

2022 Updates

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Updates

- New CDC guidance for isolation and quarantine -- shortening both to 5 days
- New MDHHS guidance supporting CDC isolation and quarantine recommendations for general public and K-12 education (uncertain for congregate settings)
- Updated CDC guidance on managing healthcare personnel with COVID-19 or exposure to it
- Impending approval of booster shots for ages 12-15 and when that will be available in Saginaw County
- New guidance allowing boosters as early as 5 months after primary series rather than 6 months
- Approval of third doses for immunocompromised individuals ages 5 and older

Work Restrictions for HCP With SARS-CoV-2 Infection and Exposures

HCP are considered “boosted” if they have received all COVID-19 vaccine doses, including a booster dose, as recommended by CDC. HCP are considered “vaccinated” or “unvaccinated” if they have NOT received all COVID-19 vaccine doses, including a booster dose, as recommended by CDC.

For more details, including recommendations for healthcare personnel who are immunocompromised, refer to Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 (conventional standards) and Strategies to Mitigate Healthcare Personnel Staffing Shortages (contingency and crisis standards).

Work Restrictions for HCP With SARS-CoV-2 Infection

Vaccination Status	Conventional	Contingency	Crisis
Boosted, Vaccinated, or Unvaccinated	10 days OR 7 days with negative test [†] , if asymptomatic or mildly symptomatic (with improving symptoms)	5 days with/without negative test, if asymptomatic or mildly symptomatic (with improving symptoms)	No work restriction, with prioritization considerations (e.g., asymptomatic or mildly symptomatic)

Work Restrictions for Asymptomatic HCP with Exposures

Vaccination Status	Conventional	Contingency	Crisis
Boosted	No work restrictions, with negative test on days 2 [‡] and 5–7	No work restrictions	No work restrictions
Vaccinated or Unvaccinated, even if within 90 days of prior infection	10 days OR 7 days with negative test	No work restriction with negative tests on days 1 [‡] , 2, 3, & 5–7	No work restrictions (test if possible)

[†]Negative test result within 48 hours before returning to work

[‡]For calculating day of test: 1) for those with infection consider day of symptom onset (or first positive test if asymptomatic) as day 0; 2) for those with exposure consider day of exposure as day 0

Remdesivir

- A recent randomized placebo-controlled outpatient study evaluated three daily intravenous (IV) infusion of remdesivir given within seven days of symptom onset.
- This study found that the reduction in hospitalization rates was similar to that achieved by using anti-SARS-CoV-2 monoclonal antibody-based therapy (7).
- Remdesivir is expected to be effective against the Omicron variant based on in vitro data; however, in vivo data are currently limited (8).
- Outpatient use of remdesivir requires support of IV infusion centers with appropriate skilled staffing.

Antivirals

- Paxlovid (ritonavir-boosted nirmatrelvir) and molnupiravir, are now available under Emergency Use Authorization by FDA for treating COVID-19 in outpatients with mild to moderate disease.
- Each drug is administered twice daily for five days.
- There are considerable differences in efficacy, risk profiles, and use restrictions between the two oral antivirals.
- From their individual clinical trials, compared to placebo, severe outcomes (hospitalization or death) were reduced by 88% for Paxlovid compared to 30% for molnupiravir (9).
- Initiating treatment with these oral antivirals must begin within five days of symptom onset to maintain product efficacy

Paxlovid

- Paxlovid is currently in very limited supply and use should be prioritized for higher risk populations.
- Due to the potential for severe drug-drug interactions with ritonavir, a medication used for HIV treatment, CDC strongly suggests that healthcare providers not experienced in prescribing Paxlovid refer to the NIH Statement on Paxlovid Drug-Drug Interactions | COVID-19 Treatment Guidelines.
- Healthcare providers could also contact a local clinical pharmacist or an infectious disease specialist for advice.

Paxlovid

- Used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older
- Weighing at least 88 pounds (40 kg)]
- With positive results of direct SARS-CoV-2 viral testing
- Who are at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid

- **Dosing of PAXLOVID (see full Fact Sheet for Healthcare Providers)**
- PAXLOVID is nirmatrelvir tablets co-packaged with ritonavir tablets. Nirmatrelvir must be co-administered with ritonavir.
- • Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.
- • Administer orally with or without food.
- • Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.
- • **Dose reduction for moderate renal impairment (eGFR \geq 30 to $<$ 60 mL/min):** 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.
- • PAXLOVID is not recommended in patients with severe renal impairment (eGFR $<$ 30 mL/min).
- • PAXLOVID is not recommended in patients with severe hepatic impairment (Child-Pugh Class C).
- • Alert the patient of the importance of completing the full 5-day treatment course and to continuing isolation in accordance with public health recommendations to maximize viral clearance and minimize transmission of SARS-CoV-2.

Paxlovid: Side Effects

- Possible side effects of PAXLOVID are:
- Liver Problems, loss of appetite, jaundice, dark-colored urine, pale colored stools and itchy skin, abdominal pain.
- Resistance to HIV Medicines. If you have untreated HIV infection, PAXLOVID may lead to some HIV medicines not working as well in the future.
- Other possible side effects include: altered sense of taste, Diarrhea, high blood pressure, muscle aches

Contraindication

- Do not take PAXLOVID if:
- Allergy to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID.

Taking following medicines:

- Alfuzosin o Pethidine, piroxicam, propoxyphene o Ranolazine o Amiodarone, dronedarone, flecainide, propafenone, quinidine o Colchicine o Lurasidone, pimozide, clozapine o Dihydroergotamine, ergotamine, methylergonovine o Lovastatin, simvastatin o Sildenafil (Revatio®) for pulmonary arterial hypertension (PAH) o Triazolam, oral midazolam o Apalutamide o Carbamazepine, phenobarbital, phenytoin o Rifampin o St. John's Wort (*hypericum perforatum*)

Molnupiravir

Molnupiravir is expected to be active against all circulating variants of concern, including Omicron (8).

Molnupiravir should only be used when other options are not available, due to its lower efficacy.

Molnupiravir use is not recommended in pregnancy because of potential mutagenicity.

Molnupiravir is also not recommended in patients who are breastfeeding or pediatric patients due to limited data within these populations and concerns for potential bone growth toxicity in the young.

Limitation of Use

- **Limitations of Authorization Use**

- • PAXLOVID and molnupiravir are not authorized in patients under 12 and 18 years of age, respectively.
- • Medications are not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- • Medications are not authorized for pre-exposure or post-exposure prophylaxis of COVID-19.
- • Medications are not authorized for use longer than 5 consecutive days.

Instructions on Prescribing Antivirals

- 1. Prescriber determines if medication is currently available in the area.
 - a. Paxlovid limited to Metro Detroit, Flint, Saginaw areas. (see [Meijer COVID-19 Therapeutics Website- Tittabawassee](#))
 - b. Molnupiravir is expected to be in all Meijer pharmacies by January 3, until then, see Page 2 below for current availability. Note this should only be prescribed when timely access to other authorized therapies (e.g., monoclonal antibodies) is delayed.
- 2. Determine if patient meets eligibility criteria for medication including review of patient's current medications for interactions (with Paxlovid).
- 3. Prescriber discusses risk and benefits with patient and provides a copy of the *FDA Fact Sheet for Patients and Care Givers* for either [Paxlovid](#) or [molnupiravir](#).

Instructions on Prescribing Antivirals

- 4. Prescriber determines closest pharmacy to patient that has desired medication.
- 5. Complete applicable prescription either via fillable PDF form or print to paper to complete.
 - a. All requested information must be provided, or prescription will not be filled.
 - b. Prescriber must sign prescription.
 - c. Include fax number of pharmacy (lower right corner of prescription) to facilitate faxing
 - d. Phone prescriptions will not be accepted.
- 6. Have prescription faxed to pharmacy. If faxing is unavailable, may provide copy to patient but this
 - will delay processing.
- 7. Meijer will make filling this prescription a priority. During pharmacy business hours should ready for
- pick up within 30 minutes. Patient should avoid entering the store for prescription pick up.

Script

(Must meet all below and FDA Emergency Use Authorization Criteria)

- Positive test for SARS-CoV-2
- Symptom onset within 5 days: Specify Symptom Onset Date:
- Age \geq 12 YO and weight $>$ 40 kg
- No medication interactions identified

Priority Eligibility Criteria

(Must meet one of criteria below)

- Age \geq 12 YO with moderate to severe immunocompromise regardless of vaccine status **or**
Specify Condition:
- Age \geq 75 YO and not maximally vaccinated (completion of all recommended vaccinations for age group, including booster)

Patient Order

Medication: nirmatrelvir 150 mg tablet and ritonavir 100 mg tablet

Instructions: Take 1 nirmatrelvir tablet by mouth with 1 ritonavir tablet by mouth, with both tablets taken together twice daily for 5 days.

Dispense: #10 nirmatrelvir tablets and #10 ritonavir tablets (use renal adjustment sticker)

Refills: No Refills

Prescriber Name

Prescriber Signature