

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

In the Matter of)
)
 K S S) OAH No. 15-0653-MDX
) Agency No.

DECISION

I. Introduction

K S S is a Medicaid recipient. Her physician requested that the Medicaid program provide her with a prescription drug known as “Harvoni.” The Division of Health Care Services (Division) denied the request. Ms. S requested a hearing to challenge the denial.

The hearing was held on June 19, 2015. Ms. S represented herself. Angela Ybarra, a Medical Assistance Administrator with the Division, represented the Division. Erin Narus, a licensed pharmacist employed by the Division, testified on the Division’s behalf.

The evidence shows that Ms. S’s condition is not sufficiently severe to qualify for Harvoni, per established Division guidelines. Therefore, the Division’s decision denying prior authorization is affirmed.

II. Facts

The following facts were established by a preponderance of the evidence.

Ms. S has been diagnosed with hepatitis C (genotype 2), but she does not have cirrhosis or advanced fibrosis.¹ Ms. S’s physician prescribed Harvoni to treat her hepatitis. Harvoni is a drug which requires prior authorization from the Division before Medicaid will pay for it.² On May 1, 2015, Ms. S’s physician requested that the Medicaid program approve coverage (“prior authorization”) for Harvoni for her.³

The Division denied Ms. S’s physician’s prior authorization request for Harvoni on May 2, 2015.⁴ The basis for the denial was that “submitted disease severity does not meet the criteria for Alaska Medicaid approval.”⁵ The Division’s representative explained at the hearing that this reference to “disease severity” meant that pre-authorization was denied to Ms. S because her

¹ Exh. E24.
² Ms. Narus’ testimony.
³ Exh. E20.
⁴ Exh. E2.
⁵ *Id.*

hepatitis-C is not sufficiently severe to meet the Division’s criteria.⁶ Ms. S appealed the Division’s denial.

At the time Ms. S’s physician requested prior authorization for Harvoni, the Division’s drug utilization committee had established guidelines that required, in part, that a person had to have either cirrhosis or fibrosis of a certain severity before the Division would authorize a number of medications (Sovaldi, Olysio, or Harvoni) for treatment of Hepatitis C.⁷

III. Discussion

Ms. S has the burden of proof by a preponderance of the evidence to establish that the Division’s denial was incorrect.⁸ She has not met that burden.

The Alaska Medicaid program requires prior authorization for a number of medications.⁹ In determining whether to grant prior authorization for a medication (or any service), Alaska regulation 7 AAC 105.130 states that the “factors that the department will consider include the service’s medical necessity, clinical effectiveness, cost-effectiveness, and likelihood of adverse effects”¹⁰ Harvoni is one of the medications that requires prior authorization before the Medicaid program will pay for it. The Division took the above-quoted factors into account when it developed its authorization criteria for Harvoni and other hepatitis-C medications.¹¹ In considering cost-effectiveness, the Division had to take into account the very high cost of these medications¹² and the need to prioritize treatment for severely ill, low-income patients.¹³

The Division adopted clear clinical guidelines which must be met before prior authorization will be granted for Harvoni. These criteria are based in part on the level of severity of a person’s hepatitis-C, focusing primarily on the severity of “fibrosis” (damage resulting from inflammation) of the liver.¹⁴ In this case, the evidence demonstrated that Ms. S’s hepatitis-C has not reached the severity level required by the Division’s eligibility criteria.¹⁵ In addition, Harvoni is FDA-approved only for patients suffering from genotype-1 hepatitis C, and would not

⁶ Ms. Narus’ testimony.

⁷ Exh. J1; Ms. Narus’s testimony.

⁸ 7 AAC 49.135.

⁹ 7 AAC 105.130(a)(13); 7 AAC 120.130(a)(1).

¹⁰ 7 AAC 105.130(c).

¹¹ Ms. Narus’ testimony.

¹² *Id.* The Division estimated that Ms. S’s Harvoni treatment would have cost at least \$75,000.

¹³ Ms. Narus’ testimony.

¹⁴ Ms. Narus’ testimony.

¹⁵ Exh. E24; Ms. Narus’ testimony.

be an appropriate treatment for Ms. S's genotype-2 hepatitis C.¹⁶ Given this fact, it is unclear why Ms. S's physician prescribed Harvoni for her.

Ms. S did not dispute that the degree of severity of her hepatitis-C does not currently meet the Division's criteria for Harvoni. Rather, she disagrees with the concept that authorization can be denied just because her symptoms are not yet severe; in her view, authorization should be granted so that she can attempt to treat and cure the disease before her hepatitis-C reaches a severe stage.¹⁷ Although acknowledging that the severity of her hepatitis-C is relatively low, Ms. S believes that it is causing her to suffer from symptoms of other illnesses. While Ms. S's view appears to be logical (i.e., why wait for the disease to become more severe if a treatment is available for it now?), it fails to take into account the Division's need to prioritize treatment for the more severely ill hepatitis-C patients in Alaska.

Ms. S's hepatitis-C is undisputedly not at a stage where it is severe enough to satisfy the clinical guidelines necessary for prior authorization for Harvoni (and in addition the drug apparently is not an appropriate treatment for genotype-2). Given these facts, the Division was correct to deny prior authorization for Harvoni.

IV. Conclusion

The Division's decision to deny Ms. S's prior authorization request for Harvoni is affirmed.

DATED this 24th day of September, 2015. Signed

Andrew M. Lebo
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 9th day of October, 2015.

By: Signed

Name: Cheryl Mandala

Title: Administrative Law Judge

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

¹⁶ Ms. Narus' testimony.

¹⁷ Ms. S's testimony. Ms. S did not argue at hearing that the Division's authorization criteria for Harvoni were not properly promulgated, an argument that was addressed in a recent OAH decision regarding a Medicaid patient's request for Sovaldi authorization. *See In Re C.I.*, OAH No. 14-1140-MDC (Commissioner of Health and Social Services (1/23/15); not yet published).