

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

In the Matter of)
)
 B T)
_____)

OAH No. 14-1233-MDX
Agency No.

DECISION

I. Introduction

Mr. T appealed the denial of authorization for a medication. Because the denial was consistent with federal and state regulations, and was based on the reasonable grounds that the Food and Drug Administration had not approved the medication for people in Mr. T's circumstances, the Division's denial is affirmed.

II. Facts

B T suffers from Hepatitis-C. Because the disease severely damaged his liver, he received a liver transplant. Following his liver transplant, his doctor prescribed the medication Sovaldi. Sovaldi is a relatively new medication that is a direct acting agent on Hepatitis-C.

When his medical providers requested Medicaid approval of Sovaldi for Mr. T, the Division of Health Care Services denied approval. Erin Narus, a doctor of pharmacy who serves on the drug utilization committee for the Department of Health and Social Services, explained that although the committee has approved Sovaldi for certain cases, it has not approved it for post-liver transplant patients. She testified that at this time, the Federal Drug Administration has not approved Sovaldi for post-liver transplant patients.¹

Mr. T appealed. A telephonic hearing was held on August 27, 2014. W H assisted Mr. T in presenting his case. Mr. T's care assistant, Ms. Q testified at the hearing. Angela Ybarra represented the Division.

At the hearing, Ms. Q explained that the infection resides in the blood—just because Mr. T has a new liver, he will not be healthy unless he is able to receive the medication necessary to destroy the infection.² Ms. H explained that Mr. T had been accepted into a program called Gilead/Support Path that made the medication available to Mr. T. He was pursuing his appeal, however, in case the program should cease to provide the medication and to ensure that she could demonstrate that Mr. T had exhausted all other avenues.³

¹ Narus testimony.
² Q testimony.
³ H testimony.

III. Discussion

Following the hearing, the Division provided exhibits that confirm Ms. Narus’s testimony that the drug utilization committee has adopted criteria for denial of prior authorization of Sovaldi when “[p]atient is post-liver transplant.”⁴ The explanation given for that criterion is that “safety and efficacy have not been established.”⁵ The Division provided documentation that appears to be from the manufacturer that verifies that “[t]he safety and efficacy of Sovaldi have not been established in post-liver transplant patients.”⁶ Under federal law, the state may impose prior authorization requirements for any outpatient drugs for which Medicaid funding is sought.⁷

Under 7 AAC 120.130(a), a provider must obtain prior authorization for prescription drugs. For new drugs not on the department’s list, the drug must be approved on an interim basis by the review committee established under 7 AAC 120.120.⁸ Here, the committee has specifically disapproved Sovaldi for post-liver transplant applications because this application has not been approved by the FDA. Although this result creates a challenge for patients in Mr. T’s shoes, it is a reasonable action for the committee to take. Accordingly, the Division’s denial is affirmed.

IV. Conclusion

The Division’s denial of Medicaid authorization of Solvadi for Mr. T is affirmed because it is not approved for patients in Mr. T’s circumstances.

DATED this 24th of September, 2014.

By: Signed _____
Stephen C. Slotnick
Administrative Law Judge

⁴ Division Exhibit E at 4.

⁵ *Id.*

⁶ Division Exhibit H at 12. The record appears to indicate that clinical trials are currently underway for post-transplants patients.

⁷ *See* 42 USC § 1396r-8(d)(1)(A).

⁸ 7 AAC 120.130(a)(2)(B).

Adoption

Under a delegation from the Commissioner of Health and Social Services, I adopt this Decision as the final administrative determination in this matter, 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 Alaska R. App. P. 602(a)(2) within 30 days after the date of this decision.

DATED this 9th day of October, 2014.

By: Signed _____
Name: Stephen C. Slotnick
Title: Administrative Law Judge/DOA

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