

**BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS  
ON REFERRAL BY THE COMMISSIONER OF HEALTH AND SOCIAL SERVICES**

In the Matter of: )  
 )  
 T H ) OAH No. 16-0128-MDX  
 ) Agency No.

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**DECISION**

**I. Introduction**

The issue in this case is whether the Division of Health Care Services (Division or DHCS) was correct, under the Alaska Medicaid program's regulations governing prescription drugs, to deny T H's physician's request for Medicaid's payment of the cost of a prescription drug combination called "Viekira Pak." The Division denied the physician's request for prior authorization of the drug based on the assertion that Mr. H's Hepatitis C is not severe enough to satisfy the Alaska Medicaid program's prior authorization criteria for Viekira Pak.<sup>1</sup>

Review of Mr. H's physician's characterization of his Hepatitis C, and review of the Division's prior authorization criteria for Viekira Pak, confirms that Mr. H is not currently eligible to receive Medicaid-funded Viekira Pak. Accordingly, the Division was correct to deny Mr. H's physician's prior authorization request for Viekira Pak in this case. The Division's decision is therefore affirmed.

**II. Facts**

**A. Mr. H's Medical Condition, Hepatitis C, and Viekira Pak**

Mr. H is 57 years old.<sup>2</sup> He has been diagnosed with Hepatitis C.<sup>3</sup> Mr. H's Hepatitis C is not yet at an advanced stage, but he wishes to begin drug therapy as soon as possible.<sup>4</sup>

Hepatitis C is a contagious liver disease that ranges in severity from a mild illness lasting only a few weeks to a serious lifelong illness.<sup>5</sup> It results from infection with the Hepatitis C virus (HCV), which is spread primarily through contact with the blood of an infected person.<sup>6</sup>

Today, most people become infected with the Hepatitis C virus by sharing needles or other equipment to inject drugs. Before 1992, when widespread screening of the blood supply began in

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<sup>1</sup> Ex. D1.

<sup>2</sup> Ex. E5.

<sup>3</sup> Exs. E5 - E8.

<sup>4</sup> Ex. C1.

<sup>5</sup> All factual findings in this paragraph are based on Exs. M1 - M7 unless otherwise stated.

<sup>6</sup> All factual findings in this paragraph are based on Exs. M1 - M7 unless otherwise stated.

the United States, Hepatitis C was also commonly spread through blood transfusions and organ transplants. People can also become infected with the Hepatitis C virus by being born to a mother who has Hepatitis C, by sharing personal care items that may have come in contact with another person's blood, and by having sexual contact with a person infected with the Hepatitis C virus.

Hepatitis C can be either "acute" or "chronic."<sup>7</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>8</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>9</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>10</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.

Although vaccines are available for Hepatitis A and Hepatitis B, no vaccine is currently available to prevent Hepatitis C.<sup>11</sup> However, several treatments are available.<sup>12</sup> There are six different genotypes of the Hepatitis C virus, and each genotype is responsive to different drugs.<sup>13</sup>

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<sup>7</sup> All factual findings in this paragraph are based on Exs. M1 - M7 unless otherwise stated.

<sup>8</sup> All factual findings in this paragraph are based on Exs. M1 - M7 unless otherwise stated.

<sup>9</sup> All factual findings in this paragraph are based on Exs. M1 - M7 unless otherwise stated.

<sup>10</sup> All factual findings in this paragraph are based on Exs. M1 - M7 unless otherwise stated.

<sup>11</sup> Ex. M7.

<sup>12</sup> Exs. I, J, K, L.

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

Mr. H has genotype 1A of the Hepatitis C virus (HCV).<sup>14</sup> Viekira Pak is one of the primary medications currently used to treat adults with genotype 1A HCV.<sup>15</sup> On January 5, 2016, Mr. H's physician requested prior authorization from the Division's contractor, Magellan Health, for Alaska Medicaid's payment for Viekira Pak to treat Mr. H.<sup>16</sup> On January 8, 2016, Magellan Health issued a notice letter denying the prior authorization request.<sup>17</sup> The notice stated that the request for prior authorization for Viekira Pak 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>18</sup> The notice provided the address of the web page containing the criteria for the Division's approval of Viekira Pak to treat genotype 1A HCV.<sup>19</sup>

On February 4, 2016, Mr. H requested a hearing to contest the Division's denial of his physician's prior authorization request for Viekira Pak.<sup>20</sup> Mr. H's hearing was held on March 10, 2016. Mr. H participated in the hearing by phone, represented himself, and testified briefly on his own behalf.<sup>21</sup> Medical Assistance Administrator Terri Gagne participated in the hearing by phone and represented the Division. The Division's Pharmacist, Rebecca Wall, participated by phone and testified for the Division. By the end of the hearing, it was apparent that no material factual issues were in dispute, and that the sole issue was whether the Division had correctly interpreted and applied its regulations. 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>22</sup> Many prescription medications, although covered by Alaska Medicaid, require prior authorization from the Division's contractor, for a medically accepted indication, before the drug

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<sup>13</sup> Exs. I, J, K, L.

<sup>14</sup> Ex. E5.

<sup>15</sup> Exs. I, J, K, L.

<sup>16</sup> Exs. E5 - E19.

<sup>17</sup> Ex. D.

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

<sup>19</sup> Ex. D1.

<sup>20</sup> Ex. C1.

<sup>21</sup> Mr. H, who was testifying from a cell phone from the parking lot of the local No Name, was agitated and frustrated by the Division's decision. He said what he wished to say within the first 5 to 10 minutes of the hearing, and then indicated that he did not wish to participate further and asked to be excused. Mr. H was excused, after which brief testimony was received from the Division's pharmacist Rebecca Wall.

<sup>22</sup> See 7 AAC 120.110 ("Covered Outpatient Drugs and Home Infusion Therapy") and 7 AAC 120.112 ("Non-covered Drugs").

can be dispensed.<sup>23</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 those drugs on the prior authorization list.<sup>24</sup>

The Division maintains a list of those prescription medications that require prior authorization.<sup>25</sup> Viekira Pak is one of the prescription medications on Alaska Medicaid's prior authorization list.<sup>26</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>27</sup> The relevant prior authorization criteria for Viekira Pak, when (as here) used to treat HCV genotype 1, are:<sup>28</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 [emphasis added] . . . AND

In this case, the prior authorization request submitted by Mr. H's physician identified Mr. H's diagnosis as "chronic hepatitis C, genotype 1A;"<sup>29</sup> and identified Mr. H's "Metavir Fibrosis Score" (which scores the patient's level of fibrosis, from the lowest score of F-0 to the highest score of F-4), as "difficult to determine," but somewhere between F-0 and F-2.<sup>30</sup>

The Division's approval criteria for Viekira Pak, when (as here) prescribed to treat Hepatitis C, genotype 1 (which includes genotype 1A), require (among other things) a Metavir Fibrosis score of F-2 to F-4 or equivalent (see criterion number three at page four, above). Here, Mr. H's doctor identified Mr. H's Metavir Fibrosis score as somewhere between F-0 and F-2.<sup>31</sup>

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<sup>23</sup> 7 AAC 120.130(a).

<sup>24</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>25</sup> Exs. F, G, H. 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>26</sup> Ex. F2, line eight. 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>27</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>28</sup> Exs. J1 - J4.

<sup>29</sup> Ex. E5.

<sup>30</sup> Ex. E6.

<sup>31</sup> Ex. E6.

Because a Metavir Fibrosis score of F-0 or F-1 is a nonqualifying score, while a Metavir Fibrosis score of F-2 is a qualifying score, it was necessary for the Division to perform an additional calculation in order to determine Mr. H's eligibility for Viekira Pak.<sup>32</sup> First, the Division took the newest lab results available on Mr. H, collected on January 14, 2016.<sup>33</sup> Next, the Division entered the numerical figures from the January 14, 2016 lab test results into a formula, developed by researchers, originally published in the Journal of Hepatology in 2006.<sup>34</sup> This formula considers the claimant's age (here 57), the recipient's AST level<sup>35</sup> (here 23), the recipient's platelet count (here 185) and the claimant's ALT level<sup>36</sup> (here 27), to reach what the formula refers to as a "fibrosis-4 score."<sup>37</sup> Ms. Wall testified that Mr. H's fibrosis-4 score, calculated under this formula, is 1.36.<sup>38</sup> Ms. Wall testified that, although the fibrosis-4 score is not exactly the same as a Metavir Fibrosis score, Mr. H's fibrosis-4 score correlates to a Metavir Fibrosis score of less than two, which is the minimum qualifying score. Ms. Wall also testified that Mr. H's score is very close to a qualifying score, so he may become eligible for the drug in the near future.

In summary, although Mr. H appears to meet the other criteria, his Metavir Fibrosis score is not currently high enough to qualify him to receive Viekira Pak through Alaska Medicaid. Accordingly, the Division was correct to deny his doctor's prior authorization request.

#### **IV. Conclusion**

The Division did not dispute that Mr. H has a significant need for an affordable and effective prescription drug treatment for his Hepatitis C. However, the Division is required to follow its Medicaid regulations as written.<sup>39</sup> Likewise, the Office of Administrative Hearings does not have the authority to create exceptions to these regulations.<sup>40</sup> To provide the drug at issue

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<sup>32</sup> Rebecca Wall's hearing testimony.

<sup>33</sup> Exhibit N2; Rebecca Wall's hearing testimony.

<sup>34</sup> Exhibit N8; Rebecca Wall's hearing testimony.

<sup>35</sup> AST, or aspartate aminotransferase, is one of the two "liver enzymes." See United States Department of Veterans Affairs' website at <http://www.hepatitis.va.gov/patient/hcv/diagnosis/labtests-AST.asp> (accessed March 10, 2016). When liver cells are damaged, AST leaks into the bloodstream and the level of AST in the blood becomes higher than normal. *Id.* Thus, a high AST level often indicates liver damage. *Id.* The AST level in most patients with hepatitis C goes up and down. *Id.* The normal AST range for men is 8 to 48 U/L. *Id.*

<sup>36</sup> The alanine transaminase (ALT) blood test measures the level of the enzyme ALT in the blood. See MedLine Plus, a U.S. National Library of Medicine website located at <https://www.nlm.nih.gov/medlineplus/ency/article/003473.htm> (accessed March 10, 2016). An increased ALT level is usually a sign of liver disease. *Id.* The normal ALT range for men is 10 to 40 U/L. *Id.*

<sup>37</sup> Exhibit N8; Rebecca Wall's hearing testimony.

<sup>38</sup> Exhibit N8; Rebecca Wall's hearing testimony.

<sup>39</sup> "Administrative agencies are bound by their regulations just as the public is bound by them." *Burke v. Houston NANA, L.L.C.*, 222 P.3d 851, 868 – 869 (Alaska 2010).

<sup>40</sup> See 7 AAC 49.170.

to someone in Mr. H's current medical condition would require changes in state law. Those changes cannot be made through the hearing process.

Based on Mr. H's physician's characterization of his Hepatitis C, Mr. H does not currently satisfy the Division's prior authorization criteria for Viekira Pak. Accordingly, the Division was correct to deny Mr. H's physician's prior authorization request. The Division's decision is therefore affirmed.

Dated this 13th day of April, 2016.

*Signed* \_\_\_\_\_  
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 22<sup>nd</sup> day of April, 2016.

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

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