Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	DENIED	**Appeal Number:**	2300854
Decision Date:	6/6/2023	**Hearing Date:**	03/01/2023
Hearing Officer:	Kenneth Brodzinski	**Record Open to:**	03/20/2023

Appearance for Appellant:

Pro se

Appearance for MassHealth:

Cassandra Horne; Kailey Emery: Jeramiah Mancuso; David Mello, MD and Stefan Topolski MD for Commonwealth Care Alliance

Interpreter:

Russian

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:**	Prior Authorization
Decision Date:	6/6/2023	**Hearing Date:**	03/01/2023
MassHealth's Rep.:	Cassandra Horne - CCA	**Appellant's Rep.:**	Pro se
Hearing Location:	Quincy		

Authority

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

Jurisdiction

Through notices dated December 29, 2022, MassHealth's agent, Commonwealth Care Alliance (CCA), issued Level 1 denials of Appellant's prior authorization request for BlephEx, TearCare, low level light therapy and platelet rich plasma tears (Exhibit A). Appellant filed her fair hearing requests in a timely manner on January 30, 2023 (see 130 CMR 610.015(B) and Exhibit A). Denial of assistance constitutes valid grounds for appeal (see 130 CMR 610.032).

Action Taken by MassHealth

MassHealth's agent, CCA, issued Level 1 denials of Appellant's prior authorization request for BlephEx, TearCare, low level light therapy and platelet rich plasma tears.

Issue

The appeal issue is whether MassHealth's agent, CCA, properly applied the controlling regulation(s) to accurate facts when it issued Level 1 denials of Appellant's prior authorization request for BlephEx, TearCare, low level light therapy and platelet rich plasma tears.

Summary of Evidence

Both parties appeared by telephone. Both parties filed a packet of documents: CCA (Exhibit B). Appellant (Exhibit C). Post hearing, Appellant filed additional documentation (Exhibit D); CCA made no post-hearing filing and otherwise did not respond to Appellant's post-hearing submission.

CCA must comply with all Medicaid (MassHealth) regulations when serving as MassHealth's agent in supplying health insurance to MassHealth members such as Appellant. The CCA representatives testified that it denied a level-one appeal for Appellant relative to its earlier denial of a prior authorization request submitted by Appellant's provider for BlephEx, TearCare, low level light therapy and platelet rich plasma tears.

The CCA representatives testified that the requested items/procedures were not medically necessary insofar as they are experimental. CCA noted that Appellant's own provider, who filed the authorization request, submitted a note along with the request stating that there are no CPT billing codes for the requested items/procedures and the items/procedures are *"elective services that are self-pay"* (i.e., not covered by insurance) (Exhibit B, pages 8 and 9). The submitting provider also stated: *"We only sent this P/A because the [Appellant] insisted"* (Id). Handwritten at the very top of the request alongside asterix marks is the notation *"Sending this request per patient"* (Exhibit C, page 2).

According to CCA, after performing an extensive literature review, they found no evidence of strong calibered controlled comparative cohort trials in the peer reviewed medical literature to indicate that these items/procedures are safe and effective in the long term for the treatment of dry eyes. Additionally, there is no supportive evidence through compendium or guidelines to suggest that these procedures are standard medical practice in the setting of practices. According to CCA, there are also many therapeutic measures which can be used to treat dry eyes, including punctal occlusion, xiidra, cequa, cyclosporine (Restasis), and tyrvaya, which are supported in the literature. The prior authorization request fails to indicate that Appellant has tried these available alternatives.

CCA acknowledged that platelet rich plasma tears has some supporting evidence in the literature, but it is typically reserved for treatment resistant keratoconjunctivitis sicca (dry eyes) which has failed multiple medical therapies. According to CCA, the written authorization request filed by Appellant's treating medical provider fails to indicate that Appellant has tried any lacrimal gland-stimulating agents to increase her tear production. The request also fails to indicate any trials with multiple available over-the-counter eye lubricants. For these reasons, CCA determined that the subject authorization request fails to demonstrate medical necessity pursuant to the MassHealth medical necessity regulation.

CCA noted that the initial review and denial, as well as the level 1 appeal, were made by Board-

Certified Ophthalmologists.

CCA also provided a summary of the clinical review provided with the authorization request, including a clinical encounter note dated November 4, 2022. According to the note, Appellant had visual acuity of 20/25 on the right and 20/30 on the left. The corneal examination revealed decreased tear film with meibomian gland dysfunction bilaterally. The fundus examination was unremarkable. Tear lab osmolarity testing revealed 297 mOsm on the right and 300 mOsm on the left. Blepharitis and conjunctiva sclerosis were seen on external photography. Appellant was diagnosed with worsening dry eye syndrome alongside meibomian gland dysfunction for eyelids. Short-term anti-inflammatories were recommended to reduce and control the inflammatory burden. Punctal occlusion was also recommended. Additionally, BlephEx, tearcare, and low-level light therapy were recommended x3 alongside platelet rich plasma.

Appellant complained that CCA's document packet was not provided to her well in advance of the hearing and was provided to her in English instead of Russian. Appellant also questioned why she has to bring these matters before the Board of Hearings in an appeal instead of being able to discuss it in person with CCA.

Appellant spent the majority of her time testifying about her condition. Appellant testified that she was diagnosed with Graves' disease in 2017. The disease has significantly impacted her eyes. Appellant testified that her vision is often blurry, her eyes get very red and dry, and she often has stabbing pains which feel like needles in her eyes. Appellant also described how the condition causes blood vessels in her eyes to burst. Appellant stated she has a lot of pain and pressure in her right eye, and she is generally sensitive to light.

Appellant testified that she tried Restasis (cyclosporine), which only gave her some short-term relief, and eventually stopped having any effect. Appellant testified that she has also tried Xiidra, but had an adverse reaction in that it burned her eyes, caused more redness, and caused blood vessels to burst. Appellant also testified that she has been trying cequa, but it has not been working.

Appellant testified that she has seen numerous doctors and eye specialists and complained that she was never told by any of her doctors, until just recently, that her dry eye condition was actually a symptom of her main condition, meibomian gland dysfunction. According to Appellant's understanding of this condition, she is missing the gland that produces tears. Based on this understanding, Appellant asserted that eyedrops will not work because the gland is missing. Appellant testified that she was told by one doctor over the phone that drops will not work for her because her meibomian gland dysfunction is too severe and drops will not restore tear production. She also stated that this doctor told her the only option was to proceed with the items/procedures identified in the prior authorization request. Appellant noted that she is seeking reimbursement because she is currently privately paying for the light therapy. Appellant emphasized that she has tried everything recommended by her doctors, but her

condition is only getting worse. Appellant noted that the items/procedures being sought in the prior authorization request were ordered by her doctor, not herself. Appellant testified that she was also told by her doctor that, if she does not get this treatment, she will go blind.

Appellant did not refer directly to any of the documents she provided at the time of hearing except to urge the hearing officer to look at the copies of photographs of her eyes which are contained in the packet (Exhibit C).

Lastly, Appellant stated that she wishes to discuss this matter with CCA by phone and wants CCA to develop a plan for her because she does not want to be left without any treatment.

The record was left open to allow Appellant to submit additional documentation. By the record close date of March 13, 2023, Appellant made two filings. The first contains, *inter alia*, copies of Appellant's medical records and an Affidavit signed by Appellant dated March 8, 2023. The second is a one-page article concerning Platelet Rich Plasma therapy (Both combined as Exhibit D). Affidavit and article are at the end of Exhibit D. Through her Affidavit, Appellant provided additional detail and clarity about her course of treatment to date. She noted that the Affidavit was needed because she felt she was not able to adequately express herself using an inadequate interpreter during the hearing and her own limited English. She notes that she was able to complete the Affidavit with the help of an English translator while not under the constraints and pressures she encountered during the hearing.

By the record-close date and the date of this decision, CCA has made no response to Appellant's post-hearing submission.

Findings of Fact

By a preponderance of the evidence, this record supports the following findings.

1. CCA must comply with all Medicaid (MassHealth) regulations when serving as MassHealth's agent in supplying health insurance to MassHealth members such as Appellant.

2. CCA denied a level-one appeal for Appellant relative to its earlier denial of a prior authorization request submitted by Appellant's provider for BlephEx, TearCare, low level light therapy and platelet rich plasma tears.

3. Appellant's own provider, who filed the authorization request, submitted a note along with the request stating that there are no CPT billing codes for the requested items/procedures and the items/procedures are *"elective services that are self-pay"* (i.e., not covered by insurance) (Exhibit B, pages 8 and 9).

4. The submitting provider also stated: *"We only sent this P/A because the [Appellant] insisted"* (Id).

5. Handwritten at the very top of the request alongside asterix marks is the notation *"Sending this request per patient"* (Exhibit C, page 2).

6. A board-certified Ophthalmologist at CCA performed an extensive review of the medical literature and found no evidence of strong calibered controlled comparative cohort trials in the peer reviewed medical literature to indicate that the requested items/procedures are safe and effective in the long term for the treatment of dry eyes.

7. CCA found no supportive evidence through compendium or guidelines to suggest that the requested items/procedures are standard medical practice in the setting of practices.

8. There are therapeutic measures which can be used to treat dry eyes, including punctal occlusion, xiidra, cequa, cyclosporine (Restasis), and tyrvaya, which are supported in the literature.

9. The prior authorization request that was filed fails to indicate that Appellant has tried these available alternatives.

10. Platelet rich plasma tears has some supporting evidence in the literature, but it is typically reserved for treatment resistant keratoconjunctivitis sicca (dry eyes) which has failed multiple medical therapies.

11. The written authorization request filed by Appellant's treating medical provider fails to indicate that Appellant has tried any lacrimal gland-stimulating agents to increase her tear production.

12. The subject request also fails to indicate any trials with multiple available over-the-counter eye lubricants.

13. CCA determined that the subject authorization request fails to demonstrate medical necessity pursuant to the MassHealth medical necessity regulation.

14. According to a clinical encounter note dated November 4, 2022, Appellant had visual acuity of 20/25 on the right and 20/30 on the left. The corneal examination revealed decreased tear film with meibomian gland dysfunction bilaterally. The fundus examination was unremarkable. Tear lab osmolarity testing revealed 297 mOsm on the right and 300 mOsm on the left. Blepharitis and conjunctiva sclerosis were seen on

external photography.

15. According to the clinical encounter note dated November 4, 2022, Appellant was diagnosed with worsening dry eye syndrome alongside meibomian gland dysfunction for eyelids. Short-term anti-inflammatories were recommended to reduce and control the inflammatory burden. Punctal occlusion was also recommended. Additionally, BlephEx, tearcare, and low-level light therapy were recommended x3 alongside platelet rich plasma.

16. Appellant was diagnosed with Graves' disease in 2017; the disease has significantly impacted her eyes.

17. Appellant's vision is often blurry, her eyes get very red and dry, and she often has stabbing pains which feel like needles in her eyes.

18. Appellant suffers from ruptured blood vessels in her eyes.

19. Appellant has pain and pressure in her right eye, and she is generally sensitive to light.

20. Appellant has self-reported trying Restasis (cyclosporine), which only gave her some short-term relief, and eventually stopped having any effect.

21. Appellant has self-reported that she has also tried Xiidra but had an adverse reaction in that it burned her eyes, caused more redness, and caused blood vessels to burst.

22. Appellant has self-reported that she has been trying cequa, but it has not been working.

23. Appellant has seen numerous doctors and eye specialists.

24. Appellant is seeking reimbursement because she is currently privately paying for intense pulse light (IPL) therapy.

Analysis and Conclusions of Law

"The burden of proof is on the appealing party to show that the order appealed from is invalid, and we have observed that **this burden is heavy.**" *Massachusetts Inst. of Tech. v. Department of Pub. Utils*., 425 Mass. 856, 867, 684 N.E.2d 585 (1997) (emphasis added).

The fact that the requested items/procedures do not have their own CPT codes is not determinative of whether or not they are reimbursable, but it is consistent with the assertion that

such items/procedures may be new or experimental, as new and/or experimental items/procedures do not have their own specific CPT codes.

Appellant's own provider, who filed the prior authorization request, clearly let CCA know that it was only filing the request at Appellant's insistence. Appellant's provider acknowledged that the requested items/procedures are typically not covered by insurance and are self-pay items. This is supported by Appellant's own submission, which includes an article on how to pay for items/procedures to treat Dry Eye Disease and Meibomian Gland Dysfunction. This article also acknowledges that treatments such as TearCare and pulsed light therapy are generally not covered by insurance and patients are often left with only cash-pay options (Exhibit C, pages 9 and 10).

Nevertheless, the record establishes that CCA considered the medical necessity of the requested items/procedures. As MassHealth's agent, CCA is obligated to appropriately apply MassHealth regulations in making its determinations. The MassHealth medical necessity regulation at 130 CMR 450.204 states:

> 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.

In order to meet the above-cited medical necessity requirements, an item/procedure must satisfy BOTH subsections 1 and 2 of Section (A). On this record, CCA has adequately shown that the authorization request under review fails both subsections 1 and 2.

Subsection 1 (*"reasonably calculated to . . ."*) concerns efficacy and safety. CCA's determination on the lack of medically documented efficacy both in the medical literature and in the standard of care as practiced was supported by the Board-Certified Ophthalmologist who reviewed and cited the pertinent medical literature (see, Exhibit B, page 10). This was not overcome by documentation filed by Appellant that consisted largely of her medical records and some selected articles about the nature of certain therapies and procedures but contained no formal peer-reviewed studies.

Subsection 2 requires that, in order for an item/procedure to be deemed "medically necessary" for MassHealth coverage purposes, there must be no available comparable alternatives that are less costly to MassHealth. The subject request must document the trial of any such alternative or explain why such alternatives would not be medically advisable, and this information must come from the physician filing the request. It cannot come from Appellant's testimony during a hearing. At hearing, Appellant testified that she had tried some of the listed alternatives including Restasis, Xiidra and Cequa. The medical records that Appellant submitted at hearing contain information, self-reported by Appellant, about using some of these treatments. However, information about trials must be documented in the medical records submitted with the written prior authorization request and should show the dates, dosage, duration of the trial as well as the results as confirmed by the physician. Putting this requirement to the side and giving Appellant the benefit of the doubt, however, still leaves untried several available treatments that are supported by the medical literature. These include punctal occlusion and tyrvaya. As long as such alternatives exist and remained untried, medical necessity cannot be established for the requested items/procedures in the subject prior authorization request, as the request fails to meet subsection (A)(2) of the controlling regulation.

Lastly, it bears mentioning that one of the requested therapies sought in the subject request was "low level light therapy" (Exhibit C, page 2). At hearing, Appellant stated she was seeking reimbursement for light therapy that she was paying for out of pocket. This therapy was identified in her Affidavit as "Intense pulsed light (IPL)" therapy (Exhibit D, Affidavit paragraphs 28, 29, 30 and 31). IPL therapy was not a part of the subject prior authorization request.

On this record, Appellant has failed to meet her burden of showing that CCA's determination to deny the subject prior authorization request was invalid. Accordingly, the appeal is DENIED.

Order for Commonwealth Care Alliance

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.

Kenneth Brodzinski
Hearing Officer
Board of Hearings

cc:
MassHealth Representative: Commonwealth Care Alliance SCO, Attn: Cassandra Horne, 30 Winter Street, Boston, MA 02108