# Office of Medicaid
# BOARD OF HEARINGS

**Appellant Name and Address:**

[redacted]

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| **Appeal Decision:** | Denied | **Appeal Number:** | 2403677 |
| **Decision Date:** | 5/30/2024 | **Hearing Date:** | 04/17/2024 |
| **Hearing Officer:** | Christopher Jones | | |

**Appearances for Appellant:**
Pro se
[redacted]

**Appearances for MCO:**
Cassandra Horne – Appeals and Grievances Manager
Jeremiah Mancuso, RN – Clinical Nurse for Appeals
Dr. David Melo – Senior 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

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| **Appeal Decision:** | Denied | **Issue:** | Managed Care Organization; Denial of Internal Appeal; Medical Procedure |
| **Decision Date:** | 5/30/2024 | **Hearing Date:** | 04/17/2024 |
| **MCO's Reps.:** | Cassandra Horne; Jeremiah Mancuso; Dr. David Melo | **Appellant's Reps.:** | Pro se; wife |
| **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 of Denial of Level 1 Appeal dated March 1, 2024, Commonwealth Care Alliance's One Care plan ("CCA" or the "MCO") denied the appellant's prior authorization request for Intracept heat destruction of nerves in lower spine. (Exhibit 1, pp. 6-11.) The appellant filed this appeal in a timely manner on March 8, 2024. (Exhibit 1; 130 CMR 610.015(B).) Denial of assistance by a managed care contractor is grounds for appeal. (130 CMR 610.032(B).)

## Action Taken by the MCO

CCA denied the appellant's medical procedure because it considers the Intracept "procedure to be investigational (unproven) and experimental."

## Issue

The appeal issue is whether CCA was correct, pursuant to 130 CMR 450.204 and 433.404(B), in determining that the appellant's requested procedure was not medically necessary because it is "experimental."

## Summary of Evidence

The appellant is a MassHealth member who is enrolled in Commonwealth Care Alliance's One Care plan. CCA is a managed care organization administering Medicaid benefits on behalf MassHealth, and the One Care plan is an integrated care plan that helps coordinate both Medicare and Medicaid benefits for enrolled members. (See Exhibit 7.) On January 22, 2024, a prior authorization request for the Intracept procedure (CPT Code 64628) was submitted to CCA, which was denied the following day. (Exhibit 6, pp. 18, 87.) On February 1, 2024, an internal appeal was filed with additional information from the appellant's physician. (Exhibit 6, p. 99-137.)

The appellant's physician described the Intracept procedure as filling "a treatment gap for those patients that do not receive adequate relief from traditional conservative methods and do not have instability to indicate fusion is the appropriate treatment. [The appellant] has tried and failed conservative treatment without relief." (Exhibit 6, p. 100.) The appellant's physician also disputes the characterization of the Intercept procedure as "experimental and investigational." "The physician writes:

> [T]here is sufficient science published in peer-reviewed publications. This procedure improves the quality of life of patients suffering from vertebrogenic low back pain. The lntracept Procedure, not just the device received Initial FDA clearance the summer of 2016. That clearance means the procedure is safe and effective.

(Exhibit 6, p. 100.)

The appellant's physician also attached a document entitled, "lntraosseous Basivertebral Nerve Ablation Evidence Summary" (Oct. 03, 2023). This publication included a bibliography listing 61 publications, and a secondary bibliography listing 39 publications was also attached. (Exhibit 6, pp. 121-137.) This letter, medical records, and publication were also submitted to the Board of Hearings as the appellant's hearing exhibit. (Exhibit 4.)

The appellant's medical record is undisputed. He is a [redacted] male with a history of chronic low back pain. He has received a variety of treatments in the past and works with a chiropractor. He no longer attends physical therapy. He is prescribed pain medication, and he has received spinal injections in the past, which have alleviated his leg pain, but has not significantly improved his back pain. The appellant has "Modic changes" to his L2, L3, L4 and S1 vertebrae, but he does not have significant stenosis. (Exhibit 6, pp. 162-163.)

CCA's representatives testified that there have been some promising studies showing that the Intracept procedure would be helpful with the appellant's condition, but that the evidence is still developing. Specifically, they argued that there are no independent, long-duration studies. The only study to provide the clearest evidence was produced by the device manufacturer and is suspect as biased. They testified that the evidence is progressing, and that they have been looking at the procedure a lot over the last few years, however the consensus is still that the evidence is

not quite there yet. They noted that both the Centers for Medicare and Medicaid Services and MassHealth prohibit coverage for experimental and investigational treatment. They argue that there is not sufficient evidence that the appellant would have a beneficial outcome from this procedure.

CCA's exhibits include its criteria regarding how to determine whether procedures are considered "experimental, investigational, and unproven." (Exhibit 6, pp. 47-82.) This document includes a list of procedures considered "experimental," along with a date the literature was last reviewed. Procedure codes 64628 and 64629, for "[t]hermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral (Intracept)" were last reviewed on February 21, 2023, and continued to be deemed experimental, investigational, and unproven. (Exhibit 6, p. 54.) CCA's exhibit also includes an independent, utilization review case report that opines "further study is required to determine the safety, effectiveness, toxicity, maximum tolerated dose, and efficacy of the [Intracept procedure]. It is generally not the standard therapy; therefore, it is not accepted by the professional medical community." (Exhibit 6, p. 178.)

The appellant asked what he was supposed to do instead, and he was referred back to his medical care team. The appellant and his wife testified that they have tried alternatives, and there has been very little success. The appellant did not want to be on pain medication forever, and his chronic pain is a significant detriment to his quality of life. The appellant's wife argued that he should be allowed to take the chance, and she testified that he can only stand for around 10 minutes at a time now. This procedure was recommended because it was significantly less invasive than a fusion procedure, and they were told that if they went forward with the fusion, they could not come back later and try this. However, if this failed, they could still move forward with the fusion. (See also Exhibit 6, p. 105.)

# Findings of Fact

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

1) The appellant is enrolled in Commonwealth Care Alliance's One Care plan, an integrated care plan that manages his Medicare and Medicaid benefits. (See Exhibit 7; testimony by CCA's representatives.)

2) The appellant is a [redacted] man with chronic low back pain. He works with a chiropractor and has tried a variety of medical interventions in the past, including physical therapy, pain medication, and spinal injections (Testimony by CCA's representatives; Exhibit 6, pp. 13-16.)

3) On January 22, 2024, a prior authorization request for the Intracept procedure was submitted to CCA, which was denied the following day. (Exhibit 6, pp. 18, 87.)

4) On February 1, 2024, an internal appeal was filed with additional information from the appellant's physician. (Exhibit 6, p. 99-137.)

5) Through a Notice of Denial of Level 1 Appeal dated March 1, 2024, CCA denied the appellant's internal appeal for the Intracept procedure. (Exhibit 1, pp. 6-11.)

6) CCA does not cover the Intracept procedure, citing that it is "experimental" based upon the state of published studies and the coverage criteria of Medicare and Medicaid. (Testimony by CCA's representatives; Exhibit 6, pp. 47, 54, 178.)

# Analysis and Conclusions of Law

Also referred to as "One Care plans," Integrated Care Organizations ("ICO") are a program under the Duals Demonstration program for individuals eligible for both Medicare and Medicaid. Members select their ICOs and are eligible to change ICOs or disenroll from the Duals Demonstration program entirely. (See 130 CMR 508.007.) Members may be automatically enrolled in an ICO if they disenroll from the ICO without disenrolling from the Duals Demonstration program. (130 CMR 508.007(D).) Members enrolled in a managed care provider are entitled to a fair hearing under 130 CMR 610.000 to appeal a determination by an MCO if the member has exhausted all remedies available through the contractor's internal appeal process. (130 CMR 508.010.)

Typically, MassHealth and ICOs must cover any service that is deemed "medically necessary." The regulatory definition of "Medical Necessity" is:

> (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*.

(130 CMR 450.204(A).)

MassHealth's regulations further identify that "[a]dditional 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).) One such requirement is that MassHealth "does not pay a physician for performing, administering, or dispensing any experimental, unproven, cosmetic, or otherwise medically unnecessary procedure or treatment." (130 CMR 433.404(B).) CCA's Member Handbook echoes this restriction. (See Exhibit 7, pp. 114.)

This appeal poses the question of what qualifies as an "experimental" medical procedure. The Board of Hearings has a highly circumscribed jurisdiction. (See 130 CMR 610.032.) A fair hearing decision must be "based upon evidence, testimony, materials, and legal rules, presented at the hearing, including the MassHealth agency's interpretation of its rules, policies, and regulations." (130 CMR 610.082(A); see also 610.065(A)(7).) Furthermore, a fair hearing decision is limited to "the parties to that case and cannot be disputed again between them in any other administrative proceeding nor used as binding precedent by other parties in other proceedings." (130 CMR 610.085(A)(2).)

There is no clearly defined standard of review in the regulations for deciding when medical care is "experimental." The structure of the Board of Hearings indicates that hearing officers are not intended to set policy that would be widely applicable to MassHealth members.[1] CCA regularly reviews the state of evidence regarding medical advancements, and in February 2023 determined the Intracept procedure remained unproven. The fact that the Intracept procedure appears to be more widely covered and accepted indicates that it is moving toward being incorporated into the widely held standard of care. However, at this time, there is no reason to overturn MassHealth and CCA's determination of this procedure as experimental, and therefore not "medically necessary."

For these reasons, this appeal is DENIED.

# Order for CCA

None.

[1] There is no published guidance by MassHealth governing the Intracept procedure. Further, Medicare does not appear to cover this procedure in Massachusetts. The Medicare Local Coverage Determination ("LCD") DL39642 was finalized on January 28, 2024, approving coverage for Intraosseous Basivertebral Nerve Ablation in California, Nevada, Hawaii, American Samoa, and the Northern Mariana Islands. It is not effective in Massachusetts. (Available at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39642&ver=6; last visited May 21, 2024.)

## 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 Jones
Hearing Officer
Board of Hearings

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

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