Frequently Asked Questions (FAQs)

Contents

MEDICAID

NOTE: For Medicaid-related questions not listed in the FAQs, please contact MDHHSPharmacyServices@Michigan.gov.

1. **When will the system be set up where MAVYRET® will be approved without prior authorization (PA)?**

The system will be set up to approve MAVYRET® without PA effective 4/1/21.

2. **When will the Preferred Drug List (PDL) be updated to reflect the changes?**

The Preferred Drug List was updated on 4/1/21 and can be found at https://michigan.magellanrx.com/provider/external/medicaid/mi/doc/en-us/MIRx_PDL.pdf.

3. **When will expanded treaters (non-specialists) be able to prescribe MAVYRET®?**

Expanded treaters will be able to prescribe effective 4/1/21.

4. **What has to be submitted with a MAVYRET® claim now that no PA is required?**

The claim will be paid if submitted in accordance with our Pharmacy Claims Processing Manual: https://michigan.magellanrx.com/provider/external/medicaid/mi/doc/en-us/MIRx_D0_claims_processing_manual.pdf. Diagnosis codes are not required on these claims.

5. **Will MAVYRET® be covered without a PA in the rare case a patient requires 12 weeks of therapy?**

Yes.

6. **For patients currently taking another Direct-Acting Antiviral (DAA) therapy (Zepatier, Epclusa, etc.), will they be able to complete their course of therapy (i.e., refills)?**

Yes.

7. **Will there be specific PA criteria listed in the PDL for the non-preferred DAAs?**

Non-preferred DAAs will require a PA explaining why MAVYRET® is not clinically appropriate: MIRx_PAfaxform_General.pdf (magellanrx.com)

8. **Are prisoners covered by Medicaid upon release and therefore able to get MAVYRET® without a PA?**

We are working on a Targeted Case Management benefit that provides support and resources for individuals recently released from a correctional facility, including some degree of in-reach, but this has not yet been implemented.

9. Can patients fill their MAVYRET® prescription at any Specialty or Retail Pharmacy?

Yes.

10. What is the co-pay for MAVYRET® under this agreement? What is the co-pay for a non-preferred DAA?

For Medicaid, co-pay for MAVYRET® is $1, and co-pay for non-preferred DAAs are $3. There are no co-pays for viral hepatitis treatments for Healthy Michigan Plan.

11. Can more than 4 weeks of therapy be prescribed at a single time (e.g., 8 weeks of therapy, or less frequently 12 weeks of therapy, as opposed to 4 weeks with refill(s))?

Pharmacies are authorized to dispense up to 102 days of therapy at a single time. However, many pharmacies may default to dispensing in 4-week increments, unless the script specifies an 8- or 12-week supply.

12. Is MAVYRET® covered for patients on Emergency Services Only (ESO) Medicaid?

Yes. MAVYRET® is covered for beneficiaries on Emergency Service (ESO) Medicaid. The Pharmacy should indicate level of service 3 (emergency) on the claim.

13. When an individual has both Medicaid and other health insurance coverage, is the individual eligible for Mavyret through Medicaid?

If the claim is denied by the individual's primary insurance (or if the primary insurance requires a prior authorization and the PA is denied), the individual would be eligible for Mavyret through Medicaid. The pharmacy would need to enter an Other Payer Reject code when submitting the claim. The pharmacy can contact MDHHSPharmacyServices@Michigan.gov if technical assistance is needed.

CLINICAL

Pre-Treatment Testing for HCV

1. How soon after exposure to HCV can HCV RNA be detected?

People with recently acquired acute infection typically have detectable with HCV RNA levels as early as 1-2 weeks after exposure to the virus.

2. How soon after exposure to HCV can HCV antibodies be detected?

Detection of HCV antibodies occurs an average of 8-11 weeks after exposure, although cases delayed seroconversion have been documented in people who are immunosuppressed (e.g., those with HIV infection).

3. Is obtaining the HCV genotype important before therapy start?

Both Mavyret and Epclusa are pangenotypic meaning they treat all HCV genotypes, so genotype testing is no longer required for all individuals. In those with evidence of cirrhosis and/or past unsuccessful HCV treatment, treatment regimens may differ by genotype thus pretreatment genotyping may be recommended in such cases. In patients with no prior treatment and/or without evidence of cirrhosis, HCV genotyping is not needed.

4. Is there a pre-set of labs that should be sent before therapy?

We recommend the following pre-treatment labs:

Within 6 months of initiating treatment:

- Complete blood count (CBC)
- Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])
- Calculated glomerular filtration rate (eGFR)

Any time prior to starting antiviral therapy:

- Quantitative HCV RNA (HCV Viral Load)
- HIV antigen/antibody test
- Hepatitis B surface antigen

Before initiating antiviral therapy:

- Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age
- HCV genotype in a patient with prior HCV treatment and/or cirrhosis

5. What is the cut off to treat viral load?

A positive HCV RNA identifies the presence of hepatitis C and would be an indication for treatment regardless of the viral level. There is no low or high viral load "cut off" to determine whether a patient qualifies for treatment.

Course of Seroconversion

1. Is it possible for someone to become infected with HCV and then spontaneously clear the infection?

Yes. However, 55 to 85% of people who become infected with HCV will develop chronic HCV infection. Patients who have a hepatitis C viral load that detectable should be treated.

2. Can people become infected with a different strain of HCV after they have clear the initial infection?

Yes. Prior infection with HCV does not protect against later infection with the same or different genotypes of the virus. This is because people infected with HCV typically have an ineffective immune response due to changes in the virus during infection.

At least annual HCV RNA screening is recommended for persons who inject drugs and for men living with HIV who have condomless sex with men.

Decompensated Cirrhosis

1. How do I link someone to care HCV and decompensated cirrhosis?

a) Individuals with cirrhosis are considered to have decompensated cirrhosis if they score 7 or higher on the Child -Turcotte-Pugh score and/or develop any of the following complications: ascites, jaundice, variceal hemorrhage, or hepatic encephalopathy.

b) To calculate Child-Turcotte-Pugh score, there are helpful calculators, for example: https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp

c) For patients with decompensated cirrhosis, refer to hepatology or transplant hepatology, such as at University of Michigan, Henry Ford Hospital, or Beaumont Hospital.

Post-Treatment Evaluation

1. Do you do 12-week post-treatment lab work to ensure the virus has been eradicated? How do you keep your patients compliant with the 12-week post-treatment labs?

A cure from hepatitis C (sustained virologic response or SVR) is defined as a negative HCV RNA test done at least 12 weeks after completing treatment. We encourage patients to be seen in clinic for a follow-up visit at least 12-weeks after therapy to discuss having this final test and any additional follow-up needed such as liver cancer screening in the patients with cirrhosis.

Guidance for People Living With Hepatitis C

1. Should people with hepatitis C be restricted from working in certain occupations or settings?

No. No one should be excluded from work, school, play, child-care, or other settings on the basis of their infection status. There is no evidence that hepatitis C can be transmitted from food handlers, teachers, or other service providers in the absence of blood-to-blood contact.

2. Should a woman with hepatitis C be advised against breastfeeding?

No. There is no evidence that breastfeeding spreads hepatitis C. Currently, both the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists support breastfeeding in HCV-infected women. Not enough information is available regarding the risks of transmission through breastfeeding by infected mothers with cracked or bleeding nipples. However, because HCV is a bloodborne infection, if a mother with hepatitis C has cracked or bleeding nipples, she should stop nursing temporarily until her nipples heal.

Miscellaneous

1. Can a patient have a normal liver enzyme (e.g., ALT) level and still have chronic hepatitis C?

Yes. It's common for patients with chronic hepatitis C to have fluctuating liver enzymes levels, with periodic returns to normal or near normal levels. Liver enzymes can remain normal for over a year despite chronic liver disease.