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

In the Matter of	)	
	)	
B C	)	OAH No. 17-0803-MDX
	)	Agency No.

DECISION

I. Introduction

B C is a Medicaid recipient. Ms. C's physician requested that the Medicaid program provide her with a prescription drug known as "Harvoni." The Division of Health Care Services denied the request. Ms. C requested a hearing to challenge the denial. Because the evidence shows that, under the division criteria in effect at the time of Ms. C's request, Ms. C's condition is not sufficiently severe to qualify for Harvoni; and because under the new clinical guidelines, Harvoni is a non-preferred agent and a medically appropriate preferred agent, Mavyret, is available, 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 Chronic Hepatitis-C, genotype 1a.[1] Ms. C's physician, Dr. Q W referred Ms. C to a liver specialist, Dr. H T.[2] Based on Dr. T's recommendation, Dr. W prescribed Harvoni to treat Ms. C's Hepatitis-C.[3]

Harvoni (ledipasvir/sofosbuvir) is a Direct Acting Antiviral (DAA) drug for treatment of patients with chronic Hepatitis-C genotype 1, 4, 5, or 6 infection.[4] Because of the high cost of the drug and the division's need to maintain the financial integrity of the state's Medicaid program by prioritizing treatment first to those with the greatest need, Harvoni requires prior authorization from the division before Medicaid will pay for it.[5] The division's drug utilization committee establishes guidelines for prior authorization of Harvoni.[6] Those guidelines require, among other criteria, that a person have a

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1 Ex. E at 5.
2 Dr. W Testimony.
3 Ex. E at 20.
4 Ex. J; Ex. K; Erin Narus Testimony.
5 Ex. F at 2; Ex. H at 3; Ex. O; Erin Narus Testimony.
6 *See* Ex. J.

Metavir Fibrosis score of F2-F4 before the division will authorize payment for Harvoni to treat Hepatitis-C.[7]

On June 23, 2017, Dr. W submitted a request for prior authorization for Harvoni for Ms. C to the division.[8] In the section of the form that asks the physician to identify the patient's Metavir Fibrosis Score, Dr. W checked the box labeled "F0."[9]

The division denied the preauthorization request because Ms. C's disease severity—as documented in the medical records attached to the request—did not meet the criteria for Alaska Medicaid approval of Harvoni.[10] The division issued a Notice of Denial on June 26, 2017.[11] And Ms. C requested a hearing.[12]

On September 15, 2017, the drug utilization committee updated the clinical criteria for Hepatitis-C Direct Acting Antiviral Agents.[13] In particular, the committee selected a newly-FDA-approved, less-expensive DAA, Mavyret (glecaprivar/pibrentasvir), as an approved and preferred treatment for patients with a Metavir Fibrosis Score of F0 or F1.[14] Under the new guidelines, effective October 1, 2017, the division no longer considers disease severity for the preferred DAA treatment, Mavyret.[15] But a request for a non-preferred agent, such as Harvoni, when a medically appropriate preferred agent, such as Mavyret, is available, is a basis for denying prior authorization.[16] Ms. C meets the new criteria for treatment with Mavyret.[17]

A hearing was held on September 19, 2017. Laura Baldwin, a Medical Assistance Administrator, represented the division. Erin Narus, the lead pharmacist who oversees the State's Medicaid pharmacy program, testified on the division's behalf. Ms. C represented herself. Ms. C testified, and she called Dr. W to testify on her behalf.

At the hearing, Dr. W testified that the Hepatitis-C virus has been present in Ms. C's liver for years, and she opines that treatment will become more expensive if they wait for Ms. C to get sicker.[18] Dr. W explained that Dr. T, a specialist in the field, conducted thorough testing and evaluation and

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7 Ex. J at 2; Erin Narus Testimony.
8 Ex. E at 7.
9 Ex. E at 5; *see also* Ex. E at 11-12.
10 Ex. D; Ex. E at 1, 5, 11-12.
11 Ex. D.
12 Ex. C.
13 Erin Narus Testimony; Ex. N; Ex. S.
14 Erin Narus Testimony; Ex. N; Ex. S.
15 Erin Narus Testimony; Ex. N.
16 Erin Narus Testimony; Ex. N at 4.
17 Erin Narus Testimony; Ex. E; Ex. N.
18 Dr. W Testimony.

recommended Harvoni—that in Dr. T's view, Harvoni is the safest and most effective treatment.[19] According to Dr. W, Dr. T was not comfortable prescribing Mavyret as the drug was still too new.[20]

After the hearing, the record was left open to allow the parties the opportunity to supplement. The division submitted additional documents about the new DAA treatment criteria and the approved drug, Mavyret. A supplemental hearing was held on September 28, 2017.

At the supplemental hearing, Ms. Narus explained why the drug utilization committee selected Mavyret. The committee unanimously selected Mavyret as the preferred DAA after reviewing clinical evaluations, including efficacy and safety, of the various products available; pharmacy reimbursement projections based on a population health model; cost effectiveness; fraud, waste, and abuse; rise in drug resistant virus variants; federal funding; and impact to the financial integrity of the Alaska Medicaid Pharmacy program.[21] Clinical trials used to support FDA-approval of Mavyret—trials that studied the sustained virologic response 12 weeks after finishing the treatment course—demonstrated efficacy rates between 95% and 100%, depending on the treatment subpopulation used.[22] On September 21, 2017, the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) updated their Hepatitis-C treatment guidelines to support Mavyret (glecaprevir/pibrenasvir) as a recommended regimen for the most common treatment subpopulations seen in Alaska Medicaid.[23] Accordingly, Mavyret is a comparable, equally effective, less-expensive alternative to Harvoni.[24]

IV. Discussion

Ms. C has the burden of proof by a preponderance of the evidence to establish that the division's denial of Harvoni was incorrect.[25] She has not met that burden.

The Alaska Medicaid program requires prior authorization for many medications, such as Harvoni.[26] In determining whether to grant prior authorization for a medication, 7 AAC 105.130 states that the "factors the department will consider include the service's medical necessity, clinical effectiveness, cost-effectiveness, and likelihood of adverse effects[.]"[27] The division applied the factors listed in 7 AAC 105.130(c) when it developed its prior authorization clinical criteria for Harvoni and

19 Dr. W Testimony.
20 Dr. W Testimony.
21 Erin Narus Testimony; Ex. S.
22 Erin Narus Testimony; Ex. S at 3.
23 Erin Narus Testimony; Ex. R at 3; Ex. S at 3.
24 Erin Narus Testimony; Ex. R at 3; Ex. S. *Compare* Ex. K at 7-8, 31-32 *to* Ex. P at 6-7, 25.
25 7 AAC 49.135.
26 7 AAC 105.130(a)(13); Ex. Q at 1; Ex. F; Ex. G; Ex. H.
27 7 AAC 105.130(c).

other Direct Acting Antivirals for Hepatitis-C.[28] 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.[29]

The division adopted clear clinical guidelines which must be met before authorization will be granted for Harvoni. At the time of Ms. C's prior authorization request, these criteria were based in part on the level of severity of a person's Hepatitis-C, focusing primarily on the severity of "fibrosis" of the liver.[30] Under new guidelines, effective October 1, 2017, the division no longer considers disease severity for the preferred DAA treatment, Mavyret.[31] But a request for a non-preferred agent, such as Harvoni, when Mavyret is available, is a basis for denying prior authorization.[32]

Here Ms. C did not dispute that the degree of severity of her Hepatitis-C does not meet the division's criteria that were in effect at the time of her prior authorization request.[33] Ms. C's Metavir Fibrosis Score was F0, which falls below the criteria in effect at the time of Ms. C's request.[34] Rather, Ms. C and her doctor disagree that authorization should be denied just because Ms. C's symptoms are not yet severe; in their view, authorization should be granted so that Ms. C can attempt to treat and cure the disease before her Hepatitis-C makes her sicker.[35] While Ms. C's (and Dr. W's) view appears to be logical (i.e. why not try to cure the disease before it causes liver damage?), it fails to take into account the division's need to keep the Medicaid program fiscally sound by prioritizing treatment for the more severely ill Hepatitis-C patients in Alaska. In short, Ms. C's Hepatitis-C is undisputedly not at a stage where it is severe enough to satisfy the clinical criteria for prior authorization for Harvoni in effect at the time of her request for prior authorization.

Similarly, because Mavyret—a medically appropriate preferred agent—is available, and because Ms. C meets the new criteria for treatment with Mavyret, prior authorization for Harvoni would have been denied under the new clinical criteria as well.[36] Although Dr. W expressed a clear preference for prescribing Harvoni over Mavyret, Ms. C presented no evidence that she has any contraindication to Mavyret.[37] Ms. C, likewise, did not present evidence disputing that Mavyret is a medically appropriate

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28 Ex. J; Exhibit N; Exhibit S.
29 Erin Narus Testimony; Ex. O; Ex. F at 2; Ex. H at 3; Ex. S at 5.
30 Erin Narus Testimony; Ex. J at 2.
31 Erin Narus Testimony; Ex. N.
32 Erin Narus Testimony; Ex. N at 4.
33 Erin Narus Testimony; Ex. J at 2; Ex. E at 5; *see also* Ex. E at 11-12.
34 Ex. E at 5; *see also* Ex. E at 11-12.
35 Ex. C at 2; Dr. W Testimony.
36 Erin Narus Testimony; Ex. N at 4; Ex. E at 5; *see also* Ex. E at 11-12.
37 *See* Dr. W Testimony.

treatment for her Hepatitis-C. On the contrary, the preponderance of the evidence supports the division's conclusion that Mavyret is available, equally effective, and safe for treating Ms. C's Hepatitis-C.[38]

Accordingly, although Harvoni may be Ms. C's physicians' treatment of choice, given the facts presented, the division was correct to deny prior authorization for Harvoni.

V. Conclusion

The division's decision to deny Ms. C's June 23, 2017 prior authorization request for Harvoni is affirmed.

Dated: October 4, 2017

Signed
Jessica L. Srader
Administrative Law Judge

Adoption

The undersigned, by delegation from 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 23rd day of October, 2017.

By: *Signed*
Name: Jessica L. Srader
Title: Administrative Law Judge

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

[38] Erin Narus Testimony; Ex. R at 3; Ex. S. *Compare* Ex. K at 7-8, 31-32 *to* Ex. P at 6-7, 25.