STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

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# MEMORANDUM

**DATE:** May 10th, 2021

**TO:** Medicaid Health Plans (MHP)

**FROM:** Medical Services Administration (MSA)

**SUBJECT:** Care Coordination Plan for We Treat Hep C Initiative

MDHHS has announced a public health campaign called *We Treat Hep C*, aimed at eliminating Hepatitis C Virus (HCV) in Michigan. The initiative involves increasing the number of people who are tested for HCV, increasing the number of providers who treat HCV, and expanding access to HCV curative treatments. MHPs will play a central role in this initiative. This memo provides background on HCV and the campaign, and outlines the expectations for MHPs around care coordination.

## Hepatitis C

HCV is a liver infection caused by the hepatitis C virus. It is spread through contact with blood from an infected person. The most common way HCV is transmitted is through sharing needles, syringes or other equipment used to prepare and inject drugs. HCV is the most common bloodborne infection in the United States. For some people, HCV 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 the Centers for Disease Control and Prevention (CDC) advises that approximately half of people with HCV are undiagnosed, which means the number of infected people may be as high as 200,000.[1] Among Medicaid beneficiaries, 21,580 have an HCV diagnosis,[2] though when taking undiagnosed persons into account we estimate that it is closer to 40,000. The number of persons unknowingly living with undiagnosed HCV infection is why broad population-based HCV testing is important. The CDC recommends that all adults ages 18 and

[1] In 2019, approximately 115,000 persons were reported to the Michigan Data Surveillance System as living with HCV. Approximately 50% of persons living with HCV are unaware of their infection. Thomas, D.L. (2020), State of the Hepatitis C Virus Care Cascade. Clinical Liver Disease, 16: 8-11. https://doi.org/10.1002/cld.915

[2] This includes all Medicaid and HMP beneficiaries with a medical claim or encounter paid between October 1, 2019 and March 4, 2021 which included a diagnosis code for chronic HCV or unspecified HCV.

older should be tested for HCV at least once in a lifetime.[3] In addition, pregnant women should be tested during each pregnancy.[4]

## HCV Treatment

Up until a few years ago, HCV treatment required weekly injections and oral medications that many affected people could not take because of other health problems or side effects. In recent years, new drugs called Direct-Acting Antivirals (DAA) – were developed to treat Hepatitis C. DAAs are oral medications that can cure the disease when taken every day for several weeks, and have few side effects or contraindications. With success rates of over 95%, these drugs have the potential to virtually eliminate the disease. However, the extraordinarily high prices associated with these drugs has prevented their broader use in the population.

As a reminder, DAAs are currently carved out of Medicaid Health Plan responsibility and are covered through Fee-for-Service. In FY16 the Legislature approved an appropriation transfer which provided funding to cover specialty HCV products for Medicaid and Healthy Michigan Plan enrollees. MDHHS prioritized treatment for beneficiaries with HCV based on severity of condition. MDHHS started covering additional patients in April 2016, and in FY17 the Legislature approved an additional appropriation transfer to expand coverage.

Historically MDHHS has required prior authorization for all DAAs, which included criteria such as documentation of the beneficiary's use of illegal drugs or abuse of alcohol within the past six months. It also included a requirement that the DAA be prescribed by or in consultation with a gastroenterologist, hepatologist, liver transplant or infectious disease specialist. Because there are a limited number of these specialists in the state, few beneficiaries were able to meet the criteria for receiving treatment. MDHHS approves approximately 1800 prior authorizations for DAAs annually, which is far fewer than the number of beneficiaries who have HCV.

## We Treat Hep C

Last year, MDHHS worked with providers, academic institutions, patient advocacy groups, local health departments, and state government officials to develop a comprehensive plan to eliminate HCV in Michigan. This report, called *Michigan's State Plan on Eliminating Hepatitis C*, outlined an action plan that included data strategy, reducing stigma, education and training for providers, and expanding access to HCV curative treatments.

MDHHS conducted a survey of providers across all specialties and practice areas to identify existing barriers to HCV testing and treatment. Seventy-four percent of providers said that if there were no policy barriers related to HCV treatment, they would be open to treating HCV patients (Attachment A).

On World Hepatitis Day, July 28, 2020, MDHHS launched the *We Treat Hep C* initiative to expand access to treatments. It partnered with MDOC to issue a Request for Proposals to drug manufacturers to provide DAAs to these agencies at significant discounts, in return for being the preferred product for these programs. After reviewing the proposals, the agencies selected the manufacturer AbbVie as the Apparent Successful Bidder.

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[3] The 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 Testing Recommendations for Hepatitis C Virus Infection and Recommended Testing Sequence.

[4] *Ibid*.

## Expanding Access to Treatment

MDHHS has entered into a three-year agreement with the manufacturer AbbVie to expand access to the Direct-Acting Antiviral (DAA) MAVYRET® (glecaprevir/pibrentasvir) for Medicaid and Healthy Michigan Plan beneficiaries. MAVYRET is an oral prescription medication used to treat adults and children ages 12 and older with HCV. In most cases, the treatment regimen is three pills taken once daily for eight weeks. Starting April 1, clinical prior authorization (PA) is no longer required for MAVYRET when prescribed in accordance with Food and Drug Administration-approved labeling. This includes removal of the requirement that HCV medications must be prescribed by or in consultation with a specialist. All providers who have prescriptive authority will be able to prescribe this treatment to beneficiaries with HCV.

MAVYRET is the only DAA identified as Preferred on the *Michigan Preferred Drug List/Single PDL*. PA will still be required for Non-Preferred agents, with documentation explaining why the preferred agent MAVYRET cannot be used. Beneficiaries who are currently taking a Non-Preferred agent will be able to complete their course of therapy.

## Program Goal

Through the We Treat Hep C initiative, MDHHS' goal is to treat all of the estimated 40,000 Medicaid beneficiaries with HCV. With the removal of PA on the curative therapy, this goal is within reach. It will involve:

- Screening all adult beneficiaries for HCV, per CDC recommendations
- Prescribing treatment for those with a confirmed HCV diagnosis

Removing PA means that any provider who can prescribe will be able to prescribe MAVYRET and other DAAs. DAAs are safe and have few contraindications or side effects. In most cases, treatment can be prescribed by a PCP. However, many PCPs do not have experience treating HCV due to historical prior authorization requirements limiting treatment to specialists. Therefore, the success of this program depends on getting more providers to treat HCV. MHPs should work with their network providers to incorporate HCV testing in routine primary care, and support providers as they learn how to treat this condition. MHPs should also focus efforts on outreach to beneficiaries on the importance of being tested for HCV, and should work with CHWs to contact beneficiaries who may be difficult to reach, including those who are homeless, transient, disabled, or non-English speakers. Further details on care coordination requirements are below.

## MHP Coordination Activities

- **Provider Outreach**
  - Conduct outreach to network providers on the CDC's new universal testing guidelines
  - Work with providers to incorporate orders for HCV tests in routine primary care
  - Ensure that CDC HCV testing algorithms are followed (running an HCV virus detection test or PCR for any persons who tests positive for HCV antibody)
  - MHPs can use MSA Provider Letter L 21-21 or its text in their outreach to providers
  - Over half of providers surveyed said that educational curriculums would be helpful in facilitating HCV treatment in their practices (Attachment A). Therefore, MDHHS has partnered with organizations to make a variety of resources available to providers treating HCV patients. These resources include:
    - Consulting line for all health care professionals with questions about HCV treatment provided by Henry Ford Health System. The consulting line operates from 8 am – 5 pm daily: (313) 575-0332

        - On-demand webinars, live training events, office hours and other resources for health care professionals on treating HCV, provided by the Midwest AIDS Training and Education Center (MATEC) at Wayne State University School of Medicine, Division of Infectious Diseases, available at matecmichigan.org
        - Education and case consultation on HCV through Michigan Opioid Collaborative
        - Additional resources at Michigan.gov/WeTreatHepC
    - MHPs should promote these resources to their network providers. Also, MHPs are encouraged to develop and share any additional resources that may be useful to network providers.
    - Providers who want to be notified of new training opportunities and events should send a request to MDHHS-Hepatitis@michigan.gov to be added to the listserv.
    - In addition to general outreach, MHPs should provide targeted outreach and support to providers in areas with a high prevalence of HCV as well as providers who treat opioid use disorder
    - DAAs may be dispensed in maintenance supplies (see *MI Medicaid Maintenance Drug List*). To promote medication adherence, MHPs should work with providers and pharmacies to ensure that MAVYRET is dispensed in an 8-week supply (or 12-week supply when appropriate). The provider can indicate the quantity 168 on the prescription for a 56-day supply (i.e., 8 weeks).

- **Beneficiary Outreach**
    - By July 1, send letter to beneficiaries ages 18 and older with general information on HCV and getting tested using beneficiary letter template. The letter should be sent to all beneficiaries ages 18 and older. In addition, MHPs should send the letter to beneficiaries who join the health plan after July 1. Consider including the CDC Hepatitis C Fact Sheet with beneficiary letters. MDHHS will review data on testing rates in the six months following the letters being sent and will provide guidance to the MHPs on whether letters should be sent to beneficiaries who have not been tested.
    - Include information about Hepatitis C and the importance of getting tested in beneficiary newsletter.
    - Provide materials in beneficiaries' preferred language. Ensure communication efforts meet national Culturally and Linguistically Appropriate Services (CLAS) standards.
    - MDHHS creative assets are available for MHPs to share via social media/websites
    - Utilize CHWs, Community Based Organizations and homeless shelters to conduct outreach to beneficiaries that are transient/difficult to reach, including those who are homeless, disabled or those living with substance use disorders.
    - Ensure that beneficiaries have access to providers, laboratories and pharmacies through transportation, telemedicine and mail order where appropriate.
    - Incorporate Hepatitis C testing and treatment in all care management/care coordination discussions.
    - MHPs must develop a roster of beneficiaries with an HCV diagnosis and without a record of treatment. The roster should include housing information, to assist with this high-risk population, and primary spoken language to provide appropriate outreach materials. MHPs should do telephonic outreach (calls) to these beneficiaries.
    - Follow-up with beneficiaries who have a positive HCV test as well as their providers on initiating treatment with MAVYRET
    - Encourage providers to enroll patients receiving treatment in the MAVYRET Nurse Ambassador program
    - Follow up with beneficiaries receiving treatment and offer support on medication adherence. In addition, MHPs should confirm that beneficiaries who have one

pharmacy claim for MAVYRET have a claim for a refill no more than 4 weeks after the first claim. In most cases, MAVYRET is an 8-week regimen, dispensed in a 4-week carton. MHPs should consult file 5165, the Daily Carve-Out Utilization File, on their beneficiaries who are receiving MAVYRET or another DAA.

- **Pharmacy Outreach**
  - Notify network pharmacies on removal of prior authorization requirement for MAVYRET
  - Ensure that network pharmacies in areas where HCV is prevalent have adequate stock of MAVYRET
  - DAAs may be dispensed in maintenance supplies (see *MI Medicaid Maintenance Drug List*). To promote medication adherence, MHPs should work with providers and pharmacies to ensure that MAVYRET is dispensed in an 8-week supply (or 12-week supply when appropriate).

## HCV and Health Equity

The HCV epidemic and its unchecked growth among communities of color, people who inject drugs, immigrants, justice-involved individuals and others are symptoms of larger systems of stigma and health inequity. African Americans have a chronic HCV infection rate that is 2.4 times higher than that of Caucasians.[5] They also have a higher rate of chronic liver disease, which is often hepatitis C-related. In addition, African Americans have the highest mortality rates of liver cancer, of which HCV is a major cause.[6] A significantly lower proportion of African Americans receive HCV confirmatory testing and genotype testing (a marker that the patient is being evaluated for treatment) compared to Caucasians. See the MDHHS fact sheet *Racial Disparities in Hepatitis C Infection and Health Outcomes* for more information.

The removal of prior authorization requirements on MAVYRET will mean that more providers will be able to prescribe it, which may help reduce health disparities. However, the significant disparity in access to health services for communities of color[7] means that further interventions are needed to address health inequity. As MHPs develop their strategies to identify and treat beneficiaries with HCV, they should consider Social Determinants of Health to ensure the equitable access to health care and treatment among all their members, including members of racial/ethnic minorities, those whose primary language is not English, those in rural areas, and those with disabilities. Earlier diagnosis, improved HCV testing, linkage to care, and treatment can greatly improve HCV-related health outcomes and reduce racial disparities.

## Reporting and Monitoring

Over the next year, MSA will collaborate with MHPs to develop performance measures on HCV screening and treatment. In addition, care coordination efforts on testing and treatment will be included as topics for discussion in focus studies and quarterly meetings. To prepare for those discussions, MHPs should review utilization of the following codes:

[5] *Racial Disparities in Hepatitis C Infection and Health Outcomes.* MDHHS Fact Sheet, 2014.
[6] Islami, et al. Disparities in liver cancer occurrence in the United States by race/ethnicity and state. Ca Cancer J Clin 2017;67:273–289 at 275.
[7] "Adults' Access to Preventive/Ambulatory Health Services (20-44years) by Race/Ethnicity 2012-2018." *Medicaid Health Equity Project Year 8 Report*, page 29.

- CPT Codes for HCV Antibody Test
  - 86803
  - 86804
  - 80074
- CPT Codes for HCV RNA Test
  - 87520
  - 87521
  - 87522
- HCPCS Code for HCV Screening for High-Risk Individuals
  - G0472
- Diagnosis Codes for Chronic HCV
  - ICD-9
    - 070.44
    - 070.54
  - ICD-10
    - B182
- National Drug Codes (NDC) for DAAs

| Brand Name | Generic Name | NDC standardized to 11 digits |
|---|---|---|
| DAKLINZA | daclatasvir | 00003001101 |
| DAKLINZA | daclatasvir | 00003021301 |
| DAKLINZA | daclatasvir | 00003021501 |
| ZEPATIER | elbasvir and grazoprevir | 00006307402 |
| VIEKIRA XR | dasabuvir and ombitasvir and paritaprevir and ritonavir | 00074006301 |
| VIEKIRA XR | dasabuvir and ombitasvir and paritaprevir and ritonavir | 00074006328 |
| TECHNIVIE | ombitasvir, paritaprevir and ritonavir | 00074308228 |
| VIEKIRA PAK | ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets | 00074309328 |
| OLYSIO | simeprevir | 59676022507 |
| OLYSIO | simeprevir | 59676022528 |
| SOVALDI | sofosbuvir | 61958150101 |
| HARVONI | ledipasvir and sofosbuvir | 61958180101 |
| EPCLUSA | sofosbuvir and velpatasvir | 61958220101 |
| MAVYRET | glecaprevir and pibrentasvir | 00074262528 |
| VOSEVI | sofosbuvir and velpatasvir and voxilaprevir | 61958240101 |

## Conclusion

Thanks to recent medical advancements in HCV treatment, no one should have to live with, or die from, HCV. The *We Treat Hep C* initiative is an exciting new chapter in MDHHS' long partnership with MHPs to improve health care quality in the state. We look forward to working with you to eliminate this deadly virus.

## Resources

- Press Release #1 – July 28, 2020
- Press Release #2 - April 1, 2021
- CDC's new universal testing guidelines
- MDHHS Hepatitis C Virus Surveillance Data

- Hepatitis C General Information (cdc.gov)
- Michigan's State Plan on Eliminating Hepatitis C
- Provider Letter – L 21-21
- Website – Michigan.gov/WeTreatHepC
- Michigan Medicaid Preferred Drug List/Single PDL
- HCV Clinical Consulting Line through Henry Ford Health System
- Education and case consultation on HCV through Michigan Opioid Collaborative
- MAVYRET Nurse Ambassador program
- Frequently Asked Questions

**Attachment A**

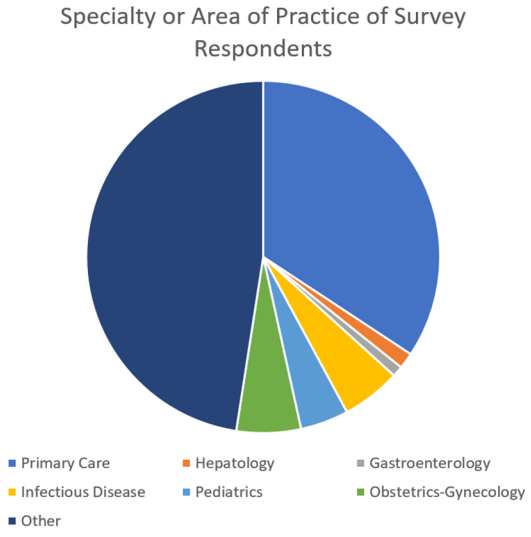
# HEPATITIS C TESTING AND TREATMENT CAPACITY ASSESSMENT

**Goal:**

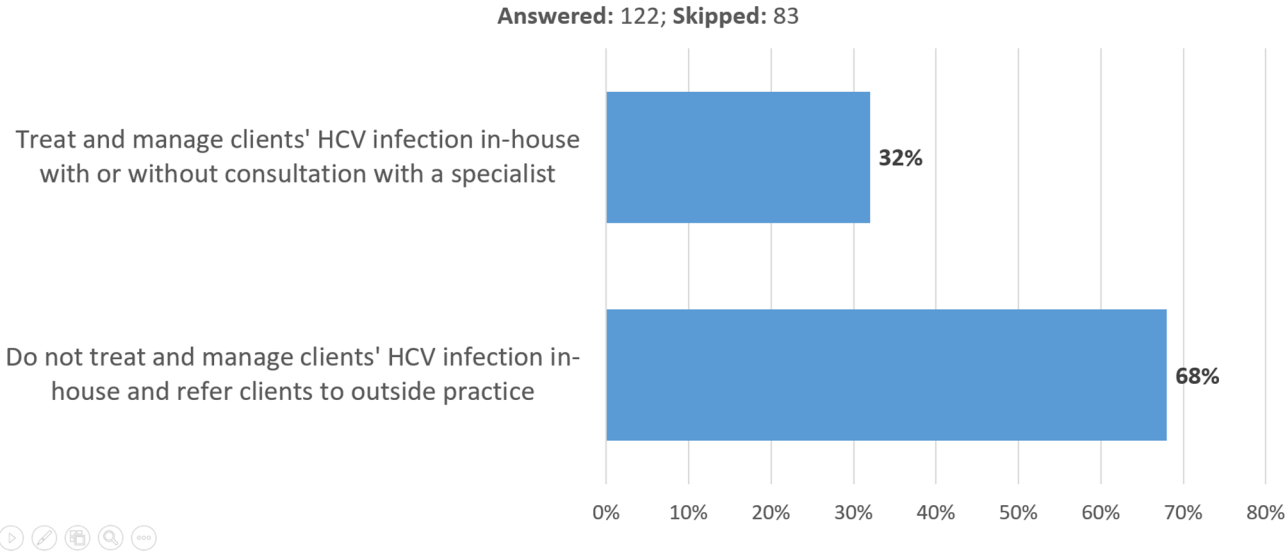
- To identify existing barriers to HCV testing and treatment and equip providers with the tools, knowledge, and resources to improve health of patients

- Survey Respondents (n = 205)

- Primary care: 34%
- Hepatology: 2%
- Gastroenterology: 1%
- Infectious Diseases: 5%
- Pediatrics: 4%
- Obstetrics-Gynecology: 6%
- Other: 48%




# Q: When a client is diagnosed with HCV, do you:



## Q: If there were no policy barriers related to HCV treatment, would you be open to treating persons for HCV in your practice?


## Q: Please select the method(s) below that would help facilitate treatment of HCV in your practice. Select all that apply: