Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Dismissed	**Appeal Number:**	2305699
Decision Date:	11/29/2023	**Hearing Date:**	11/09/2023
Hearing Officer:	Alexis Demirjian	**Record Open to:**	11/27/2023

Appearance for Appellant:
[redacted] Esq,
Health Law Advocates

Appearance for MassHealth:
Cassandra Horne, Appeals and Grievance Coordinator
Jeremiah Mancuso, Clinicals RN Appeals and Grievance Manager
Kaley Ann Emery, Appeals Supervisor

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:	Dismissed	**Issue:**	OneCare; Medicare Part D Denial
Decision Date:	11/29/2023	**Hearing Date:**	11/09/2023
CCA's Rep.:	Ms. Horne Mr. Mancuso Ms. Emery	**Appellant's Rep.:**	Attorney [redacted]
Hearing Location:	Telephonic	**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 June 23, 2023, Commonwealth Care Alliance (One Care Plan – Medicaid/Medicare Plan) denied the appellant's prior authorization under Medicare Part D for Lidocaine Ointment 5% because the prior authorization listed a diagnosis that has not been approved by the United States Food and Drug Administration (FDA) for use of the requested drug. (Exhibit 3). The appellant filed a level one appeal which was denied. (see 130 CMR 610.015(B) and Exhibit 5). The appellant then filed an appeal with the Center for Medicare and Medicaid Services (CMS) Independent Review Entity (IRE), which was also denied because the drug requested to treat the condition in the prior authorization is for off -label use. (See Exhibit 5, p. 20) The IRE letter included information to appeal the denial to an Administrative Law Judge, the appellant did not appeal this determination. (see 130 CMR 610.012 (H)). On August 4, 2023, the appellant then filed an appeal with the Board of Hearings of the denial of the prior authorization.[1] Enrollees in dual demonstrations program use a coordinated appeals process that provides enrollees with access to both the MassHealth and Medicare process. (see 130 CMR 610.018).

CCA raised a jurisdictional argument regarding whether the case was properly before the Board of

[1] On July 12, 2023, BOH received a Request for Fair Hearing that was not properly filed. On July 13, 2023, MassHealth dismissed the appeal, and the appellant subsequently cured the deficiency on August 4, 2023.

Hearings. A record open period was allowed following the hearing for the appellant's representative to brief the issue and provide any supporting documentation related to medical necessity. The appellant submitted their memorandum of law and a letter from the appellant's physician, dated November 15, 2023, on November 17, 2023. The appellant's submission has been incorporated as Exhibit 9. CCA was given until Monday, November 27, 2023, to respond to the appellant's memorandum and additional evidence. CCA did not submit a response and the record closed November 28, 2023.

Action Taken by CCA One Care

CCA One Care denied the appellant's prior authorization for Lidocaine Ointment 5%.

Issue

The appeal issue is whether CCA was correct in denying prior authorization for the requested drug.

Summary of Evidence

Dual Coverage

The appellant has been enrolled in CCA One Care since January 1, 2017. One Care is a (Medicare-Medicaid Plan). Under a three-way contract between the United States Department of Health and Human Services Centers for Medicare & Medicaid Services, in partnership with the Commonwealth of Massachusetts and Commonwealth Care Alliance ("contract") the duties, obligations, responsibilities, and requirements of the parties are set forth. (Exhibit 8)

Section 2.12 of the contract describes the appeal process for CCA One Care members. (Id.) The contract clearly states that Medicare Part D Appeals may not be filed with the Board of Hearings. (See § 2.12.1.2.5 at Id.) It goes on to state that appeals related to drugs excluded from Part D, that are covered by MassHealth, must be filed with the Board of Hearings. (See § 2.12.1.2.6 at Id.)

In this matter, the prior authorization denial under appeal is related to a request for 5% lidocaine ointment. This drug requires a prescription and is covered by Medicare Part D, it is not an uncovered drug subject to §2.12.1.2.6 of the contract.

Procedural History

On or about June 15, 2023, the appellant's doctor placed a prior authorization request for a prescription of 5% lidocaine ointment. The prior authorization stated the reason for the prescription was for the appellant's lower back pain. The provider is a neurologist and did not provide any additional documentation explaining why they were requesting this medication to treat the appellant's condition. The appellant's condition is not among the FDA approved usage for this drug.

The prior authorization request was promptly denied because the records sent by the appellant's provider did not meet the criteria for approval. (Exhibit 5, p.5) Further stating:

> Your doctor has asked for lidocaine 5% ointment for long term low back pain. The drug has not been approved by the United States Food and Drug Administration (FDA) for the treatment of this health issue. Also, this drug is not an appropriate treatment choice for this health issue, per the Medicare-approved drug information compendia. We did not get the extra records that are needed to approve this request from your doctor. We tried to reach your doctor for those records. We did not get a reply. Therefore, the safety and effectiveness of this drug has either not been established or shown to be inconclusive treatment of your health issue.

On June 21, 2023, the appellant filed a first level appeal. The notes for the appeal state that the prescription was a medical necessity because over the counter 4% lidocaine patches do not provide lasting relief. (Exhibit 5, p. 8)

On June 23, 2023, Dr. David Mello, CCA Medical Director, denied the level one appeal stating that:

> A full and careful review of the provided documentation was performed in the context of the provided documentation was performed in the context of the CCA Knowledge Base. Based on the provided documentation; this appeal is denied based on the following:
>
> The diagnosis provided by the requesting provider has not been approved by the United States Food and Drug Administration (FDA). Also, the health issue given is not included and/or is not an appropriate treatment choice per the Medicare approved drug information compendia: a. Chronic lower back pain b. M54.9 – Dorsalgia, unspecified. (Exhibit 5, p. 11)

The June 23, 2023, notice included appeal rights through a CMS Independent Review Entity (IRE). The appellant then appealed the June 23, 2023rd denial through the IRE.

On July 7, 2023, the IRE denied the appellant's appeal. Stating that "Commonwealth Care Alliance" is not required to cover LIDOCAINE according to Medicare rules. The denial explained:

> Section 1860D-2(e)(4) of the Social Security Act defines "medically-accepted indication," in part by reference to Section 1927 (k)(6) of the Social security Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act , or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in Section 1927(g)(1)(B)9i) of the Social Security Act. The recognized compendia are: 1) American Hospital Formulary Service Drug Information, and 2)DRUGDEX® Information System.
>
> Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically accepted indications using the tools and data available to them to make such determinations. Part D sponsors must reference all the Centers for Medicare and Medicaid Services recognized compendia to determine whether there are any supportive citations, prior to determining that a drug is not being used for a medically accepted indication….

The IRE conducted an independent and de novo review of the denial of the Lidocaine 5% ointment. Finding:

> Use of the requested drug to treat the noted condition is an off-label use. The Medicare-approved compendia do not contain any citations to support the use of the requested drug, as prescribed, for the treatment of this condition. Therefore, the drug is being prescribed for a non-medically accepted indication.

The appellant was informed that he could appeal that decision to an Administrative Law Judge. (Exhibit 5, p. 20)

Subsequently, the appellant filed an appeal before the Board of Hearings. (Exhibit 2) In support of their appeal, the appellant's attorney submitted a packet of information to the Board of Hearings. The packet included prescribing information from an earlier prior authorization request for a Lidocaine Patch that had also been denied, the medical documentation submitted at hearing was from December 22, 2022, nearly a year old. The appellant's hearing packet also included parts of the contract that were cited above.

Summary of Appellant's Testimony and Argument

The appellant's attorney focused on the contract provisions related to 2.4 Covered Services which states:

> The Contractor must authorize, arrange, integrate, and coordinate the provision of all Covered Services for its Enrollees. (See Appendix A and Appendix B0. Covered Services must be available to all Enrollees, as authorized by the Contractor Covered Services will be managed and coordinated by the Contractor through the Interdisciplinary Care Team (ICT) (See Section 2.5.3)

Appellant's counsel then referenced Appendix A which focuses on Medical Necessity, highlighting that CCA must provide all Covered Services that are Medically Necessary, including but not limited to, those Covered Services that:

a. Prevent, diagnose, or treat health impairments;
b. Attain, maintain, or regain functional capacity.

Additionally, under this section CCA may not arbitrarily deny or reduce the amount, duration, or scope of a required Covered Service solely because of a diagnosis, type of illness, or condition of the Enrollee.

The appellant's attorney argued that because MassHealth does not require a prior authorization for requested drug, that Medicare's standards were arbitrary and that the drug should be provided to him under his MassHealth coverage.

The appellant also argues that this denial should not be considered a Part D denial because the appellant has dual coverage.

Summary of CCA'S Testimony and Argument

CCA argues that the prior authorization was properly processed under the appellant's Medicare Part D plan. In response to the appellant's assertion that MassHealth should cover the drug because Medicare denied payment, CCA points out that coverage is different from approving a prior authorization. Both Medicare and MassHealth cover the requested drug, both require that a patient's condition must be listed under appropriate compendia and be an approved usage under the FDA.

CCA maintains that the denial was proper because the appellant's treating physician did not provide documentation that supported the use of this drug for off-label usage.

Finally, CCA argues that this appeal is not properly before the Board of Hearings because the contract it entered into with MassHealth and CMS explicitly states that Medicare Part D appeals may not be appealed to the Board of Hearings.

Provider's Letter Submitted During Record Open

On November 17, 2023, the appellant submitted a letter from his provider stating:

[Appellant] suffers from chronic intractable lower back pain. A prescription for lidocaine 5%

ointment or patches is medically necessary. Topical lidocaine 4%, Ibuprofen 800 mg, physical therapy as well as right L5/S1 epidural steroid injection have previously provided limited relief.

(Exhibit 9)

Findings of Fact

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

1. On or about June 15, 2023, the appellant's doctor placed a prior authorization request for a prescription of 5% lidocaine ointment. (Testimony; Exhibit 5, p.)

2. The prior authorization requested the prescription for the appellant's lower back pain. The provider is a neurologist and did not provide any additional documentation explaining why they were requesting this medication to treat the appellant's condition since the appellant's condition is not among the FDA approved usages for this drug. (Testimony; Exhibit 5, p.5)

3. On June 21, 2023, the appellant filed a first level appeal. (Testimony; Exhibit 5, p.8)

4. On June 23, 2023, Dr. David Mello, CCA Medical Director, denied the level one appeal stating that:

> A full and careful review of the provided documentation was performed in the context of the provided documentation was performed in the context of the CCA Knowledge Base. Based on the provided documentation; this appeal is denied based on the following:
>
> The diagnosis provided by the requesting provider has not been approved by the United States Food and Drug Administration (FDA). Also, the health issue given is not included and/or is not an appropriate treatment choice per the Medicare approved drug information compendia: a. Chronic lower back pain b. M54.9 – Dorsalgia, unspecified. (Exhibit 5, p. 11)

5. On July 7, 2023, the IRE denied the appellant's appeal. Stating that "Commonwealth Care Alliance" is not required to cover LIDOCAINE according to Medicare rules. The denial explained:

> Section 1860D-2(e)(4) of the Social Security Act defines "medically-accepted indication," in part by reference to Section 1927 (k)(6) of the Social security Act, to any use of a covered Part

D drug which is approved under the Federal Food, Drug, and Cosmetic Act , or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in Section 1927(g)(1)(B)9i) of the Social Security Act. The recognized compendia are: 1) American Hospital Formulary Service Drug Information, and 2)DRUGDEX® Information System.

Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically accepted indications using the tools and data available to them to make such determinations. Part D sponsors must reference all the Centers for Medicare and Medicaid Services recognized compendia to determine whether there are any supportive citations, prior to determining that a drug is not being used for a medically accepted indication….

(Exhibit 5, p.20)

6. The IRE conducted an independent and de novo review of the denial of the Lidocaine 5% ointment. Finding:

Use of the requested drug to treat the noted condition is an off-label use. The Medicare-approved compendia do not contain any citations to support the use of the requested drug, as prescribed, for the treatment of this condition. Therefore, the drug is being prescribed for a non-medically accepted indication.

(Exhibit 5, p. 20)

7. The appellant's provider fails to address why this drug should be authorized for an unapproved usage. (Exhibit 9)

Analysis and Conclusions of Law

Pursuant to regulation 130 CMR 508.001, "MassHealth Member Participation in Managed Care:"

(A) Mandatory Enrollment with a MassHealth Managed Care Provider. MassHealth members who are younger than 65 years old must enroll in a MassHealth managed care provider available for their coverage type. Members described in 130 CMR 508.001(B) or who are excluded from participation in a MassHealth managed care provider pursuant to 130 CMR 508.002(A) are not required to enroll with a MassHealth managed care provider.

(B) Voluntary Enrollment in a MassHealth Managed Care Provider. The following MassHealth members who are younger than 65 years old may, but are not required

to, enroll with a MassHealth managed care provider available for their coverage type: (1) MassHealth members who are receiving services from DCF or DYS; (2) MassHealth members who are enrolled in the Kaileigh Mulligan Program, described in 130 CMR 519.007(A): The Kaileigh Mulligan Program. Such members may choose to receive all services on a fee-for-service basis; (3) MassHealth members who are enrolled in a home- and community-based services waiver. Such members may choose to receive all services on a fee-for-service basis; or (4) MassHealth members who are receiving Title IV-E adoption assistance as described at 130 CMR 522.003: Adoption Assistance and Foster Care Maintenance. Such members may choose to receive all services on a fee-for-service basis.

(C) Senior Care Organizations (SCO). MassHealth members who are 65 years of age or older may enroll in a SCO pursuant to 130 CMR 508.008(A).

(D) Integrated Care Organizations (ICO). Also referred to as "One Care plans." Members enrolled in an ICO (One Care plan) are participants in the Duals Demonstration, also known as "One Care." MassHealth members who are 21 through 64 years of age at time of enrollment may enroll in an ICO pursuant to 130 CMR 508.007(A).

(Emphasis added)

Next, pursuant to MassHealth regulation 130 CMR 508.007 (A),

In Order to be eligible to enroll in an integrated care organization (ICO), a MassHealth member must meet all 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);
(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 501.002: Definition of Terms;

Commonwealth Care Alliance (CCA) is a private company that has contracted with the Center for Medicare and Medicaid Services (CMS) and MassHealth to provide for the administration of Medicare, Medicaid, and State Services. (See Exhibit 8, Three-Way Contract). The contract sets forth the terms and conditions by all parties to the contract. (Id.) The Contract includes an entire section titled 2.12 Enrollee Appeals.

Under 2.12.1.1. All contractors shall utilize, and all Enrollees may access the existing Medicare Part D Appeals Process, as described in Appendix F. Consistent with existing rules, Part D Appeals will be automatically forwarded to the IRE if the Contractor misses the applicable adjudication timeframe. The Contractor must maintain written records of all Appeal activities and notify CMS and MassHealth of all internal appeals.

The next section of the contract, 2.12.1.2, is titled **Integrated/Unified Non-Part D Appeals Process Overview.** (See Exhibit 8, p. 142) (Emphasis added). This is important because the contract is clearly identifying that Part D Appeals under the contract between the parties have a different and distinct appeal path.

The contract then goes on to explicitly state under 2.12.1.25, **Part D Appeals may not be filed with the Board of Hearings.** (Emphasis added.) (Id.)

Further drawing a distinction, the contract states that Appeals related to drugs excluded from Part D that are covered by MassHealth must be filed with the Board of Hearings. (Id).

This brings us to the MassHealth regulations concerning ICO appeals, under 130 CMR 610.018, if an appeal is denied by the ICO internal appeals process a member may appeal to either IRE, BOH, or described in 130 CMR 610.018 (A) through (C).

(A) If the member's appeal is denied in whole or in part, the ICO must automatically forward an external appeal about Medicare Services to the IRE. The member may simultaneously appeal the ICO decision to BOH.

(B) Services that are not covered Medicare fee-for-service may only be appealed to the BOH. The ICO must notify the member if the service is not covered by Medicare and that the member has the right to appeal to the BOH.

(C) IF the BOH or the IRE decides in the members, favor the ICO must provide or arrange for the service in dispute as expeditiously as the member's health condition requires but no later than 72 hours from the date the ICO receives the notice of the BOH or the IRE decision.

While the MassHealth regulation does not explicitly state that services covered by Medicare under Part D may not be appealed to the Board of Hearings, according to 130 CMR 610.018 (B), only services not covered by Medicare fee-for-service may be appealed to the Board of Hearings. This language, read in conjunction with the clear and unambiguous the language of the contract, shows the parties intent which is appeals to the Board of Hearings are only appropriate when a drug is excluded from Medicare Part D, but is covered by MassHealth. (See Exhibit 6, § 2.12.1.2.6)

Here the drug is covered by both Medicare and Medicaid, and both coverages require that

individuals must meet the criteria as set forth in the compendia for either insurance to cover the expense for the drug. The FDA has not approved the drug for treatment of the appellant's medical condition. In this case, the reason the requested drug was not authorized is because the physician requested the drug for off-label use and has not provided any compelling explanation the drug is suitable for the appellant's condition. The denial is not because Medicare does not cover the drug.

MassHealth is a Payer of Last Resort

To the extent that the appellant argues that this is not an appeal of a Medicare Part D denial, it is worth noting that MassHealth is a payer of last resort. All resources available to a member, including, but not limited to, all health and casualty insurance, must be coordinated and applied to the cost of medical services provided by MassHealth. (See 42 CFR Part 433, Subpart D.) Except to the extent prohibited by 42 U.S.C. 1396a(a)25(E) or (F), all providers must make diligent efforts to obtain payment first from other resources, including casualty payer payments, so that the MassHealth agency will be the payer of last resort. The MassHealth agency will not pay a provider and will recover any payments to a provider if it determines that, among other things, the provider has not made such diligent efforts. Under no circumstances may a provider bill a member for any amount for a MassHealth-covered service, except as provided by 130 CMR 450.130.

MassHealth members who have Medicare and MassHealth are known as "Dual Eligibles." Federal and state requirements provide that MassHealth is a payer of last resort for any MassHealth member with other insurance – including Dual Eligibles. That means that a provider must obtain payment from other liable parties, including Medicare, before billing MassHealth. Thus, this request for prior authorization for a drug, covered by both Medicare and MassHealth, was properly billed as a Medicare Part D claim.

The denial of a prior authorization of the requested drug is a Medicare Part D denial. Although the appellant's attorney argues that the hearing officer should view the prior authorization under the MassHealth authorization process, the hearing officer declines to do so. The denial clearly states that this is a Medicare Part D denial. The appellant has appealed this denial as though it were a denial of Medicare Part D claim throughout both the internal review and CMS IRE review process.

The contract explicitly states that appeals of Medicare Part D denials may not be filed at the Board of Hearings. Thus, this appeal is not properly before the Board of Hearings and is **DISMISSED.**

It is worth noting that, even if this appeal had not been dismissed, the evidence offered in support of authorizing this drug for off-label use was not compelling. During the record open period, the appellant was allowed to produce a letter from the appellant's treating physician in support of authorizing the medication. The letter failed to address the fact that the treating physician is seeking coverage for a drug not approved by the FDA for the appellant's condition. The appellant's treating physician did not include any studies or research that would support the

authorization for this drug to be used off-label for the appellant's physical condition. For those reasons, the letter of medical necessity was insufficient.

Order for MassHealth

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.

Alexis Demirjian
Hearing Officer
Board of Hearings

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

Appellant Representative: [redacted]