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NH DIVISION OF Public Health Services
Department of Health and Human Services

COVID-19 Pandemic, Update # 52
Paxlovid and Molnupiravir Oral Antiviral Medications

Key Points and Recommendations:

- **Paxlovid**: On December 22nd, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization for Pfizer's Paxlovid oral antiviral medication for the treatment of mild-to-moderate COVID-19 in persons **12 years of age or older** who weigh at least 40 kg AND who are at high risk for progression to severe COVID-19, including hospitalization or death.
    - Paxlovid includes the SARS-CoV-2 protease inhibitor nirmatrelvir combined with ritonavir (an HIV protease inhibitor), which is included to boost the plasma concentration of nirmatrelvir; both medications must be taken together.
    - A phase 2/3 randomized, double-blind, placebo-controlled clinical trial (EPIC-HR) found that Paxlovid reduced the risk of hospitalization or death by 88% compared to placebo.
    - Prescribing providers should review and follow the instructions found in FDA's Fact Sheet for Healthcare Providers.
    - Patients and caregivers need to be provided FDA's Fact Sheet for Patients, Parents and Caregivers prior to administration.
    - Treatment course is 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) taken orally twice daily for 5 days (see FDA Fact Sheet for dosing information in patients with renal or hepatic impairment).
    - Initiate treatment as soon as possible after diagnosis and within 5 days of symptom onset.
    - Review patient medications prior to prescribing Paxlovid to ensure no contraindications or drug interactions [see FDA Fact Sheet for more information about contraindications (section 4) and potential drug interactions (section 7)].
        - Advise patients using combined hormonal contraception to use an alternate contraceptive method because Paxlovid may reduce the efficacy of hormonal contraception.
- **Molnupiravir**: On December 23rd, the U.S. FDA issued an Emergency Use Authorization for Merck's Molnupiravir oral antiviral medication for the treatment of mild-to-moderate COVID-19 in persons **18 years of age or older** who are at high risk for progression to severe COVID-19, including hospitalization or death, AND for whom alternative COVID-19 treatment options are not accessible or not clinically appropriate.
    - Molnupiravir is a nucleoside analogue that inhibits SARS-CoV-2 replication by incorporation into viral RNA resulting in an accumulation of errors in the virus genome and inhibition of replication.
    - A phase 3 randomized, double-blind, placebo-controlled clinical trial (MOVe-OUT) found that Molnupiravir reduced the risk of hospitalization or death by about 30% compared to placebo.
    - Prescribing providers should review and follow the instructions found in FDA's Fact Sheet for Healthcare Providers.
    - Patients and caregivers need to be provided FDA's Fact Sheet for Patients and Caregivers prior to administration.

  - Treatment course is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days (no dosage adjustment is recommended based on renal or hepatic impairment).
  - Initiate treatment as soon as possible after diagnosis and within 5 days of symptom onset.
  - Avoid use during pregnancy – providers must assess pregnancy status in females of childbearing potential prior to use (see FDA Fact Sheet, sections 5.1 and 8.3). Animal reproductive studies have shown that Molnupiravir may cause fetal harm when administered to pregnant individuals.
  - Breastfeeding is not recommended during treatment and for 4 days after the final dose. Animal studies have shown that Molnupiravir may be passed to nursing infants through breast milk and may affect bone and cartilage growth.
  - Sexually active males and females must be counselled about correctly and consistently using a reliable method of contraception as follows:
    - Females of childbearing potential: During treatment and for 4 days after the last dose of molnupiravir.
    - Males who are sexually active with females of childbearing potential: During treatment and for at least 3 months after the last dose.

- For the next two weeks, NH will be sent 240 doses of Paxlovid and 1,040 doses of Molnupiravir each week. The initial doses of Paxlovid will be allocated to NH hospitals, and Molnupiravir will be allocated to pharmacies that service NH Skilled Nursing Facilities (SNFs) and a limited number of urgent care facilities. Additionally, the U.S. Health Resources and Services Administration is distributing antivirals to a limited number of NH Federally Qualified Heath Centers (FQHCs). A listing of facilities receiving antivirals to treat COVID-19 will be available in the next couple of weeks on the NH DHHS COVID-19 Treatment Resources website and will be regularly updated as distribution expands.
- Providers should continue to refer to the NIH COVID-19 Treatment Guidelines and the IDSA Guidelines for treatment and prevention of COVID-19.
- Report any serious adverse events and medication errors that occur within 7 days of the onset of the event to FDA's MedWatch.
- Starting in January 2022, the NH Division of Public Health Services (DPHS) **Healthcare Provider and Public Health Partner** webinars will occur on the **2nd and 4th Thursday** of each month from 12:00 – 1:00 pm (**next call will be Thursday, January 13th**):
  - Zoom link: https://nh-dhhs.zoom.us/s/94059287404
  - Call-in phone number: (646) 558-8656
  - Meeting ID: 940 5928 7404
  - Password: 353809

- For any questions regarding this notification, please call the NH DHHS, DPHS, Bureau of Infectious Disease Control at (603) 271-4496 during business hours (8:00 a.m. – 4:30 p.m.).
- If you are calling after hours or on the weekend, please call the New Hampshire Hospital switchboard at (603) 271-5300 and request the Public Health Professional on-call.
- To change your contact information in the NH Health Alert Network, please send an email to DHHS.Health.Alert@dhhs.nh.gov.

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