NC DHHS COVID-19 Bi-Weekly LHD Webinar

February 22, 2022
## Opening Remarks & Leadership Update

| Opening Remarks & Leadership Update | Beth Lovette, RN, BSN, MPH  
Deputy Director/Section Chief  
Local and Community Support |
|---|---|
| Epi Picture | Zack Moore, MD, MPH  
State Epidemiologist and Epidemiology Section Chief |
| Policy | Elizabeth Cuervo Tilson, MD, MPH  
State Health Director  
Chief Medical Officer |
| Vaccine Update | Ryan Jury, RN, MBA  
COVID-19 Vaccine Program Director |
| Therapeutics | Tim Davis, PharmD, BCNP, PMP  
Medical Countermeasures Coordinator |

QUESTIONS?
Please use the Zoom Q&A function or email your questions to: questionsCOVID19webinar@gmail.com
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# Vaccine Update

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It is no longer necessary to delay COVID-19 vaccination following receipt of monoclonal antibodies or convalescent plasma.

Updated guidance on receiving a booster dose if vaccinated outside the United States.

Updated contraindication and precaution section to include history of myocarditis or pericarditis after an mRNA COVID-19 vaccine.

The latest versions of all Statewide Standing Orders can always be found here.
**Vaccine Vaccination Schedule**

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

**Key Takeaways:**
- Pfizer & Moderna Booster Interval shortened to 3 months after 3rd Dose for Immunocompromised populations
- Additional (mRNA) dose recommended after Janssen primary series

*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.

Source: CDC
WHAT WE'RE DOING: A VIAL IN EVERY FRIDGE

Moving from mass vaccination to vaccine everywhere to reduce missed opportunities

Ensuring we never miss an opportunity to vaccinate

77% of parents say they trust their child’s pediatrician to provide reliable information on vaccines for children*

44% of the unvaccinated that would feel most comfortable getting vaccinated at their doctor’s office**

46% of parents with an unvaccinated child aged 5-11 who say hearing from people they trust would make them much more likely to get their child vaccinated

100% of locations with vaccine on hand = 0% missed opportunities to counsel, validate, and vaccinate

*NC Department of Health and Human Services

**NC Department of Health and Human Services
BRIEF OVERVIEW: VACCINE UPDATES

LTC Booster
- Current NC SNF resident booster rate at 73%, above national average of 68%
- Current NC Non-SNF Resident Booster Rates reported via Survey Outreach at 82% (362 Unique Responses from Facilities)
- Conducting Help Desk phone and email outreach aiding in vaccination data validation for LTCFs as well as partnership LTCFs with Vaccine Vendors

FDA/CDC Updates
- Revised booster schedule and guidance updates for moderately or severely immunocompromised
  - Pfizer & Moderna Booster Interval shortened to 3 months after 3rd Dose for Immunocompromised populations
  - Additional (mRNA) dose recommended after Janssen primary series
- Updated CDC guidance for those outside the US

Vial in Every Fridge
- Moving from the idea of mass vaccination to reducing missed opportunities by offering vaccine
  - Currently 72.9% of total VFC providers are enrolled, very close to our goal of 80%
  - Looking into additional levers for provider recruitment, discussions with non-traditional associations
## Therapeutics

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BEBTELOVIMAB

**EUA issued by FDA on February 11th**

**Authorization**
- Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg):
  - With positive COVID-19 test (of any kind)
  - Who are at high risk for progression to severe COVID-19
  - For whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate

**Mechanism of Action**
- Monoclonal antibody that binds to the SARS-CoV-2 spike protein and blocks attachment to human cells

**Dosage and Administration**
- 175mg administered as a single IV injection over at least 30 seconds, followed by 1 hour of observation
- Must be administered as soon as possible after positive COVID-19 test and within 7 days of symptom onset

**Storage and Handling**
- Must be stored in a refrigerator at 2°C to 8°C (36°F to 46°F)
Monoclonal antibodies, or mAbs, are antibodies made in a laboratory to fight a particular infection. The Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for the use of monoclonal antibody therapies for adult and pediatric patients aged 12 and older. mAbs are given to patients with an infusion, subcutaneous injection, or intramuscular injection. They are used for treatment or prevention. There are three mAb products currently authorized for use that are effective against the SARS-CoV-2 Omicron variant:

<table>
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<tr>
<th>mAbs Generic Name</th>
<th>Also known as</th>
<th>Authorized Indication</th>
<th>Route of Administration</th>
<th>Dosing Regimen</th>
<th>Authorized Patient Population</th>
<th>Standing Order?*</th>
<th>Efficacy</th>
</tr>
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<tr>
<td>Sotrovimab</td>
<td>Sotrovimab</td>
<td>COVID-19 Treatment within 10 days of symptoms</td>
<td>Intravenous Infusion</td>
<td>500 mg of sotrovimab</td>
<td>Patients aged 12 years and older and weighing at least 40 kg</td>
<td>Yes, revised February 15&lt;sup&gt;th&lt;/sup&gt;</td>
<td>79% effective in preventing hospitalization or death. Retains efficacy against Omicron. In-vitro data suggests some reduced efficacy against BA.2 subvariant. Clinical impacts unknown at this time</td>
</tr>
<tr>
<td>Bebtelovimab</td>
<td>Bebtelovimab</td>
<td>COVID-19 Treatment within seven (7) days of symptoms</td>
<td>Intravenous Infusion</td>
<td>175 mg of bebtelovimab</td>
<td>Patients aged 12 years and older and weighing at least 40 kg</td>
<td>Yes, as of February 15&lt;sup&gt;th&lt;/sup&gt;</td>
<td>Placebo controlled trial data not available to determine % effectiveness at reducing hospitalization. Retains efficacy against both the omicron variant and the BA.2 omicron subvariant</td>
</tr>
<tr>
<td>Tixagevimab / cilgavimab</td>
<td>EVUSHELD AZD7442</td>
<td>Pre-exposure prophylaxis (PrEP)</td>
<td>Intramuscular Injection</td>
<td>Two simultaneous IM injections every six (6) months</td>
<td>Patients aged 12 years and older who are immunocompromised or have a contraindication for COVID-19 vaccines</td>
<td>No – per FDA/HHS</td>
<td>77% effective in preventing SARS-CoV-2 RT-PCR symptomatic illness Retains efficacy against Omicron</td>
</tr>
</tbody>
</table>

*Per the Public Readiness and Emergency Preparedness Act, pharmacies were added to the eligible providers and can now administer monoclonal antibody treatment

Note: the EUAs for REGEN-COV and Bamlanivimab and Etesevimab are paused due to ineffectiveness against the Omicron variant

*
The FDA has issued EUAs for the use of oral antiviral therapies for adult and pediatric patients aged 12 and older (molnupiravir authorized for 18+ only). Oral antivirals are administered orally and only used for treatment. There are two (2) types of oral antivirals that have been authorized for use for COVID-19. Both therapeutics target mild-to-moderate COVID-19 in individuals who are at risk of severe illness:

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<tr>
<td>Molnupiravir</td>
<td>MK-4482, Merck</td>
<td>Treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and for whom alternate treatment is not accessible or clinically appropriate</td>
<td>Oral</td>
<td>Must start within five (5) days of symptom onset Not recommended during pregnancy</td>
<td>800 mg twice-daily for five (5) days</td>
<td>Adult patients aged 18 years and older</td>
<td>No – per FDA/HHS</td>
<td>30% effective in preventing hospitalization or death when started within five (5) days of symptom onset Retains efficacy against Omicron</td>
</tr>
<tr>
<td>Paxlovid</td>
<td>Nirmatrelvir / Ritonavir, Pfizer</td>
<td>Treatment of mild-to-moderate COVID-19 in adult and pediatric patients (12+) who are at risk for progressing to severe COVID-19</td>
<td>Oral</td>
<td>Must start within five (5) days of symptom onset Dosage adjustment required for moderate renal impairment (eGFR ≥30 to &lt;60 mL/min) Extensive drug interactions list</td>
<td>300 mg of nirmatrelvir and 100 mg of ritonavir twice-daily for five (5) days</td>
<td>Patients aged 12 years and older</td>
<td>No – per FDA/HHS</td>
<td>88% effective in preventing hospitalization or death when started within five (5) days of symptom onset Expected to maintain effectiveness across all variants</td>
</tr>
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</table>
THERAPEUTICS OVERVIEW

Please Note: VEKLURY (remdesivir) is commercially available for purchase and is not allocated by the federal government.

Veklury is an antiviral medication that works by inhibiting an enzyme that is essential for SARS-CoV-2 viral replication. The FDA has granted full approval for treatment in both hospitalized and non-hospitalized patients who are 12 years of age or older. The FDA has also issued an EUA for treatment in both hospitalized and non-hospitalized patients less than 12 years of age.


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<td>Remdesivir</td>
<td>VEKLURY</td>
<td><strong>Full FDA Approval</strong> Treatment of COVID-19 for adult and pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19</td>
<td>Intravenous Infusion</td>
<td>May only be administered in settings in which healthcare providers have immediate access to medications to treat severe infusion or hypersensitivity reactions and the ability to activate EMS</td>
<td>For patients weighing 40kg or greater: 200mg loading dose on Day 1, followed by a once-daily maintenance dose of 100mg from Day 2 For patients weighing less than 40kg: 5mg/kg loading dose on Day 1, followed by a once-daily maintenance dose of 2.5mg/kg from Day 2</td>
<td>Full FDA Approval Adults and pediatric patients (aged 12 years and older and weighing at least 40 kg)</td>
<td>No</td>
<td>87% effective at preventing hospitalization/death compared to placebo in non-hospitalized patients considered at high-risk for progression to severe COVID-19</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>EUA</strong> Treatment of COVID-19 for pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19</td>
<td></td>
<td></td>
<td>Full FDA Approval Pediatric patients aged 12 years and older weighing 3.5kg to less than 40kg, or pediatric patients less than 12 years of age weighing at least 3.5kg</td>
<td>Pediatric patients aged 12 years and older weighing 3.5kg to less than 40kg, or pediatric patients less than 12 years of age weighing at least 3.5kg</td>
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**Generic Name**
- Remdesivir
- VEKLURY

**Also known as**
- VEKLURY

**Authorized Indication**
- Full FDA Approval
  - Treatment of COVID-19 for adult and pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19
- EUA
  - Treatment of COVID-19 for pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19

**Route of Administration**
- Intravenous Infusion

**Administration Requirements**
- May only be administered in settings in which healthcare providers have immediate access to medications to treat severe infusion or hypersensitivity reactions and the ability to activate EMS
- For non-hospitalized patients, treatment must be initiated as soon as possible after diagnosis and within seven (7) days of symptom onset

**Dosing Regimen**
- For patients weighing 40kg or greater: 200mg loading dose on Day 1, followed by a once-daily maintenance dose of 100mg from Day 2
- For patients weighing less than 40kg: 5mg/kg loading dose on Day 1, followed by a once-daily maintenance dose of 2.5mg/kg from Day 2

**Authorized Patient Population**
- Full FDA Approval
  - Adults and pediatric patients (aged 12 years and older and weighing at least 40 kg)

**Standing Order?**
- No

**Efficacy**
- 87% effective at preventing hospitalization/death compared to placebo in non-hospitalized patients considered at high-risk for progression to severe COVID-19
- Retains efficacy against Omicron
While our state allocations of COVID-19 therapeutics are expected to remain relatively steady in the coming weeks, supply constraints have begun to ease due to a rapid decline in COVID-19 cases. As such, NCDHHS has removed the recommendation to prioritize treatment to patients in Tiers 1, 2, or 3 of the NIH treatment panel guidelines. Providers now can utilize all COVID-19 therapeutics as authorized through the FDA Emergency Use Authorization for each product. Providers are still encouraged to reference the NIH COVID-19 Treatment Panel statement on Product Prioritization for help in determining which COVID-19 therapeutic may be the best option for their patients.
RECIPIENT WAYFINDING

The ‘Find COVID-19 Treatment’ section on the NC DHHS website includes an updated ‘Site Finder’ tool that enables recipients to:
• Search for nearby treatment sites
• Discover available treatments each site offers for administration
• Find resources to schedule an appointment (phone numbers, websites)

The ‘Information For Individuals at Higher Risk’ section on the NC DHHS website includes a ‘Site Finder’ tool specifically for EVUSUHEL treatment locations.

There are now more than 500 therapeutic provider locations statewide.
Q&A