Michigan Department of Health and Human Services
PO Box 30479
Lansing MI 48909

DATE

For questions and/or problems, or help to translate, call the Beneficiary Help Line at 1-800-642-3195 or TTY 1-866-501-5656.

Spanish: Si necesita ayuda para traducir o entender este texto, por favor llame al telefono, 1-800-642-3195 or TTY 1-866-501-5656

Arabic: TTY 1-866-501-5656

إذا كان لديكم أيّ سؤال، يرجى الإتصال بخط المساعدة على الرقم المجاني ٣١٩٥-٦٤٢-٨٠٠-١

Dear Beneficiary:

Re: Coverage of Direct Acting Antivirals (DAAs) for Hepatitis C

You are getting this notice because records show you were denied coverage of a certain type of drug known as a Direct Acting Antiviral, or DAA. DAAs treat Hepatitis C. The Michigan Department of Health and Human Services (MDHHS) is changing its coverage requirements for DAAs as part of an agreement to settle a lawsuit. This notice tells you about the settlement and how you may be able to get coverage of DAAs.

What is the lawsuit about?

A Medicaid beneficiary asked MDHHS to cover a DAA and MDHHS denied that request. This beneficiary filed a lawsuit and said that MDHHS was not following federal guidelines for DAA coverage. The case is called *M.R. v. Lyon*, and the case is No. 17-cv-11184. Both sides agreed to settle the lawsuit, and a judge approved the settlement. As part of the settlement, MDHHS is changing how it covers DAAs.

What are the terms of the settlement?

MDHHS is changing how it looks at fibrosis scores when deciding whether to cover DAAs for people on Medicaid. A fibrosis score measures damage to the liver. Starting October 1, 2018, people with a fibrosis score of F1 or higher will have access to DAAs, even if they don't have other health problems. On October 1, 2019, MDHHS will expand this further to include people with a fibrosis score of F0 or higher.

MDHHS is also updating its Prior Authorization Criteria and Request Form (or "DAA Approval Form"), providing this notice to affected class members and paying attorney fees and costs. Visit www.michigan.gov/HepCLawsuit for more information on the settlement.

Other requirements for DAA coverage will still apply, and your doctor still has to get MDHHS approval of DAAs in advance. The attached DAA Approval Form explains these coverage requirements. Your doctor can call the Clinical Call Center (prior authorization) at 1-877-864-9014 or visit https://michigan.fhsc.com/Providers/Forms.asp if he or she has questions about this approval process.

How do I get access to DAAs?

Take this notice to your doctor and ask if a DAA is right for you. If it is, your doctor must ask MDHHS to approve the drug using the DAA Approval Form included with this notice. Your doctor can mail the form or fax it. If you lose this form, you or your doctor can get a new one at https://michigan.fhsc.com/Providers/Forms.asp. MDHHS will not cover DAAs for people who are no longer eligible for Medicaid, no matter when your doctor returns the form.

Your doctor may have to order lab tests or other procedures to complete the form, so don't delay. Call your doctor today.

If your request for DAA coverage is denied, you will get another notice. This notice will tell you how to ask for a hearing if you don't agree with that decision and will include a hearing request form.

Where can I get more information?

If you have questions about the settlement, call Aaron V. Burrell of Dickinson Wright, PLLC, at 313-223-3500.

If you have questions for a lawyer, go to www.michiganlegalhelp.org and click on "Find a Lawyer" to find your local free legal services office.

Finally, you can go to www.michigan.gov/HepCLawsuit for more information and any updates to the settlement.

Sincerely,

Medical Services Administration
Michigan Department of Health and Human Services

Attachment

Prior Authorization Criteria for Hepatitis C Treatment: Current Treatment Criteria

- **Providers are encouraged to complete the fax form located at:** https://michigan.fhsc.com/Providers/Forms.asp
- **Preferred agents are noted on the Preferred Drug List:** https://michigan.fhsc.com/Providers/DrugInfo.asp

The patient must meet the following criteria for treatment coverage of hepatitis C:

1. The patient must be 18 years of age or older.
2. The patient must have the diagnosis of chronic hepatitis C.

For initial requests:

1. The patient's RNA viral load must be documented prior to initiation of treatment (lab results must be submitted).
2. The calculated Child-Pugh score must be documented, if the patient has cirrhosis.
3. The Genotype must be obtained (lab results preferred).
4. The patient must have one of the following:
   a) HIV co-infection
   b) Prior liver transplant
   c) Serious extra hepatic manifestation of hepatitis C, such as cryoglobulinemia or membranoproliferative glomerulonephritis
   d) Metavir fibrosis score of F2–F4 with supporting documentation of one of the following:
   [**NOTE: Coverage to expand to F1 or above on 10/01/2018; then expand again to F0 or above on 10/01/2019**]
      - Serum marker supporting a level of fibrosis of F2–F4 [APRI ≥ 0.5, OR FIB-4 ≥1.45, OR Fibrotest/Fibrosure ≥0.48 (scores must be calculated where appropriate with supporting labs submitted)]; **OR**
      - Fibroscan ≥7.0 kPA; **OR**
      - Fibrospect ≥ 42; **OR**
      - Shear Wave Velocity ≥ 1.34 meters/second **or**
      - Liver biopsy demonstrating F2, F3, F4 or cirrhosis (report must be submitted); **OR**
      - Ultrasound/ MRI or CT of the abdomen which demonstrates one of the following documented in the radiology report: cirrhosis, esophageal varices, ascites, splenomegaly; **OR**
      - EGD demonstrating esophageal varices; **OR**
      - Clinical signs and symptoms consistent with substantial or advanced fibrosis or cirrhosis
        – History of hepatic encephalopathy requiring treatment with medication or hospitalization within the past 12 months
        – History of portal hypertension as demonstrated by variceal bleeding or radiographic evidence of a transjugular intrahepatic portsystemic shunt (TIPS) procedure
        – Ascites

Prior Authorization Criteria for Hepatitis C Treatment: Current Treatment Criteria

5. Lab testing **(copy of results must be submitted unless otherwise noted):**
   - Genotype
   - Detectable HCV RNA viral load (within the past year)
   - ALT/AST (within the past six months)
   - CBC (within the past six months)
   - GFR (within the past six months)
   - PT/INR (within the past six months)
   - Bilirubin (within the past six months)
   - Albumin (within the past six months)
6. The medication must be prescribed by a gastroenterologist, hepatologist, liver transplant or infectious disease physician. If the prescribing provider is not one of the identified specialists noted, the prescriber must submit documentation of consultation/collaboration of the specific case with one of the afore-mentioned specialists which reflects discussion of the history and agreement with the plan of care with the date noted in the progress note.
7. Documentation of the patient's use of illegal drugs or abuse of alcohol must be noted (i.e., current use of illegal drugs or abuse of alcohol within the past 6 months). The Department will consider this in terms of optimizing treatment. *Note: Illegal drugs are any controlled substance obtained without a valid prescription.*
8. Documentation of commitment to the planned course of treatment and monitoring (including SVR 12), as well as patient education addressing ways to reduce the risks for re-infection must be submitted.
9. Patients with a Metavir F4 score must have liver imaging (preferably an abdominal ultrasound or CT, but MRI accepted) with results for hepatocellular carcinoma (HCC) surveillance submitted. If positive for HCC, please indicate how this will be addressed in the plan of care.

For renewal requests:

The patient's most recent RNA viral load must be documented and must show a 2 log decrease or be undetectable by treatment week 12.

For retreatment requests:

Document post-treatment and current HCV RNA and reconfirm genotype.

Michigan Department of Health and Human Services (MDHHS)
Prior Authorization Request
Hepatitis C Medications

Attachment - B 18-28

All information on this form must be addressed. Incomplete forms will be returned only once for missing information. Mark as 'N/A' if no information is available or does not apply.

Beneficiary Information

LAST NAME: **FIRST NAME:**

MEDICAID NUMBER: **DATE OF BIRTH:** – –

GENDER: MALE ☐ FEMALE ☐

Prescriber Information

LAST NAME: **FIRST NAME:**

PLEASE SELECT ONE: ☐ MD ☐ DO ☐ NP ☐ PA **OTHER:**

NPI NUMBER: **SPECIALTY:**

PHONE NUMBER: – – **FAX NUMBER:** – –

Person Completing Form

LAST NAME: **FIRST NAME:**

TITLE:

PHONE NUMBER: – – **FAX NUMBER:** – –

DATE: _____ **REQUESTED START DATE:** _____

Pharmacy

NAME:

PHONE NUMBER: – – **FAX NUMBER:** – –

Please complete this form and submit along with the following required documentation: genotype, HCV RNA value, test or lab that documents the level of liver fibrosis/Metavir score, liver imaging results and, if applicable, a dated progress note reflecting collaborative agreement with specialist for this specific patient.

SVR12 results must be available upon request by Michigan Medicaid.

Drug Information

Drug Name, Dosage Form & Strength	Quantity Dispensed:	Duration of Therapy:

Prescriber's Specialty
(The prescriber must be a GI, ID specialist or a Hepatologist, otherwise collaboration/consultation is expected.)

Indicate the prescriber's specialty:

☐ Gastroenterologist ☐ Hepatologist ☐ Infectious disease ☐ Liver Transplant Infectious disease

For providers not identified above: If the prescribing provider is not one of the above listed specialists, it is expected the prescriber has collaborated / consulted with one of the above noted specialists. Please identify the specialty of the prescriber

☐ Internal medicine ☐ Family medicine ☐ NP ☐ PA ☐ Other_____

Consulting/collaborating specialist name: _____

In addition, please include supporting documentation that demonstrates consultation/collaboration with the specialist (e.g., consult notes, progress notes.)

Submit requests to:
Magellan Medicaid Administration
11013 W Broad Street Suite 500, Glen Allen, VA 23060
Fax: 888-603-7696 Phone: 877-864-9014
This form is available at michigan.fhsc.com → Providers → Forms

Revision Date 1/2018

Magellan Rx MANAGEMENT

Diagnosis – ***Treatment-naïve or Treatment-experienced boxes must be checked; supporting documentation required if experienced***

☐ Chronic Hepatitis C ☐ No cirrhosis ☐ Compensated cirrhosis (Child-Pugh A)

☐ Decompensated cirrhosis (Child-Pugh score class B or C) ☐ Hepatocellular carcinoma ☐ Status post-liver transplant

Choose one: ☐ Treatment initiation ☐ Continuation of current therapy, current week _____

☐ Treatment-naïve ☐ Treatment-experienced: ☐ Interferon; ☐ ribavirin; ☐ Direct-Acting Antivirals *(name of medications)*_____

Current HCV Genotype: ☐1a ☐ 1b, ☐ 2, ☐ 3, ☐ 4, ☐ 5, ☐ 6, Polymorphisms ☐ Yes ☐ No ☐ N/A; *If yes, submit results*

Diagnostic/Disease Severity Evidence

Indicate and submit supporting documentation for:

APRI Score: _____ FIB4 Score: _____

Metavir score: ☐ F0 ☐ F1 ☐ F2 ☐ F3 ☐ F4

If metavir F4, please submit most recent liver imaging results (i.e., ultrasound, CT scan) to assess for hepatocellular carcinoma.

Select the following, if known, and provide documentation:

☐ Ultrasound-based transient elastography (Fibroscan) score ≥ 7.0 kPA ☐ Fibrotest (FibroSure) score of ≥ 0.48

☐ Fibrospect ≥ 42 ☐ Shear Wave Velocity ≥ 1.34 meters/second

☐ Ascites ☐ Esophageal varices ☐ Splenomegaly ☐ Hepatic Encephalopathy (within past 12 months)

☐ Transjugular Intrahepatic Portsystemic Shunt (TIPS) ☐ Biopsy, results_____

Lab Values

☐ PT/INR values _____ ☐ Bilirubin _____ ☐ Albumin _____ ☐ Child-Pugh score _____

Initial Baseline: HCV RNA value: _____ date drawn: _____ (Must be within the past 12 months)

For renewals, has viral load reached a 2 log decrease or undetectable level? ☐ Yes ☐ No
Week: _____ HCV RNA value: _____ date drawn: _____

For retreatment, document post-treatment HCV RNA value: _____; current HCV RNA value _____ ; reconfirm genotype: _____

Other Co-morbid condition(s), if appropriate

HIV: ☐ Yes ☐ No

History of severe renal impairment (eGFR<30 mL/min/1.73m^2) or end stage renal disease requiring hemodialysis: ☐ Yes ☐ No

Other: ☐ Yes ☐ No
If yes to any, please give details: _____

Social History

Is patient currently using illegal drugs or abusing alcohol? ☐ Yes ☐ No
If no, has patient been abstinent for 6 months? ☐ Yes ☐ No

Adherence

Does the patient have a current treatment plan that includes the following: ☐ Yes ☐ No

- Documented commitment to adherence with the planned course of treatment and monitoring.
- Documentation of counseling on how to reduce the risks for re-infection.

Submit requests to:
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Fax: 888-603-7696 Phone: 877-864-9014
This form is available at michigan.fhsc.com → Providers → Forms