

**Office of Medicaid
BOARD OF HEARINGS**

Appellant Name and Address:



Appeal Decision:	Denied	Appeal Number:	2304380
Decision Date:	11/9/2023	Hearing Dates:	08/17/2023 09/19/2023
Hearing Officer:	Scott Bernard		

Appearance for Appellant:



Via Videoconference

Appearance for Integrated Care Organization (ICO):

Cassandra Horne (the appeals manager)
Dr. David Mello (the senior medical director)
Kaley Ann Emery (Appeals Supervisor)
Jeremiah Mancuso, RN (08/17 only)

Via Videoconference



*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:	ICO Prior Authorization (PA); Hyperbaric Oxygen Therapy
Decision Date:	11/9/2023	Hearing Dates:	08/17/2023 09/19/2023
ICO's Reps.:	Cassandra Horne; Dr. David Mello; Kaley Ann Emery; Jeremiah Mancuso, RN (08/17 only)	Appellant's Rep.:	
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 May 21, 2023, the Integrated Care Organization (ICO) denied the appellant's prior authorization (PA) request for oxygen chamber therapy because it determined that the requested treatment did not meet the requirements to be considered medically necessary. (See 130 CMR 450.204 and Exhibit (Ex.) 3). The appellant filed this appeal in a timely manner on May 26, 2023¹. (See 130 CMR 610.015(B) and Ex. 1). A managed care provider's decision to deny authorization of a requested service, including the type or level of service, including determinations based on the type or level of service, requirements for medically necessity, appropriateness, setting, or effectiveness of a covered benefit is valid grounds for appeal. (See 130 CMR 610.032(B)(2)).

¹ The appellant, however, did not submit the notice he was appealing. (See below).

On May 30, 2023, the Board of Hearings sent the appellant a letter notifying him that it would dismiss his appeal within 10 days unless he submitted an entire copy of the notice he was appealing. (Ex. 2). The appellant submitted the requested notice by fax on June 7, 2023. (Ex. 3). In a letter dated June 9, 2023, the Board initially scheduled the appellant's hearing for July 12, 2023. (Ex. 4). At the appellant's attorney's request, the hearing was rescheduled to August 17, 2023. (Ex. 5; Ex. 6; Ex. 7). On August 17, 2023, in the middle of the hearing, the appellant and his wife had to evacuate their apartment because of a fire alarm. For that reason, the hearing was continued to September 19, 2023. (Ex. 8).

Action Taken by the ICO

The ICO denied the appellant's PA request for oxygen chamber therapy because it determined that it was not medically necessary.

Issue

The appeal issue is whether the ICO was correct, pursuant to 130 CMR 450.204, in determining that the requested treatment did not meet the medical necessity standards.

Summary of Evidence

The appeals manager testified to the following. The appellant has been enrolled in the ICO since February 1, 2023. The appellant, through his provider, submitted a PA request for hyperbaric oxygen therapy (HBOT) to be performed at a hyperbaric oxygen treatment center for dates for service from May 22 through August 22, 2023. (Ex. 9, pp. 8-21, 22-35).

One of the ICO's medical directors reviewed and denied this request. (Ex. 9, p. 53). The medical director stated the following in his notes:

This is a standard Out of Network request for...Management of oxygen chamber therapy ...and...Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval for this member. The member... for whom the aforementioned request was submitted...whose symptom[s] complex presentation involves the diagnosis/issue of discomfort in his hands and feet related to Bystolic use since 2014 resulting in loss of strength and numbness in both hands. Given the provided documentation, the member does not meet the Guidelines for the requested therapeutic modality. The request is denied. DECISION: Given the reviewed documentation, this request does not meet criteria for medical necessity as there is insufficient evidence that the requested service meets the "reasonable and necessary" standard for medical necessity outlined in CCA Medical Necessary Guidelines (i.e. MNG # 045) Medical Necessity. The request is denied, as documented. (Ex. 9, p. 53).

The ICO notified the appellant that it was denying his request for service in a letter dated May 16, 2023. (Ex. 9, pp. 54-60). The appellant filed a Level 1 appeal on May 19, 2023. (Ex. 9, p. 63).

As a result the senior medical director reviewed the request. (Ex. 9, p. 129). In his notes, the senior medical director wrote the following:

This is a level one appeal request for this member whose request for out of network Oxygen chamber therapy was denied. A full and careful review of the provided documentation including MCMC review and recommendation was performed in the context of the [Knowledge Base.

Additional information WAS NOT submitted on appeal by the requesting provider. If additional information was submitted by the requesting provider, this information was reviewed by this physician reviewer.

[ICO] member with medical history of medical history of [sic] coronary artery disease, hypertension, sleep apnea obesity, and right meniscus tear. Member with complaints of discomfort in hands and feet related to Bystolic use since 2014. He has numbness and loss of strength in both hands. He also has a right lower extremity venous stasis ulcer. Request denied as it did not meet criteria for medical necessity per InterQual review. The requested hyperbaric oxygen therapy is considered investigational for this member's diagnosis. There have not been large enough studies to support the use of hyperbaric oxygen therapy in this case. Until larger studies provide evidence, it is still considered investigational. Based on the Medicare definition for medical necessity, the requested procedure is not considered medically necessary in this case. There is lack of quality evidence studies to support the use of hyperbaric oxygen therapy for the member's diagnosis. Given the reviewed documentation, this request does not meet criteria for medical necessity as there is insufficient evidence that the requested service meets the "reasonable and necessary" standard for medical necessity outlined in CCA MNG 045 Medical Necessity.

Decision: The original decision is upheld and this First Appeal is denied. (Ex. 9, p. 129).

The ICO notified the appellant that it was denying this request for service in a letter dated May 21, 2023. (Ex. 2; Ex. 9, pp. 135-140). The letter informed the appellant of his appeal rights under Medicaid, as well as the Medicare rules. (Ex. 2; Ex. 9, pp. 135-140). The ICO automatically forwarded his appeal to Medicare's Independent Review Entity (IRE). The IRE reviewed the appellant's appeal and denied it, as well. The appeals manager stated that the present appeal concerns the appellant's appeal rights under the MassHealth/Medicaid rules.

The senior medical director stated that the appellant requested HBOT for the treatment of pain and discomfort in his hands and feet related to use of Bystolic. The appellant had been using Bystolic since 2014, which has resulted in a loss of strength and numbness in both hands. The

senior medical director and a board certified specialist both reviewed the request on appeal. The ICO denied the request because there was not a substantial body of evidence to show that the requested therapy would be helpful in treating the appellant's condition. The senior medical director stated that the treatment would be considered experimental and investigational in this particular scenario and as a result could not be approved by Medicare or under the MassHealth guidelines. The senior medical director stated that the ICO used InterQual to review this case. (Ex. 9, pp. 44-49). The ICO also incorporated the language of 130 CMR 450.204, which indicates that services that are considered to be experimental and investigational cannot be covered by MassHealth. The senior medical director stated that the requested therapy does not have FDA approval as a treatment for the appellant's diagnosis. (Ex. 9, pp. 143-145).

The appellant's attorney asked the senior medical director to confirm that the appellant also had non-healing wounds on his legs and to assess a photograph of that area of the appellant's right leg. (Ex. 12, pp. 19, 40-41). The senior medical director confirmed receiving a copy of that photo, which appeared to be a blister. The senior medical director stated that non-healing wounds were not part of the diagnosis reported in the PA request. The senior medical director stated that the area appeared to have darkening of the skin or chronic venous stasis changes of the leg in addition to the blister. The senior medical director stated that the standard treatment for chronic venous stasis would be compression and elevation of the leg.

The appellant's attorney stated that the ICO denied the requested three months of HBOT referencing the medical necessity guidelines. (Ex. 9, pp. 36-37; Ex. 12, pp. 3-4). The appellant's attorney noted that these guidelines do have a disclaimer that states that it is not a rigid rule. The appellant's attorney argued that the fact that a member does not meet these criteria do not in and of itself indicate that no coverage can be issued for these services. The appellant's attorney also stated that the InterQual sheet that was referenced in the denial is also not a determinative tool. The InterQual sheet itself states that it reflects clinical interpretations and cannot alone either resolve medical ambiguities of a particular situation or provide the sole basis for definitive decisions. (Ex. 9, pp.; 44-49; Ex. 12, pp. 5-10).

The appellant testified the following. The appellant stated that he lives with his wife. The appellant testified that he has venous peripheral insufficiency. He stated that this causes pooling of the blood in his legs and causes his legs to feel very heavy. The appellant began medical treatment for this condition in [REDACTED] after having a fall at a local recycling center. Since that time, the doctors have usually recommended standard treatments, like using seven different creams, elevation, and compression. Additionally, he has undergone physical therapy at least four times but the increased circulation, rather than improving his condition, just exacerbates that condition.

The appellant stated that in addition to the above, he has had flare ups at least four times a year since [REDACTED] resulting in blisters and open wounds on different parts of his legs. The appellant stated that the skin on his legs is very sensitive. He has to cover them when he goes outside so that he does not bump them or open any wounds. The appellant has been

prescribed antibiotics over the past five years as treatment for any open wounds he has had. The appellant has inflammation in his hands, legs, and feet, as well. The appellant is also allergic to non-steroidal anti-inflammatory drugs (NSAIDs), lisinopril, and other anti-inflammatory drugs which would otherwise help with his condition. (See Ex. 9, p. 5).

The appellant stated that he has been seeing his PCP since April. The appellant's PCP has prescribed antibiotics and sent the appellant to Wound Care. The appellant has also been seeing a hand doctor since [REDACTED] 2022. The appellant visited the hyperbaric oxygen chamber therapy clinic in [REDACTED]. It was after this visit that the three months of therapy was prescribed. The appellant stated that the effect of going to so many doctors over the last five years was that he felt that his legs were never going to get better, and he would never feel or walk normally again.

The appellant stated that it has affected his quality of life because he could not do the things that he enjoyed like driving his car, going for walks, and going into a pool at the YMCA. It made it hard for him to get in the shower for regular hygiene. The appellant could not do other enjoyable activities such as bowling and photography. The appellant stated that he is unable to work and he has been on disability since [REDACTED]. This was for his legs and because of the lack of mobility in his hands, feet, and legs. The appellant stated he was seeking hyperbaric oxygen therapy because the clinic states that they do cover it for the venous peripheral insufficiency, which also causes inflammation in his body.

The appellant's wife testified to the following: she stated that she has known the appellant since [REDACTED]. The appellant's wife noted the decline in his quality of life in the last several years. She stated that, when she first met the appellant, they would take long walks and drives together. Now the appellant is not able to move very well without assistance or pain. The appellant's wife stated that, currently, all that they were doing for him was taking him to doctor's appointments. Seeing him go to appointment after appointment and have them just basically say elevate your legs, rest, but lose weight. Of course, the best way to lose weight is moving in some way, but the appellant is in constant pain from either the inflammation or the injury that happened to him in [REDACTED]. The appellant's wife stated that they have exhausted five years doing the same conservative treatments for the appellant over and over and over again with no results. The appellant's wife stated that the appellant was asking for this treatment because even if the end result was less than full mobility it would be an improvement over what has happened thus far.

The appellant's attorney stated that the requested treatment has become medically necessary for the appellant. The appellant has been prescribed conservative treatments for non-healing wounds since [REDACTED]. He's visit a multitude of medical providers. No treatments have been effective so far. In fact, now it's led to this loss of mobility and a great loss in his quality of life. He is expected to live with this condition, and it has clearly severely affected his quality of life. Therefore, given his unique medical conditions, and the lack of any other effective treatments, this therapy has become medically necessary. The appellant's attorney argued that the CIO

prides itself on being able to respond to its members unique health needs, so this is an opportunity for the ICO to follow through on that promise.

The senior medical director stated that he appreciated that this was a difficult situation for the appellant and his wife. The senior medical director stated that while there are benefits to hyperbaric therapy to treat certain medical conditions, the body of evidence supporting its use to treat the appellant's condition is lacking. The evidence submitted in support of this therapy to treat this condition was not peer reviewed. Although this does not necessarily mean that the treatment would not be effective, there is insufficient evidence of its effectiveness here. Following the Medicare and Medicaid rules, the IPO could not approve this treatment because it is experimental and investigational rather than a proven, effective treatment.

Findings of Fact

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

1. The appellant has been enrolled in the ICO since February 1, 2023. (Testimony of the appeals manager).
2. The appellant, through his provider, submitted a PA request for HBOT to be performed at a hyperbaric oxygen treatment center for dates for service from May 22 through August 22, 2023. (Ex. 9, pp. 8-21, 22-35).
3. One of the ICO's medical directors reviewed the appeal and denied this request. (Ex. 9, p. 53).
4. The ICO notified the appellant that it was denying this request for service in a letter dated May 16, 2023. (Ex. 9, pp. 54-60).
5. The appellant filed a Level 1 appeal on May 19, 2023. (Ex. 9, p. 63).
6. As a result the senior medical director reviewed and denied the request. (Testimony of the appeals manager).
7. The ICO notified the appellant that it was denying this request for service in a letter dated May 21, 2023. (Ex. 2; Ex. 9, pp. 135-140).
8. The appellant has a medical history of coronary artery disease, hypertension, sleep apnea obesity, and right meniscus tear. (Ex. 9, p. 129).
9. The appellant has complaints of discomfort in hands and feet related to Bystolic use since 2014 as well as numbness and loss of strength in both hands and a right lower extremity venous stasis ulcer. (Testimony of the senior medical director; Ex. 9, p. 153; Ex. 12, pp. 19, 40, 41).

10. The appellant's venous peripheral insufficiency causes pooling of the blood in his legs and causes his legs to feel very heavy. (Testimony of the appellant).
11. The appellant has had flare ups at least four times a year since [REDACTED] resulting in blisters and open wounds on different parts of his legs. (Testimony of the appellant).
12. The appellant stated that the skin on his legs is very sensitive, and he has to cover them when he goes outside so that he does not bump them and open any wounds. (Testimony of the appellant).
13. The appellant has been prescribed antibiotics over the past five years in order to treat any open wounds he has had. (Testimony of the appellant).
14. The appellant has inflammation in his hands, legs, and feet but he is allergic to NSAIDs, lisinopril, and other anti-inflammatory drugs which would otherwise help with his condition. (Testimony of the appellant; Ex. 9, p. 5).
15. The appellant has been prescribed creams for his legs, but these have not resulted in a lessening of his pain and discomfort. (Testimony of the appellant).
16. The appellant has also been told to rest and elevate the leg, but this also has not resulted in a change to his condition. (Testimony of the appellant).

Analysis and Conclusions of Law

MassHealth members who are younger than 65 years old must enroll in a MassHealth managed care provider available for their coverage type. (130 CMR 508.001(A)). One such type of managed care is an ICO. (130 CMR 508.001(D)). In order to be eligible to enroll in an ICO, a MassHealth member must be 21 through 64 years of age at the time of enrollment; be eligible for MassHealth Standard² or MassHealth CommonHealth³; be enrolled in Medicare Parts A and B, be eligible for Medicare Part D, and have no other health insurance that meets the basic-benefit level⁴; and live in a designated service area of an ICO. (130 CMR 508.008(A)(1)). When a member is enrolled in an ICO, the ICO will authorize, arrange, integrate, and coordinate the provision of all covered services for the member. (130 CMR 508.007(C)).

MassHealth 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. (130 CMR 450.204). A service is medically necessary if it is reasonably calculated to prevent, diagnose, prevent the

² As defined in 130 CMR 450.105(A): MassHealth Standard.

³ As defined in 130 CMR 450.105(E): MassHealth CommonHealth.

⁴ As defined in 130 CMR 501.001: Definition of Terms.

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 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 MassHealth. (130 CMR 450.204(A)).

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. (130 CMR 450.204(B)). Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines. (130 CMR 450.204(D)).

The appellant and his wife provided very detailed and credible testimony concerning the appellant's medical condition and the effect of that condition on his ability to function. They also provided further credible testimony that the treatments that the appellant has received over the years have not effectively treated his underlying conditions. The appellant has not demonstrated that the requested treatment, HBOT, met the standards of the medical necessity rule in the regulations, however. The record contains a paucity of evidence that HBOT would effectively treat the appellant's condition. Without this evidence, the ICO's decision to deny the PA request was justified under the circumstances. Therefore, this appeal is DENIED.

Order for the ICO

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.

Scott Bernard
Hearing Officer
Board of Hearings

cc:

Commonwealth Care Alliance ICO, Attn: Cassandra Horne, 30 Winter Street, Boston, MA 02108