Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2416841
Decision Date:	02/28/2025	**Hearing Date:**	12/11/2024
Hearing Officer:	Cynthia Kopka	**Record Open to:**	1/13/2025

Appearance for Appellant:

[redacted]

Appearances for Respondent:

Cassandra Horne, Operations Manager, Appeals and Grievances
Jeremiah Mancuso, Clinical RN Appeals and Grievances Manager
Dr. David Mello, Medical Director

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:**	Managed Care Organization – Denial of Internal Appeal
Decision Date:	02/28/2025	**Hearing Date:**	12/11/2024
Respondent's Rep.:	Cassandra Horne, Jeremiah Mancuso, Dr. David Mello	**Appellant's Rep.:**	[redacted]
Hearing Location:	Quincy (remote)	**Aid Pending:**	No

Authority

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

Jurisdiction

By notice dated October 4, 2024, Commonwealth Care Alliance (CCA), a MassHealth Integrated Care Organization (ICO), denied Appellant's Level I appeal for a fluid circulating cold pad with pump, billing code E0218. Exhibit 1. Appellant filed this appeal in a timely manner on November 1, 2024. Exhibit 2. 130 CMR 610.015(B). Denial of assistance is a valid basis for appeal. 130 CMR 508.010, 130 CMR 610.032(B).

Action Taken by CCA

CCA denied Appellant's request for a fluid circulating cold pad with pump.

Issue

The appeal issue is whether CCA was correct in determining that a fluid circulating cold pad with pump was not medically necessary.

Summary of Evidence

CCA's representatives, including the operations manager for appeals and grievances, nurse review manager, and medical director, appeared by phone and provided written materials in support. Exhibits 4 and 5. Appellant appeared by phone and submitted records in support. Exhibit 6. A summary of testimony and written materials follows.

Appellant, who is in her [redacted] has been enrolled in CCA's OneCare program since February 1, 2017. Appellant's medical history includes left shoulder impingement syndrome and rotator cuff tendinopathy. On July 29, 2024, CCA received a request on Appellant's behalf for durable medical equipment (DME): *to wit*, a fluid circulating cold pad with pump ("the requested device").[1] Exhibit 4 at 13. CCA's notes indicate that this was a new request after a previous request from March 2024 for the same device had been denied and appealed by Appellant. *Id*. at 3, 13.

On August 12, 2024, CCA denied Appellant's request. Exhibit 1, Exhibit 4 at 14. On this denial, CCA wrote

> You asked for a fluid circulating cold pad with pump. This is a powered/active cold therapy unit. We do not have notes from your provider that state you cannot use a standard ice pack to control your pain and swelling. We do not have evidence that you cannot use a non-powered/passive unit. We asked your provider for office visit notes that states why you need this item. Your provider did not have additional notes to send us. We do not have evidence that this item is reasonable and necessary.

Exhibit 4 at 15. In making the determination, CCA reviewed the PA request received July 29, 2024, office visit notes from [redacted] dated November 16, 2023, a letter of medical necessity from [redacted], PA-C dated March 05, 2024, and a physical therapy discharge note from [redacted], PT dated [redacted]. *Id*. at 15, 28-29, 33, 38-40.

CCA wrote that based on Medical Necessity Guideline (MNG) #045, CCA will cover items or services that are reasonable and necessary under state and federal guidelines. However, the request as submitted was not reasonable or necessary, as CCA did not have evidence that other covered items cannot meet Appellant's medical needs. CCA wrote that there are other covered items, such as an ice pack or a non-powered, gravity-fed cold compression unit (also referred to as a passive unit), that are more cost effective at managing pain. CCA instructed Appellant to contact her provider to discuss if other items would meet her needs. *Id*. at 16.

[1] The requested device is referred to many different ways in the record: e.g., powered/active cold therapy unit, cold compression device, cryotherapy device, BioCryo cuff. When not quoting the record, this decision will refer to it as "the requested device."

On October 1, 2024, CCA received Appellant's Level I appeal by phone. *Id*. at 25. CCA's notes indicate that Appellant appealed the denial because the requested device is medically necessary, and her provider submitted all proper documentation. *Id*. On October 3, 2024, CCA's medical director reviewed Appellant's Level I appeal. *Id*. at 48. Dr. Mello noted that current medical literature does not recommend cold compression or cryotherapy devices over ice packs for the management of shoulder pain. *Id*. Dr. Mello noted that new information submitted for the Level I appeal showed that Appellant has attended physical therapy (PT) with improvement and was recommended for home exercise. Appellant's pain had reduced from 10/10 to 6.5/10 with PT, and she experiences relief with icing twice a day for 30 minutes. *Id*. at 40. Dr. Mello's notes indicate that the requested device is not medically necessary based on the patient's diagnosis, is experimental/investigational, and is not furnished in accordance with accepted standards of medical practice, or the most cost-effective supply/service which can safely be provided. *Id*. Dr. Mello testified that the request and appeal were reviewed in conjunction with a PT specialist, who determined there was no evidence of medical necessity, and that the requested device was not the standard of care over the use of cold packs.

On October 2, 2024, CCA referred the appeal to an independent review entity (IRE), MCMC, which supported CCA's denial. *Id*. at 41-47. MCMC determined that current medical literature does not recommend cold compression or cryotherapy devices over ice packs for the management of shoulder pain. *Id*. at 42. In Appellant's case, Appellant has chronic left shoulder pain and attended PT with improvement and was recommended for home exercises. Appellant noted relief with icing twice a day for 30 minutes. *Id*. MCMC concluded that the requested device did not meet MNG #045: it is not medically necessary based on Appellant's diagnosis, is experimental/investigational, and is not furnished in accordance with accepted standards of medical practice, or the most cost-effective supply/service which can safely be provided. *Id*. at 42-43.

On October 4, 2024, CCA notified Appellant in writing that her Level I appeal was denied. *Id*. at 50. According to the invoice submitted by Appellant's provider, the total cost of the requested device is $2,325, including the BioCryo Cold Compression Therapy System ($1,500), the isolated shoulder garment with gel pack ($700), and additional gel pack ($125). *Id*. at 30-31.

According to the PT notes in the record, Appellant has experienced shoulder pain after being injured in a motor vehicle accident (MVA) in September 2023. *Id*. at 40. Appellant's PT wrote in the discharge note: "According to the Journal of Orthopedic Trauma, cryotherapy is recommended for acute musculoskeletal pain however, there is no consensus on the delivery method of cryotherapy." *Id*. at 40.[2] The PT recommended Appellant "utilize cryotherapy options for pain management." *Id*.

Appellant's submission included her records from her visit with an orthopedic surgeon on

[2] Citing Hsu J, Mir H, Wally M, Seymour R. Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury. *Journal of Orthopaedic Trauma*. 2019; 33 (5): e158-e182. doi: 10.1097/BOT.0000000000001430).

November 16, 2023. Exhibit 6 at 1-3. The orthopedic surgeon diagnosed Appellant with left shoulder impingement, rotator cuff tendinitis without instability status post MVA and recommended PT. *Id*. Records show that duplicative requests for the device were ordered by [redacted] PA-C, on June 16, 2023, November 27, 2023, December 11, 2023, and March 5, 2024. *Id*. at 5, 10. The letter of medical necessity from [redacted], PA-C dated March 5, 2024 states that Appellant "would benefit from cryotherapy to help with her ongoing shoulder pain as well as a course of physical therapy." *Id*. at 7.

Appellant argued that CCA's treatment of her requests for the device were suspicious. Appellant asserted that if CCA was going to deny the appeal, CCA would have done so when the initial request was made last year. Appellant feels that CCA has been playing with her. Appellant asked BOH to review recordings of phone calls Appellant has had with CCA as evidence of this. Though the hearing record was held open through January 13, 2025 to allow time for Appellant to submit additional evidence, nothing was received by the deadline or to date.

Appellant denied that the device was as costly as CCA claimed. Appellant argued that she searched online and found a device for significantly less. Appellant argued that ice packs do not adequately relieve her pain because they melt too quickly. Appellant does not have enough room in her freezer to make enough ice to fill a passive unit.

Findings of Fact

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

1. Appellant has been enrolled in CCA's OneCare program since February 1, 2017.

2. On July 29, 2024, CCA received a request on Appellant's behalf for a fluid circulating cold pad with pump. Exhibit 4 at 13.

3. On August 12, 2024, CCA denied Appellant's request, writing that the provider did not provide notes supporting the need for a powered device to control pain and swelling as opposed to ice packs or a non-powered, passive unit. Exhibit 1, Exhibit 4 at 14-15.

4. On October 1, 2024, CCA received Appellant's Level I appeal by phone. *Id*. at 25.

5. On October 2, 2024, CCA referred the appeal to MCMC, which supported CCA's denial. *Id*. at 41-47.

6. MCMC determined that current medical literature does not recommend cold compression or cryotherapy devices over ice packs for the management of shoulder pain. *Id*. at 42.

7. On October 4, 2024, CCA notified Appellant in writing that her Level I appeal was denied. *Id*. at 50.

8. Appellant filed this appeal in a timely manner on November 1, 2024. Exhibit 2.

9. Appellant's PT, citing medical literature, wrote in the discharge note: "According to the Journal of Orthopedic Trauma, cryotherapy is recommended for acute musculoskeletal pain however, there is no consensus on the delivery method of cryotherapy." The PT recommended Appellant "utilize cryotherapy options for pain management." *Id*. at 40

10. According to the invoice submitted by Appellant's provider, the total cost of the requested device with accessories is $2,325. *Id*. at 30-31.

Analysis and Conclusions of Law

MassHealth members younger than 65 years old, except those excluded under 130 CMR 508.004, must enroll in the Primary Care Clinician (PCC) Plan or a MassHealth-contracted MCO available for their coverage type. 130 CMR 450.117(A) and 130 CMR 508.002. MassHealth managed care options include an integrated care organization (ICO) for MassHealth Standard and CommonHealth members who also meet the requirements for eligibility set forth under 130 CMR 508.007. Members who participate in an ICO obtain all covered services through the ICO. 130 CMR 450.117(K).

A member may enroll in an ICO if he or she meets the following criteria:

> (A) Eligibility.
>
> > (1) In order to be eligible to enroll in an integrated care organization (ICO), a MassHealth member must meet all of the following criteria, and may not be enrolled or concurrently participate in any of the programs or plans listed in 130 CMR 508.007(F):
> >
> > > (a) be 21 through 64 years of age at the time of enrollment;
> > >
> > > (b) be eligible for MassHealth Standard as defined in 130 CMR 450.105(A): *MassHealth Standard* or MassHealth CommonHealth as defined in 130 CMR 450.105(E): *MassHealth CommonHealth*;
> > >
> > > (c) 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 level as defined in 130 CMR 501.001: *Definition of Terms*; and
> > >
> > > (d) live in a designated service area of an ICO.

130 CMR 508.007.

The ICO will authorize, arrange, integrate, and coordinate the provision of all covered services for the member. Upon enrollment, the ICO is required to provide evidence of its coverage, the range of available covered services, what to do for emergency conditions and urgent care needs, and how to obtain access to specialty, behavioral-health, and long-term services and supports. 130 CMR 508.007(C). ICO members may appeal a determination made by an ICO to the Board of Hearings pursuant to 130 CMR 508.010.

CCA's One Care Plan is a MassHealth ICO. CCA's One Care Member Handbook, pertinent pages included as Exhibit 5, provides which services the plan covers. Per the handbook, CCA's One Care plan covers "all medically necessary DME that Medicare and MassHealth usually pay for" and that prior authorization may be required. Exhibit 5 at 67.

MassHealth covers durable medical equipment (DME) provided to eligible members subject to regulatory restrictions and limitations. 130 CMR 409.403, 409.413(B)(9). For MassHealth to pay for DME, the equipment must meet medical necessity criteria. 130 CMR 409.414(B). The regulatory definition of medical necessity is set forth at 130 CMR 450.204, which states in relevant part:

> (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, or 517.007.

See also 130 CMR 409.414(B)(2) (MassHealth does not pay for DME that is determined by the MassHealth agency not to be medically necessary pursuant to 130 CMR 450.204, which includes but is not limited to items that "are more costly than medically appropriate and feasible alternative pieces of equipment").

According to 130 CMR 409.417 (emphasis added),

> (A) All DME covered by MassHealth must meet the medical necessity requirements set forth in 130 CMR 409.000 and in 130 CMR 450.204: *Medical Necessity*, and any

applicable medical necessity guidelines for specific DME published on the MassHealth website.

(B) For items covered by MassHealth for which there is no MassHealth item-specific medical necessity guideline, and for which there is a Medicare Local Coverage Determination (LCD) indicating Medicare coverage of the item under at least some circumstances, the provider must demonstrate medical necessity of the item consistent with the Medicare LCD. However, if the provider believes the durable medical equipment is medically necessary even though it does not meet the criteria established by the local coverage determination, the provider must demonstrate medical necessity under 130 CMR 450.204*: Medical Necessity*.

(C) For an item covered by MassHealth for which there is no MassHealth item-specific medical necessity guideline, and for which there is a Medicare LCD indicating that the item is not covered by Medicare under any circumstance, the provider must demonstrate medical necessity under 130 CMR 450.204: *Medical Necessity*.

MassHealth does not have medical necessity guidelines related specifically to cold therapy devices.[3] However, CMS's LCD – Cold Therapy L33735 (a copy of which is included in the record as Exhibit 7) provides that a "fluid circulating cold pad with pump (E0218) will be denied as not reasonable and necessary." Exhibit 7 at 3. Therefore, according to 130 CMR 409.417(C), Appellant must demonstrate that the requested device is medically necessary under 130 CMR 450.204.

Appellant's providers did not provide a sufficient rationale why the requested device would be medically necessary to relieve Appellant's pain. Appellant's PT recommended cryotherapy for Appellant but did not specify the delivery method or present any rationale why a less costly option would not work for Appellant. Appellant argued that traditional ice packs do not last long enough to relieve her pain, and that a passive unit would not work for her because she does not have enough room in her freezer to make the ice necessary for the passive unit. These arguments without a documented provider justification are not sufficient to demonstrate the medical necessity and significant expense of the requested device.

CCA's denial of the appellant's Level 1 appeal was not in error. Accordingly, this appeal is denied.

Order for CCA

None.

[3] *See* https://www.mass.gov/lists/masshealth-guidelines-for-medical-necessity-determination (last reviewed February 25, 2025).

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.

Cynthia Kopka
Hearing Officer
Board of Hearings

MassHealth Representative: Commonwealth Care Alliance SCO, Attn: Nayelis Guerrero, 30 Winter Street, Boston, MA 02108