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

In the Matter of)
)
NC) OAH No. 15-0278-MD
) Agency No.

DECISION

I. Introduction

N C is a Medicaid recipient. Her physician requested that the Medicaid program provide her with a prescription drug known as "Sovaldi." The Division of Health Care Services (Division) denied the request. Ms. C requested a hearing to challenge the denial.

The hearing was held on May 12, 2015. Ms. C 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. C's condition is not sufficiently severe to qualify for Sovaldi, per established Division guidelines. The Division's decision denying prior authorization is affirmed.

II. Facts

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

Ms. C has been diagnosed with hepatitis C, but she does not have cirrhosis or fibrosis. Ms. C's physician prescribed Sovaldi to treat her hepatitis. Sovaldi is a drug which requires prior authorization from the Division before Medicaid will pay for it. On February 17, 2015, Ms. C's physician requested that the Medicaid program approve coverage ("prior authorization") for Sovaldi for Ms. C. 3

The Division denied Ms. C's prior authorization request for Sovaldi on February 19, 2015.⁴ The basis for the denial was that her physician had not informed the Division that she had "tried other drugs that cost less or that [she has] certain kinds of health problems." The

¹ Exhs. H10, H18.

Ms. Narus' testimony.

Although the physician's request for prior authorization does not appear in the record, the date of the request is referenced in Ms. C's request for hearing at Exh. C1 and in the Division's position statement at p. 2.

Exh. D.

⁵ Exh. D1.

Division's representatives explained at the hearing that the latter reference to "certain kinds of health problems" refers to the pre-authorization criteria regarding severity of a patient's hepatitis-C; in other words, pre-authorization was denied to Ms. C because her hepatitis-C is not sufficiently severe to meet the Division's criteria. Ms. C appealed the Division's denial

At the time Ms. C requested prior authorization for Sovaldi, 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. C 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.

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"

Sovaldi is one of the medications which 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 Sovaldi and other hepatitis-C medications.

In considering cost-effectiveness, the Division had to take into account the very high cost of these medications and the need to prioritize treatment for severely ill, low-income patients.

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The Division adopted clear clinical guidelines which must be met before prior authorization will be granted for Sovaldi. 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

⁶ Ms. Narus' testimony.

Exh. J2; 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).

Ms. Narus' testimony.

Ms. C's Sovaldi treatment was estimated to cost \$89,000 (Ms. Narus' testimony).

Ms. Narus' testimony.

Ms. Narus' testimony.

Ms. C does not dispute that the degree of severity of her hepatitis-C does not currently meet these criteria for Sovaldi. In fact, her physician indicated in a previous request for prior authorization that Ms. C's diagnostic scores "are not suggestive of fibrosis." Rather, Ms. C 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. Although Ms. C'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. C's hepatitis-C is undisputedly not at a stage where it is severe enough to satisfy the clinical guidelines necessary for prior authorization for Sovaldi. While Sovaldi may be Ms. C's physician's treatment of choice, given these facts, the Division was correct to deny prior authorization for Sovaldi.

V. Conclusion

The Division's decision to deny Ms. C's prior authorization request for Sovaldi is affirmed.

DATED this 13th day of May, 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 2nd day of June, 2015.

By: <u>Signed</u>

Name: <u>Andrew M. Lebo</u>

Title: <u>Administrative Law Judge</u>

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

Exh. H10.

Ms. C's testimony. Ms. C did not argue that the Division's authorization criteria for Sovaldi were not properly promulgated, an argument that was addressed in a recent OAH decision regarding another 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).