Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2176566
Decision Date:	11/23/2021	**Hearing Date:**	10/07/2021
Hearing Officer:	Scott Bernard	**Record Open to:**	10/13/2021

Appearance for Appellant:
Pro se via telephone

Appearance for the ACO:
Kay George, RN (the ACO representative) *via* telephone

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street, Quincy, Massachusetts 02171

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	ACO PA
Decision Date:	11/23/2021	**Hearing Date:**	10/07/2021
The ACO's Rep.:	Kay George, RN	**Appellant's Rep.:**	*Pro se*
Hearing Location:	Quincy Harbor South		

Authority

This hearing was conducted pursuant to Massachusetts General Laws Chapter 118E, Chapter 30A, and the rules and regulations promulgated thereunder.

Jurisdiction

Through a notice dated August 18, 2021, the ACO denied the appellant's prior authorization (PA) request for NJX Platelet Plasma treatment because it determined that the treatment was considered experimental. (see 130 CMR 450.204 and Exhibit 1). The appellant filed this appeal in a timely manner on August 30, 2021. (See 130 CMR 610.015(B) and Ex. 1). The decision of a managed care contractor to deny a requested service is valid grounds for appeal. (See 130 CMR 610.032).

The record was left open until October 13, 2021 for the ACO to review documentation submitted by the appellant prior to the hearing. On October 13, 2021, the ACO submitted a response at which time the record closed. (Ex. 5).

Action Taken by the ACO

The ACO denied the appellant's PA request for NJX Platelet Plasma.

Issue

The appeal issue is whether the ACO was correct, pursuant to 130 CMR 450.204, in determining that the PA request should be denied.

Summary of Evidence

The ACO representative stated that on July 27, 2021, the appellant's provider submitted this PA request for platelet rich plasma (PRP) injection. (Ex. 4B, p. 5). The appellant is an individual under

the age of 65 with a diagnosis of bilateral moderate elbow medial epicondylitis. (Id.). The provider was requesting one unit under code 0232T, which is among the treatment codes that the ACO had determined are experimental/investigational. (See Ex. 4B, pp. 38, 40). Citing 130 CMR 450.204(B), the ACO representative stated that medically necessary services must be of a quality that meets professionally recognized standards of health care and must be substantiated by records including evidence of such medical necessity and quality. An experimental treatment of this nature would therefore not be covered because it is experiment/investigational for treatment of the appellant's diagnosis. The ACO representative stated that PRP injections are not supported by the scientific literature as a treatment for the appellant's diagnosis of bilateral moderate elbow medial epicondylitis.

On August 10, 2021, the PA request was referred for peer review. (Ex. 4B, p. 21). The Peer Review Report that resulted stated that the appellant presented with complaints of left elbow pain on July 7, 2021. (Id.). The appellant had treatment with cortisone injection to the lateral condyle with good results and now presented with chronic medial elbow pain. (Id.). The left elbow exam showed mild to moderate medial epicondylar tenderness. (Id.). The appellant had previous treatment with cortisone injections and physical therapy. (Id.). The ACO representative stated that the epicondyles are round prominences at the end of the humerus where ligaments and tendons are attached. The appellant's ongoing treatment did not show his condition improving. The peer report concluded that there was no proven superiority of PRP over these other therapies, however. (Ex. 4B, p. 21).

The ACO representative referred to the document entitled "Care Services – Medical Technology Assessment" which was included in the ACO's hearing packet. (Ex. 4B, pp. 52-53). The ACO representative stated that this document describes the procedure by which the ACO evaluates requests to use new procedures. The ACO representative also stated that the ACO submitted a list of research articles concerning the efficacy of the PRP treatment and the appellant's medical diagnosis. (Ex. 4C). These articles contra-indicate the efficacy of PRP injections for the appellant's condition.

The appellant first asked whether the ACO had received a copy of the article he submitted with his appeal.[1] (See Ex. 1, pp. 5-10; Ex. 3, pp. 2-7). The ACO representative stated that the ACO had not received this document. The appellant stated that he had been through three sessions or courses of occupational/physical therapy. The appellant stated that he had received two cortisone injections and been informed that third is not indicated. The appellant reported that his condition did not improve after the second injection. The appellant stated that he therefore disagreed with the statement in the notice under appeal that he had not undergone these treatments yet. (See Ex. 1, p. 3).

The ACO representative apologized that the notice was incorrect but affirmed that the ACO was, in fact, aware that the appellant had received this treatment.

The appellant stated that based on what his doctor told him and on the information in the article, he believed that the PRP injection was the best treatment for him at this time and was only thing that

[1] Hunter L. Bohlen, BA *et al*, *Platelet-Rich Plasma Is An Equal Alternative to Surgery In the Treatment of Type 1 Medial Epicondylitis*, THE ORTHOPEDIC JOURNAL OF SPORTS MEDICINE, 2020; 8(3).

makes sense. The appellant stated that he has had the medial epicondylitis for 16 months. The appellant stated that he has received the cortisone injections and PT/OT. The appellant stated that additionally he has rested it and has not been abusing his arm or wrist. The appellant stated he gets flares in the elbow and pain in the wrist. According to the article, PRP is a viable alternative in the treatment of type 1 medial epicondylitis and that side effects (such as tingling and numbness in the hand or wrist, which do occur with other treatments) would not occur. The appellant stated that without the PRP therapy, the next step would be surgery. The appellant testified that the article states that the outcomes of the PRP therapy are reported as better than those for other treatments and require less recovery time. The appellant stated that the cost of surgery was larger than that for PRP but could not cite where he got this information. The appellant did state that the article did provide information concerning the efficacy of the PRP treatment. The appellant stated that some private insurers and workers' compensation insurers did pay for this treatment. The appellant pointed out that some of the articles that the ACO used in making its determination were older.

The ACO representative stated that the ACO was not basing its decision on the cost of the procedure but rather the denial was based on the experimental nature of the procedure. The ACO representative requested time so that the ACO could review the article. The record was left open for seven days to allow the ACO to review the article and submit a response.

On October 13, 2021, the Board of Hearings received a 10 page fax from the ACO, including a two page letter written by the ACO's Vice President and Medical Director for Utilization Management and Clinical Informatics, who is an MD. (Ex. 5). The ACO's response letter points out that in the article the appellant submitted, the authors admit that the study used was not randomized or blinded, was retrospective, and was at Level of Evidence 3, which is relatively low quality. (Ex. 5, pp. 2, 10). The letter further states that the article did not compare the efficacy of PRP injection to whole blood injection, which the literature noted was an option. (Id.). Finally, the letter concluded that the study authors themselves agree that the study has issues and in the future well designed trials were indicated. (Ex. 5, p. 3). The letter stated that the authors of the article did not have the statistical power to change the total weight of evidence. (Id.).

Findings of Fact

Based on a preponderance of the evidence, I find the following:

1. The appellant is an individual under the age of 65 with a diagnosis of bilateral moderate elbow medial epicondylitis. (Ex. 4B, p. 5).

2. On July 27, 2021, the appellant's provider submitted this PA request for PRP injection. (Ex. 4B, p. 5).

3. The appellant had been through three sessions or courses of OT/PT and received two cortisone injections. (Testimony of the appellant; Ex. 4B, p. 21; Testimony of the ACO representative).

4. The appellant's condition has not improved after the course of these therapies. (Testimony of the appellant; Ex. 4B, p. 21).

5. On August 10, 2021, the PA request was referred for peer review. (Ex. 4B, p. 21).

6. The peer report concluded that there was no proven superiority of PRP over other therapies, however. (Ex. 4B, p. 21).

7. The ACO provided a copy of its process for evaluating requests for Medical Technology Assessment and a two-page list of scholarly articles it used in order to make its determination concerning the PRP injection. (Ex. 4B, pp. 52-53; Ex. 4C).

8. Through a notice dated August 18, 2021, the ACO denied the appellant's PA request for PRP treatment because it determined that the treatment was considered experimental. (Ex. 1).

9. The appellant submitted a 2020 article concerning a study of the efficacy of PRP injections. (Ex. 1, pp. 5-10; Ex. 3, pp. 2-7).

10. The ACO requested time to review and submit a response concerning the article and was given until October 13, 2021 to do so. (Testimony of the ACO representative).

11. On October 13, 2021, the ACO submitted a packet, including a two-page letter responding to the article the appellant submitted. (Ex. 5).

12. The ACO's response letter points out that in the article the appellant submitted the authors admit that the study used was not randomized or blinded, was retrospective, and was at Level of Evidence 3, which is relatively low quality. (Ex. 5, pp. 2, 10).

13. The letter further states that the article did not compare the efficacy of PRP injection to whole blood injection, which the literature noted was an option. (Ex. 5, p. 2).

14. Finally, the letter concluded that the study authors themselves agree that the study has issues and future well designed trials were indicated. (Ex. 5, p. 3).

Analysis and Conclusions of Law

Pursuant to 130 CMR 508.001(A), MassHealth members who are younger than 65-years old must enroll in a MassHealth managed care provider available for their coverage type. Members enrolled in a managed care provider are entitled to a fair hearing under 130 CMR 610.000 to appeal a determination by an Accountable Care Organization (ACO), if the member has exhausted all remedies available through the contractor's internal appeal process. (130 CMR 508.010). The appellant is entitled to a fair hearing under 130 CMR 610.000 as he has exhausted the internal appeal process offered through his ACO. As MassHealth's agent, Fallon is required to follow MassHealth laws and regulations pertaining to a member's care.

450.204: Medical Necessity

> The MassHealth agency does not pay a provider for services that are not medically necessary and may impose sanctions on a provider for providing or prescribing a service or for admitting a member to an inpatient facility where such service or admission is not medically necessary.

(A) A service is medically necessary if

(1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and

(2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007: *Potential Sources of Health Care*, or 517.007: *Utilization of Potential Benefits*.

(B) Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality. A provider must make those records, including medical records, available to the MassHealth agency upon request. (*See* 42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)

(C) A provider's opinion or clinical determination that a service is not medically necessary does not constitute an action by the MassHealth agency.

(D) Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.

(E) Any regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative evidence that such service is reasonably calculated to have the effect described in 130 CMR 450.204(A)(1).

The record shows that the appellant has not shown by a preponderance of the evidence that the ACO's decision denying the PA request was incorrect. The ACO determined that the PRP treatment was experimental and unproven in the context of the appellant's medical condition. The ACO submitted documentation indicating the process by which it came to this conclusion. The ACO provided citations that supported its conclusion. The appellant contended that his medical condition would respond to the PRP treatment. The appellant asserted that prior treatments had not resulted in the condition improving, which was a point the ACO did not dispute. The appellant submitted one article describing the possible efficaciousness of the use of PRP injections to treat his condition. The ACO, however, pointed out that the article's authors admit that the study used was not randomized or blinded, was retrospective, and was at Level of Evidence 3, which is relatively low quality. The ACO also indicated that the article only seemed to contend that the evidence supported future well designed trials. One can therefore conclude that this was not sufficient evidence to overturn the ACO's decision.

For the above stated reasons, the appeal is DENIED.

Order for the ACO

None.

Notification of Your Right to Appeal to Court

If you disagree with this decision, you have the right to appeal to Court in accordance with Chapter 30A of the Massachusetts General Laws. To appeal, you must file a complaint with the Superior Court for the county where you reside, or Suffolk County Superior Court, within 30 days of your receipt of this decision.

Implementation of this Decision

If you experience problems with the implementation of this decision, you should report this in writing to the Director of the Board of Hearings, at the address on the first page of this decision.

Scott Bernard
Hearing Officer
Board of Hearings

cc:

Fallon Health Member Appeals and Grievances, 10 Chestnut Street, Worcester, MA 01608