THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

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Dear Health Care Providers and Tribal Health Partners,

With the Omicron surge now here in Alaska, you may be getting questions from patients about COVID-19 therapeutics and whether they are eligible to receive them. Attached to this letter please find talking points from our clinical team at the Alaska Department of Health and Social Services (DHSS) to help you respond to questions and make informed clinical decisions for your patients. This DHSS webpage may also be helpful.

In our public messaging, we're urging Alaskans who test positive for COVID-19 and are at high risk for severe illness to talk to their health care provider. We are also letting Alaskans know that COVID-19 treatments, such as monoclonal antibodies and antiviral drugs, are in extremely limited supply nationally due to the Omicron surge and are only available for certain high-risk populations. All of the treatments need to be started as soon as possible after symptoms begin, some in as soon as five days.

Only one monoclonal antibody treatment, sotrovimab, has been shown to be effective against the Omicron variant. This medication is in extremely scarce supply nationally and is currently only recommended for people who are 12 years or older, weigh at least 88 pounds and are at highest risk for severe disease from COVID-19.

There are also two oral antiviral therapeutics available, paxlovid and molnupiravir. These are also in very limited supply and can only be used for certain individuals who are at risk for severe illness from COVID-19. It is important that individuals be evaluated by their provider to ensure there are no contraindications.

The prophylactic monoclonal antibody, Evusheld, is not in scarce supply, but is currently only available in select healthcare facilities that care for immunocompromised patients.

This information and more can be found in the talking points.

Our helpline, 907-646-3322, is available to help Alaskans if they have questions about testing, vaccines or therapeutics. Our helpline cannot provide medical advice but is able to help connect Alaskans with available resources.

Sincerely,

Dr. Anne Zink, MD, FAACP, Chief Medical Officer, Alaska Department of Health and Social Services

Outpatient COVID-19 Therapeutic Considerations

Last updated: January 7, 2022

EVUSHELD

- It is given to those 12 and up (and at least 40 kg) via an IM injection for *pre-exposure prophylaxis*
    - Not for *treatment* of COVID-19
- To be given every 6 months in areas where SARS-CoV-2 is circulating
- NOT AUTHORIZED by the FDA in unvaccinated individuals for whom COVID-19 vaccination is recommended
    - However, persons who received a dose of COVID-19 vaccine and had a documented anaphylactic reaction to that dose are eligible
- Patients must be assessed by a medical provider licensed to prescribe medications and prescribed for an individual patient
    - Individuals should reach out to their healthcare provider as EVUSHELD is currently only available in select healthcare facilities that care for immunocompromised patients
- Persons must be moderately to severely immunocompromised to be eligible
- Patient criteria:
    - Currently receiving active treatment for solid tumors and hematologic malignancies
    - Received a solid organ transplant and are taking immunosuppressive therapy
    - Received a chimeric antigen receptor T cell therapy or a hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
    - Have a moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
    - Have advanced or untreated HIV infection (defined as people with HIV and CD4 T lymphocyte cell counts <200/mm^3, a history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
    - Are receiving active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents that are classified as severely immunosuppressive, tumor-necrosis blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B cell-depleting agents)

- Additional information for health care providers
    - This prophylactic medication is not currently in scarce supply
    - Providers should communicate proactively to their eligible patients to get them scheduled for administration

Sotrovimab

- For treatment of COVID-19 in persons aged 12 years and up and weighing at least 40 kg (88 lbs)
- Should be given as soon as possible after testing positive on a directed* (see footnote below) COVID-19 test *within 10 days of symptom onset* for those at high-risk for severe disease
    - Administration is via IV infusion with a 1-hour post-infusion observation period
    - Must be given in a facility with the capacity to manage anaphylaxis
- This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
    - Access at community infusion centers
- Currently the only monoclonal antibody treatment option that is effective against the Omicron variant
- Common high-risk factors:
    - Being moderately to severely immunocompromised
        - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
    - High risk conditions
        - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

- Additional information for health care providers
    - Refrain from using REGEN COV and BAM+ETE at this point because they are ineffective against the Omicron variant
    - This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
        - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/

PAXLOVID

- For treatment of COVID-19 in persons aged 12 years and up and weighing at least 40 kg (88 lbs)
- Should be given as soon as possible after testing positive on a directed* (see footnote below) COVID-19 test *within 5 days of symptom onset* for those at high-risk for severe disease
    - Oral medication given twice a day for 5 days
- Patients must be assessed by a medical provider licensed to prescribe medications and prescribed for an individual patient
- This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
    - Access through community pharmacies
        - https://healthdata.gov/Health/COVID-19-Public-Therapeutic-Locator/rxn6-qnx8/data
- Common high-risk factors:
    - Being moderately to severely immunocompromised
        - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
    - High-risk conditions
        - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

- Additional information for health care providers
    - There are many drug-drug interactions associated with this medication
        - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/

        - https://www.covid19-druginteractions.org/
        - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/
    - Renal dose adjustment for creatinine clearance <60 mL/min and not recommended in CrCl <30 mL/min
    - This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
        - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/
    - We expect availability to increase substantially in the next 1–2 months

Molnupiravir

- For treatment of COVID-19 in persons aged 18 years and up who are not pregnant
- Should be given as soon as possible after testing positive on a directed* (see footnote below) COVID-19 test *within 5 days of symptom onset* for those at high-risk for severe disease
    - Oral medication given twice a day for 5 days
- Patients must be assessed by a medical provider licensed to prescribe medications and prescribed for an individual patient
- This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
    - Access at community pharmacies
        - https://healthdata.gov/Health/COVID-19-Public-Therapeutic-Locator/rxn6-qnx8/data
- Common high-risk factors:
    - Being moderately to severely immunocompromised
        - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
    - High-risk conditions
        - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

- Additional information for health care providers
    - Use only when the other options (i.e., sotrivimab, PAXLOVID, remdesivir) are unavailable
    - Assess pregnancy status
        - Advise patients of childbearing potential to use effective contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir
        - 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
    - Bone and cartilage toxicity: not authorized for use in patients aged <18 years because it may affect bone and cartilage growth
    - This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
        - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/
    - We expect availability to increase considerably in the next 1–2 months

Remdesivir

- For treatment of COVID-19 in persons aged 12 years and up and weighing at least 40 kg (88 lbs)
- Should be given as soon as possible after testing positive on a directed* (see footnote below) COVID-19 test *within 7 days of symptom onset* for those at high-risk for severe disease
    - Given via IV infusion daily for 3 consecutive days with a daily 1-hour post-infusion observation period
    - Must be given in a facility with the capacity to manage anaphylaxis
- This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
    - Access at community infusion centers
- Common high-risk factors:
    - Being moderately to severely immunocompromised
        - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
    - High risk conditions
        - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

- Additional information for health care providers
    - FDA approved and commercially available (not distributed through the US Department of Health and Human Services)
    - Currently no outpatient billing codes
    - Not available to purchase for non-hospital facilities
    - This medication is in extremely scarce supply nationally, and thus is currently only recommended for those at highest risk for severe disease from COVID-19
        - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/

**A directed COVID-19 test is defined as CLIA-waved (rapid antigen or rapid molecular) or CLIA-certificated lab test. At-home (over-the-counter) tests, where patient identity or results are not provider-verified, are not considered directed.*