Public Health Update with the Indiana Department of Health

January 19, 2022

Quality Improvement Organizations
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CENTERS FOR MEDICARE & MEDICAID SERVICES

Qsource

Agenda

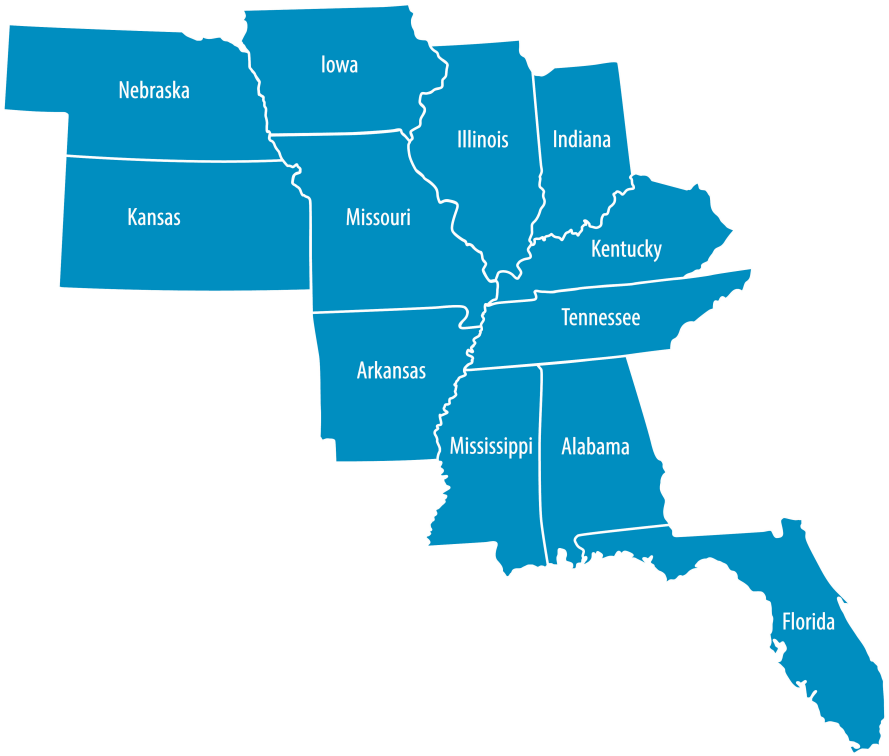
- Opening Remarks
- Housekeeping
- Presentation
- Q&A
- Closing Remarks

Who We Are

Qsource has more than 45 years of experience working with with healthcare providers, Medicare and Medicaid.

Currently operate in 11 states overseeing ESRD, EQRO and QIO activities.

Serves as the Medicare Quality Innovation Network-Quality Improvement Organization (QIN-QIO) for Indiana.



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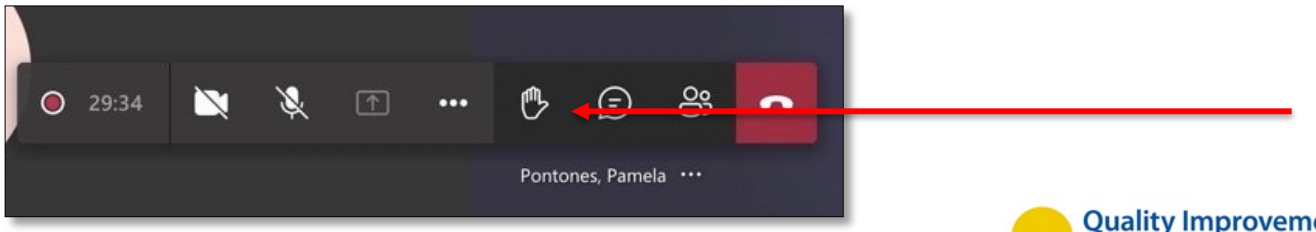
Housekeeping Items: Chat

- To ensure maximum sound quality, participant lines have been muted during the presentation; however, we welcome questions and comments via the chat box on the right-hand side of your screen
- During the Q&A portion of the presentation, we will unmute your lines.
- To submit questions or comments:
  - Use the chat box or,
  - Raise your hand to verbally ask your question



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Polling Question

In which setting do you work?

A. Long Term Care
B. Hospital
C. Home Health
D. Community-Based Organization
E. Other

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PUBLIC HEALTH UPDATES

PAM PONTONES, MA

DEPUTY STATE HEALTH COMMISSIONER

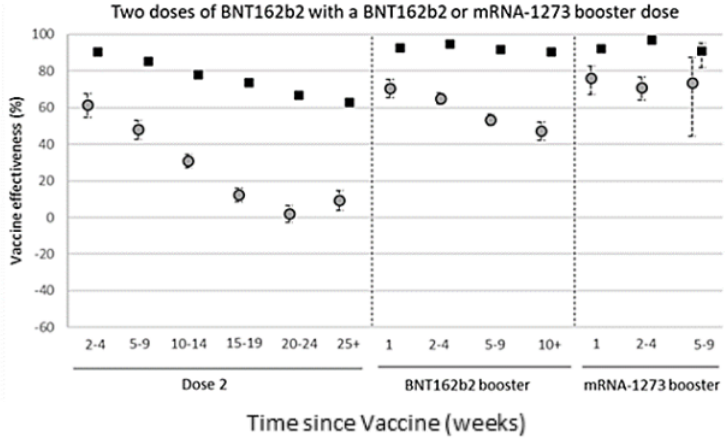
STATE EPIDEMIOLOGIST

01/19/2022

Vaccine Effectiveness with Omicron

Pfizer mRNA vaccine effectiveness (VE) is lower for symptomatic infection due to Omicron compared to Delta

- **Post 2-dose**: increased waning immunity for Omicron (~15%) vs. Delta (~60%) at 25+ weeks post 2nddose
- **Booster**: ~65% VE against Omicron 2 weeks; decreases to 45% at 10+ weeks



SARS-CoV-2 variants of concern and variants under investigation: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043807/technical-briefing-33.pdf

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Stay Up to Date with Vaccines

- Up to date means a person has received all recommended COVID-19 vaccines, including any booster dose(s) when eligible and additional doses for immunocompromised
- Fully vaccinated means a person has received their primary series of COVID-19 vaccines plus 2 weeks

Pfizer-BioNTech[1]	Moderna[1]	Johnson & Johnson's Janssen[1,2]
Booster Dose Everyone ages 12+ should get a booster dose at least 5 months after the last dose in their primary series. • Teens 12–17 should only get a Pfizer-BioNTech COVID-19 Vaccine booster • Everyone 18+ should get a booster dose of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines)	**Booster Dose** Everyone ages 18+ should get a booster dose of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) at least 5 months after the last dose in their primary series.	**Booster Dose** Everyone ages 18+ should get a booster dose of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) at least 2 months after the first dose of J&J/Janssen COVID-19 Vaccine. You may get J&J/Janssen in some situations.
When Boosted A person is considered "boosted" right after getting their booster dose.	**When Boosted** A person is considered "boosted" right after getting their booster dose.	**When Boosted** A person is considered "boosted" right after getting their booster dose.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html

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Updated Booster Authorizations

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) *Only Pfizer-BioNTech can be used as a booster in those age 12-17.	Moderna Pfizer-BioNTech Janssen (J&J)	Janssen (J&J) Pfizer-BioNTech Moderna

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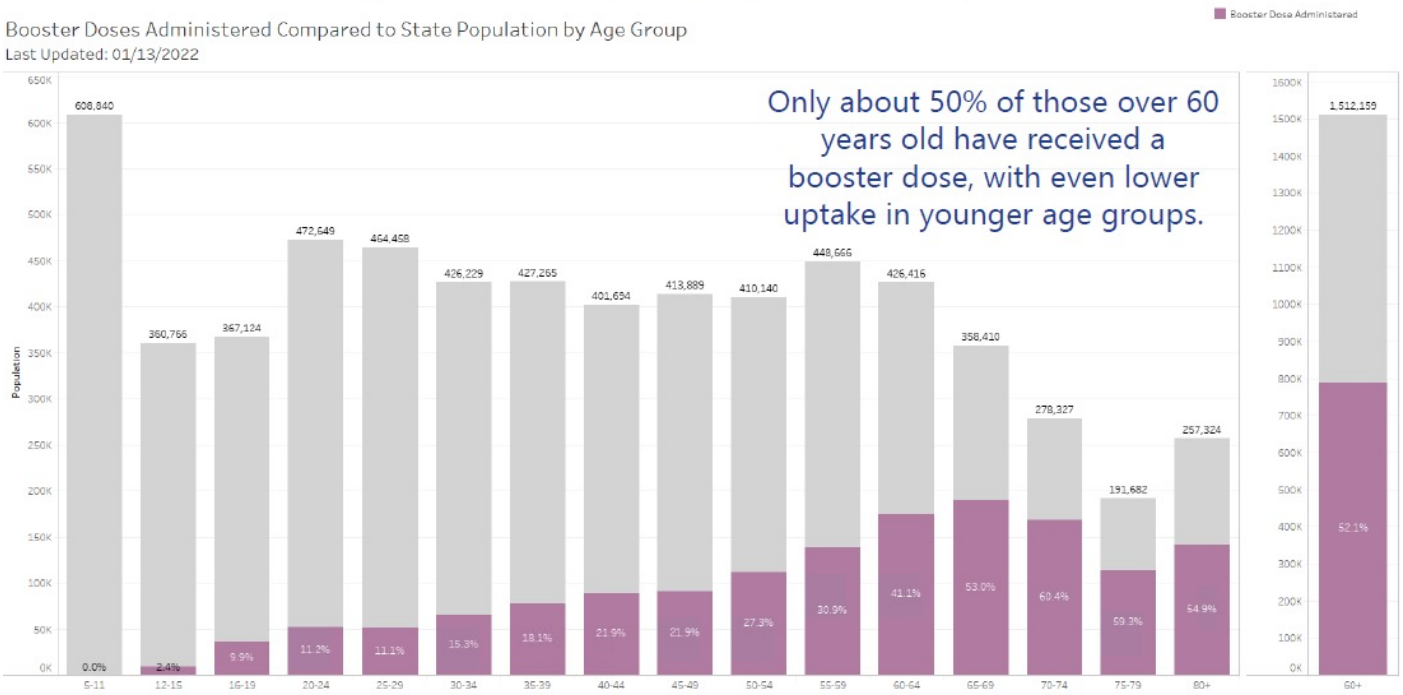
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-shortens-interval-booster-dose-moderna-covid-19-vaccine-five-months

Booster Dose Administration



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Isolation

IF YOU	Stay home for at least 5 days	Ending isolation if you had symptoms	Take precautions until day 10
Tested positive for COVID-19 or have symptoms, regardless of vaccination status	Stay home for 5 days and isolate from others in your home. Wear a well-fitted mask if you must be around others in your home.	End isolation after 5 full days if you are fever-free for 24 hours (without the use of fever-reducing medication) and your symptoms are improving. **Ending isolation if you did NOT have symptoms** End isolation after at least 5 full days after your positive test. **If you were severely ill with COVID-19** You should isolate for at least 10 days. Consult your doctor before ending isolation.	**Wear a mask** Wear a well-fitted mask for 10 full days any time you are around others inside your home or in public. Do not go to places where you are unable to wear a mask. **Avoid travel** **Avoid being around people who are at high risk**

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https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html

Quarantine: NOT up-to-date on vaccines

IF YOU	Quarantine for at least 5 days	After quarantine	Take precautions until day 10
Were exposed to COVID-19 and are NOT up-to-date on COVID-19 vaccinations	**Stay home** Stay home and quarantine for at least 5 full days. Wear a well-fitted mask if you must be around others in your home. **Get tested** Even if you don't develop symptoms, get tested at least 5 days after you last had close contact with someone with COVID-19.	**Watch for symptoms** Watch for symptoms until 10 days after you last had close contact with someone with COVID-19. **If you develop symptoms** Isolate immediately and get tested. Continue to stay home until you know the results. Wear a well-fitted mask around others.	**Wear a mask** Wear a well-fitted mask for 10 full days any time you are around others inside your home or in public. Do not go to places where you are unable to wear a mask. **Avoid travel** **Avoid being around people who are at high risk**

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https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html

Quarantine: Up-to-date on vaccines or + in 90 days

IF YOU	No quarantine	Watch for symptoms	Take precautions until day 10
Were exposed to COVID-19 and are up-to-date with vaccination OR had confirmed COVID-19 within the past 90 days (you tested positive using a viral test)	You do not need to stay home **unless** you develop symptoms. **Get tested** Even if you don't develop symptoms, get tested at least 5 days after you last had close contact with someone with COVID-19	Watch for symptoms until 10 days after you last had close contact with someone with COVID-19. **If you develop symptoms** Isolate immediately and get tested. Continue to stay home until you know the results. Wear a well-fitted mask around others.	**Wear a mask** Wear a well-fitted mask for 10 full days any time you are around others inside your home or in public. Do not go to places where you are unable to wear a mask. **Avoid travel** **Avoid being around people who are at high risk**

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https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html

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COVID-19 PREVENTION AND THERAPEUTICS

SHIREESHA VUPPALANCHI, MD

MEDICAL DIRECTOR
FOR LONG-TERM CARE

01/19/2022

Prevention and Therapeutics

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Evusheld

- On Dec. 8, the U.S. Food and Drug Administration (FDA) issued an EUA for AstraZeneca's Evusheld COVID-19 monoclonal antibody product
- Evusheld is a combination product that includes two recombinant human monoclonal antibodies (tixagevimab and cilgavimab) targeting the spike protein of SARS-CoV-2; these monoclonal antibodies are administered as two separate consecutive intramuscular (IM) injections
- This long-acting monoclonal antibody therapy can be used for pre-exposure prophylaxis (PrEP) in
  - Persons 12 years of age or older, who weigh at least 40 kg, and who are either
    - 1) moderately to severely immunocompromised (see FDA Fact Sheet below for medical conditions or treatments that might result in moderate to severe immunosuppression), or
    - 2) not recommended to receive COVID-19 vaccination due to a history of a vaccine contraindication

NOTE: This product is NOT for treatment of people infected with SARS-CoV-2 and NOT for post-exposure prophylaxis (PEP).

Evusheld

- The PROVENT Phase 3 clinical trial found that tixagevimab/cilgavimab recipients experienced a 77% reduction in incidence of COVID-19 compared placebo and showed effect for 6 months postadministration (re-dosing can be considered every 6 months)
- Tixagevimab/cilgavimab is not a substitute for vaccination and any age-eligible person who is immunocompromised should still be vaccinated against COVID-19; tixagevimab/cilgavimab can be administered at least 2 weeks after vaccination
- **Less effective against Omicron than previous variants**

Paxlovid (nirmatrelvir-ritonavir)

- Twice daily for five days
- Start within five days of symptom onset
- Adults and Age 12 or more at least 40 KG or more
- Mild to moderate COVID, at high risk for progression
- Confirmed Covid positive

NOT FOR

- Hospitalized
- Pre-exposure or post-exposure
- Longer than five consecutive days

https://www.fda.gov/media/155049/download

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Molnupiravir

- Adults (>18)
- Twice daily for five days
- Start within five days of symptom onset
- Mild to moderate COVID, at high risk for progression
- Confirmed Covid positive
- Other alternative COVID-19 treatment options authorized are not accessible (Sotrovimab, Paxlovid, Remdesivir)

Not for

(1) For use in patients less than 18 years of age

(2) For initiation of treatment in patients requiring hospitalization due to COVID-19.

(3) Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19.

(4) For use for longer than 5 consecutive days.

(5) For pre-exposure or post-exposure prophylaxis for prevention of COVID-19

https://www.fda.gov/media/155053/download

Molnupiravir

Not recommended for use during pregnancy.

- Molnupiravir is only authorized to be prescribed to a pregnant individual
  - After the prescribing healthcare provider has determined that the benefits of being treated with molnupiravir would outweigh the risks
  - After the prescribing health care provider has communicated the known and potential benefits and the potential risks
- **Females** of childbearing potential are advised to use a **reliable method of birth control** correctly and consistently during treatment with molnupiravir and **for four days after the final dose**.
- **Males** of reproductive potential who are sexually active with females of childbearing potential are advised to use a reliable method of birth control correctly and consistently during treatment with molnupiravir and **for at least three months** after the final dose.
- Questions and concerns about reliable birth control methods that are appropriate for use during treatment with molnupiravir, as well as how molnupiravir may affect sperm cells, should be directed at one's healthcare provider.
- Lactation: Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.

https://www.fda.gov/media/155053/download

Sotrovimab

- Currently, this is the only monoclonal antibody with activity against the omicron variant
- Federal government's current supply of sotrovimab is extremely limited
- Relative risk reduction of 85% in preventing progression
- IV infusion followed by monitoring
- As soon as possible, within 10 days of start of illness

Remdesivir to prevent progression to severe illness

- As effective as monoclonals
- IV-administered in three sequential doses (one per day)
- Plentiful supply but infected person must visit infusion center for three sequential visits
- Randomized, double-blind, placebo-controlled trial involving non-hospitalized patients with COVID-19 who had symptom onset within the previous 7 days and who had at least one risk factor for disease progression
- 200 mg on day 1 and 100 mg on days 2 and 3
- 279 patients in the remdesivir group and 283 in the placebo group.
- Covid-19–related hospitalization or death from any cause occurred in 2 patients (0.7%) in the remdesivir group and in 15 (5.3%) in the placebo group
- A total of 4 of 246 patients (1.6%) in the remdesivir group and 21 of 252 (8.3%) in the placebo group had a COVID-related medically attended visit by day 28
- No patients had died by day 28. Adverse events occurred in 42.3% of the patients in the remdesivir group and in 46.3% of those in the placebo group

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Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients | NEJM

COVID-19 Treatment Guidelines

The COVID-19 Treatment Guidelines Panel's Interim Statement on Patient Prioritization for Outpatient Anti- SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints

Last Updated: December 23, 2021

https://www.covid19treatmentguidelines.nih.gov/

Tier	Risk group
1	Immunocompromised individuals regardless of vaccine status **or** Unvaccinated individuals age ≥75 y or age ≥65 y with additional risk factors*
2	Unvaccinated individuals age ≥65 y or age <65 y with risk factors*
3	Vaccinated individuals age ≥75 y or age ≥65 y with additional risk factors*
4	Vaccinated individuals age ≥65 y or age <65 y with risk factors*

Risk factors for progressing to severe COVID include advanced age, cancer, cardiovascular disease, chronic kidney disease, chronic lung disease, diabetes, immunocompromised, obesity, pregnancy, sickle cell disease, other conditions

* https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

PowerPoint Presentation (idsociety.org)

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How do the therapies stack up?

	1) Nirmatrelvir/r	2) Sotrovimab	3) Remdesivir	4) Molnupiravir
Efficacy (prevention hospitalization or death)	•**Relative risk reduction: 88%** •Absolute risk: 6.3%→0.8% •NNT: 18	•**Relative risk reduction: 85%** •Absolute risk: 7%→ 1% •NNT: 17	•**Relative risk reduction: 87%** •Absolute risk: 5.3%→0.7% •NNT: 22	•**Relative risk reduction: 30%** •Absolute risk: 9.7%→6.5% •NNT: 31
Pros	•Highly efficacious •Oral regimen •Ritonavir studied (safe) in pregnancy	•Highly efficacious •Monoclonals typically safe in pregnancy •Few/no drug interactions	•Highly efficacious •Studied in pregnancy •Few/no drug interactions	•Oral regimen •Not anticipated to have drug interactions
Cons	•Drug drug interactions	•Requires IV infusion followed by 1 hour observation	•Requires IV infusion on 3 consecutive days	•Low efficacy •Concern: mutagenicity •Not recommended in pregnancy/children

PowerPoint Presentation (idsociety.org)

Outpatient Treatment Options

Option	Patient Population
Nirmatrelvir/ ritonavir	• Patient not on interacting medications • As soon as possible and within 5 days of symptom onset
Sotrovimab	• Patient on interacting medication/able to come to health care facility • As soon as possible and within 10 days of symptom onset
Remdesivir	• Patient in health care facility or through home infusion service • As soon as possible and within 7 days of symptom onset
Molnupiravir	• Patient not able to be treated with one of the options above • Not pregnant (if given during pregnancy, shared decision making) • As soon as possible and within 5 days of symptom onset

PowerPoint Presentation (idsociety.org)

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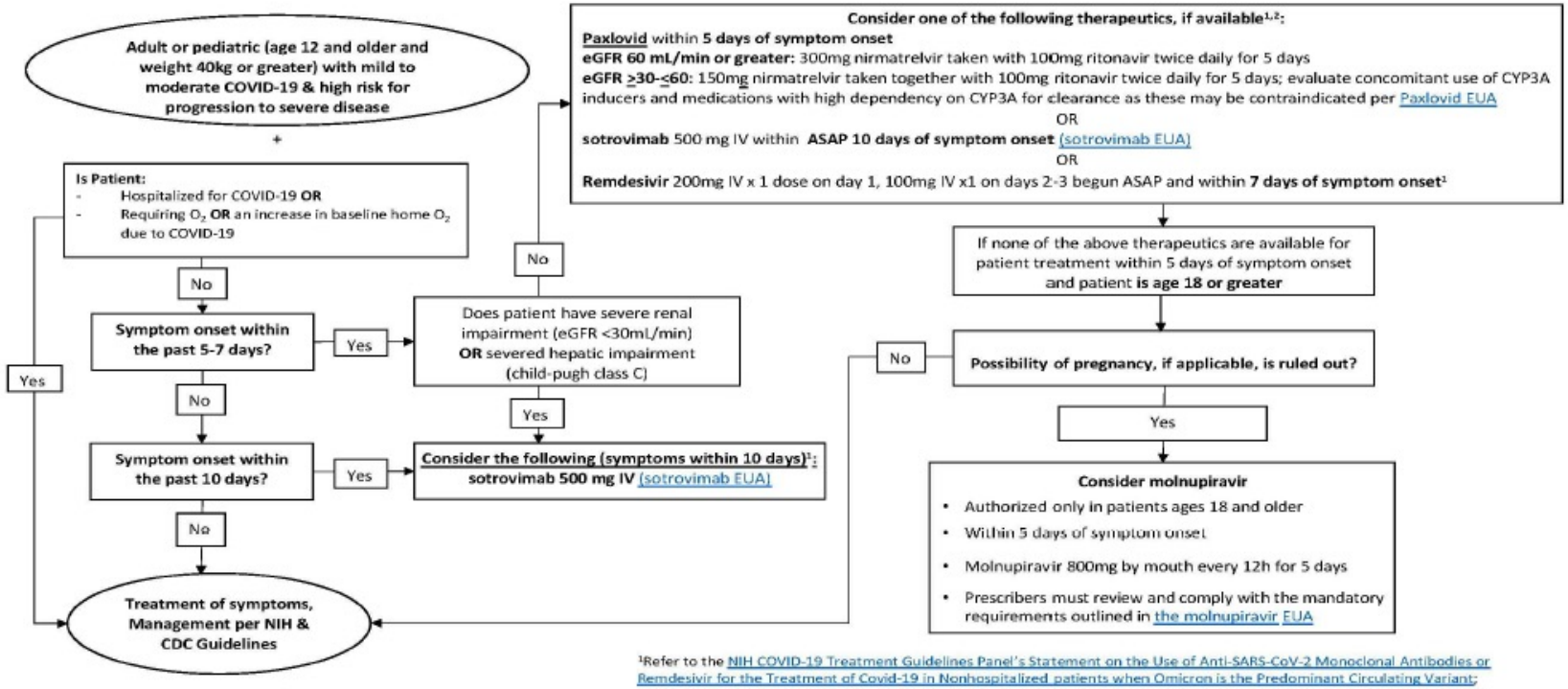
COVID-19 Outpatient Therapeutics Decision Guide



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant[1]

December 30, 2021

[1]Refer to the NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

[2] COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)

PowerPoint Presentation (idsociety.org)

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Preventive and Therapeutic options

No illness	Exposed	Mild to moderate	Hospitalized/ ICU
Vaccines			
Monoclonal antibodies for pre-exposure prophylaxis (LAAB)= EvuSheld	~~mAb for PEP =Bamlanivimab and etesevimab~~ - ~~Casirivimab and imdevimab~~	Sotrovimab Paxlovid Molnupiravir IV Remdesivir ~~Bamlanivimab and etesevimab~~ - ~~Casirivimab and Imdevimab~~	Steroids, Remdesevir, Baricitinib, Tocilizumab Resp support

Monoclonal Antibody COVID-19 Infusion | Guidance Portal (hhs.gov)

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Treatment Guidelines from NIH

- The National Institutes of Health has developed COVID-19 Treatment Guidelines to provide clinicians with guidance on how to care for patients with COVID-19
- Because clinical information about the optimal management of COVID-19 is evolving quickly, these Guidelines will be updated frequently as published data and other authoritative information become available

https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/introduction/

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Questions?

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