It’s Worth a Shot
Updates About the COVID-19 Vaccine Mandate

February 16, 2022
Housekeeping Items

- Add your webinar topics and clinician ideas or needs into chat!
- We will meet every Wednesday through April 13, 2022!
Emergency Use Authorization (EUA)


https://www.youtube.com/watch?v=iGkwaESsGBQ&t=105s
## Outpatient COVID-19 Therapies

<table>
<thead>
<tr>
<th></th>
<th>Paxlovid (Pfizer)</th>
<th>Sotrovimab (GlaxoSmithKline)</th>
<th>Remdesivir (Gilead)</th>
<th>Molnupiravir (Merck)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age eligibility</strong></td>
<td>12+</td>
<td>12+</td>
<td>All</td>
<td>18+</td>
</tr>
<tr>
<td><strong>Initiate within number days of symptom onset</strong></td>
<td>&lt; 5 days</td>
<td>&lt; 10 days</td>
<td>&lt; 7 days</td>
<td>&lt; 5 days</td>
</tr>
<tr>
<td><strong>Mechanism of action</strong></td>
<td>Viral protease inhibitor that halts viral replication</td>
<td>Monoclonal antibody against spike protein; blocks viral entry</td>
<td>Nucleoside analog that halts viral replication</td>
<td>Nucleoside analog that inhibits viral replication by viral mutagenesis</td>
</tr>
<tr>
<td><strong>Route of administration</strong></td>
<td>Oral</td>
<td>IV</td>
<td>IV</td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Duration of treatment</strong></td>
<td>Five days</td>
<td>One infusion</td>
<td>Three infusions over three days</td>
<td>Five days</td>
</tr>
</tbody>
</table>

Source: [https://dhss.alaska.gov/dph/Epi/id/Pages/COVID-19/therapeutics.aspx](https://dhss.alaska.gov/dph/Epi/id/Pages/COVID-19/therapeutics.aspx)
Nirmatrelvir/ritonavir (Paxlovid)

- 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir orally twice daily for 5 days
- Adjustment for renal impairment
  - moderate renal impairment (eGFR ≥30 to <60 mL/min), the dosage is 150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days
  - Not recommended in patients with severe renal impairment (eGFR <30 mL/min)
- Hepatic Impairment
  - Not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C)
- Contraindicated with drugs that are highly dependent on CYP3A
  - Side effects: altered sense of taste, diarrhea, high blood pressure, muscle aches
• 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food
• No dosing adjustment for renal or hepatic impairment
• Not recommended in pregnancy or breastfeeding
• Side effects
  • diarrhea, nausea, and dizziness
Monoclonal Antibodies

Sotrovimab

• Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing and

• Who are at high risk for progression to severe COVID-19, including hospitalization or death

Source: https://www.fda.gov/media/149534/download
Bebtelovimab—approved February 11, 2022

- With positive results of direct SARS-CoV-2 viral testing and
- Who are at high risk for progression to severe COVID-19, including hospitalization or death, and
- For whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

Source: https://www.fda.gov/media/156152/download
Veklury (Remdesivir)

- Treatment of coronavirus disease 2019 (COVID-19) in pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg, with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing who are hospitalized or
- Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
Therapeutics Decision Tree

View a larger version by visiting:
EVUSHELD (tixagevimab/cilgavimab)

- Intramuscular injections as **pre-exposure prophylaxis** for adults and adolescents who do not have SARS-CoV-2 infection, who have not been recently exposed to an individual with SARS-CoV-2 infection, **AND** who:
  1. Are moderately to severely immunocompromised and may have inadequate immune response to COVID-19 vaccination **or**
  2. Are not able to be fully vaccinated with any available COVID-19 vaccines due to a documented history of severe adverse reaction to a COVID-19 vaccine or any of its components

• Treatment Guidelines Panel’s Statement on Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19: https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/


• Paxlovid EUA: https://www.fda.gov/media/155050/download

• Remdesivir EUA: https://www.fda.gov/media/137566/download

• Molnupiravir EUA: https://www.fda.gov/media/155054/download

• Sotrovimab EUA: https://www.fda.gov/media/149534/download

• EVUSHELD EUA: https://www.fda.gov/media/154701/download

• Bebtelovimab EUA: https://www.fda.gov/media/156152/download

• FDA full list of EUA Drugs and Non-Vaccine Biological Products: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs

• Therapeutics Finder: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/


Vaccine Accessibility

State Vaccine Provider Programs

• Enrollment requirements:
  • Storage unit and temperature monitoring capabilities meet minimum CDC standards
  • Medical licenses for prescribing providers listed on the provider agreement are current
  • Necessary information for vaccine distribution system
  • Staff training
  • Program management plan
Vaccine Accessibility

State Vaccine Provider Programs

Inventory management
- Minimum Order Quantities
- Transfer ability

Storage and expiration tracking
- Administration, waste, inventory, reconciliation, ordering

Training/dedicated staff
Direct Order Breakdown

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Direct Minimum Order Size</th>
<th># Vials per Shipment</th>
<th>Refrigeration Storage Time 2°C and 8°C (36°F and 46°F)</th>
<th>Freezer Storage Time -50°C and -15°C (-58°F and 5°F)</th>
<th>Usage Breakdown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Ped (orange cap)</td>
<td>100 doses</td>
<td>10</td>
<td>10 weeks</td>
<td>N/A</td>
<td>One vial per week</td>
</tr>
<tr>
<td>Pfizer Adol/Adult (grey cap)</td>
<td>300 doses</td>
<td>50</td>
<td>10 weeks</td>
<td>N/A</td>
<td>One vial per business day</td>
</tr>
<tr>
<td>Moderna</td>
<td>100 doses</td>
<td>10</td>
<td>30 days</td>
<td>Until Expiration (at least 3 months)</td>
<td>Refrigerated: ~3 vials per week Freezer and Refrigerated: ~3 vials per month</td>
</tr>
</tbody>
</table>
Reviewing Our Options

Connecting our Resources

- State immunization departments
- Local health departments
  - Federally Qualified Health Centers (FQHC)
- Hospitals
- Pharmacies
**Wyoming Immunization Unit:**
https://health.wyo.gov/publichealth/immunization/immunization-provider-resources/public-vaccine-programs/
COVID-19 Vaccine Information: 800-438-5795 (Weekdays 8am-5pm)
Holly.scheer@wyo.gov

**Alaska Immunization Unit:**
Immunization Program Manager matthew.bobo@alaska.gov

**Montana Immunization Unit:**
https://dphhs.mt.gov/publichealth/immunization/
Adult Immunization Coordinator trisha.gardner@mt.gov

**Hawaii Immunization Unit:**
doh.covid-enrollment@doh.hawaii.gov
Immunization Branch at (808)586-8332 or (833)711-0645
Thank you!

Join us next week on Wednesday, February 23, 2022.

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