MICHIGAN'S TEST TO TREAT PROGRAM
INFORMATION FOR HEALTH CARE PROVIDERS

Michigan.gov/Coronavirus

May 23, 2022

Purpose: Provide guidance for health care providers about the Test to Treat program and insight for health care facilities about the requirements needed to become part of the program.

Background: In March 2022, the federal government launched the Test to Treat program, a nationwide initiative designed to ensure rapid access to no-cost COVID-19 oral antiviral medications for certain high-risk individuals who have tested positive for COVID-19, who are experiencing mild to moderate symptoms, and who are at high-risk for severe disease including hospitalization and/or death. Test to Treat sites will provide COVID-19 tests, determine eligibility of patients to receive COVID-19 therapy, and prescribe medication that can be filled on-site or at affiliated pharmacies. A list of Michigan Test to Treat sites can be found at MI COVID-19 Test to Treat locator. For a complete list of Test to Treat locations please visit the National Test to Treat Locator.

The Test to Treat program will provide access to COVID-19 testing and treatment in a single location. However, this program is not a replacement for the relationship between patients and their usual provider. Patients may continue to be tested and treated by their own qualified health care providers, who also can prescribe these oral antivirals. Patients can pick up those prescriptions wherever oral antivirals are distributed. For a complete list of locations please visit the MI COVID-19 Therapeutics Locator. In compliance with the FDA Emergency Use Authorization (EUA), only a qualified health care provider may prescribe these medications. Pharmacists will not be able to prescribe oral antiviral medications.

Test to Treat Site Selection Criteria

- Provide medical services for COVID-19 outpatients, which include:
  - Point-of-Care rapid COVID-19 testing, an evaluation to at-home test, or a test performed by another facility.
  - Eligibility determination to receive oral antivirals by a licensed health care provider after a positive test result, and if eligible and available, provide medication on-site.
  - Co-located or affiliated pharmacy able to readily dispense medication to eligible patients.
- Provide services to all individuals, regardless of insurance status.
- Accept new patients for priority same-day or next-day visit for COVID-19 services.

Test to Treat Locator

Use the MI COVID-19 Test to Treat Locator to find a Test to Treat site.

Test to Treat and Insurance Status

Test to Treat sites should provide services to all individuals, regardless of insurance status. It is important to note that the Health Resources and Services Administration's (HRSA) COVID-19 Uninsured Program **no longer accepts claims** for testing, treatment, monoclonal antibody, and vaccine administration due to a lack of sufficient funds. Providers should discuss any associated costs with the patients. Please view the Centers for Medicare & Medicaid Services webpage for more billing information.

COVID-19 High-Risk Groups

The FDA has indicated in the EUA that these medications are intended for those who are at increased risk of hospitalization or death, but are not hospitalized when treatment is started. Those who are immunocompromised or not up to date on COVID-19, and those with any of the following conditions identified in the FDA EUAs are particularly at risk:

- Older age (for example ≥65 years of age)
- Obesity or being overweight (e.g., BMI >25 kg/m2), or BMI ≥85th percentile pediatrics
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (e.g., COPD, moderate to severe asthma, etc.)
- Sickle cell disease
- Neurodevelopmental disorders (e.g., cerebral palsy) or other complexity conditions
- Medical-related technological dependence (e.g., tracheostomy, gastrostomy)
- Other conditions identified by the CDC for the person at risk for disease severity

Test to Treat Available Treatments

COVID-19 treatments included in the Test to Treat program are the two oral antiviral pills – Pfizer's Paxlovid and Merck's Lagevrio (molnupiravir). Both oral antiviral medications were granted EUA by the FDA for non-hospitalized patients with mild to moderate COVID-19 who are at high-risk of severe disease progression including hospitalization or death.

Paxlovid (nirmatrelvir/ritonavir)

Prescribers must comply with requirements of the FDA Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid.

Paxlovid consists of nirmatrelvir boosted by ritonavir. Both are protease inhibitors. Moreover, ritonavir is a CYP3A inhibitor (an enzyme in the liver responsible for the metabolism of a wide variety of drugs). Therefore, Paxlovid may increase the plasma concentration of drugs that are cleared mainly by CYP3A. Health care providers and pharmacists must **review the list of medications** the patient is taking before starting Paxlovid. Because Paxlovid is only used for five days, Drug-Drug Interactions' management (e.g., dose adjustment or medication stop for a small period) may be considered when prescribing Paxlovid.

- Mechanism: antiviral (protease inhibitor).
- Given orally twice daily for five days (Initiate Paxlovid treatment as soon as possible).
- Started within five days of symptom onset (symptoms' onset day is day zero).
- Age >12 YO and weight >40 kg (88 pounds).
- 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 five days.
- Dose reduction for moderate renal impairment (eGFR ≥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 five 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).
- Evaluate for drug-to-drug interactions.

Lagevrio (molnupiravir)

Prescribers must comply with requirements of the FDA Fact Sheet for Healthcare Providers: Emergency Use Authorization for Molnupiravir.

Lagevrio consists of molnupiravir, the active drug (in vivo) incorporates into the genome of RNA virus which inhibits viral reproduction by causing accumulation of mutations known as viral error catastrophe. It is considered an **alternative therapy** used when other treatment options are not accessible or clinically appropriate. Due to potential Embryo-Fetal Toxicity, Lagevrio is not recommended for use during pregnancy. Females taking Lagevrio should use a reliable method of contraception for the duration of treatment and for **four days** after the last dose of Lagevrio. Males who are sexually active with females of childbearing potential should use a reliable method of contraception during treatment and for at least **three months** after the last dose. Molnupiravir is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth.

- Mechanism: antiviral (mutagenic).
- Given orally twice daily for five days (Initiate Lagevrio treatment as soon as possible).
- Started within five days of symptom onset (symptoms' onset day is day zero).
- Age >18 YO.
- Dosage: 800 mg (four 200 mg capsules) taken orally every 12 hours for five days, with or without food.
- Contraindicated in pregnancy.

Additional Information

Additional information on these medications can be obtained through the MDHHS Therapeutics webpage: Michigan.gov/COVIDtherapy select "For Health Care Providers". Questions may be submitted by email to mdhhs-covid-therapies@michigan.gov.