

Maine DHHS

COVID-19 Vaccines & Therapies Clinical Updates

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COVID-19 Clinician Discussion

- COVID-19 vaccines - recent updates
- NEW: Pfizer vaccine booster for younger children
- NEW: shortening time to Pfizer & Moderna boosters
- Implications of omicron
- Changes to COVID-19 monoclonal antibody therapies
- Updates COVID-19 long-acting monoclonal antibodies
- NEW: COVID-19 oral antiviral medication(s)
- Q&A

Current COVID-19 Vaccines

Pfizer BioNTech

- mRNA vaccine
- Trial with >44,000 in multiple countries
- Efficacy in initial trials 94.5%
- Minimal adverse reactions
- 2nd dose at 21D
- FDA approved for ≥16yo
- FDA authorized for 5-15yo
- Can be refrigerated for 30D
- **Booster authorized >12yo**
- **Booster authorized at 5mo**
- **3rd dose authorized for 5-11yo immunocompromised**

Moderna

- mRNA vaccine
- Trial with >30,000 in US
- Efficacy in initial trials 94.1%
- Minimal adverse reactions
- 2nd dose at 28D
- FDA authorized for ≥18yo
- Booster authorized for ≥18yo
- Can be refrigerated for 30D
- **Booster authorized at 5mo**

J&J/Janssen

- Viral vector vaccine
- Trial with >43,800 in multiple countries
- Efficacy in initial trials >66.1% overall, 72% US
- Minimal adverse reactions
- Single dose
- FDA authorized for ≥18yo
- Booster authorized for ≥18yo
- Can be stored at room temperature

COVID-19 Vaccines: Boosters

- FDA EUA & US CDC recommend booster dose for all eligible individuals
- Booster updates:
 - Pfizer: booster for 12yrs & older, give at 5 mos [NEW]
 - Moderna: for 18yrs & older, give at 5 mos [NEW]
 - J&J: for 18yrs & older, give booster at 2+ mos
- Pfizer: 3rd shot for 5-11yo immunocompr'd [NEW]
- Any vaccine can be used for booster regardless of vaccine product used for primary vaccination (“Mix & Match”) *except for 12-17 yr olds which must be Pfizer*
- US CDC: “fully vaccinated” = completed initial series
“up to date” = fully vax'd + rec'd boosters [NEW]

COVID-19 Vaccines: Boosters

Do I qualify for a COVID-19 vaccine booster and which one?

Which primary vaccine series did you complete?	Pfizer-BioNTech	Moderna	Janssen (J&J)
You can get a booster if:	It's been at least 5 months since completing a primary series AND you are:	It's been at least 5 months since completing a primary series AND you are:	It's been at least 2 months since completing primary vaccination AND you are:
	Age 12+	Age 18+	Age 18+
If eligible, you can get a booster of:	Pfizer-BioNTech* Moderna Janssen (J&J) <small>*Only Pfizer-BioNTech can be used as a booster in those age 12-17.</small>	Moderna Pfizer-BioNTech Janssen (J&J)	Janssen (J&J) Pfizer-BioNTech Moderna

For more information, visit www.fda.gov/covid19vaccines.



<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine>

COVID-19 Available Booster Sites

- Check [Gov's COVID-Vaccine website](#) for dates & times!!
- Augusta Armory: Tues & Sat 9A-4P & Thurs 12N- 7:
- Auburn Mall: Tues-Fri 8A – 5P
- Portland area:
 - MaineHealth (110 Free St) – by appt
 - NLH: Pier One building, So Ptld
- York County EMA-Sanford open for walk-ins Tues, Thurs, Fri, Sat, Sun

COVID-19: Implications of Omicron

- Multiple mutations – potential implications re:...
 - Markedly increased transmissibility
 - Possibly less disease severity
 - Immunologic “escape” from therapeutics (REGEN-COV & bam-ete not effective)
- Practical implications: ramp up the basics!
 - Masking & distancing
 - Vaccination, vaccination, vaccination
 - Boosters for all

COVID Therapeutics Update

- mAbs – omicron implications
 - Now Sotrovimab only (Omicron >80% prevalence)
- Oral anti-virals
 - Paxlovid
 - Molnupiravir
- Outpatient IV remdesivir
- LAABs – Evusheld
 - Prioritized for “Tier 1” immunocompromised
- ME CDC HAN’s: <https://www.maine.gov/dhhs/mecdc/newhan.shtml>
 - Jan 3: Review of COVID Therapeutics
 - Jan 7: Update on COVID Therapeutics

Implications of Omicron

- Omicron now detected in all states, w/ prevalence est'd ~95% all COVID infections in US
- In vitro studies suggest REGEN-COV, bam-ete are likely ineffective in treating omicron
- **HHS will pause allocations of REGEN-COV & bam-ete to states that have greater than 80% prevalence of Omicron variant based on [CDC NOWCAST](#) data**
- Omicron prevalence in Maine currently est'd at >80%
- **Therefore, ME DHHS will suspend allocations of REGEN-COV & bam-ete starting week of Jan 10, 2022**

Current FDA Authorized COVID-19 mAb Therapies for Non-Hospitalized Individuals

Bamlanivimab + Etesevimab (Lily)

- FDA EUA for treatment of

NOTE: HHS has advised not using bam-ete or REGEN-COV once omicron prevalence is >80% in region

- risk for progression to severe COVID-19, including hosp or death
- *For patients under 18 years of age in Maine, please consult with your local pediatric infectious disease expert
- Less active against beta & gamma variants
- In vitro studies support effectiveness for delta variant, but not omicron
- Available from federal supply

Casirivimab + Imdevimab (REGEN-COV)

- FDA EUA for treatment of

- progression to severe COVID-19, including hosp or death
- Still provides protection against Delta variant
- Can be admin'd via IV infusion or subcu injection (IV preferred)
- In vitro studies support effectiveness for delta variant, but not omicron
- Available from federal supply

Sotrovimab (Xevudy - GSK)

- FDA EUA for treatment of mild-mod COVID-19 in adults & children >12yo (≥40 kg) who are at high risk for progression to severe COVID-19, including hosp or death
- Not auth'd for PEP
- Admin'd via IV infusion
- In vitro studies support effectiveness for omicron
- Available from federal supply

Accessing mAb Tx: Issues

- Limited federal supply of doses & increased demand has created shortages
- Some ability to move doses across sites
- Goal: give within 10D of symptom onset, but often seeing delays in testing, access to tx
- Providers not widely aware of where & how to send patients for treatment
- List of Maine mAb infusion sites [posted online](#)

Long-Acting Antibodies (LAAB): Evusheld

- Long-acting antibody (LAAB) combination for pre-exposure prophylaxis of COVID-19 authorized by FDA (Dec 8)
- Authorized for adults and certain pediatric individuals with immune compromised systems not expected to mount adequate immune response following vaccination, or for whom vaccination not indicated due to health conditions or history of severe allergic reactions
- Initial supply limited: Maine receiving ~400 doses/month
- Distributing through five major cancer centers w/ regional approach
- Given constrained supply, initial focus on “Tier 1” pts with severe immunocompromise

Current Authorized COVID-19 Oral Anti-Virals for Non-Hospitalized Individuals

Paxlovid (Pfizer)

- FDA EUA for treatment of mild-mod COVID-19 in adults & children 12 & older ($\geq 40\text{kg}$) who are at high risk for progression to severe COVID-19, including hosp or death
- Contraindicated for multiple drug interactions, serious liver disease
- Dose adjustment needed for renal impairment
- ~85% reduced risk of hosp or death compared to placebo when given *within 5d of sx onset*
- Given as 3 tabs twice/D X5D
- Appears to be active against omicron
- Maine initial supply: 240 courses

Molnupiravir (Merck)

- FDA EUA for treatment of mild-mod COVID-19 in adults 18yo & older who are at high risk for progression to severe COVID-19, including hosp or death *AND* for whom other COVID tx options not accessible or clinically appropriate
- Contraindicated in pregnancy
- ~30% reduced risk of hosp or death compared to placebo when given *within 5d of sx onset*
- Given as 4 tabs twice/D X5D
- Appears to be active against omicron
- Maine initial supply: 1040 courses

Distribution of COVID-19 Oral Anti-Virals

- Maine distributing through retail pharmacy chains:
 - Walmart (12): <http://walmart.com/covidmedication>
 - Hannaford (3):
<https://www.hannaford.com/covid19antivirals>
- Feds also distributing some doses to limited number FQHCS (Maine: PCHC & HealthReach)
- Clinicians asked to prioritize within FDA EUA indications for individuals dx'd with COVID at high-risk for developing severe disease
- Additional ME CDC communications (HAN) anticipated re: patient prioritization

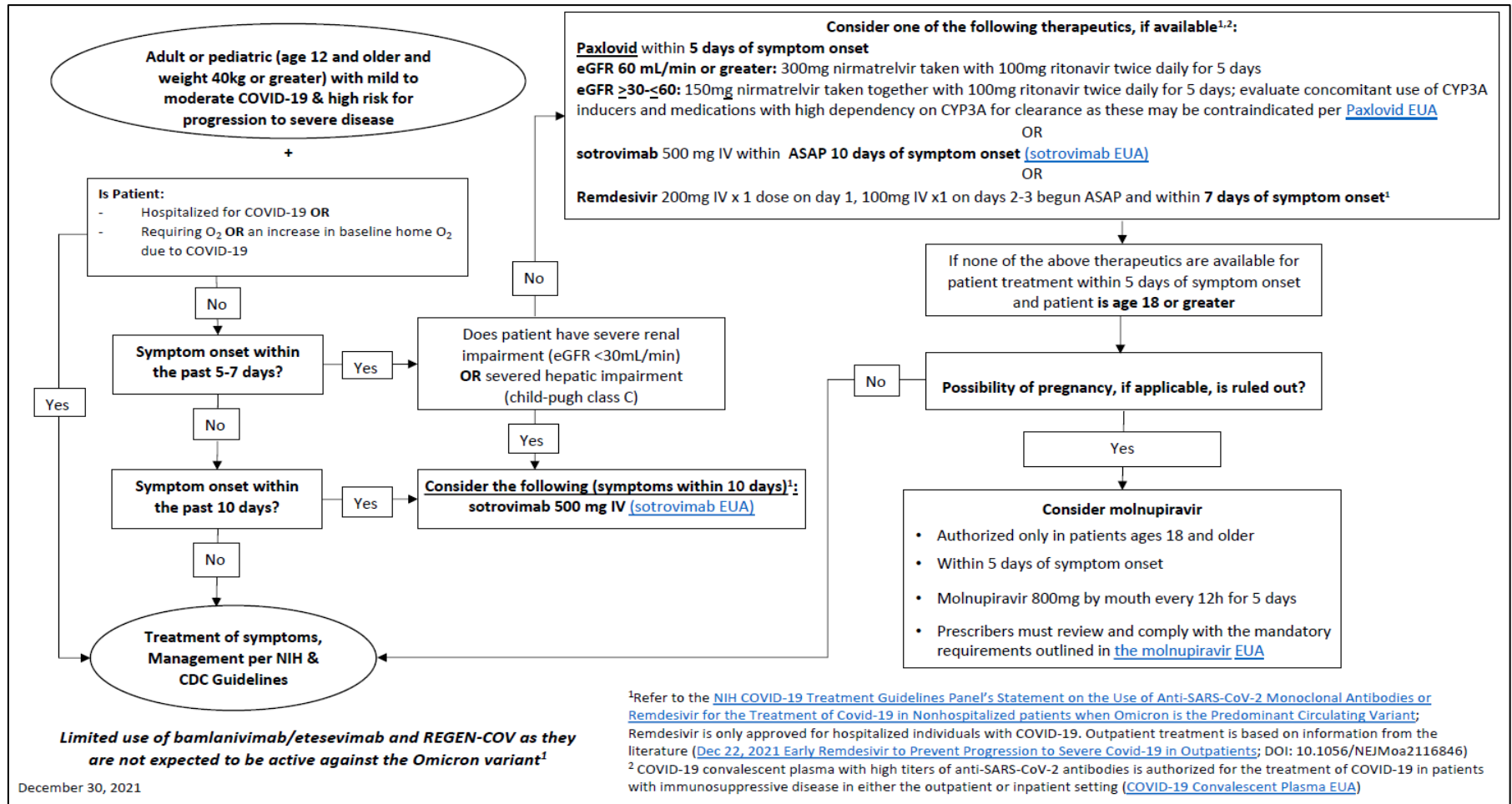
Remdesivir

- Use previously limited to inpatients, but recent study of remdesivir in OP setting showed good results:
 - Randomized trial of 562 non-hospitalized COVID pts
 - Found 87% lower risk of hospitalization or death for those treated with remdesivir vs. placebo
- Providers may consider “off-label” use of remdesivir for some patients
- Given via IV infusion daily X3D
- **NEW CMS HCPCS code J0248** for remdesivir admin in OP setting; code available for use by all payers, effective for dates of svc on or after 12/23/2021

Oral Anti-Viral Drugs: Access and Administration Challenges

- Initially constrained supply
 - Feds will allocate doses to states; states select channels
 - Maine will initially distribute via retail pharmacies – subset of Walmart & Hannaford pharmacies
 - As supply increases, will expand scope of availability
- Need for rapid treatment requires rethinking of current testing and diagnostic workflows
 - Increase use of rapid testing in clinical settings
 - Opportunities to identify pts at high-risk/ candidates for COVID treatments at time of testing

COVID Therapeutics: Clinical Decision Making



December 30, 2021

<https://www.phe.gov/emergency/events/COVID19/therapeutics/Documents/COVID-Therapeutics-Decision-Aid.pdf>

Approach to Prioritizing COVID Therapeutics with Limited Supply

- [NIH Interim Statement](#) on Pt Prioritization
 - Tier 1: Immunocomp'd and unvax'd ≥ 75 yo or ≥ 65 yo w/ risk factors
 - Tier 2: unvax'd ≥ 65 yo or < 65 yo w/ risk factors
 - Tier 3: vax'd ≥ 75 yo or ≥ 65 yo w/ risk factors
 - Tier 4: vax'd ≥ 65 yo or < 65 yo w/ risk factors
- Health system approaches
 - St Josephs Healthcare
 - NLH
 - Other?

Q&A

- Questions?
- Other issues?
- **NOTE: ME DHHS/CDC COVID-19 Clinician Info Sessions now held monthly on 2nd Tues/mo at 7:30AM via Zoom:**
<https://zoom.us/j/6218434986?pwd=dEJoNEVRSkVSN2dwZlJ5WEI3WjJsZz09>
Meeting ID: 621 843 4986
Passcode: 338847
One tap mobile: +13017158592,,6218434986#,,,,,0#,,338847#
- **Next mtg Tues, Feb 8, 7:30AM**

Additional COVID Resources

- [Coronavirus Disease 2019 \(COVID-19\) | US CDC](#)
- [US CDC COVID-19 Vaccines Clinical Considerations](#)
- [Maine COVID-19 Vaccines \(maine.gov\)](#)
- [Maine COVID-19 Vaccines FAQ](#)
- [Maine COVID-19 Vaccination Sites](#)
- HHS/ASPR Website (mAbs): www.phe.gov/mAbs
- HHS Website (mAbs): <https://combatcovid.hhs.gov/>
- [FDA Paxlovid EUA Health Care Provider Fact Sheet](#)
- [FDA Molnupiravir EUA Health Care Provider Fact Sheet](#)

Presenters

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