

Q&A ON HERC PROCESS FOR NEW HEPATITIS C TREATMENTS

What's happening

Oregon is in the process of reviewing hepatitis C treatments now that there are expanded options. The last review occurred in 1999.

General background on Hepatitis C

- About 1-2% of the US population is estimated to be affected by hepatitis C, which equates to about 78,000 Oregonians
- Of every 100 persons infected with HCV, approximately:
 - 75–85 will go on to develop chronic infection
 - Only 20-30% whose disease is limited to an acute infection will develop symptoms
 - 60–70 will go on to develop chronic liver disease
 - Most will experience minimal or no symptoms of the disease for the first few decades after infection
 - 5–20 will go on to develop cirrhosis over a period of 20–30 years
 - Those who drink excessive amounts of alcohol are 100 times more likely to develop cirrhosis
 - 1–5 will die from the consequences of chronic infection (liver cancer or cirrhosis)
 - Those who are also infected with HIV or hepatitis B have the highest risk of developing liver cancer

What are the newer treatments for hepatitis C?

Drugs Sofosbuvir (marketed as Sovaldi) and simeprevir (marketed as Olysio) received FDA approval in December 2013. Treatment lasts only 12 or 24 weeks, depending on the genetic type of hepatitis C being treated, and it can be used to treat all six genotypes. The cost of the treatment is \$1,000 a pill, resulting in retail costs of \$84,000 per treatment regimen in addition to the cost of other drugs used.

How effective is the new drug?

It's too early to tell for sure. According to a recent report from the Center for Evidence Based Policy, "Sofosbuvir may eventually be shown to be a valuable treatment for hepatitis C. However, due to the lack of well-designed comparative studies, there is not yet clear evidence that this drug should be used routinely to treat patients."

What does this mean for Oregon?

An estimated 75,000 Oregonians are thought to have hepatitis C. Among OHP clients, there are about 5,600 people known to have hepatitis C. Estimates suggest another 13,000 people are affected but undiagnosed.

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Oregon wants to ensure that people suffering from hepatitis C get appropriate care. The state's Pharmacy and Therapeutics Committee (P&T) has developed prior authorization criteria to restrict coverage of the new drugs to only those "Fee for Service" clients with advanced liver disease or those with certain accompanying conditions. The committee is also considering a "readiness to treat" protocol to assure patients who use the new drugs have the best outcomes; e.g., are not using alcohol or IV drugs and are able to follow the daily treatment protocol.

- Even with these guidelines in place, the estimated cost to OHP is more than \$168 million over the next 12 months – to treat only approximately 30% of the hep C population with stage 3 and 4 disease.
- One CCO medical director estimated that covering the new drugs for just 25% of the affected OHP population would use up their entire OHP pharmacy budget.
- Costs to all state programs (OHP, PEBB-OEBB, DOC and State Hospital) are estimated to be \$250m with the current P&T guidelines in place.

What is the HERC doing?

At its June 12 meeting, the Value-based Benefits Subcommittee of the Health Evidence Review Commission will consider the evidence of effectiveness for these new treatments and their cost in prioritizing the importance of these treatments in relation to all other health services.

- The HERC's Prioritized List of Health Services is used by the legislature to determine the benefit package for more than 900,000 Oregonians currently receiving health care benefits through the Oregon Health Plan
- Options for HERC to consider:
 - Use prioritization to place this treatment on the lower portion of the Prioritized List based on the poor quality data to support it and the low value
 - Not make a prioritization decision but simply refer to the P&T criteria to limit use to those for which there is greatest chance of benefit based on disease and patient characteristics
 - Refer to P&T criteria, and add additional criteria to further restrict use based on the evidence, or lack thereof

HERC staff recommendations

After reviewing the evidence, the HERC medical director and staff have recommended that treatment for hepatitis C be included on Lines 205 and 360 of the prioritized list only when using drugs receiving FDA approval prior to 2012.

For treatment with the new group of drugs, HERC staff recommended pharmacotherapy be included on line 644 when the patient meets the criteria of use defined by the Pharmacy and Therapeutics Committee, and that the treatment be restricted to patients who meet criteria that ensures they are candidates for successful treatment.

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Why are HERC staff recommending placing treatment with the new group of drugs “below the line”?

Two critical parts of HERC’s deliberations are evaluating clinical effectiveness and cost effectiveness. In this case, the quality of the evidence on the effectiveness of treatment with the new group of drugs is still poor and the cost is extraordinarily high.

Will CCOs still be able to offer the new drugs?

Coordinated Care Organizations have a global budget and the flexibility to make decisions about appropriate coverage beyond what is funded on the prioritized list.

How will this decision affect OHP clients?

OHP clients will still have access to needed care. Fortunately, hepatitis C is a very slowly progressive disease. Most patients who have it will never progress to cirrhosis. The proposed guidelines call for ongoing monitoring of patients, and comorbidity and individual circumstances will always be taken into account.

What’s next?

The Value-based Benefits Subcommittee will consider the recommendations on June 12, 2014. Any decisions by the subcommittee would need to be approved by the full HERC. The changes could be implemented no earlier than October 1, 2014.