

April 6, 2021

<Provider Name>
<Provider Address 1>
<Provider Address 2>
<City> <State> zipcode5-zipcode4

Dear Provider:

Re: Removal of Prior Authorization for Hepatitis C Treatment

The Michigan Department of Health and Human Services (MDHHS) is removing administrative barriers to improve access to a hepatitis C virus (HCV) treatment for program beneficiaries. This policy is part of the MDHHS We Treat Hep C Initiative to eliminate HCV in Michigan.

Effective April 1, 2021, the product MAVYRET[®] (glecaprevir/pibrentasvir) will no longer require clinical prior authorization (PA) when prescribed in accordance with Food and Drug Administration (FDA)-approved labeling. This includes removal of the requirement that HCV medications must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist. All providers who have prescriptive authority will be able to prescribe this treatment to their patients with HCV.

MDHHS seeks the assistance of the clinical community to eliminate HCV as a health threat in Michigan by:

- Screening¹ all adults for HCV infection at least once in their lifetime
- Evaluating those with confirmed HCV infection for treatment
- Prescribing curative therapies for any beneficiary infected with HCV

¹ The Centers for Disease Control (CDC) defines an HCV screen to mean a blood draw to detect antibodies to HCV, which are indicative of HCV exposure. For persons that are reactive for HCV antibody, a subsequent test (that often can be run from the same specimen), can be run to detect HCV virus RNA in the blood to confirm presence of HCV Infection. See the CDC's Recommended Testing Sequence from the for identifying current HCV infection at https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_flow.pdf.

The following are recommendations, tools and resources to assist in making a Hepatitis C-free Michigan a reality.

Background on Hepatitis C

Hepatitis C is a liver infection caused by the hepatitis C virus (HCV). It is spread through contact with blood from an infected person. For some people, hepatitis C is a short-term illness that resolves spontaneously, but for most people who become infected with HCV, it becomes a chronic infection. Chronic HCV can result in serious, even life-threatening, health problems like cirrhosis and liver cancer.

People with HCV often have no symptoms and do not feel sick. When symptoms appear, they often are a sign of advanced liver disease. Approximately 115,000 people in Michigan are known to have HCV, though when taking undiagnosed persons into account, that number may be as high as 200,000. The number of persons unknowingly living with undiagnosed HCV infection is why broad population-based HCV screening is so important. Screening, testing and treatment can save and prolong life.

Direct-Acting Antiviral (DAA) medications use molecules that target specific nonstructural proteins of the virus which results in disruption of viral replication and infection. They are oral medications taken once per day for several weeks. With cure rates above 90%, these drugs can virtually eliminate the disease. The medications can be prescribed using simplified treatment algorithms for most patients, and do not require specialized clinical oversight or management.

We Treat Hep C Initiative

MDHHS launched the We Treat Hep C Initiative to take important steps towards eliminating HCV in Michigan. MDHHS partnered with the Michigan Department of Corrections (MDOC) to issue a Request For Proposals (RFP) for drug manufacturers of DAAs to provide a significant discount to these agencies. After evaluating proposals, the agencies awarded the contract to the manufacturer AbbVie for its DAA MAVYRET to be the preferred agent for the Medicaid, Healthy Michigan Plan (HMP) and incarcerated populations. To expand access to treatment, previous PA criteria (i.e., prescription by or in consultation with a specialist and documentation of current or recent substance use) will no longer be required.

HCV Screening and Testing

The Centers for Disease Control and Prevention (CDC) recommends that all adults ages 18 and older should be screened for HCV at least once in a lifetime. Screening for HCV involves measuring antibody to HCV in a person's serum. A reactive or positive test (detection of the antibody) is not a diagnosis of the disease; it only

indicates that a person was previously exposed to the virus. If the antibody test is reactive, a nucleic acid test (also known as a polymerase chain reaction [PCR] test) for HCV ribonucleic acid (RNA) is needed to determine whether the person currently has active HCV infection. Often, the antibody test and the RNA test can be performed on a single blood draw, with a positive antibody test automatically reflexing to the HCV RNA test. If the HCV RNA test is positive, the beneficiary can be prescribed HCV treatment. In most instances, a simplified HCV treatment algorithm can be followed. See additional information in the “Resources for Providers” section.

Treatment Coverage

MAVYRET is an oral prescription medication used to treat adults and children ages 12 and older with chronic HCV genotypes 1-6. In most cases, the treatment regimen is three pills taken once daily for eight weeks. MAVYRET treats all common HCV genotypes; therefore, a genotype test is not required before starting a patient on MAVYRET. Starting April 1, 2021, MAVYRET will be the only DAA identified as Preferred on the Michigan Preferred Drug List (PDL) and will no longer require clinical PA when prescribed in accordance with FDA-approved labeling.

PA will still be required for the following PDL Non-Preferred agents, with documentation explaining why the preferred agent MAVYRET cannot be used:

- Epclusa™
- Harvoni™
- ledipasvir/sofosbuvir
- sofosbuvir/velpatasvir
- Sovaldi™
- Vosevi™
- Zepatier™

The PDL is available at <https://michigan.magellanrx.com/provider/>.

Follow-Up After Treatment

Beneficiaries who have received treatment should be tested for HCV RNA 12 weeks (or longer) after treatment completion. Undetectable or unquantifiable HCV RNA 12 weeks or longer after treatment completion is defined as a sustained virologic response (SVR) which is consistent with cure of HCV infection.

Pregnant Women

The CDC recommends that all pregnant women should be screened for HCV during each pregnancy. This will aid providers in identifying HCV-infected mothers, which can lead to treatment for the mother during the postpartum period. It can also help

identify infants who should receive testing at a pediatric visit. There are currently no approved curative treatments available for pregnant women or children under 3 years, but curative treatments are available for women who are not pregnant and for children 3 years of age and older.

Telehealth

As a reminder, during the COVID-19 public health emergency, the CDC and State encourage the use of telehealth technology whenever possible to maintain social distancing and slow the spread of COVID-19. Refer to Medicaid Provider Bulletins MSA 20-12, 20-13 and 20-30 on the temporary expansion of telehealth services, available at www.michigan.gov/MedicaidProviders >> Policy, Letters & Forms >> 2020.

Resources for Providers

HCV DAAs are safe, associated with high rates of cure, and have few side effects and contraindications. Some HCV patients may need to have their treatment managed by a specialist, such as those with hepatitis B virus or HIV co-infection, those who previously failed HCV treatment, or those with liver cancer or who have had a liver transplant. However, most cases of HCV can be treated by primary care physicians. Providers may find the following resources helpful:

Centers for Disease Control and Prevention:

- HCV Screening/Testing Recommendations: <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>
- Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection: https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_flow.pdf

Simplified HCV Treatment Algorithms from the American Association for the Study of Liver Diseases:

- Evaluation and Treatment Algorithm for patients without cirrhosis: https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCV-Guidance_TxN-Simplified-Tx-No-Cirr_e.pdf
- Evaluation and Treatment Algorithm for patients with compensated cirrhosis: https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCV-Guidance_TxN-Simplified-Tx-Comp-Cirr_e.pdf

Provider Education and Technical Assistance

The Michigan site of the Midwest AIDS Training and Education Center (MATEC) is located at Wayne State University School of Medicine, Division of Infectious Diseases. It will be developing on-demand webinars, live training events, office hours and other resources for providers on treating HCV. These resources will be available at www.mi.gov/wetreathepc and matecmichigan.org.

HCV Clinical Consulting Line

MDHHS has partnered with Henry Ford Health System to provide a free consulting line for all health care professionals with questions about HCV treatment. This consulting line will operate from 8 am – 5 pm daily and will be available for providers starting April 1, 2021: (313) 575-0332.

Additional Resources

- Additional resources for providers are available at www.michigan.gov/WeTreatHepC.

Recent medical advancements means that no one should have to live with HCV. Thank you for your partnership in eliminating this deadly virus.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Massey', followed by a horizontal line.

Kate Massey, Director
Medical Services Administration