Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2408286
Decision Date:	9/16/2024	**Hearing Date:**	8/7/2024
Hearing Officer:	Cynthia Kopka		

Appearance for Appellant:
Pro se

Appearances for Respondent:
John Shinn, Esq.
Dr. Thomas Amoroso

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 – prior authorization
Decision Date:	9/16/2024	**Hearing Date:**	8/7/2024
Respondent's Reps.:	John Shinn, Esq.; Dr. Thomas Amoroso	**Appellant's Rep.:**	Pro se
Hearing Location:	Quincy (remote)	**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

By notice dated May 9, 2024, Tufts Health Plan, a MassHealth Accountable Care Organization (ACO) (hereinafter, "Tufts" or "Respondent"), denied Appellant's appeal seeking prospective coverage of an INTRACEPT® Intraosseous Nerve Ablation System procedure. Exhibit 1. Appellant filed a timely appeal to the Board of Hearings (BOH) on May 22, 2024. Exhibit 2. 130 CMR 610.015(B). Denial of assistance is a valid basis for appeal. 130 CMR 508.010(B), 130 CMR 610.032(B).

Action Taken by Respondent

Tufts denied Appellant's request for prospective coverage of an Intracept procedure.

Issue

The appeal issue is whether Tufts was correct in denying Appellant's request for prospective coverage of an Intracept procedure.

Summary of Evidence

Respondent was represented at hearing by phone by an attorney and medical director. Respondent submitted records in support, Exhibits 4-6. Appellant appeared by phone. A summary of testimony and records follows.

Appellant is enrolled in Tufts Health Plan Together, a MassHealth Accountable Care Organization (ACO) which acts as an agent of MassHealth and must follow all MassHealth regulations. Appellant is in her [redacted] and has a medical history including chronic lower back pain. Exhibit 4 at 22, 31. On March 25, 2024, Respondent received a request for prior authorization of INTRACEPT® Intraosseous Nerve Ablation System ("Intracept procedure") to address Appellant's low back pain. The complete request, with letter of medical necessity, medical records, and literature in support is included in Exhibit 4 at 14-93. Respondent's representative testified that the procedure involves radiofrequency ablation (or RFA), which is the destruction of the basivertebral nerve (BVN) for purposes of reducing or eliminating pain in the low back. The Intracept procedure is one type of methodology for performing RFA.

On March 26, 2024, Respondent denied coverage of the Intracept procedure, as the service is considered experimental/investigational; and therefore, not medically necessary and excluded from coverage. Exhibit 4 at 11, 144. The denial states:

> the services you requested do not meet the guidelines above because this procedure is considered to be investigational and experimental in clinical trials and therefore not a covered benefit. Tufts Health Plan restricts coverage to those devices, treatments, or procedures for which the safety and efficacy have been proven, and which are comparable or superior to conventional therapies. Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered investigational (unproven) and is excluded from coverage.

Id. at 144.

On April 8, 2024, Appellant's case manager submitted an appeal for coverage of the Intracept procedure. *Id*. at 158. The full appeal is included in Exhibit 4 at 153-232 and contains medical records and literature published in medical journals.

On April 29, 2024, an outside reviewing entity, [redacted] reviewed the appeal and upheld the denial on the basis that coverage of the Intracept Procedure is considered experimental and investigational for Appellant based on the Noncovered Investigational Services list and the definition of experimental and investigational included in this case. *Id*. at 255. On May 7, 2024, the appeal was reviewed by the Tufts Health Plan's Utilization Review (UR) Appeals Committee and a decision was made to uphold the denial. *Id*. at 11, 253. On May 9, 2024, Respondent notified Appellant that her appeal was denied on the basis that the procedure does not meet guidelines because the service is investigational and experimental. *Id*. at 259.

Respondent's representative testified that the Intracept procedure is listed on Respondent's Medical Necessity Guidelines – Noncovered Investigational Services, meaning the service is experimental/investigational, and therefore not covered. *Id*. at 94, 100. Respondent's representative testified that these guidelines are reviewed annually and when a procedure is requested, involve meetings with medical specialists. Additionally, [redacted] a company that performs reviews of medical technology, has issued evolving evidence review of the Intracept procedure. *Id*. at 101-140. Respondent testified that per the [redacted] report, there is not sufficient evidence to support routine use of the Intracept technology for treatment of low back pain. Respondent's representative testified that the [redacted] report included review of the articles and literature submitted by Appellant's provider in support of the request, finding that the clinical studies and systematic reviews were minimal and offered weak support for the Intracept procedure. *Id*. at 102.

Respondent's representative testified that he agrees with the basis for denial, having reviewed the literature and spoken to specialists in the field. Respondent's representative argued that there were conflicts of interest in the case studies and publishing favoring the Intracept manufacturer. In summary, the evidence presented regarding the effectiveness of the Intracept procedure was insufficient in amount and in quality to indicate that it is a safe and effective treatment of low back pain for Appellant.

Appellant testified that she has been experiencing pain for years. In 2011, she learned she has degenerative disc disease (DDD), but she was not able to care for herself as she was raising four children. Now that her youngest child is grown, she can finally care for herself. Appellant experiences extreme and constant pain in her low back which limits her life. Appellant cannot sit or stand without pain. Appellant is unable to put on socks or shoes or bathe without assistance. Appellant would not be able to run out of the house if there was a fire. If she drops something at a store, she has to ask a stranger for help. Appellant walks with a hunch. Appellant is desperate for help with her pain so she can live her life. Appellant has done physical therapy and had epidural steroid injections without relief. Appellant has personal care attendants (PCAs) help her with her daily tasks. Appellant cannot sleep more than a couple of hours at a time due to pain. Appellant is miserable.

Appellant argued that the Intracept procedure has been around for years and has helped people. It is a one-time procedure that can offer relief for over 5 years. Appellant researched the procedure and learned that it directly addresses Appellant's symptoms regarding her inability to sit, stand, or bend. This convinced Appellant that the Intracept procedure is the service she needs. Appellant's mother had back surgery and a metal plate put in her back, and she can no longer walk. Appellant wants to be able to live her life. Appellant testified that her doctor performed a test with six needles to determine if the Intracept procedure could be done. Appellant testified that she has nerve damage, so she believes an RFA of the nerve will be beneficial.

Appellant testified that her physician did not discuss alternative procedures with her. In her research, Appellant reviewed videos depicting individuals who were happy and mobile even five years after the surgery. Appellant dislikes shots and does not want to be addicted to medicine. Appellant uses Lidocaine patches, but they only work for a few hours. Other medicine that her doctors have prescribed did not work in the slightest. Appellant argued that the Food and Drug Administration (FDA) approves medicine like Humira which is horrible and causes disease. Appellant argued that the FDA approves things that are unhealthy and make people worse and does not understand why something that could help her would not be approved.

Respondent's representative testified that while the Intracept procedure is not covered as being investigational and experimental, RFA procedures are a standard medical process. Other mechanisms of RFA have been sufficiently studied and determined to be safe and effective. Examples of these procedures are listed in Exhibit 4, page 106-107. Respondent's representative testified that medical records submitted with the request did not articulate why the approved methods of RFA were ruled out for Appellant. Appellant asked Respondent's representative what the difference is with these approved procedures and the Intracept procedure and whether there was a need for multiple operations, which Respondent's representative was not able to answer. Appellant mentioned that she would try to get a second opinion.

Findings of Fact

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

1. Appellant is a member of Tufts Health Plan Together, a MassHealth ACO.

2. Appellant is in her [redacted] and has a medical history including chronic lower back pain. Exhibit 4 at 22, 31.

3. On March 25, 2024, Respondent received a request for prior authorization for the Intracept procedure to address Appellant's low back pain, with a letter of medical necessity, medical records, and literature in support. *Id*. at 14-93.

4. On March 26, 2024, Respondent denied coverage of the Intracept procedure, as the service is considered experimental/investigational; and therefore, not medically necessary and excluded from coverage. *Id*. at 11, 144.

5. On April 8, 2024, Appellant's case manager submitted an appeal for coverage of the Intracept procedure. *Id*. at 153-232.

6. On April 29, 2024 a physician specializing in pain management and anesthesiology from [redacted] reviewed the appeal and upheld the denial on the basis that coverage of the

Intracept Procedure is considered experimental and investigational for Appellant based on the Noncovered Investigational Services list and the definition of experimental and investigational included in this case. *Id*. at 255.

7. On May 7, 2024, Respondent's UR Appeals Committee decided to uphold the denial. *Id*. at 11, 253.

8. On May 9, 2024, Respondent notified Appellant that her appeal was denied on the basis that the procedure does not meet guidelines because the service is investigational and experimental. *Id*. at 259.

9. Appellant filed this timely external appeal with the Board of Hearings on May 22, 2024. Exhibit 2.

10. Tufts' Medical Necessity Guidelines – Noncovered Investigational Services lists the Intracept procedure. *Id*. at 94-100.

Analysis and Conclusions of Law

MassHealth members younger than [redacted] years old, except those excluded under 130 CMR 508.004, must enroll in the Primary Care Clinician (PCC) Plan or a MassHealth-contracted MCO available for their coverage type. 130 CMR 450.117(A) and 130 CMR 508.002.[1] MassHealth members enrolled in MassHealth-contracted managed care plans may request a fair hearing pursuant to 130 CMR 610.000 *et seq.* and appeal a determination made by an ACO if the member has exhausted all remedies available through the contractor's internal appeals process. 130 CMR 508.010(B).

Pursuant to MassHealth regulation 130 CMR 450.204, MassHealth will not pay a provider for services that are 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,

[1] When a member is eligible for managed care, the member may elect to enroll in a Primary Care ACO by selecting a Primary Care ACO and available PCP that participates in the selected Primary Care ACO. 130 CMR 508.006(B)(1). If a member is enrolled in a Primary Care ACO, the member's selected or assigned PCP will deliver the member's primary care, determine if the member needs medical or other specialty care from other providers, and make referrals for such necessary medical services. 130 CMR 508.006(B)(2)(a). All medical services, except those provided by the PCP or exempted by regulation, require a referral or authorization from the member's primary care provider. 130 CMR 450.119(I)(1) and 130 CMR 508.006(B)(2)(b).

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*.

(B) Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality. A provider must make those records, including medical records, available to the MassHealth agency upon request. (*See* 42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)

(C) A provider's opinion or clinical determination that a service is not medically necessary does not constitute an action by the MassHealth agency.

(D) Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.

(E) Any regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative evidence that such service is reasonably calculated to have the effect described in 130 CMR 450.204(A)(1).

130 CMR 450.204.

Tufts Health Plan has established medical necessity guidelines, including its list of Noncovered Investigational Services applicable to members of Tufts Health Plan Together. Exhibit 4 at 95. Per these guidelines, updated as of January 1, 2024,

> a treatment or procedure is considered investigative or unproven if reliable evidence shows that the treatment is "under study to determine its safety, efficacy, toxicity, maximum tolerated dose, or its efficacy as compared with a standard means of treatment or diagnosis". Tufts Health Plan restricts coverage to those devices, treatments, or procedures for which the safety and efficacy have been proven, or where the clinical evidence is such that the treatment is at least as beneficial as any established evidence-based alternatives. Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered investigational (unproven) and therefore not medically necessary and is excluded from coverage.

> To determine whether a device, medical treatment, supply or procedure is proven safe and effective the following hierarchy of reliable evidence is used:
>
> 1. Published formal technology assessments and/or high quality meta analyses
> 2. Well-designed randomized studies published in credible, peer-reviewed literature
> 3. High quality case-control or cohort studies
> 4. Historical control studies, or case reports and/or case series
> 5. Reports of expert opinion from national professional medical societies or national medical policy organizations
>
> With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the referred medical and scientific literature shall be considered reliable evidence. Specifically, not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included is the fact that a provider or a number of providers have elected to adopt a device, medical treatment, or procedure as their personal treatment or procedure of choice or standard of practice.

Id.

Here, Tufts lists the Intracept procedure on its list of services and technology that it considers experimental/investigational and therefore not covered. *Id*. at 95-96, 100. Respondent's representative testified that the literature submitted with Appellant's request for the Intracept procedure is not of the quality required in order to deem the procedure safe and effective.

Appellant's testimony was compelling and sympathetic. She is desperate for relief from the back pain she has suffered for years. Appellant argued that the procedure has been around long enough to demonstrate that it works and that the lack of FDA approval should not be a barrier as there are detrimental drugs and procedures that have been approved. Appellant's records do not indicate that Appellant's physician discussed and/or ruled out other, approved interventions that could be considered to relieve Appellant's pain, including other methodologies of RFA. There is not sufficient evidence that Respondent erred in denying Appellant's request for the Intracept procedure on the basis that it is experimental and investigational, and otherwise not medically necessary in the face of covered alternatives. Accordingly, this appeal is denied.

Appellant is encouraged to explore alternative procedures and technology that are covered by Tufts and can offer her relief.

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.

Cynthia Kopka
Hearing Officer
Board of Hearings

MassHealth Representative: Tufts Health Plan Plan SCO, Attn: Nicole Dally, Program Manager, Appeals & Grievance, 1 Wellness Way, Canton, MA 02021

cc: [redacted]