Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	DENIED	**Appeal Number:**	2206790
Decision Date:	11/7/2022	**Hearing Date:**	10/26/2022
Hearing Officer:	Christopher Taffe		

Appearance for Appellant:
Appellant, pro se (by phone)

Appearance for MassHealth/MCO:
Kay George, RN, Clinical Appeals Nurse – Fallon Health – Member Appeals and Grievances (by phone)

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:**	MCO – PA – DME – Iontophoresis Device
Decision Date:	11/7/2022	**Hearing Date:**	10/26/2022
MassHealth's Rep.:	K George, RN	**Appellant's Rep.:**	Appellant, pro se
Hearing Location:	HarborSouth Tower, Quincy (heard remotely)	**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

Through a notice dated August 23, 2022, Fallon Health ("Fallon"), on behalf of a MassHealth Accountable Care Organization ("ACO"),[1] informed Appellant that it was denying her Level I appeal of a prior authorization ("PA") request for a Durable Medical Equipment ("DME") Request for an Iontophoresis device, brand name DermaDry, under Service Code #1399. See Exhibit 3 and Exhibit 6, pages 10 and 11. On September 9, 2022, Appellant filed a timely request for a Fair Hearing over the phone with the MassHealth agency over this Fallon decision; this request was forwarded to the Board of Hearings (BOH). See Exhibit 1; 130 CMR 610.015(B)(7)(a).

On September 13, 2022, BOH dismissed this appeal, without prejudice, for failure to sufficiently identify the adverse and appealable action. See 130 CMR 610.035; Exhibit 2. On September 19, 2022, Appellant filed proof of the appealable action with BOH, leading to a vacate of the dismissal and the eventual scheduling of the hearing. See 130 CMR 610.035; 130 CMR 610.048; Exhibits 3 and 5.

BOH has limited jurisdiction over denials given to certain MassHealth members when those denials

[1] Specifically, Wellforce Care Plan is an ACPP or Accountable Care Partnership Plan, which is a subset of the ACO entities. See 130 CMR 610.004. Wellforce Care Plan is made up of the Wellforce Care Plan ACO and Fallon Health.

involve requests for assistance related to covered benefits from a MassHealth Managed Care Contractor ("MCC"), such as the ACO with which the member is enrolled. See 130 CMR 610.032(B); 130 CMR 508.008 (discussing the role of MCC's in the MassHealth program); 130 CMR 508.011. The denial action codified in the August 23, 2022 denial notice is one such appealable action.

Action Taken by MassHealth/Fallon

MassHealth denied Appellant's request for an Iontophoresis device.

Issue

Is there sufficient medical evidence to entitle Appellant to approval of the requested device under the controlling regulations?

Summary of Evidence

Appellant is a [redacted] female MassHealth member who receives her MassHealth or Medicaid benefits through an ACO administered by Fallon commonly referred to as the Wellforce Care Plan. See Exhibit 6, page 10.

At some point in the summer of 2022,[2] Appellant through her dermatologist provider (Dr. Ogbecie-Godec), requested approval of an Iontophoresis device (Service Code 1399), under the device brand name of DermaDry, for the treatment of problems or symptoms related to excessive sweating, or hyperhidrosis. Appellant suffers from hyperhidrosis in both axilla areas; such areas under the arm are commonly referred to as the armpit.

Based on the record and testimony, an Iontophoresis device is a device which allows an individual to pass a mild electrical current (using specific pads placed on the skin) periodically into the skin area into the affected region, which in turn has a theoretical effect on preventing or minimizing excessive sweating.

Fallon indicated that they denied the request based on both MassHealth regulations in 130 CMR 409.000 related to DME as well as information from the federal Center for Medicare and Medicaid Services (CMS), specifically the Local Coverage Determination (LCD) L33632, which discusses outpatient physical and occupational therapy services, and which has guidelines related to the approved use and coverage of Iontophoresis therapy. These documents are found in Exhibit 6. See Exhibit 6, pages 40 through 87 (containing LCD L33632) and pages 88 through 112 (containing the MassHealth regulations in 130 CMR 409.000).

Appellant has episodes of axillary sweating, which is episodic and which has occurred in the last

[2] Fallon did not testify to any date, and it is not obvious in the written record in Exhibit 6.

year, suggesting some form of correlation with her onset of a new stage of menopause for the member. Appellant testified that the sweating issues began approximately one year ago, and, while she is not in complete menopause (as she has not gone 12 months without a period), she began to have more irregularities or delays with her period approximately one year ago. Based on testimony, the timing of both conditions appears to be roughly correlated.

Appellant testified that the sweating issue involves both armpits and is neither confined nor predominate with one axilla area. She indicated that the sweating is not brought on by certain events (such as exertion or more physical activities) but it can happen at any time, even when she is idle. If and when she is home and the issue occurs, she will typically address it by using a cloth or towel to wash, clean, and/or dry the area, but it is problematic when she is out and has excessive sweating without the supplies, as it is embarrassing and thus limits or impairs her ability to do activities. Although not discussed in detail at hearing, Appellant's dermatologist indicated that it also happens at nighttime with great frequency and disturbs the sleeping. Appellant's dermatologist described the sweating as having a *"score of 2 out of 4 on the Hyperhydrosis Disease Severity Scale"*. See Exhibit 6, page 20. Neither party at hearing could explain the severity scale.

Fallon issued an initial denial of the request on July 22, 2022, and then the final Level I denial on August 23, 2022 after Appellant exercised her Level I internal appeal right with Fallon before appealing to the Board of Hearings.

The initial denial notice of July 22, 2022 from Fallon stated that the ACO recognized that the member had axillary sweating, episodic, mild and severity for about one year, possibly correlating with onset of menopause, and mostly at night. In making that decision, Fallon stated that CMS guidelines indicated that Iontophoresis will only be allowed for treatment of *"intractable, disabling primary focal hyperhidrosis"* that has not been responsive to recognized standard therapy, saying that *"Good hygiene measures, extra strength antiperspirants (for axillary hyperhidrosis) and topical aluminum chloride should initially be tried."*[3] The initial denial letter's paragraph concludes with *"As your condition is not noted to be intractable and disabling and there are other options, the device to provide the therapy is not covered"*. See Exhibit 6, page 8.

The August 23, 2022 final denial notice from Fallon of the Level I internal appeal reiterates much of the same reasoning. It also includes the following statements: *"The clinical chart notes do not support disabling hyperhidrosis as evidenced by secondary complications like infection or escoriation. Therefore, this is not considered intractable and disabling primary focal hyperhidrosis. In addition, regarding other treatments, options include Oxybutynin and glycopyrrolate. This decision follows your plans benefits."* See Exhibit 6, page 10. This text is consistent with the Peer Review Report in Exhibit 6, page 24, done by a Dermatologist for Fallon.

Appellant has never had any history of infection or escoriation (a condition involving the picking of skin) in either armpit area. She indicates the problem is more frequent and associated with hotter or more humid weather, such as the summer. During the current month of October 2022, Appellant estimates the problem has occurred at a frequency of approximately twice a week. Appellant stated

[3] This is consistent with the text from the LCD, found in Exhibit 6, page 53.

that the only time the axilla areas have anything close to rashes or skin issues is usually dry skin related to, or as a result of, the use of the Drysol.

As for alternative treatments, both parties recognize that Appellant has tried over the counter antiperspirants, as well as Drysol (applied like a stick deodorant or antiperspirant), Qbrexa (applied like an alcohol wipe swab), and she has also had Botox (injections) in both axilla areas, without much success. Drysol is a form of a topical aluminum chloride.

The June 2, 2022 note from Appellant's dermatologist states that there were five options for treatment:

> *1. Botox*
> *2. Miraldy Laser Treatment*
> *3. Iontophoresis – demadry.com*
> *4. Oral Medication*
> *5. Topicals/Antipersperant*
>
> See Exhibit 6, page 20.

Appellant has clearly used Options 1 and 5. As to Option 2, the Fallon Representative asked if it was explored and Appellant testified that she understood that it would cost a few thousand dollars per each treatment and that it wouldn't be covered by Fallon, and that was why she elected treatment # 3, which was thought to be a cheaper alternative. [Per a note written by a Fallon representative on page 34 of Exhibit 6, *"Per Dermadry.com, cost of item is <$500 and is FDA approved.*"]

As to option # 4, and oral medications, Appellant indicated she wasn't familiar with Oxybutynan and glycopyrrolate, the medications quoted in the Final Denial notice. She did state that her Primary Care Provider (PCP) had talked with her about some oral medications, but her PCP discouraged them for this issue; no specifics were given as to the reason why, but it seemed like the potential side effects did not outweigh the potential benefits, and this factored into the decision with the dermatologist.

The Fallon Representative stated at hearing that she too did not know about the two medications (Oxybutynan and glycopyrrolate) quoted in single identical sentences on pages 10, 24, and 29 of Exhibit 6 as possible alternatives, nor did the Fallon Representative know (at least initially) whether these two medications were oral medications.[4]
No information was provided on the cost of these two drug alternatives and there is no description of them in the materials provided by the MassHealth.

[4] Lastly, although not a medical option, the Fallon Representative attempted to help by informing Appellant of one clothing or commercial option that she had recently learned about, and which she thought may be of help to anyone with hyperhidrosis, regardless of whether Appellant's appeal was approved or not. In case Appellant needs clarification on the reference, the product mentioned at hearing were "Thompson Tee Shirts".

Per the MassHealth Drug List, Oxybutynin is a Urinary Dysfunction Agent with FDA-approved Therapeutic Uses including but not limited to:

- *Neurogenic detrusor overactivity*
- *Nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void*
- *Overactive bladder with symptoms of urinary frequency, urgency, or incontinence.*[5]

Per the MassHealth Drug List, glycopyrrolate is a type of medication that can be classified, depending on its form, as either an anticholinergic, an antispasmodic, or a bronchodilator.[6]

Findings of Fact

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

1. Appellant is a [redacted] female MassHealth member who receives her MassHealth benefits through the Fallon ACO. (Testimony and Exhibit 6)

2. In the summer of 2022, Appellant's dermatologist requested approval of an Iontophoresis device under the device brand name of DermaDry. (Testimony and Exhibit 6)

3. Appellant timely appealed the denial of Fallon internally, and, when Fallon issued a Level I denial notice of the internal appeal, Appellant timely filed an external appeal with the Board of Hearings. (Testimony and Exhibits 1, 3, and 6)

4. For the last year, during a time period consistent with the onset of a new stage of menopause, the Appellant has suffered from hyperhidrosis in the axilla areas of her body. (Testimony and Exhibits 5 and 6)

5. The hyperhidrosis issue is worse in the summer time and more humid months. (Testimony)

    a. During the month of October 2022, Appellant estimates the problems happens approximately two times per week. (Testimony)

    b. The problem can more frequently occur at night. (Testimony and Exhibit 6))

6. Appellant's dermatologist described the sweating as having a *"score of 2 out of 4 on the Hyperhydrosis Disease Severity Scale"*. (Exhibits 5 and 6)

7. The hyperhidrosis issues are not correlated with any specific physical activity. Appellant may wind up wiping and washing herself down with a washcloth when at home. (Testimony)

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[5] See https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=41&drugId=1316 (last viewed on October 26, 2022). Per this page, Oxybuynin medication can be in the form of tablet, liquid, or gel.

[6] See https://mhdl.pharmacy.services.conduent.com/MHDL/pubsearch.do?index=G (last viewed on October 26, 2022). Per this page, glycopyrrolate medication can be delivered by pill, powder, liquid, injection, or cloth.

8. Appellant has tried hygiene measures, extra strength antiperspirants (for axillary hyperhidrosis) and topical aluminum chloride (including Drysol) to treat this. Appellant has also tried Botox injections with little success to address this problem. (Testimony and Exhibits 5 and 6)

9. Appellant has not tried oral medications or medications such as Oxybutynin and glycopyrrolate to treat this problem. (Testimony and Exhibits 5 and 6)

10. Appellant does not have a history of infection or escoriation caused by the hyperhidrosis. (Testimony and Exhibits 5 and 6)

Analysis and Conclusions of Law

Massachusetts's Secretary of Health and Human Services is authorized to participate in many MCC programs to integrate care for individuals who may have a MassHealth benefit. Accountable Care Partnership Plans are one such type of program, generally consisting of a group of primary care providers who work with just one managed care organization to create a full network that includes PCPs, specialists, behavioral health providers, and hospitals.

Whenever an ACPP or ACO like Fallon/Wellforce makes an adverse benefit decision, it must provide notice to the affected MassHealth member. 130 CMR 508.011. A MCC has 30 days to resolve any internal appeals, and the MassHealth member then has 120 days to request a "Level II" Fair Hearing from the Board of Hearings, which is what happened here. See 130 CMR 508.012; 130 CMR 610.015(B)(7).

As to any prior authorization or PA request, the MassHealth program is generally required to cover services and treatments for its Medicaid beneficiaries that are "*medically necessary*". The MassHealth regulation at 130 CMR 450.204, within the "*All Provider*" manual, defines that term as follows:

450.204: Medical Necessity

…

(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.*

(**Bolded** emphasis added.)

Furthermore, additional guidance *"about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines."* See 130 CMR 450.204(D). By referencing other regulations and *coverage guidelines* within 130 CMR 450.204, it is clear that the law allows the MassHealth program to have other coverage limitations, exclusions, and other rules regarding medical necessity within other regulations and documents.

In this appeal, the request is for a form of DME. MassHealth cited the DME regulations in Exhibit 6, and I find the most relevant part of the DME manual to be 130 CMR 409.417 which reads in relevant part as follows:

409.417: Medical Necessity Criteria
(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. …*
(**Bolded** emphasis added.)

There are no MassHealth item-specific medical necessity guidelines for Iontophoresis devices or therapy.[7] But as the agency's ACO pointed out, there is a CMS LCD which discusses the coverage of such a device, and the relevant pages are part of Exhibit 6. Page 72 of that LCD states that as a therapy, iontophoresis is not covered, except as indicated for "*primary focal hyperhidrosis*". In that same document, the LCD elaborates by stating that iontophoresis will only be allowed for "*intractable, disabling primary focal hyperhidrosis*" and that "*Good hygiene measures, extra strength antiperspirants (for axillary hyperhidrosis) and topical aluminum chloride should initially be tried."* See Exhibit 6, page 55.

The record shows that Appellant has certainly tried some alternative options to cure this issue, but what is more problematic for her appeal is that the LCD describes the standard for the condition as having to be both "*intractable*" and "*disabling*". There is certainly some level of intractability, as the condition is hard to control. However, I find it difficult to conclude that the hyperhidrosis condition of Appellant is disabling. There is no standard of what "*disabling*" directly means in this context, but Fallon tried to offer some examples of what a disabling hyperhidrosis would be, by stating, accurately, that Appellant's condition has not caused her any skin integrity issues, including escoriation or infection. In addition, Appellant testified to the fact that, while the condition occurs

[7] See https://www mass.gov/lists/masshealth-guidelines-for-medical-necessity-determination#masshealth-guidelines-for-medical-necessity-determination-a-%E2%80%93-g- (last viewed on October 27, 2022).

on a somewhat regular basis, it is not a daily occurrence or issues during most parts of the year. It is understandable that it may be a more frequent problem in certain months or warmer weather, but the term "disabling" has a connotation indicating that the impairment should be more permanent or somewhat more constant, as well as limiting some basic physical level of functionality. Neither Appellant's testimony nor the medical records submitted on her behalf in Exhibits 5 and 6 talk in detail about how she is unable to work, or do other specific basic or essential activities of life. The records indicate the problem occurs at night, but neither the records nor the testimony indicated whether such occurrences negatively affects Appellant's sleep or other ability to do basic activities.

That is not to say that the problem is not real, nor is it to minimize Appellant's genuine and plausible claims about how it limits certain social activities and can be an embarrassment or understandable annoyance. However, the severity is noted as the level of the problem must factor into any medically necessity analysis. 130 CMR 450.204(A) talks about the need for reasonably calculating what is necessary, and severity factors into that calculation.

As one other final point of reference, the Appellant's own dermatologist classified her condition as have a score of 2 out of 4 on the "*Hyperhydrosis Disease Severity Scale*" ("HDSS"). Neither party produced evidence to help interpret this statement on severity, but a review of the internet[8] shows that the HDSS is a self-assessment and that the score of 2 represents moderate severity, with tolerable sweating issues that sometimes interfere with daily activities. Scores of 3 and 4 are severe, with frequent or constant interference.

Based on the above, the decision by Fallon to not find the requested iontophoresis device in this request to be medically necessary appears justified, as Appellant's hyperhidrosis condition is not disabling. This decision appears consistent with the rule of 130 CMR 409.417(B), as the rationale is tied to an LCD and Fallon properly applied the facts of Appellant's specific medicals to the standard in that LCD. This appeal is therefore DENIED.

Although it is unnecessary to go much further in analysis, even if Appellant's condition was more severe and disabling, the ACO's decision arguably may have been separately supported by the fact that there are still other possible medications (such as Oxybutynin and glycopyrrolate) that could have been tried or reasonable possible alternatives for Appellant. However, if the ACO wanted to argue about the of such alternatives, more details including information on the alternatives, such as the pricing and how they were delivered, would have been helpful to have for legal analysis. Lastly, if the Appellant's condition worsens or shows signs of becoming more permanent and more severe over time, and if other alternatives are unsuccessfully tried (or ruled out by her doctors for valid

[8] There are many websites on this, but whether it's a commercial website or those sites more resembling a medical journal, they are all consistent with the descriptions of what a HDSS score of 1 through 4 mean. For example, see https://www.sweathelp.org/pdf/HDSS.pdf and https://www.neatapparel.com/blogs/news/hyperhidrosis-severity-understanding-the-hdss-scale and https://jddonline.com/articles/the-hyperhidrosis-disease-severity-measure-axillary-conceptualization-and-development-of-item-conten-S1545961618P0707X (all last viewed on October 28, 2022). While the HDSS may be a useful way of classifying subjects with hyperhidrosis, some will understandably argue that it is inadequate for quantifying symptom severity with scientific accuracy, or that it may be subject to bias or reporting error. Nevertheless, the fact that Appellant scored only a 2, as opposed to a more severe 3 or 4, is another factor in supporting a conclusion that Appellant's hyperhidrosis is not disabling.

reasons), the Appellant and her providers always have the option to resubmit the request in the future.

Order for MassHealth/Fallon

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.

Christopher Taffe
Hearing Officer
Board of Hearings

cc: Fallon Health Appeals Coordinator