

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

In the Matter of)	
)	
L G)	OAH No. 16-1180-MDX
_____)	Agency No.

DECISION

I. Introduction

L G receives Medicaid benefits. His physician requested that the Medicaid program authorize payment for the prescription drug Zepatier for Mr. G. The Division of Health Care Services denied the request. Mr. G requested a hearing.

The evidence shows that Mr. G is not eligible to receive the medication Zepatier according to Medicaid program criteria. The division's denial is upheld.

II. Facts

Mr. G has a genotype 1a hepatitis C infection.¹ His physician requested prior authorization from the Medicaid program for Mr. G to receive Zepatier.² The division denied the request because it found that Mr. G's condition was not severe enough to meet program criteria for approval of the drug.³

A telephonic hearing was held on November 10, 2016. Mr. G represented himself. Medical Assistance Analyst Terri Gagne represented the division. Ms. Rebecca Wall, a pharmacist with the division, testified for the division.

III. Discussion

Under the Medicaid program, the division requires providers to obtain prior authorization before dispensing certain drugs.⁴ Zepatier is one of those drugs.⁵ In deciding whether to grant prior authorization for a drug or service, the division considers medical necessity, clinical effectiveness, cost-effectiveness, and the likelihood of adverse effects.⁶

The division's drug utilization review committee has developed a list of criteria for the prior authorization of direct acting antivirals used to treat Hepatitis C, including

¹ Exhibit E at 21.
² Exhibit E at 3 - 6.
³ Exhibit D at 1 - 2.
⁴ 7 AAC 120.130.
⁵ Zepatier is on the Alaska Medicaid Interim Prior Authorization list. Exhibit F at 2. The Alaska Medicaid Interim Prior Authorization List is authorized under 7 AAC 120.130(a)(2)(B).
⁶ 7 AAC 105.130. This regulation refers to "services," but 7 AAC 160.990(78) defines "service" for purposes of the Medicaid program to include drugs.

Zepatier. These criteria require that the patient have a diagnosis of Hepatitis C and a “Metavir Fibrosis score of F2 – F4 or the equivalent.”⁷ Zepatier is a relatively new drug, approved by the U.S. Food and Drug Administration in January of this year.⁸ However, the requirement of a fibrosis score of F2 - F4 for preapproval of Hepatitis C drugs has been in place for some time.

The criteria for prior authorization for Zepatier and other direct acting antivirals used to treat Hepatitis C have not been adopted as a regulation. That said, the Department of Health and Social Services has adopted a regulation requiring prior authorization for drugs that have been placed, in consultation with the drug use review committee (DURC) on an interim list of drugs for which prior authorization is required.⁹ The DURC is established by regulation.¹⁰ Thus, although the criteria themselves have not been adopted into regulation, they are the result of a process established in regulation. By applying the criteria to Mr. G, the division is complying with the requirements of federal law and 7 AAC 105.130. Mr. G has not argued that the division’s criteria for prior authorization are invalid or that they were misapplied.

Mr. G has been diagnosed with Hepatitis C. However, his fibrosis score is F0, meaning his liver is not yet showing the impact of the infection.¹¹ The division found that he did not have other symptoms that would be equivalent to a fibrosis score of F2 - F4.¹² Mr. G did not contest this finding.

Mr. G’s Metavir fibrosis score is below the minimum score required for authorization of Zepatier under the program. The division’s denial was consistent with the division's prior authorization criteria for Zepatier.

IV. Conclusion

The division’s denial of the request for prior authorization of the drug Zepatier for Mr. G is affirmed.

Dated: November 17, 2016.

Signed
Kathryn L. Kurtz
Administrative Law Judge

⁷ Exhibit J at 2.

⁸ FDA News Release, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm483828.htm>.

⁹ 7 AAC 120.130(a)(2)(B).

¹⁰ Exhibit J at 1 - 10. The Drug Utilization Review Committee is established under 7 AAC 120.120.

¹¹ Exhibit E at 4.

¹² Testimony of Wall.

Adoption

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

Judicial review of this decision may be obtained by filing an appeal in the Alaska Superior Court in accordance with AS 44.62.560 and Alaska R. App. P. 602(a)(2) within 30 days after the date of this decision.

DATED this 2nd day of December, 2016.

By: Signed
Signature
Kathryn Kurtz
Name
Administrative Law Judge
Title

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