



widespread screening of the blood supply began in the United States, Hepatitis C was also commonly spread through blood transfusions and organ transplants. Although it is less common, people can also become infected with the Hepatitis C virus by being born to a mother who has Hepatitis C, sharing personal care items that may have come in contact with another person's blood, such as razors or toothbrushes, and by having sexual contact with a person already infected with the Hepatitis C virus.

Hepatitis C can be either "acute" or "chronic."<sup>5</sup> Acute Hepatitis C virus infection is a short-term illness that occurs within the first six months after someone is exposed to the Hepatitis C virus. Chronic Hepatitis C is a long-term illness that occurs when the Hepatitis C virus remains in a person's body. Approximately 75% - 85% of those who become infected with Hepatitis C virus develop a chronic infection. Hepatitis C can last a lifetime and lead to serious liver problems including cirrhosis and liver cancer.

Approximately 70% - 80% of people with acute Hepatitis C do not have any symptoms.<sup>6</sup> Some people, however, can have mild to severe symptoms soon after being infected, including fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay-colored bowel movements, joint pain, and jaundice. If symptoms occur, they typically arise six to seven weeks after exposure, but the onset of symptoms can range from two weeks to six months after exposure.

In 2012 there were an estimated 21,870 cases of acute Hepatitis C reported in the United States.<sup>7</sup> An estimated 3.2 million persons in the United States have chronic Hepatitis C. Most people do not know they are infected because they do not look or feel sick.

Chronic Hepatitis C is a serious disease that can result in long-term health problems including liver damage, liver failure, liver cancer, or even death.<sup>8</sup> It is the leading cause of cirrhosis and liver cancer and the most common reason for liver transplantation in the United States. Approximately 15,000 people in the U.S. die every year from Hepatitis C-related liver disease. Of those infected with the Hepatitis C virus, about 75% - 85% will develop chronic Hepatitis C virus infection. Of those, 60% - 70% will develop chronic liver disease, 5% - 20% will go on to develop cirrhosis of the liver, and 1% - 5% will die from cirrhosis or liver cancer.

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<sup>5</sup> All factual findings in this paragraph are based on Exs. N1 - N2 unless otherwise stated.

<sup>6</sup> All factual findings in this paragraph are based on Ex. N4 unless otherwise stated.

<sup>7</sup> All factual findings in this paragraph are based on Exs. N1 - N2 unless otherwise stated.

<sup>8</sup> All factual findings in this paragraph are based on Ex. N5 unless otherwise stated.

Although vaccines are available for Hepatitis A and Hepatitis B, no vaccine is currently available to prevent Hepatitis C.<sup>9</sup> However, several treatments are available.<sup>10</sup> There are six different genotypes of the Hepatitis C virus, and each genotype is responsive to different drugs.<sup>11</sup>

Tests conducted in June 2015 indicate that Ms. T has genotype 1a or 1b HCV.<sup>12</sup> Harvoni is one of the primary medications currently used to treat adults with genotype 1a and 1b HCV.<sup>13</sup> On July 8, 2015, Ms. T's physician sought prior authorization from the Division's contractor, Magellan Health, for Alaska Medicaid's payment for Harvoni to treat Ms. T.<sup>14</sup>

### ***B. Relevant Procedural History***

On July 8, 2015, Ms. T's physician transmitted the prior authorization request for Harvoni to Magellan Health.<sup>15</sup> On July 10, 2015, Magellan Health issued a notice letter denying the prior authorization request.<sup>16</sup> The notice stated that the request for prior authorization for Harvoni had been denied because "[t]he submitted documentation describing the disease severity of your condition does not meet criteria for approval with Alaska Medicaid."<sup>17</sup> The notice provided the address of the web page containing the specific criterial prerequisite to the Division's approval of Harvoni to treat genotype 1 HCV.<sup>18</sup>

On August 8 and August 13, 2015, Ms. T requested a hearing to contest the Division's denial of her physician's prior authorization request for Harvoni.<sup>19</sup> Ms. T's hearing was held on September 10, 2015. Ms. T participated in the hearing by phone, represented herself, and testified on her own behalf. Angela Ybarra participated in the hearing by phone and represented the Division. By the end of the hearing, it was apparent that no material factual issues were in dispute. The record closed at the end of the hearing.

### **III. Discussion**

Alaska's Medicaid program covers some prescription medications, but does not cover others.<sup>20</sup> Many of the prescription medications, which are covered by Alaska Medicaid, must still

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<sup>9</sup> Ex. N7.

<sup>10</sup> Exs. M1 - M17.

<sup>11</sup> Exs. J3, M1 - M17.

<sup>12</sup> Ex. E9.

<sup>13</sup> Ex. J3

<sup>14</sup> Exs. E1 - E4.

<sup>15</sup> Exs. E1 - E4.

<sup>16</sup> Ex. D.

<sup>17</sup> Ex. D1.

<sup>18</sup> Ex. D1.

<sup>19</sup> Ex. C.

<sup>20</sup> See 7 AAC 120.110 ("Covered Outpatient Drugs and Home Infusion Therapy") and 7 AAC 120.112 ("Non-covered Drugs").

receive prior authorization from the Division's contractor, for a medically accepted indication, before the drug can be dispensed.<sup>21</sup> Pursuant to 7 AAC 120.120(a), the Department's Drug Utilization Review Committee (DURC) is the entity responsible for determining which drugs to place on the prior authorization list, and the authorization criteria for all drugs on the prior authorization list.<sup>22</sup>

The Division maintains a list of those prescription medications that require prior authorization.<sup>23</sup> Harvoni is one of the prescription medications on Alaska Medicaid's prior authorization list.<sup>24</sup>

The Division also maintains a list of the specific prior authorization criteria applicable to each of the prescription medications on the prior authorization list.<sup>25</sup> The relevant prior authorization criteria for Harvoni, when (as here) used to treat HCV genotype 1, are as follows:<sup>26</sup>

1. Adult patient age  $\geq$  18 years old; AND
2. Documentation of HCV genotype, HCV subtype, and HCV viral load is included in the authorization request; AND
3. Meets diagnosis and disease severity of Hepatitis C, Genotype 1 (GT 1), and Metavir Fibrosis score F2-F4 equivalent . . . AND
4. Documentation of previously trialed HCV therapies, dates of therapy, whether full therapy was completed or discontinued early, and, if discontinued early, the reason for the discontinuation is included in the authorization request; AND
5. Agrees to complete regimen; AND
6. Patient is abstaining from the use of illicit drugs and alcohol as demonstrated by a negative urine confirmation test within the previous 90 days (results submitted with request); any positive results are to be explained by prescriber.

In this case, the prior authorization request submitted by Ms. T's physician identified Ms. T's diagnosis as "chronic hepatitis C, genotype 1a;"<sup>27</sup> and identified Ms. T's "Metavir Fibrosis

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<sup>21</sup> 7 AAC 120.130(a).

<sup>22</sup> Under 7 AAC 120.120(f), members of the DURC are nominated by the Department and appointed by the Commissioner to a three-year term. The DURC must consist of at least "(1) one-third, but no more than 51 percent, licensed and actively practicing physicians; (2) one-third licensed and actively practicing pharmacists; (3) an employee of the department; and (4) at the discretion of the commissioner, other health care providers."

<sup>23</sup> Exs. F and G. The Division's Prior Authorization List and Interim Prior Authorization List can be found, in .pdf format, on the DHCS website at <http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx>.

<sup>24</sup> Ex. F2, line seven. The decision as to whether to place a prescription medication on the Division's Prior Authorization List or Interim Prior Authorization List is made by the DURC, discussed above.

<sup>25</sup> The eligibility criteria for drugs on the Prior Authorization List and the Interim Prior Authorization List can be found by scrolling down a chart, titled "Prior Authorization Medication Categories," found at <http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx#infectious-disease>.

<sup>26</sup> Exs. J1 - J3.

Score," which scores the patient's level of fibrosis from the lowest score of F0 to the highest score of F4, as F0 - F1.<sup>28</sup>

The Division's approval criteria for Harvoni, when (as here) prescribed to treat Hepatitis C, genotype 1 (which includes genotype 1a), require (among other things) a Metavir Fibrosis score of F2 - F4 or equivalent (see criterion number three at page four, above). Ms. T's own doctor identified her Metavir Fibrosis Score as F0 - F1.<sup>29</sup> Accordingly, although Ms. T appears to meet the other criteria, her Metavir Fibrosis Score is not currently high enough to qualify her to receive Harvoni through Alaska Medicaid. Accordingly, the Division was correct to deny her doctor's prior authorization request.

#### **IV. Conclusion**

Based on Ms. T's physician's characterization of her Hepatitis C, Ms. T does not currently satisfy the Division's prior authorization criteria for Harvoni. Accordingly, Ms. T is not currently eligible to receive Medicaid-funded Harvoni, and the Division was correct to deny her physician's prior authorization request. The Division's decision is therefore affirmed.

Dated this 4th day of November, 2015.

*Signed*  
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Jay Durych  
Administrative Law Judge

### **Adoption**

The undersigned, by delegation from of the Commissioner of Health and Social Services, adopts this Decision, under the authority of AS 44.64.060(e)(1), as the final administrative determination in this matter.

Judicial review of this decision may be obtained by filing an appeal in the Alaska Superior Court in accordance with Alaska R. App. P. 602(a)(2) within 30 days after the date of this decision.

DATED this 13th day of November, 2015.

By: *Signed*  
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Name: Jay D. Durych  
Title: Administrative Law Judge, DOA/OAH

[This document has been modified to conform to the technical standards for publication.]

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<sup>27</sup> Ex. E1.

<sup>28</sup> Ex. E2.

<sup>29</sup> Ex. E2.