID-19 vaccination dosages.

• A locator tool that will help you find doses of available Evusheld and oral antivirals such as Paxlovid near you.

• A new monoclonal antibody locator tool to locate infusion centers that provide the monoclonal antibody therapies (mAbs) recommended for treatment of COVID-19 (dependent upon the current variant).

**NEWS**

mAbs should be given within 7 days
Molnupiravir is usually a last choice
Test to Treat: Faster, Easier Access to Life-Saving COVID-19 Treatments

• Launches today 3/18/2022.

• Nationwide Test to Treat initiative gives individuals an important way to rapidly access free lifesaving treatment for COVID-19.

• Able to get tested and – if they are positive and treatments are appropriate for them – receive a prescription from a health care provider, and have their prescription filled all in one location.

• Don’t need to be tested at the site. Can use home test result.

• Still able to get prescription with a HCPs order at other pharmacies.

https://aspr.hhs.gov/TestToTreat/Pages/default.aspx
COVID-19 Risk Framework

Age
- <30
- 30-49
- 50-69
- ≥70

Comorbidity
- None
- 1
- 2
- 3+
e.g., diabetes, obesity, CKD, pregnancy, lung disease

Vaccination Status
- Full vaccination plus boosting
- Full vaccination
- Partial vaccination
- Unvaccinated

Immunosuppression
- None
- Steroids
- Lymphodepletion (e.g., Rituximab)
- Anti-metabolites (e.g., mycophenolate)
- AIDS
- Solid organ transplant
- Active heme malignancy/BMT

Consider exposure risks and societal/structural risk factors

Courtesy of Dr. William Werbel
Therapeutic Landscape for COVID-19

Vaccines
- mRNA-1273: messenger RNA vaccine (Moderna)
- BNT162b2: messenger RNA vaccine (Pfizer–BioNTech)

Neutralizing Monoclonal Antibodies
- Bamlanivimab/etesevimab
- Casirivimab/imdevimab
- Bebtelovimab

Immune Modulators
- Baricitinib
- Dexamethasone
- Tocilizumab

Pre-Exposure Prophylaxis (PrEP)
- Tixagevimab and Cilgavimab (Evusheld)

Antivirals
- Molnupiravir
- Remdesivir
- Nirmatrelvir–ritonavir (Paxlovid)
- Remdesivir

Outpatient
- Uninfected
- Exposed, Uninfected
- Mild-to-moderate Covid-19

Inpatient
- Infected with SARS-CoV-2
- Severe-to-critical Covid-19
COVID-19 Outpatient Therapeutics
Clinical Decision Aid for Ages 12+

Adult or pediatric patient (ages 12 and older weighing at least 40 kg) with mild to moderate COVID-19 and at high risk for progression to severe disease

Is patient:
- Hospitalized for COVID-19
  - OR
- Requiring O₂
  - OR
- Requires an increase in baseline home O₂ due to COVID-19?

YES → Treatment of symptoms, management per NIH & CDC Guidelines

NO → Is patient onset within the past 5–7 days?

YES → Does patient have severe renal impairment (eGFR <30 mL/min) OR Severe hepatic impairment (Child-Pugh Class C)?

NO → YES → Consider: sotrovimab⁵ 500 mg IV begun ASAP within 7 days of symptom onset

OR

bebtelovimab⁴ 175 mg single IV injection ASAP within 7 days of symptom onset

Consider one of the following therapeutics, if available¹,²:
- Paxlovid³ within 5 days of symptom onset
  - eGFR ≥ 60 mL/min: 300 mg nirmatrelvir taken with 100 mg ritonavir twice daily for 5 days
  - eGFR ≥ 30 to < 60: 150 mg nirmatrelvir taken together with 100 mg ritonavir twice daily for 5 days
- Evaluate concomitant use of CYP3A inducers and medications with high dependency on CYP3A for clearance as these may be contraindicated³,⁴

OR

sotrovimab⁵ 500 mg IV begun ASAP within 7 days of symptom onset

OR

Veklury (remdesivir)⁶ 200 mg IV x 1 dose on Day 1, 100 mg IV x 1 on Days 2–3 begun ASAP within 7 days of symptom onset

If none of these therapeutics are available, feasible to deliver, or clinically appropriate for patient treatment:

Is patient age 18 or older AND possibility of pregnancy, if applicable, ruled out?

YES → Consider molnupiravir⁷ 800 mg by mouth every 12h for 5 days begun ASAP within 5 days of symptom onset

Prescribers must review and comply with the mandatory requirements outlined in the molnupiravir EUA⁸

NO → Consider bebtelovimab²,⁷ 175 mg single IV injection ASAP within 7 days of symptom onset

References:
³ Paxlovid EUA. https://www.fda.gov/media/155650/download
⁴ Sotrovimab EUA. https://www.fda.gov/media/149534/download
⁶ Bebtelovimab EUA. https://www.fda.gov/media/156112/download
⁷ Molnupiravir EUA. https://www.fda.gov/media/155040/download

ASPR

Preparedness, Response, and Recovery
Omicron Subvariant BA.2 is Rapidly Rising in the US

https://covid.cdc.gov/covid-data-tracker/#circulatingVariants
Management of CLL

Dr. Sameer Parikh, MD, MBBS

Division of Hematology
Mayo Clinic
Rochester, MN

March 18, 2022
## REVISED COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>1st dose</th>
<th>2nd dose (21 days after 1st dose)</th>
<th>3rd dose (at least 28 days after 2nd dose)</th>
<th>Booster dose* (at least 3 months after 3rd dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech (ages 5 years and older)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderna (ages 18 years and older)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Janssen (ages 18 years and older)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

†Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used
SARS-CoV-2 Vaccination in CLL

Antibody responses to vaccination in CLL patients:
50%

Antibody response lower in patients receiving CLL treatment:

- Healthy controls: 100%
- CLL: 50%
- Treatment-naive: 75%
- On-therapy: 50%
- Off-therapy in remission: 75%
- Off-therapy in relapse: 25%

Third dose of vaccination improves response in about 25% patients:
- 2 doses: 50%
- 3rd dose: 25%
- No antibody: 25%
Get Vaccinated, But Act Like You’re Not

Questions:
- What does this mean in terms of safe activities?
- What’s needed to make CLL patients safer?
- How do patients decide to risk:
  - A family visit or meal?
  - A vacation?
  - A movie or show or concert or sporting event or museum?
  - A restaurant?
Evusheld

**Knowns:**
- Long-acting monoclonal antibody
- Passive versus active immunity
- For immunocompromised only
  - Who qualifies?

**Unknowns:**
- Activity against future Variants of Concern
- Length of Action
Treatment of CLL in 2022

Treatment Options for CLL:
- Chemoimmunotherapy
- BTK inhibitors (ibrutinib, acalabrutinib, etc.)
- BCL2 inhibitors (venetoclax)
- CD20 monoclonal antibody (rituximab, etc.)
- Combination treatments

Factors to consider prior to treatment:
- Age
- Fitness
- Genomic characteristics of CLL:
  - IGHV mutation
  - CLL FISH
- Co-morbidities:
  - Cardiac
  - Renal
- Patient preference:
  - Continuous vs. time limited treatment

COVID-19
Audience Questions & Answers
This program was made possible by grant support from

REGENERON  

janssen

pharmacyclicks®
An AbbVie Company
Thank You for Attending!

Please take a moment to complete our post-event survey, your feedback is important to us.

If you’re question was not answered, please feel free to email asktheexpert@cllsociety.org.

Join us on April 25th for our next webinar, Health and Wellness: Beyond the Medicine Cabinet.

CLL Society is invested in your long life. Please invest in the long life of the CLL Society by supporting our work.

cllsociety.org/donate-to-cll-society/