Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2402938
Decision Date:	5/23/2024	**Hearing Date:**	04/17/2024
Hearing Officer:	Christopher Jones		

Appearances for Appellant:
Pro se
[redacted]

Appearances for MCO:
[redacted]

Observing from MassHealth:
Elana Horwitz, MPH - Senior Contract Manager

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; Medical Procedure
Decision Date:	5/23/2024	**Hearing Date:**	04/17/2024
MCO Reps.:	[redacted]	**Appellant's Reps.:**	[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 letter dated January 10, 2024, Tufts Health Plan ("Tufts" or the "MCO") denied the appellant's internal Standard Appeal for coverage of an Intracept procedure. (Exhibit 1; Exhibit 6, pp. 237; 130 CMR 450.204.) Tufts Health Plan is a managed care organization acting on behalf MassHealth in administering benefits. The appellant filed this appeal in a timely manner on February 23, 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

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

Issue

The appeal issue is whether Tufts 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 Tufts Health Plan Together. Tufts Health Plan is a managed care organization administering Medicaid benefits on behalf MassHealth, and the appellant is enrolled with UMass Memorial Health as his primary care accountable care organization.[1] (See Exhibit 7.) On November 21, 2023, an initial request for coverage of the Intracept procedure was submitted to Tufts, which was denied the following day. On December 13, 2023, a Standard Appeal was filed internally with Tufts. On January 9, 2024, a utilization review team met to discuss the appealed denial and upheld the denial.

The requested procedure is the "[t]hermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance, first two vertebral bodies, lumbar or sacral," due to the appellant's "[v]ertebrogenic low back pain - low back pain, vertebral endplate pain … [s]pondylosis [without] myelopathy or radiculopathy, lumbosacral region." (Exhibit 6, p. 16.) This procedure was requested due to the appellant's

> chronic history of low back pain that began more than [eight] years ago. … To address his pain, he has had the following treatments: facet injections; lumbar epidural steroid injections, medial branch block injections and radiofrequency ablations. Medications have included: Acetaminophen, Advil, Celebrex, Celecoxib, Duloxetine, Gabapentin, Ibuprofen, Motrin, Prednisone, Tramadol and Tylenol. The pain has had a significant impact upon [activities of daily living] such as: bending/lifting, climbing stairs, standing, twisting, walking and work. Nothing has provided significant sustainable relief. His condition has been characterized by a VAS score of 5/10.
>
> He had an MRI performed on 8/30/2023. [redacted] review demonstrates Modic changes in the L5 and S1 vertebral bodies, which is the primary cause of the patient's chronic, vertebrogenic low back pain.

(Exhibit 6, p. 24.)

The Intracept procedure is described as an "Intraosseous Nerve Ablation System" that uses radiofrequency to ablate the basivertebral nerve and thereby eliminate pain signals from the endplates of a targeted vertebral body. (See Exhibit 6, pp. 29, 88.) The procedure is specifically limited to patients whose chronic lower back pain is objectively documented by an MRI showing "Modic type 1 or Modic type 2 changes," and excludes "patients with symptomatic spinal stenosis, radiculopathy, disc protrusion, or spondylolisthesis … ." (Exhibit 6, p. 89.) Tufts denied coverage because it has currently determined that the Intracept procedure is "investigational (unproven)

[1] A representative from MassHealth's MCO Contract Management department was an observer during this hearing.

and experimental." (See Exhibit 6, p. 129.) Tufts identified 130 CMR 433.404(B) as the relevant MassHealth regulation that excludes experimental medical procedures from coverage.

Furthermore, Tufts Member Handbook states:

> **Evaluating experimental and/or investigational drugs and procedures**
>
> Experimental and/or investigational drugs and procedures are new kinds of treatment. We decide whether to cover new drugs and procedures based on scientific evidence and what doctors and other clinicians recommend.
>
> As new technologies come up, we have a process to consider whether or not to cover new (experimental) procedures, including clinical trials. Before we decide to cover new procedures, equipment and prescription drugs, we look at how safe they are and how well these treatments work. For a list of non-covered experimental and/or investigational drugs and procedures, go to tuftshealthplan.com.

(Exhibit 7, p. 24.)

Under the "Covered Services List," the handbook states:

> **Excluded Services**
>
> The following services or supplies are not covered under MassHealth, unless they are medically necessary, or as noted.
>
> …
>
> • Experimental treatment
>
> …
>
> • Services not otherwise covered by MassHealth, except as determined by the contractor to be medically necessary for MassHealth Standard or MassHealth CommonHealth members under age [redacted].

(Exhibit 7, p. 92.)

The appellant's representative, [redacted] disputed this characterization of the treatment as experimental or unproven. [redacted] is an Assistant Professor of Anesthesiology and Medical Director of the Spine Center at UMass Memorial Medical Center. He objected to the qualifications of the doctors who reviewed this procedure for Tufts and argued that they lacked the expertise to provide opinions regarding this procedure's efficacy. The appellant submitted multiple studies with his appeal that supported the argument that the Intracept nerve ablation procedure was both safe and effective. There have been at least four studies, including two randomized control studies, that demonstrate that this is not an experimental procedure. He testified that the procedure is FDA cleared, and it is now recommended by the North American

Spine Society, the American Society of Pain and Neuroscience, and the International Society for the Advancement of Spine Surgery.

[redacted] has been performing the procedure for two-and-a-half years, and he has seen patients receive immediate and lasting relief. He testified that because the procedure is minimally invasive, it is much lower risk than jumping directly to a spinal fusion, and in the appellant's situation, a fusion surgery is not indicated because the appellant does not have stenosis.[2] Therefore, he believes that this is the only procedure available to treat the appellant's chronic low back pain.

[redacted] acknowledged that neither he, nor the physician to initially deny coverage, are specialists in the field of spine surgery or pain management. However, he explained the process through which these claims are reviewed. A medical policy committee reviews various procedures on an annual basis. He testified that he sits on the committee and keeps apprised of the medical literature. They also request opinions from practicing experts in the field. He attended a 25-minute discussion regarding the procedure during the last review, which involved a physiatrist. The review discussion and decision also relied upon the independent opinions of two physiatrists who are the heads of spinal departments at major Boston hospitals, as well as an independent literature review and analysis completed by Hayes, a company that provides literature review and recommendations regarding the evidence for medical technologies and procedures.

The Hayes report is entitled "Intracept Intraosseous Nerve Ablation System (Relievant Medsystems Inc.) for Treatment of Adults with Low Back Pain," and it was published on October 24, 2022. (Exhibit 6, pp. 85-140.) The Hayes report summary is that:

> Clinical studies consistently indicate benefits compared with baseline in patient-oriented outcomes after treatment with the Intracept System for [chronic low back pain] with vertebrogenic origin at up to 5 years of follow-up. One randomized controlled trial (RCT) reported statistically, but not clinically, significantly greater reductions in pain following treatment with Intracept versus sham; however, data did not convincingly indicate functional advantages over sham. A second RCT did find short-term treatment advantages over continued standard care; however, given a placebo response observed in the sham-controlled RCT, the findings of this open-label study should be interpreted carefully. Although 1 spine specialty society noted Intracept may be considered for the treatment of [chronic low back pain], no other guidance documents were identified.

[2] There does appear to be "moderate to moderately severe spinal stenosis" at vertebrae L3-4. (Exhibit 6, p. 78.) It is possible [redacted] was simply referring to stenosis at the vertebrae eligible for intraosseous basivertebral nerve ablation at L5 and S1.

(Exhibit 6, p. 86.)

Based upon its review of the literature, Hayes determined there was "minimal" support to be found in the clinical studies or systematic reviews, and "weak support for" the Intracept procedure in the existing clinical guidelines. (Exhibit 6, p. 86.) Though the report finds that studies "consistently report pain relief, functional improvement, and improved quality of life," those studies were of "generally fair to poor quality" because there were only two studies with control groups, and one of those studies crossed over the control group into the treatment group after only three months. The other study was manufacturer-funded, which raised a red flag for high potential for bias. (See Exhibit 6, pp. 86, 123.)

An independent clinical review was also completed on December 27, 2023, by an independent physician who is board certified in Anesthesiology and Pain Medicine. Dr. Dohan explained that this "MCMC" report comes through a company that hires consultants to perform utilization review supplementary to their active practice in the relevant clinical field. He testified that MCMC physicians cannot receive more than five percent of their income from utilization reviews, such as this. This review shows a three-part review, including: 1. Is the device FDA approved; 2. Have "all other appropriate covered therapies … been tried/failed or [is there] a clinical counterindication for them (supported by clinical documentation & literature); and 3. Are there "credible peer reviewed studies (studies used in the FDA approval process are acceptable) where the member shares all the characteristics of the studied population."[3] (Exhibit 6, p. 232.)

The report defines the "Intracept® Intraosseous Nerve Ablation System" as

> a radiofrequency (RF) ablation system for use in ablation of the basivertebral nerves (BVN) of the L3 through S1 vertebrae, intended to relieve chronic low back pain of at least 6 months' duration that has not responded to at least 6 months of conservative care. This is considered to be Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT).

(Exhibit 6, p. 233.)

The report states that "only a few [randomized control trials] have evaluated FDA-cleared devices for PIRFT and, in their primary analyses ([intention-to-treat] when available), these have not found that PIRFT provides statistically and clinically significant benefits. Studies were generally limited by small sample sizes and relatively short-term comparative follow-up. Medical necessity is not met as the requested procedure is not the most appropriate level of service that can be safely provided to

[3] The steps of review are confusing. The reviewer states that the appellant meets steps one and three but has not tried and failed all other appropriate covered therapies. However, the substance of the report appears solely to object to the credibility of the peer reviewed studies, which is reflected under step 3.

the patient. The report reviews the shortcomings of the two studies. One was industry-funded and lacked a control group. The other study was halted early to allow the control group to cross over into the treatment group. The reports concludes that although Intracept "may appear promising, additional studies/trials are necessary to determine efficacy as compared to other conventional therapies. The requested procedure would be considered investigational." (Exhibit 6, p. 234.) There are no alternative, untried treatments identified.

[redacted] argued randomized control trials for a surgical procedure are extraordinarily expensive and difficult to conduct, not to mention ethically dubious. He noted that the study that allowed the control arm to cross over did so because the benefits of the procedure were so remarkable in the treatment arm. The way additional evidence for new procedures like this develop are by there being more patients to receive the treatment. In order for that to happen, more insurers need to cover the treatment so that it can be performed. His opinion is that the same studies reviewed by Hayes and the physician from MCMC establish that this is no longer an experimental procedure.

The parties agreed that there is no single organization that determines when a treatment is no longer experimental. It is essentially determined on an insurer-by-insurer basis. The parties also agreed that FDA clearance for devices is a very different process than FDA approval for medications, and the FDA does not establish whether a medical device or procedure is no longer experimental, only whether the device is safe to use in a procedure. There was at least one insurer in Massachusetts that covers the procedure, but they were not a MassHealth MCO.[4] Further, [redacted] stated that there is Medicare coverage, but not in Massachusetts. Several other insurers were claimed to have proposed coverage decisions pending, and the parties believed that there was a proposed Local Coverage Determination ("LCD") for Medicare to cover the procedure as well.[5]

Tufts' representatives argued that proposed LCDs are not used as determinative guidelines until they are finalized. They explained that is why they rely heavily on outside physicians and experts, who often disagree and go against their initial decisions. [redacted] testified, however, that there has not been a single opinion in the past year that has recommended this procedure. They

[4] [redacted] also disputed whether the appellant's clinical presentation would have qualified for that insurer's coverage criteria. [redacted] disputed this assessment, but neither party was prepared to document another insurer's coverage criteria at the hearing.

[5] A quick internet search during the appeal turned up Proposed LCD DL39642, which was identified for the parties. Upon further review, this LCD 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.)

conceded that if there were a final LCD applicable to Massachusetts, they would likely follow the criteria set out therein.

The appellant testified that he has chronic back pain, and he would do anything to relieve it. He was open to suggestions, and asked what alternative treatments are available. [redacted] argued that the only other treatment available is spinal cord stimulation, which is an invasive procedure with an implant. He felt that it would be less effective, more expensive, and a significantly higher risk than the Intracept procedure. In a few years, if the appellant developed stenosis, he would be eligible for a spinal fusion, which he felt would be way more expensive with much less benefit. [redacted] was unable to provide medical advice to the appellant, as he is not the appellant's treating physician, but he noted that just because there is a procedure, does not mean that procedure going to make you better.

Findings of Fact

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

1) The appellant is a MassHealth member who is enrolled with Tufts Health Plan, a managed care organization administering MassHealth benefits. His particular benefits are provided through the primary care, accountable care organization UMass Memorial Health. (Testimony by Tufts representatives; Exhibits 6; 7.)

2) The appellant has suffered from chronic lower back pain for over eight years, and he has documented Modic changes in vertebrae L5 and S1. He does not have stenosis at those vertebrae. He has attempted multiple forms of treatment with diminishing effectiveness. (Exhibit 6, pp. 24, 77-78; Testimony by [redacted])

3) On November 21, 2023, the appellant's provider requested coverage of "[t]hermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance, first two vertebral bodies, lumbar or sacral," also known as the Intracept procedure, due to the appellant's "[v]ertebrogenic low back pain - low back pain, vertebral endplate pain … [s]pondylosis [without] myelopathy or radiculopathy, lumbosacral region." (Exhibit 6, p. 11, 16.)

4) On November 22, 2023, Tufts denied the request, stating that the Intracept procedure is "investigational (unproven) and experimental." (See Exhibit 6, p. 129.)

5) Tufts Health Plan reviews developing medical technology on an annual basis to determine coverage. With regard to vertebral nerve ablation, Tufts relied upon the independent opinions of two physiatrists who are the heads of spinal departments at major Boston hospitals, as well as an independent literature review and analysis completed by Hayes in October 2022. (Testimony by [redacted])

6) An independent physician who is board certified in Anesthesiology and Pain Medicine completed a utilization review consultation on December 27, 2023. (Exhibit 6, pp. 232-235.)

7) The Hayes report and the independent consultant both concluded that the available studies of intraosseous basivertebral nerve radiofrequency ablation do not yet establish statistically and clinically significant benefits. (See Exhibit 6, pp. 86, 233-234.)

8) The appellant relies upon the same studies and reports that were reviewed by Hayes and the independent physician, but disagrees with their conclusions. The appellant also highlights that there are recent medical society supports for these procedures. (Testimony by [redacted])

9) There are some insurers in Massachusetts who have started to cover the Intracept procedure under limited circumstances, but it is not widely covered as non-experimental in Massachusetts by insurance companies or Medicare. (Testimony by [redacted] and [redacted])

Analysis and Conclusions of Law

MassHealth members who do not have another form of insurance are generally enrolled in a managed care organization. (See 130 CMR 508.001; 508.002; see also 130 CMR 450.105.) Managed care organizations provide "management of medical care, including primary care, behavioral health services, and other medical services" for enrolled members. (130 CMR 450.117(B).) Members enrolled in a managed care provider are entitled to a fair hearing under 130 CMR 610.000 to appeal a determination by an Accountable Care Organization ("ACO") if the member has exhausted all remedies available through the contractor's internal appeal process. (130 CMR 508.010.)

Typically, MassHealth and MCOs 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).) Tufts Member Handbook, issued to the appellant, echoes this restriction. (See Exhibit 7, pp. 24, 92.)

This appeal centers on 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.[6] Tufts has developed a non-arbitrary process by which it regularly reviews the state of evidence regarding medical advancements. The fact that the Intracept procedure appears to be more widely covered and accepted indicates that it may be moving toward being incorporated into the widely held standard of care. However, at this time, there is no reason to overturn MassHealth and Tufts' denial of this procedure as experimental, and therefore not "medically necessary." For these reasons, this appeal is DENIED.

Order for Tufts Health Plan

None.

[6] The fact that a representative of MassHealth observed this hearing further indicates that if MassHealth wishes the Intracept procedure to be considered non-experimental, MassHealth can change its coverage policy regarding it.

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: Tufts Health Plan, Attn: [redacted] Program Manager, Appeals & Grievance, 1 Wellness Way, Canton, MA 02021, 617-972-9400
MassHealth Representative: Elana Horwitz, MPH, Office of Accountable Care and Behavioral Health – MassHealth
[redacted]