BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of	)	
	)	
E J	)	OAH No. 21-1941-PER
	)	Agency No. 2021-102

FINAL DECISION

I. INTRODUCTION

E J sought coverage under the State's retiree health insurance for a biologic eyedrop prescribed by her optometrist. This type of eyedrop is not subject to FDA approval. As administrator of the health plan, the Department of Administration, Division of Retirement and Benefits ("Division") denied Ms. J's request through several levels of appeal, reasoning that the eyedrops were not covered as a medical service or supply because they are an outpatient drug, and not covered as a prescription drug because they are not FDA-approved. After a remand to better develop the record, the Division provided evidence that shows this drug actually falls within the definition of covered prescription drugs. Ms. J provided evidence that this drug is medically necessary for her particular circumstances. The Division did not question or counter this evidence in any way, instead focusing on FDA approval, which is not required for coverage, and FDA advisories that, upon closer inspection, have nothing to do with this type of prescription eyedrop. Therefore, as discussed below, the Division's July 9, 2021 decision rejecting Ms. J's coverage request is reversed

II. BACKGROUND

As a retired public employee, Ms. J receives medical coverage through the AlaskaCare Retiree Health Plan ("Plan"), set forth in the AlaskaCare Retiree Insurance Information Booklet ("Booklet"). In a section of the Booklet that the Division calls the "Medical Plan," the Plan provides for "medically necessary services and supplies necessary to diagnose, care for, or treat a physical or medical condition."[1] In another section, that the Division calls the "Pharmacy Plan," the Plan provides coverage for "medically necessary" outpatient prescription drugs.[2]

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[1] Booklet at 27. The Division did not include the Booklet in the original record, but has now provided it in its supplement at Division's Exhibit A.

[2] Booklet at 61.

Ms. J suffers from dry eye caused by Sjögren's syndrome.[3] Her condition is so severe that Ms. J reported blurred vision and filaments that scratch the surface of her corneas, causing scarring and risking vision loss.[4] Her optometrist, Dr. David Karpik, treats Ms. J with a Prokera sutureless human amniotic membrane several times a year.[5] To maintain the benefits of that procedure, Dr. Karpik also prescribes Ms. J Regener-Eyes eyedrops.[6] Dr. Karpik considers these eye drops "medically necessary" for Ms. J because her eye condition "was deteriorating and under risk of further corneal ulceration or perforation."[7]

Regener-Eyes is a biologic, in the same category as vaccines or gene therapy. According to its manufacturer, it contains proteins that reduce inflammation and stimulate the eye to heal, repair, and regenerate itself.[8] Regener-Eyes are self-administered but only available by prescription from an eye doctor.[9]

Ms. J submitted a claim for Regener-Eyes on February 8, 2021.[10] The Plan's administrator denied her claim.[11] Ms. J appealed through multiple levels of review and was ultimately denied coverage because (1) the Division considered Regener-Eyes to be an outpatient prescription drug and therefore not covered under the Medical Plan; and (2) Regener-Eyes is not an FDA-approved drug and therefore not covered under the Pharmacy Plan.[12]

On appeal before OAH, the parties agreed to resolve the matter on the written record and briefs. The initial record did not include information addressing the fact that Regener-Eyes is a biologic, not a pharmaceutical. The matter was thus remanded to the Division to further develop the record. The Division provided a supplemental record and brief on February 22, 2022. Ms. J was given an opportunity to respond by March 31, 2022, but did not file a response.

III. DISCUSSION

The Pharmacy Plan covers "outpatient prescription drugs for the treatment of an illness, disease, or injury" that are "medically necessary and clinically appropriate."[13] The Division

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3 J Br. Attachment 1-2.
4 R.11.
5 R.11; J Br. Attachment 1.
6 *Id.*
7 J Br., Attachment 1.
8 R.111-12.
9 R. 30.
10 R. 115-29.
11 R. 36-52.
12 R. 6-8, 15-17, 139-42.
13 Booklet at 61, 67.

initially argued that Regener-Eyes is not covered under the Pharmacy Plan because it is not FDA-approved and because Ms. J did not submit the type of scientific literature indicative of FDA-approval.[14] On remand, the Division was instructed to consider the Plan's definition of prescription drugs, how the FDA does or does not regulate biologics, and the fact that the Plan does not limit coverage to FDA-approved drugs.[15]

The Plan defines prescription drugs as:

> [M]edical substances which must bear a label that states, "Caution: Federal law prohibits dispensing without a prescription." Coverage includes prescription drugs, prescribed by a provider that may have an over-the-counter (OTC) equivalent, or covered medical foods that bear the same label. The plan may cover prescription compounds that contain a bioidentical hormone, an active ingredient that is a bulk chemical powder which is not an FDA approved medication, and thyroid compounds containing a bulk chemical active ingredient.[16]

In its supplement, the Division included the Regener-Eyes label and argued that it is not a prescription drug under the Plan because it does include the words "Caution: Federal law prohibits dispensing without a prescription."[17] The Division relied on an email from an OptumRx consultant stating that this label language is "required on FDA approved legend (Rx only) drugs" and that Regener-Eyes does not have that language on its label because it is not FDA-approved.[18]

By its language alone, the Plan's prescription drugs definition would seem to exclude any drug that does not include the "Caution . . ." language on its label. But "Caution: Federal law prohibits dispensing without a prescription" is actually a relic of federal law, jettisoned a quarter century ago with the Food and Drug Administration Modernization Act of 1997.[19] Current federal law requires prescription drug labels to merely bear the symbol "Rx only."[20] Because of this change in the law, applying the Plan's prescription drug language literally would effectively exclude all prescription drugs from the Pharmacy Plan. Insurance contracts are interpreted to "construe grants of coverage broadly and interpret exclusions narrowly."[21] Under old federal law,

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14 Division's Opposition to E J's Brief at 17-18.
15 Order for Remand at 4-5.
16 Booklet at 68.
17 Notice of Division's Supplemental Record on Remand at 3-4.
18 Division's Ex. B at 3.
19 Public Law 105-115.
20 21 U.S.C. § 353(b)(4)(A).
21 *C.P. ex rel. M.L. v. Allstate Ins. Co.*, 996 P.2d 1216, 1223 (Alaska 2000). The Division takes issue with the Plan being considered an insurance contract in light of a Supreme Court decision concerning a municipal plan. *Best v. Fairbanks North Star Borough*, 493 P.3d 868 (Alaska 2021). The Court has made no similar ruling regarding the State's unique, constitutionally protected public employee health insurance contract. This decision need not resolve this issue because under standards of non-insurance contract interpretation, the Plan should be interpreted to cover prescription drugs that comply with current labeling standards.

the "Caution . . ." language indicated a drug had the label required for prescription drugs. The federal FDA law now requires "Rx only." The Division itself argued that the significance of the "Caution . . ." language is tied to federal FDA requirements. Thus it is reasonable to construe the Plan's prescription drug definition to include medical substances with the label "Rx only," as specified under current federal law.

The Regener-Eyes label that the Division has now provided with it supplement includes the language "Rx only." Therefore it falls within the Plan's definition of a prescription drug. Ms. J provided evidence that she in fact receives Regener-Eyes by prescription.[22] The decision under review here further acknowledges that Regener-Eyes is "obtained by prescription through an eye care professional."[23]

To be covered, though, Regener-Eyes must also be "medically necessary and clinically appropriate."[24] The Plan does not define these terms for the Pharmacy Plan, but the language indicates a fact- and claimant-specific analysis. Ms. J provided a letter from her optometrist, Dr. Karpik, who explained that he treats Ms. J with an amniotic membrane procedure to address chronic inflammation and damage to her eyes from Sjögren's syndrome.[25] To sustain the benefits of that procedure and reduce the risk of corneal ulceration or perforation, Ms. J needs follow-up treatment for dry eyes.[26] Dr. Karpik tried several products and procedures, but all of them failed until he prescribed Regener-Eyes.[27] This use is consistent with the usage noted on the Regener-Eyes label.[28] Dr. Karpik also noted names of other optometrists who have prescribe Regener-Eyes for a similar use and achieved similarly positive results.[29] Based on Ms. J's medical needs, the failure of other products and procedures, the positive results for other patients, and the positive results for Ms. J, Dr. Karpik concluded that Regener-Eyes is medically necessary for Ms. J's particular circumstances.[30]

The Division did not address or counter Dr. Karpik's facts or medical opinion or address Ms. J's particular medical needs. Instead it focused on whether Regener-Eyes is FDA-approved. In the decision on review here, the Division concluded that because Regener-Eyes are not

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22 J Br. at 2;
23 R. 7.
24 Booklet at 61, 67.
25 J Br. Attachment 1.
26 *Id.*
27 *Id.*
28 Division's Ex. F.
29 J Br. Attachment 1.
30 *Id.*

approved by the FDA, "it is likely these products would not be eligible for coverage under the pharmacy benefit, as they are not recommended by the FDA."[31] The Division concluded that Regener-Eyes is not FDA-approved based on a search of an FDA database for approved pharmaceuticals.[32] Regener-Eye is a biologic, not a pharmaceutical. It would not be in a database of pharmaceuticals. Thus the Division was directed on remand to consider the fact that Regener-Eyes is a biologic and the manner in which the FDA does or does not regulate biologics.[33]

Despite this instruction, the Division continued to focus on FDA-approval for pharmaceuticals.[34] But nowhere in the Pharmacy Plan does it restrict coverage to FDA-regulated or FDA-approved drugs. Indeed the Pharmacy Plan mentions the FDA in only three places: (1) in relation to COVID-19 vaccines; (2) in relation to bulk chemical powders which are not FDA approved; and (3) in a paragraph on how the Plan may limit coverage for prescription drugs to certain uses and durations, where it states that this determination will be based on FDA recommendations.[35] Regener-Eyes is not a COVID-19 vaccine or bulk chemical powder, nor was any issue raised here regarding use or duration of these eye drops. And even if use or duration was an issue, the Plan refers to FDA recommendation, not approval.

Furthermore, the Division offered no FDA recommendations regarding Regener-Eyes or this type of biologic. The Division did attach or reference a number of FDA-related advisories or other documents that do not appear to have any relation to Regener-Eyes. The Division attached an FDA advisory about the risks involved with prescription drugs that the FDA permits for marketing prior to FDA-approval because of an open drug efficacy study implementation proceeding, insufficient supply, or a lack of FDA-approved drugs for the condition.[36] There is no evidence in the record that Regener-Eyes is marketed under such an FDA permit. The Division attached another FDA advisory about illegal stem cell clinics.[37] There is nothing in the record to suggest Regener-Eyes is the type of clinic or product addressed in that advisory. The Division attached an FDA advisory about "regenerative medicine products" marketed without a required

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31 R. 7.
32 R. 20.
33 Order for Remand at 4-5.
34 Notice of Division's Supplemental Record on Remand at 4-6; F J Aff. ¶¶ 11-12.
35 Booklet at 67-68.
36 Division's Ex. C.
37 Division's Ex. D.

FDA license or approval.[38] Again, there is nothing in the record to suggest that Regener-Eyes is this type of product or that it requires FDA license or approval.

The Division also submitted an affidavit that cited FDA webpages on regulation of "HCT/Ps" and attached a document "of what appears to be Regener-Eyes' manufacturer" registration of HCT/Ps, indicating the registration is inactive.[39] HCT/Ps are human cells, tissues, and cellular and tissue-based products.[40] According to its label, Regener-Eyes is an HCT/P.[41] The registration process and manufacturer registration the Division cited, however, is specific to HCT/Ps regulated solely under a provision of the Public Health Services Act related to communicable diseases.[42] The record does not indicate that Regener-Eyes is or would be subject to this regulation or registration process. And while the registration document the Division submitted may be from the manufacturer of Regener-Eyes, the document does not indicate that it relates to Regener-Eyes itself. Overall, none of the FDA-related materials submitted by the Division relate to Regener-Eyes and certainly do not address Ms. J's medical need and whether Regener-Eyes meets that need.

In sum, the Plan covers medically necessary prescription drugs marketed with the label language the FDA requires for prescription drugs — currently "Rx only." The Regener-Eyes label contains this language. Ms. J's optometrist provided a professional opinion that Regener-Eyes is medically necessary for Ms. J based on (1) her medical need to sustain the effects of amniotic membrane procedures and to reduce the risk of inflammation and damage; (2) the clinical failure of other treatments for Ms. J; (3) the clinical success of Regener-Eyes for Ms. J; and (4) clinical success by other optometrists prescribing Regener-Eyes. Based on the evidence, Regener-Eyes is a prescription drug medically necessary for Ms. J and is therefore covered by the Pharmacy Plan. Because it is covered under the Pharmacy Plan, there is no need to address the parties' arguments regarding the Medical Plan.

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38 Division's Ex. E.
39 F J Aff. ¶ 12; Division's Ex. G.
40 21 C.F.R. § 1271.1.
41 Division's Ex. F.
42 *Id.*; *see also* 42 U.S.C. § 264 (Section 361 of Public Health Services Act); 21 C.F.R. 1271.10 (describing registration process for HCT/Ps regulated solely under Section 361 of Public Health Services Act).

IV. PROPOSALS FOR ACTION

Both parties submitted a proposal for action in response to a proposed version of this decision. Ms. J urged the proposed decision to be adopted. The Division requested either a different decision or a remand.

The Division argued for the first time that Ms. J had not exhausted her administrative remedies because she did not apply for coverage under the Pharmacy Plan and therefore the Pharmacy administrator has not had an opportunity to review these issues. The Division further characterized the proposed decision's findings regarding the Pharmacy Plan as *sua sponte*. These arguments are disingenuous at best. No, Ms. J did not apply under the Pharmacy Plan. But "[o]ne of the primary purposes of the exhaustion of remedies rule is to promote judicial economy by affording an institution the opportunity to correct its own errors, so as to render judicial action unnecessary."[43] The Division had that opportunity. The Division chose to address coverage under *both* the Medical and Pharmacy Plans in the decision on appeal here.[44] The Division stated in that decision that the Pharmacy Plan administrator had been involved in the decision-making process.[45] And throughout this appeal process, the Division has asked for Ms. J's appeal to be denied as it related to both the Medical and Pharmacy Plans. Much of the Division's briefing focused on FDA approval, which relates to coverage under the Pharmacy Plan. This matter was remanded to the Division specifically to address coverage under the Pharmacy Plan. And the Division supplemented the record with information about potential Pharmacy Plan coverage. If the Division thought Ms. J needed to apply under the Pharmacy Plan before coverage could be addressed in this appeal, it waived that argument by not raising it until its Proposal for Action. The Division further conceded that this appeal may address the Pharmacy Plan coverage by asking Ms. J's appeal to be denied under the Pharmacy Plan based on FDA approval. And it earlier conceded the relevance of the Pharmacy Plan by including findings and conclusions about Pharmacy Plan coverage in the decision that is on appeal here. The issues addressed in this decision are issues the Division itself raised and addressed below and in the appeal.

The Division also argued that medical necessity should be determined solely by whether a prescription drug is FDA approved, without regard to the facts related to a particular claimant's medical needs. This argument both contradicts the Plan language and defies logic. As discussed

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43 *Eidelson v. Archer*, 645 P.2d 171, 181 (Alaska 1982).
44 R. 6-8.
45 R. 7.

above, no where in the Pharmacy Plan does it state that FDA approval is required for a drug to be covered under the Plan. The Plan refers to FDA *recommendations*, not approval. And it does so in a paragraph that is specifically about drug use and duration. Neither party has raised any issues about use or duration here. But even if that was an issue, this language does not suggest that FDA recommendations alone determine medical necessity. By that logic, a man being treated for a broken leg would be covered for a birth control prescription simply because the birth control is FDA-approved. The Plan requires prescription drugs to be "medically necessary and clinically appropriate." The words "necessary" and "appropriate" compel consideration of an individual claimant's individual medical situation. As discussed above, Ms. J provided evidence of her medical needs. The Division chose not to address that evidence.

The Division further claimed that there is no support in the record for this decision to conclude that Regener-Eyes is not subject to FDA approval. But as the remand order pointed out, the record includes an internal email stating that Regener-Eyes "is made from biologics which would not be FDA approved," indicating that Regener-Eyes is not subject to FDA approval like synthetic drugs.[46] This matter was then specifically remanded for the Division to provide information on whether and how biologics like Regener-Eyes are or are not regulated by the FDA. Did the Division determine on remand the Regener-Eyes is subject to FDA-approval or any other type of FDA regulation? And did it provide evidence to support such a conclusion? No. As discussed above, the Division provided generalized FDA documents that largely appear not to relate to Regener-Eyes. This decision's statement that Regener-Eyes is not subject to FDA approval is thus based on the Division's own internal documents indicating that it is not subject to FDA approval followed by the Division failure to provide any information on remand that biologics like Regener-Eyes are subject to FDA approval.

The Division Proposal for Action did not provide a compelling reason to alter the findings and conclusions of this decision.

V. CONCLUSION

Regener-Eyes is a prescription drug that is medically necessary for Ms. J and therefore covered by the Pharmacy Plan. Accordingly the Division's July 9, 2021 decision rejecting Ms. J's coverage request is reversed.

DATED: May 31, 2022.

[46] R.25.

By: *Signed*
Rebecca Kruse
Administrative Law Judge

Adoption

This Decision is issued under the authority of AS 39.35.006. The undersigned, in accordance with AS 44.64.060, adopts this Decision and Order 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 Rule of Appellate Procedure 602(a)(2) within 30 days of the date of this decision.

Date: 5/31/2022

By: *Signed*
Signature
Rebecca Kruse
Name
Administrative Law Judge
Title

[This document has been modified to conform to the technical standards for publication. Names may have been changed to protect privacy.]

Certificate of Service: The undersigned certifies that this is a true and correct copy of the original and that on this date an exact copy of the foregoing was provided to the following individuals: E J (by mail and email); Andrew Bocanumenth (by email); Ben Hofmeister (by email); Dep't of law central email (by email).

Signature: *Signed* Date: 5/31/2022