

FREQUENTLY ASKED QUESTIONS: PRIOR AUTHORIZATION FOR HEPATITIS C VIRUS (HCV) TREATMENT

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Does MassHealth prohibit coverage of HCV treatment with direct-acting antivirals (DAAs) for a patient who is currently using alcohol or drugs or who has only recently stopped using alcohol or drugs?

A: No. As of August 1, 2016, MassHealth has no sobriety or abstinence requirement for coverage of DAA treatment for HCV. This applies to all MassHealth plans (e.g., primary care clinician (PCC), managed care (MCO), accountable care (ACO)). However, history of substance use may be relevant for ongoing monitoring of patient health.

Does MassHealth require that HCV treatment with DAAs be prescribed by or in consultation with a specialist, such as a gastroenterologist or hepatologist?

A: No. As of August 1, 2016, MassHealth policy allows primary care providers to prescribe DAA medication for treatment of HCV without the involvement of a specialist. This applies to all MassHealth plans (e.g., primary care clinician (PCC), managed care (MCO), accountable care (ACO)).

Does MassHealth require that a health care provider document a minimum level of liver damage (fibrosis) in a patient before approving DAA treatment?

A: No. As of August 1, 2016, MassHealth has no requirement that a patient's HCV progress to a minimum level of liver damage before treatment will be authorized. All beneficiaries with a chronic HCV infection qualify.

What diagnosis and clinical information are required for MassHealth to approve HCV treatment with DAAs?

A: MassHealth beneficiaries with chronic HCV infection are eligible for MassHealth-covered treatment with DAAs. There is a box in the "Diagnosis" section on the MassHealth prior authorization form that providers should check to indicate chronic HCV diagnosis.

In addition to checking the "Chronic Hepatitis C" box, providers will also generally need to provide the following information to MassHealth to have the prior authorization request approved:

- Hepatitis C virus genotype.
- Information about prior hepatitis treatment, if any.
- Fibrosis staging, specifically diagnostic tests demonstrating either early stage (Metavir score F0-F2) or advanced stage (Metavir score F3-F4). (If results are inconclusive or if imaging studies are performed and are not suggestive of cirrhosis, further diagnostic testing may be required.)
- Potential interactions between patient's current medications and DAAs.
- Baseline hepatitis C virus RNA lab value.
- In order to continue therapy beyond week 4, MassHealth requires an additional RNA lab value at week 4 of treatment and, if the patient has detectable levels, again at week 6 to determine if treatment will be discontinued.

For more complete information, providers should reference the Hepatitis Antiviral Agents Prior Authorization form: <https://masshealthdruglist.ehs.state.ma.us/MHDL/pubdownloadpa.do?id=5063>.

What if I believe a patient has chronic HCV, but I do not have historical lab results or medical records showing this?

A: Chronic HCV is confirmed by test results showing both the presence of HCV antibodies and of HCV RNA. One way to demonstrate chronic HCV, according to the American Association for the Study of Liver Disease (AASLD), is by HCV RNA tests conducted 6 months apart that both indicate the presence of HCV RNA. Other information (e.g., report of prior HCV treatment) may also sufficiently indicate that a patient has chronic HCV.

If, based on available clinical and laboratory information and a provider's expertise, that provider believes that a patient has chronic HCV, the provider should check off that diagnosis on the prior authorization form.

Is a patient covered under MassHealth allowed only one course of treatment with DAAs? What happens if a patient gets reinfected?

A: No. There is no written "one shot" rule in MassHealth – a patient may receive more than one course of DAA treatment. This applies to all MassHealth plans (e.g., primary care clinician (PCC), managed care (MCO), accountable care (ACO)).

If there is an interruption in treatment and the prior authorization expires, what is the protocol for re-initiating treatment?

A: Under MassHealth policy, a new authorization for treatment must be obtained. A patient would need to get a new baseline hepatitis C virus RNA test. The patient could not re-start treatment based on the prior baseline RNA test that was used to begin the prior course of treatment. The purpose of this policy is to have a recent baseline RNA test to compare with the RNA value at 4 weeks of treatment (to confirm whether the treatment is working). If a prior authorization (PA) has recently expired and a patient has not yet received or started taking the medication, a provider can advocate with MassHealth to adjust the PA by contacting the MassHealth Drug Utilization Review Program at (800) 745-7318.

How much is the patient co-pay for HCV DAA medications in MassHealth?

A: \$3.65 for the initial prescription and each refill (the same as most other medications under MassHealth). Note that even if a patient cannot afford this, a pharmacy is not allowed to deny a MassHealth beneficiary medications for nonpayment.

What should I do if I think that I'm not getting adequate information or that a patient's prior authorization request has been improperly denied by MassHealth?

A: Please contact Phil Waters (pwaters@law.harvard.edu) at the Center for Health Law and Policy Innovation of Harvard Law School.

