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

In the matter of	)	
	)	
C J	)	OAH No. 14-1140-MDX
	)	Agency No.

DECISION

I. Introduction

C J, a Medicaid recipient, requested prior authorization for the prescription drug Sovaldi. The Division of Health Care Services (Division) denied the request because Mr. J did not meet the Sovaldi criteria developed by the drug utilization review committee (DURC). Mr. J appealed the denial.

It is uncontested that Mr. J did not meet the Sovaldi prior authorization criteria. At hearing, Mr. J challenged the criteria development process as failing to comply with regulatory requirements. Although Mr. J did raise some doubt regarding the criteria development process, it fell short of invalidating the Sovaldi criteria. Therefore, the Division's decision denying Mr. J's Sovaldi prior authorization is affirmed.

II. Facts

A. Mr. J's Prior Authorization Request Denial

Mr. J has chronic viral Hepatitis-C, a contagious disease that compromises the liver.[1] Mr. J's medical records indicate his Hepatitis-C is genotype 1 and he has not previously undergone treatment.[2] Mr. J has had two liver biopsies.[3] His most recent, in 2010, revealed an inflammatory grade of 2/4 with a Fibrotic stage of F1.[4]

On June 2, 2014, Dr. Daryl McClendon requested prior authorization for Sovaldi, a relatively new Hepatitis C treatment.[5] On June 3, 2014, the Division, through its contractor Magellan, denied the prior authorization request because Mr. J did not meet the criteria for Sovaldi Medicaid coverage.[6]

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1 Ex. E.
2 Ex. E. Treatment naïve means that a patient has not previously undergone treatment for an illness.
3 Ex. E.
4 Ex. E, p.
5 Ex. E, p. 2 -10.
6 Ex. D.

On June 26, 2014, Mr. J appealed the denial.[7] After several continuances, a hearing was held on November 24, 2014. Goriune Dudukgian represented Mr. J. Kimberly Allen represented the Division. Chad Hope, the Division's pharmacy program manager, and Erin Narus, Medicaid pharmacist and DURC member, testified. Both Ms. Hope and Ms. Narus testified extensively regarding Sovaldi and the requirements for its prior authorization.

B. Sovaldi

Sovaldi is very effective. In controlled studies, Sovaldi offered a sustained virologic response (SVR) of up to 89%. An SVR stops liver damage and is commensurate to a virologic cure.[8] Sovaldi is also very expensive. A course of Sovaldi treatment costs approximately $84,000.[9] According to Mr. Hope, if the more than 1,200 Medicaid recipients in Alaska with Hepatitis C were treated with Sovaldi, the cost would consume more than the entire Alaska Medicaid medication budget.[10] However, since Sovaldi's FDA approval, far fewer than 100 Alaska Medicaid recipients have requested prior authorization for Sovaldi.[11]

Because of Sovaldi's high price tag and the number of people diagnosed with Hepatitis C, Sovaldi's cost and coverage guidelines have sparked nationwide debate.[12] Alaska developed Sovaldi prior authorization criteria that took into account both high costs and anticipated new drugs with fewer potential complications but similar virologic responses.[13] Sovaldi treatment for genotype 1 patients, like Mr. J, requires the use of interferons, which some patients do not tolerate well.[14] Some of the Hepatitis drugs expected to hit the market soon will not require interferon usage and will arguably be safer for patients.[15]

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7 Ex. C.

8 Ex. E, p. 9; Ex. F, p. 1; Hope testimony. Mr. Hope testified that outside of controlled studies the SVR is 20% less.

9 Hope testimony.

10 Hope testimony. Gilead, Sovaldi's manufacturer, has a support path program that may cover the cost of Sovaldi for patients whose insurance has twice denied coverage. This decision does not consider the program because the Division did not base its denial on the possibility that Mr. J's Sovaldi prescription might be covered through the Gilead program.

11 Hope testimony.

12 Hope testimony; Narus testimony. Mr. Hope testified that there are between 10 – 15 million patients with Hepatitis C nationwide. Mr. Hope also testified that Sovaldi and similarly high-priced Hepatitis medications threaten the entire healthcare delivery system.

13 Hope testimony.

14 Narus testimony.

15 Narus testimony.

C. The Division's Sovaldi Criteria and Prior Authorization Process

Alaska Medicaid requires prior authorization for many services, including prescription drugs listed on the *Alaska Medicaid Prior-authorized Medications List* or interim list.[16] The department, through DURC, develops prior authorization criteria for these prescription drugs.[17] From December 27, 2013, to April 18, 2014, Sovaldi's prior authorization criteria were the same as the generic new drug guidelines.[18] The generic criteria for a new drug require at least one failed therapy before approval.[19]

The Division developed Sovaldi-specific criteria. In developing the criteria, the Division reviewed a variety of resource materials and discussed Sovaldi guidelines with community organizations, the department's Chief Medical Officer, and the Medicaid medical director.[20] The Division then provided DURC with proposed Sovaldi criteria. DURC addressed the proposed Sovaldi criteria during at least two of its meetings, with public notice of the meetings and a published agenda available on its website.[21] The proposed criteria were not posted on the website.[22]

DURC balanced numerous factors, including clinical guidelines, cost effectiveness, immediacy of need, and patient safety in developing the Sovaldi criteria.[23] DURC developed general, not patient-specific criteria, meaning that the Division would grant prior authorization for patients who met the criteria and deny coverage for those who did not.[24] DURC encountered a range of Sovaldi guideline recommendations in the source materials.[25] Some advocated for limited coverage, while others advocated for liberal coverage.[26] DURC held extensive discussions and reached its decision by consensus.[27]

On April 18, 2014, DURC unanimously adopted Sovaldi prior authorization criteria.[28] The prior authorization criteria states that a patient must be an adult, who has not been treated

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16 7 AAC 105.130(13); 7 AAC 120.130.
17 7 AAC 120.120; 42 USC 1396r-8(g).
18 Hope testimony. The U.S. Food and Drug Administration approved Sovaldi on December 6, 2013. *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm377888.htm.
19 Hope testimony.
20 Hope testimony.
21 Hope testimony.
22 Hope testimony.
23 Narus testimony.
24 Magellan, a Division subcontractor, processes prior authorizations requests.
25 Hope testimony.
26 Hope testimony.
27 Hope testimony.
28 Hope testimony; Ex. G.

with Sovaldi, who has abstained from illicit drugs and alcohol for at least three months, who meets the diagnosis and disease severity, and agrees to complete the regimen.[29] A patient must meet all of the criteria for approval.

Mr. J does not meet the diagnosis and disease severity criteria. The criteria for Hepatitis C, genotype 1 patients require liver biopsy results with a fibrosis scale or stage equal or greater to F3.[30] Mr. J's fibrosis scale is F1.[31] Fibrosis stage F3 means the patient has bridging fibrosis or intermediate scarring of the liver.[32] Fibrosis stage F4 means significant scarring or cirrhosis.[33] Mr. J's F1 score indicates his liver damage is not to this advanced stage.

The April 18, 2014, criteria prioritize Sovaldi approval for those patients with more advanced liver damage.[34] The theory is that treating and stopping liver damage in those patients is the first priority.[35] Patients with less liver damage may be able to wait for newer drugs to enter the market.[36] Alaska's patient prioritization criteria are in line with Sovaldi treatment recommendations issued by the Infectious Disease Society of American and the American Association for the Study of Liver Diseases.[37]

The Division's Medicaid Prior Authorization website listed Sovaldi criteria in two places: on its *Alaska Medicaid Interim Prior Authorization List*, and on the main webpage.[38] The interim list catalogued Sovaldi as a class 1 drug with prior authorization requiring at least one previously failed therapy, the generic criteria for new drugs.[39] The interim list did not contain the April 18, 2014 Sovaldi criteria. The main webpage has a direct link to the April 18, 2014,

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29 Ex. G. Sovaldi is the brand name for Sofosbuvir. The criteria use "Sofosbuvir." There are additional criteria for HIV-1 co-infected patients that do not apply to Mr. J.

30 Ex. D. There are numerous other criteria, but the fibrosis scale score was most pertinent and the basis of the denial.

31 Ex. E, p. 5 – 6.

32 Narus testimony.

33 Hope testimony; Ex. G;

34 Narus testimony.

35 Narus testimony.

36 Narus testimony.

37 Ex. F. This exhibit was not a basis for the Division's denial. Ms. Narus came upon these guidelines in preparation for hearing.

38 Ex. 1; http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx. On the day of hearing, Sovaldi was listed on the Division's website on the *Interim Prior Authorization Medication list* link. Sovaldi is no longer on the interim list, as of the proposed decision date.

39 Ex. 1; http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/InterimPriorAuthorizationList.pdf.

Sovaldi criteria.[40] Sovaldi is not listed on the *Alaska Medicaid Prior-Authorization Medication List.*[41]

III. Discussion

Mr. J has the burden of proof by a preponderance of the evidence to establish the Division's denial is incorrect.[42] He has not met that burden.

The Division may impose prior authorization requirements for Medicaid-covered outpatient drugs.[43] By regulation, the department is to consider the medical necessity, clinical effectiveness, cost-effectiveness, and likelihood of adverse effects, as well as service-specific requirements when determining whether to grant prior authorization.[44] The department may place minimum or maximum quantities on a service or require other services before the recipient receives the requested service to maintain the financial integrity of the department and the Medicaid program.[45] The department may also limit its payment to minimum and maximum quantities allowed of a specific prescribed drug or limit the number of refills to prevent waste or to address fraud or abuse.[46] DURC develops the criteria used by the Division to determine whether to grant a prior authorization request.[47]

A. Issue in dispute

The Division argues that the sole issue for hearing is whether Mr. J met the April 18, 2104, Sovaldi prior authorization criteria.[48] This issue is not in dispute. Mr. J did not meet the April 18, 2014, Sovaldi criteria when the Division denied his prior authorization request on June 3, 2014. Instead, Mr. J argues that the criteria are invalid because DURC did not adhere to the drug use review process required by federal and state regulations.[49] Mr. J requests a remand to

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40 http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Sovaldi_PA_Criteria.pdf.

41 http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Pa-Drug-list.pdf. The *Alaska Medicaid Prior Authorization list* did not contain Sovaldi as of the hearing date or proposed decision date.

42 7 AAC 49.135.

43 7 AAC 120.130; 42 USC § 1396r–8(d)(1)(A)

44 7 AAC 105.130(c).

45 7 AAC 105.130(c).

46 7 AAC 120.130(c).

47 7 AAC 120.120; Narus testimony.

48 Division's Amended Position Statement (October 29, 2014). This decision does not explore whether 7 AAC 120.130 was correctly applied. Mr. J is not challenging that he did not meet the criteria. Nor is he challenging the Division's ability to require prior authorizations. The Division argues that regulation allows it to place limitations on drugs. No one is challenging that fact.

49 Mr. J explicitly stated he was not challenging whether the Division complied with the Administrative Procedures Act or Federal Medicaid claims in this forum.

the Division for prior authorization processing under the "generic prior authorization criteria," outlined for Sovaldi in the *Alaska Medicaid Interim Prior Authorization List*.[50]

B. Drug use review requirements

DURC is Alaska's drug use review program and is governed by 7 AAC 120.120. The Alaska regulation adopts federal requirements for predetermined standards, or criteria development.[51] The regulations establish mandatory requirements for criteria development.[52]

1. Source materials information

One of Mr. J's challenges to the Sovaldi criteria focused on source material requirements. The governing regulation sets forth the following requirements for the source materials that DURC considers when developing prescription drug criteria:

> Requirements for predetermined standards. The predetermined standards used in the DUR program must meet the following requirements:
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> (1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts) and the following compendia:
>
> (i) American Hospital Formulary Service Drug Information;
>
> (ii) United States Pharmacopeia–Drug Information;
>
> (iii) American Medical Association Drug Evaluations.[53]

Here, Mr. J alleges that DURC relied on source materials that do not meet the requirement of being consistent with the American Hospital Formulary Service Drug Information, United States Pharmacopeia–Drug Information, American Medical Association Drug Evaluations.

Ms. Narus was primarily responsible for the information reviewed by DURC.[54] Ms. Narus gathered and reviewed information from the Infectious Disease Society, the Department of Veteran Affairs, the World Health Organization, the Food and Drug Administration, California Technical Assessment Forum, SVR studies, and a wide array of other sources, including peer-reviewed medical literature. Ms. Narus did not have a listing available to her at the hearing. She did not recall whether DURC reviewed the specific compendia in regulation. Specifically, Ms.

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[50] Ex. 1. Sovaldi was listed on the interim list between December 2013 and December 2014. As of the date of this proposed decision, the Division's website no longer lists Sovaldi on either its regular or interim medication prior authorization list.

[51] 7 AAC 120.120 adopts a number of federal regulations. The most relevant regulation in terms of this decision is 42 C.F.R. § 456.703.

[52] 42 C.F.R. § 456.703(f).

[53] 42 C.F.R. § 456.703.

[54] Hope testimony.

Narus stated she was not aware of DURC considering the American Hospital Formulary Service Drug Information compendia. She did not recall whether DURC considered US Pharmacopeia or AMA Drug Evaluation compendia. The agency record does not contain a list of source material reviewed.

Neither Ms. Narus nor Mr. Hope could recall whether DURC verified that its source materials were consistent with the required compendia. This could be somewhat understandable- DURC adopted the criteria many months ago and Mr. Hope and Ms. Narus may not have anticipated specific questions regarding this aspect of the criteria development process. However, the compendia consistency for source material is a requirement for every predetermined standard, not just for Sovaldi. It is telling that the Division's witnesses, both very involved in DURC criteria development process, were unable to recall whether DURC's source materials were consistent with the required compendia. One can infer that lack of memory in such key players indicates that DURC may not have ensured the compendia consistency requirement.

However, this doubt does not establish that the source materials considered were actually inconsistent with the compendia. Both Ms. Narus and Mr. Hope testified credibly that DURC and Division staff considered peer-reviewed medical literature and looked at numerous articles. Mr. J presented no evidence aside from legal argument to establish that the source materials were inconsistent with the compendia. However, legal argument is not evidence.

Mr. J requested citations to the source material reviewed, not copies of the source material itself. The Division objected that this inquiry was outside the scope of hearing.[55] Mr. J's attorney clarified that he was not seeking discovery. He opined that if the Division did not provide source material information, the record would reflect this lack of information. The Division did not supplement the record.

The question to be decided here is whether Mr. J has met his burden of proving that the source materials used by DURC were not consistent with the three compendia listed in the regulation. Mr. J did not seek a discovery order requiring the Division to provide source material citations and none was issued. Even if the source material were in the record, Mr. J would still need to establish that the source material was inconsistent with the required compendia. This

[55] The Division's reliance on the drug use review process opened the door to Mr. J's inquiry into the legitimacy of the Sovaldi criteria development process.

would necessitate in-depth analysis and briefing or additional testimony on the subject. The record here is not sufficient to invalidate the criteria on the compendia issue.

2. Other drug use review requirements[56]

Regulations also require that differences among source materials be resolved by developing consensus solutions.[57] Mr. Hope testified that differences were resolved through consensus. No evidence indicates otherwise.

Criteria must also to be tested against claims data prior to adoption.[58] Neither Mr. J nor the Division questioned Ms. Narus regarding claims data testing. It was not clear that Mr. Hope was aware of this regulatory requirement when asked if claims data testing occurred during the Sovaldi criteria development process. However, Mr. Hope testified that because of Sovaldi's recent approval, there was scant claims data to compare. The requirement presupposes enough claims data to make a meaningful comparison.

Like the compendia issue, this issue raises a concern with compliance. However, where the record does not contain enough information to determine one way or another if an action occurred, the default is not a presumption of non- occurrence. A presumption of regularity attaches to official acts of public officers and, in the absence of contrary evidence, courts presume official duties are properly discharged.[59]

Little hard evidence exists to overcome this presumption of regularity. The record does not show conclusively whether claims data testing occurred. Nor does it show whether there is a process for waiving data testing in the absence of sufficient data. Mr. J did not call other DURC members to testify. In addition, aside from the Sovaldi criteria, the record does not contain any documentation from the DURC process. Mr. J relies on assertions of non-compliance without supporting evidence.

IV. Conclusion

Mr. J's burden was to demonstrate that it is more likely than not that the criteria development process was flawed, not that it there is a chance it was flawed. Mr. J raised some

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[56] There are additional regulatory requirements, but this decision only addresses the regulatory requirements raised by Mr. J.

[57] 42 C.F.R. § 456.703(f)(2).

[58] 42 C.F.R. § 456.703(f)(6).

[59] *See In Re F.N.*, OAH No. 07-0012-PER at 5 (OAH December 5, 2007)(citing Jerrel v. State, 851 P.2d 1365, 1371-72 (Alaska App. 1993); *Gallego v. United States*, 276 F.2d 914, 917 (9th Cir. 1960) ("Where no evidence indicating otherwise is produced, the presumption of regularity supports the official acts of public officers, and courts presume that they have properly discharged their official duties"), quoted with approval in *Wright v. State*, 501 P.2d 1360, 1372 (Alaska 1972)).

doubts as to the underlying criteria development process. However, he fell short of establishing that the April 14, 2014, Sovaldi criteria are invalid or that DURC did not adhere to the drug use review requirements.[60]

As noted, the Division correctly determined that Mr. J did not meet the April 18, 2014, Sovaldi criteria and properly denied his prior authorization request. The Division's denial is affirmed.

Dated: January 2, 2015

Signed
Bride Seifert
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 23rd day of January, 2015.

By: *Signed*
Name: Bride Seifert
Title/Division: ALJ/OAH

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

[60] This decision makes no assumptions regarding the validity of any Sovaldi criteria updates since the June 3, 2014, denial.