Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2177659
Decision Date:	12/14/2021	**Hearing Date:**	11/24/2021
Hearing Officer:	Rebecca Brochstein		

Appearances for Appellant:

[redacted]

Appearances for MassHealth/AHP:
Richard DelVecchio, Mgr. Appeals & Grievances
Lily Kam, MD, AHP Medical Director
Christina Joseph, Member Appeals Coordinator
Lakshman Swamy, MH Medical Director
Karen Powell, MH MCO Contract Mgr.

Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street
Quincy, MA 02171

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	Prior Approval
Decision Date:	12/14/2021	**Hearing Date:**	11/24/2021
MCO's Reps.:	Richard DelVecchio Dr. Lily Kam Christina Joseph Dr. Lakshman Swamy Karen Powell	**Appellant's Reps.:**	[redacted]
Hearing Location:	Board of Hearings (Remote)		

Authority

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

Jurisdiction

Through a notice dated August 13, 2021, AllWays Health Partners (AHP), a managed care organization (MCO) which contracts with MassHealth, notified the appellant that it had denied his appeal regarding his request for coverage of the Intracept procedure (Exhibit 1). The appellant filed a timely appeal with the Board of Hearings on September 16, 2021 (130 CMR 610.015(B); Exhibit 2). Denial of a request for services is a valid basis for appeal (130 CMR 610.032).

Action Taken by MCO

AHP denied the appellant's request for coverage of the Intracept procedure.

Issue

The appeal issue is whether AHP was correct in denying the appellant's request for the Intracept procedure.

Summary of Evidence

Representatives from AHP offered the following factual background through testimony and documentary evidence: The appellant is a MassHealth member who is enrolled in an AllWays Health Partners (AHP) managed care program. In or around May 2021, the appellant's provider, Dr. Michael C. Connolly, submitted a prior authorization request for coverage of the Intracept procedure to treat chronic back pain. Dr. Connolly also submitted a letter in support of the request. In his letter he describes the Intracept procedure as "a safe, minimally invasive spine procedure, which uses radiofrequency (RF) to ablate the basivertebral nerve (BVN) and thereby eliminate pain signals from the endplates of a targeted vertebral body." The letter offers the following background information and justification for the request:

> I am writing on behalf of [appellant] to request prior authorization for intraosseous ablation of the basivertebral nerve, which is accomplished with the Intracept Procedure. Having considered all available treatment options for my patient, I consider this procedure to be the most viable treatment to achieve sustainable long-term relief for my patient's chronic low back pain. The Intracept procedure received FDA clearance in 2016.
>
> **Summary of Patient History:**
> [Appellant] is a [male in his late 50s]. He has a history of low back pain that began over one year ago. He has had multiple treatments that included: injections, medication management and physical therapy. The pain has had a significant impact upon ADLs. Medications have included: Gabapentin and Amitriptyline. Nothing has provided significant sustainable relief. He is 5'6" and weighs 179 lbs. with a BMI of 28.89. The severity of pain on the VAS ranges between 7/10 – 9/10.
>
> He had an MRI performed . . . on 9/11/2020. The MRI demonstrated Modic type I changes at L5-S1 disc space. As such, his chronic low back pain is coming from the vertebrogenic changes at L5 and S1.
>
> **Patient's prognosis:**
> [Appellant's] pain is disabling, affects his quality of life on a daily basis and has been of long-term duration. Given that he had failed non-operative treatment, I feel that his only solution is the Intracept Procedure. Nothing is going to abate the pain generated by the basivertebral nerve short of its ablation. If he were to either not have the Intracept Procedure performed or failed to get relief of pain, then the only remaining option is an invasive surgical procedure, which would be less than ideal to try and solve his problem. He would like to avoid this invasive type of surgery. However, he needs relief from his ongoing pain.
>
> The long-term use of NSAIDs and opioids are not ideal given the current opioid substance abuse in our country and the effects they have upon the stomach, liver and kidneys.
>
> **Treatment Recommendation:**

> Given the above history, physical examination, the debilitating nature of his axial pain and radiologic findings, I believe, the Intracept Procedure is medically necessary for my patient. I am requesting that you consider the supportive documentation and benefits that the Intracept procedure provides patients suffering from chronic low back pain. (Exhibit 4 at 36-37)

Dr. Connolly included supporting documents about the Intracept System and provided a summary of several studies which he argued "demonstrate the Intracept procedure to be safe and effective for the treatment of chronic low back pain in appropriately selected patients." See Exhibit 4 at 36-38.

On June 16, 2021, AHP denied the request. Relevant portions of the denial notice include the following:

> We are sending you this letter to inform you that we are unable to approve the request for the [requested] treatment/service because the clinical information provided to AllWays Health Partners does not meet our medical necessity criteria for the following reasons:
>
> **Clinical Information Reviewed**: Per clinical information submitted by the requesting provider, Michael C. Connolly, MD, AllWays Health Partners received a request for intracept procedure and Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance for dates of service June 04, 2021 – September 02, 2021. You are a 59-year-old with severe chronic low back pain. Dr. Connolly proposed a plan for an Intracept procedure for pain control. Clinical notes submitted note changes in your lumbar spine. However, the clinical notes submitted have no formal imaging report, no formal conservative treatment courses and no examination noted.
>
> **Reason Requested Service Does not meet medical necessity criteria**: The request was reviewed against the following medical policy/criteria; Medical Policy Experimental and Investigational Document Number: 026, April 2021. Based upon the clinical information provided, the request does not meet medical necessity guidelines in this criteria. Your case was reviewed by an independent reviewer, Medical Review Institute of America Inc. (MRIOA), This physician reviewer is board certified by the American Board of Neurological Surgery in General Neurological Surgery.
>
> Your condition and the requested medication/service Intracept Procedure and Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance does not comply with the criteria and is not medically necessary or appropriate for you. Your doctor has asked for a procedure used for patients requiring pain control (Intracept procedure). This procedure is to treat low back pain and is considered investigational. Further studies must be done to show that this works to treat your condition. There is not enough evidence to show that it improves health outcomes. Based on this information, you do not meet the requirements for coverage. This determination was based off AllWays Health Partners medical policy experimental and investigational procedures. Please discuss this with your doctor to determine the next appropriate steps for your care. (Exhibit 4 at 9-

10)

On July 15, 2021, the appellant's provider filed an appeal with AHP, seeking reversal of the original denial. On August 13, 2021, after a third-party review by MRIOA, AHP notified the appellant and his provider that it was upholding the denial. The notice includes the following explanation:

> **Reasons the Medical Evidence does not meet the medical review criteria:** Your doctor requested Intracept Procedure to treat pain in your lower back. We reviewed your medical records and are unable to approve this request because the service is considered investigational. According to AllWays Health Partners' coverage criteria "**Experimental and Investigational**," further studies must be done to show that this works to treat your condition. There is not enough evidence to show that it improves health outcomes. . . . (Exhibit 4 at 129)

At hearing, the AHP Medical Director, Dr. Lily Kam, testified to the basis of the denial. Pointing to information in the MRIOA report, she testified that the requested service is not a covered procedure because it is experimental and investigational for the appellant's condition. She stated that there is limited evidence of its long-term benefit; she also noted that this position is in line with all other health plans in the state. Dr. Kam referred to the results of an MRI of the lumbar spine, stating that there were no changes on the endplate at L5-S1. She testified that the imaging does not suggest a vertebrogenic source of the appellant's symptoms. As such, she testified, there is no clinical indication for the appellant to have this procedure.[1]

The MassHealth Medical Director, Dr. Lakshman Swamy, testified that this procedure would be advisable and possibly approved in some cases, but that the radiological evidence to justify it for this member is not present. He stated that Dr. Connolly's notes do not line up with the imaging information in the record.

Dr. Kam and Dr. Swamy indicated that they reviewed the medical literature submitted by the appellant's representatives but did not find it persuasive for this case. Dr. Kam pointed out that there were not a lot of patients in the study and the evidence in support of the procedure is not high-quality.

The appellant was represented at hearing by Dr. Michael Marks, the Senior Medical Director for Relievant Medsystems, Inc., the medical device company that developed the Intracept procedure. Relievant's Patient Access Case Manager also appeared at the hearing. Dr. Marks disputed AHP's characterization of the Intracept procedure as investigational, emphasizing that the procedure was cleared by the FDA in 2007 and that CMS assigned it a procedure code effective January 2022. He

[1] The second MROIA report states as follows: "This procedure is not experimental/investigational and is scientifically supported. However, there is no clinical indication for the procedure in this clinical setting. The patient presents with symptoms of nerve root compression/irritation. The imaging studies do not support a vertebrogenic source for the patient's symptoms." See Exhibit 4 at 45.

argued that the science is strong to support its use and that the FDA clearly defined the basis for its use, indicating that it has been deemed safe and effective. Specifically, the FDA determined that the Intracept system is indicated for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by either Type 1 or Type 2 Modic changes on an MRI. See Exhibit 2 at 25.[2] Dr. Marks indicated that a number of peer-reviewed studies that support this procedure's use have been published in medical journals.

Dr. Marks testified that the appellant meets the FDA criteria for the Intracept procedure because he has had chronic low back pain for more than six months, the pain has not responded to a variety of conservative treatments during that time (e.g., spinal injections, physical therapy, medication), and an MRI revealed Type 1 Modic changes at L5-S1. He stated that this is the only effective available treatment for the appellant's pain.

The appellant's representatives submitted medical records with the request for hearing. These records include the MRI report (dated September 11, 2020) and a progress note from an office visit with Dr. Connolly (dated May 18, 2021). The MRI report includes the following:

- Findings:
  - ALIGNMENT: Minimal dextroscoliosis with apex at L3
  - VERTEBRAL BODIES AND BONE MARROW: Vertebral bodies are normal in height. Right hemilaminectomy at L5-S1. Mild degenerative endplate signal change anteriorly at L1-2 and on the left side at L3-4. Postoperative changes at the marrow is otherwise normal in signal without evidence of edema or marrow replacing lesion.
  - CORD: Conus position at L1 is normal. The distal spinal cord, conus medullaris and cauda equina are within normal limits.
  - DISC SPACES: The disk spaces are well preserved.
  - SOFT TISSUES: Paravertebral soft tissues are unremarkable.
  - ENHANCEMENT: There is no abnormal enhancement.
- Evaluation of individual levels demonstrates: L1-2: No central canal or neural foraminal narrowing; L2-3: No central canal or neural foraminal narrowing. L3-4: Unchanged mild narrowing the spinal canal. L4-5: Unchanged mild spinal stenosis with encroachment on the lateral recesses and neural foramina without progression from prior study. L5-S1: No recurrent disc herniation. Small amount of enhancing material consistent with scar in the right lateral recess. This surrounds the right S1 nerve root as it exits the thecal sac. Disc osteophyte encroachment on the neural foramina, greater on the right than left side, is unchanged.
- Impression: No evidence recurrent disc herniation. Scar tissue in the right lateral recess at L5-S1 surrounding the right S1 nerve root in the lateral recess. Study otherwise

[2] Modic changes are defined as "vertebral endplate damage with subchondral bone inflammatory reaction." See Exhibit 5, from *Intra-osseous basivertebral nerve radiofrequency ablation (BVA) for the treatment of vertebrogenic chronic low back pain (*DeVivo et al, 2020).

unchanged from the recent unenhanced examination. (Exhibit 2 at 16-17)

Dr. Connolly's office note includes the full, verbatim findings from the MRI report, but adds the following line at the end: "MRI imaging reviewed. Type I Modic changes are seen adjacent to the superior endplate of S1 and inferior endplate of L5 with high signal on T2 and fat suppression imaging and low signal on T1 imaging. See pictures below." See Exhibit 2 at 12. The assessment from the date of service (May 18, 2021) is as follows:[3]

> The patient has a long history of back pain dating back 18 months. His symptoms are primarily lumbar and associated with type 1 Modic change at L5-S1. My impression is that his pain is vertebrogenic. He has not responded to facet blockade and steroid injection or prolonged courses of physical therapy and home exercise in conjunction with medications. I discussed basivertebral nerve ablation with him. I used a spine model and explained the nature of the procedure. He expressed understanding and would like to proceed. (Exhibit 2 at 13)

The record was held open for the appellant's representatives to submit copies of the studies supporting use of the Intracept procedure. Dr. Marks submitted several studies during the record-open period. See Exhibit 5.

Findings of Fact

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

1. The appellant is a MassHealth member who is enrolled in an AllWays Health Partners (AHP) managed care program.

2. In or around May 2021, the appellant's provider submitted a prior authorization request for coverage of the Intercept procedure to address the appellant's chronic low back pain. The provider indicated that based on MRI results, the appellant's chronic low back pain "is coming from the vertebrogenic changes at L5 and S1."

3. The Intercept procedure uses radiofrequency (RF) to ablate the basivertebral nerve and eliminate pain signals from the endplates of a targeted vertebral body.

4. The Intracept procedure was approved by the FDA in 2007 for treatment of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by either Type 1 or Type 2 Modic changes on an MRI.

5. The appellant has had chronic low back pain for over a year and has tried treatments that include injections, medications, and physical therapy.

[3] The medical record includes assessments from previous office visits as well.

6. The appellant had an MRI in September 2020. The report includes the following:

    a. Findings:
        - ALIGNMENT: Minimal dextroscoliosis with apex at L3
        - VERTEBRAL BODIES AND BONE MARROW: Vertebral bodies are normal in height. Right hemilaminectomy at L5-S1. Mild degenerative endplate signal change anteriorly at L1-2 and on the left side at L3-4. Postoperative changes at the marrow is otherwise normal in signal without evidence of edema or marrow replacing lesion.
        - CORD: Conus position at L1 is normal. The distal spinal cord, conus medullaris and cauda equina are within normal limits.
        - DISC SPACES: The disk spaces are well preserved.
        - SOFT TISSUES: Paravertebral soft tissues are unremarkable.
        - ENHANCEMENT: There is no abnormal enhancement.

    b. Evaluation of individual levels demonstrates: L1-2: No central canal or neural foraminal narrowing; L2-3: No central canal or neural foraminal narrowing. L3-4: Unchanged mild narrowing the spinal canal. L4-5: Unchanged mild spinal stenosis with encroachment on the lateral recesses and neural foramina without progression from prior study. L5-S1: No recurrent disc herniation. Small amount of enhancing material consistent with scar in the right lateral recess. This surrounds the right S1 nerve root as it exits the thecal sac. Disc osteophyte encroachment on the neural foramina, greater on the right than left side, is unchanged.

    c. Impression: No evidence recurrent disc herniation. Scar tissue in the right lateral recess at L5-S1 surrounding the right S1 nerve root in the lateral recess. Study otherwise unchanged from the recent unenhanced examination.

7. In an office note from May 2021, the provider included the full findings from the MRI report, but added the following comment: "MRI imaging reviewed. Type I Modic changes are seen adjacent to the superior endplate of S1 and inferior endplate of L5 with high signal on T2 and fat suppression imaging and low signal on T1 imaging. See pictures below."

8. On June 16, 2021, AHP denied the request because it determined that the procedure is considered investigational and experimental in treatment of the appellant's condition.

9. On July 15, 2021, the appellant's provider filed an appeal with AHP.

10. On August 13, 2021, AHP upheld the denial.

11. On September 16, 2021, the appellant filed a timely appeal of the denial with the Board of Hearings.

Analysis and Conclusions of Law

Under 130 CMR 508.006, MassHealth members who are enrolled in managed care plans are entitled to a fair hearing under 130 CMR 610.000*: MassHealth: Fair Hearing Rules* to appeal:

> (A) the MassHealth agency's determination that the MassHealth member is required to enroll with a MassHealth managed care provider under 130 CMR 508.001(A);
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> (B) a determination by the MassHealth behavioral-health contractor, by one of the MassHealth managed care organization (MCO) contractors, or by a senior care organization (SCO), as further described in 130 CMR 610.032(B), if the member has exhausted all remedies available through the contractor's internal appeals process;
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> (C) the MassHealth agency's denial of a request for an out-of-area MassHealth managed care provider under 130 CMR 508.002(F); or
>
> (D) the MassHealth agency's disenrollment of a member from a MassHealth managed care provider under 130 CMR 508.002(G).

Pursuant to 130 CMR 450.204(A), MassHealth does not pay for services that are not medically necessary. A service is considered "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 or cause to aggravate a handicap, or result in illness or infirmity; and
>
> (2) there is no other medical services or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to [MassHealth]. . . .

At issue in this case is AHP's denial of the appellant's prior authorization request to undergo the Intercept procedure to address his chronic low back pain. AHP denied the request on the basis that the procedure is experimental and investigational. However, records from the internal appeal reflect AHP later refined its position to say that the procedure itself "is not experimental/investigational and is scientifically supported," but that the appellant does not meet the clinical criteria for it because "[t]he imaging studies do not support a vertebrogenic source for the patient's symptoms." See Exhibit 4 at 45. This position was echoed in Dr. Swamy's testimony at hearing. The parties are therefore in agreement that the procedure is not experimental or investigational per se. The dispute is whether the appellant meets the clinical criteria for it.

As indicated above, the FDA approved use of the Intracept procedure "for the relief of chronic low back pain of at least 6 months duration that has not responded to at least six months of conservative care, and is also accompanied by either Type 1 or Type 2 Modic changes on an MRI." See Exhibit

4 at 25. The record is clear that the appellant has had chronic low back pain for at least six months duration, and that the pain has not responded to at least six months of conservative care. The question is whether the MRI revealed either Type 1 or Type 2 Modic changes.

The appellant's provider, Dr. Connolly, contended in his PA submission that the MRI performed in September 2020 "demonstrated Modic type I changes at L5-S1 disc space," and "[a]s such, his chronic low back pain is coming from the vertebrogenic changes at L5 and S1." See Exhibit 4 at 36. The MRI report, however, does not say anything about Modic changes at L5-S1. See Exhibit 2 at 16-17. Notably, the provider reproduced the entire MRI report, verbatim, into an office note from May 2021, but he then seemingly inserted his own commentary immediately after: "MRI imaging reviewed. Type I Modic changes are seen adjacent to superior endplate of S1 and inferior endplate of L5 with high signal on T2 and fat suppression imaging and low signal on T1 imaging. See pictures below." See Exhibit 2 at 12. The provider's allegation of Modic changes at L5-S1 appears to be based on his own reading of the MRI images and not on the objective findings in the MRI report itself. This is not persuasive.

As the objective evidence fails to show Modic changes on the MRI, the appellant has not demonstrated that he meets the FDA's basic clinical criteria for use of the Intracept procedure. AHP's denial was therefore proper under the first prong of the medical necessity regulation, as the requested procedure is not "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 or cause to aggravate a handicap, or result in illness or infirmity." See 130 CMR 450.204(A)(1).

This appeal is therefore denied.

Order for AHP/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.

Rebecca Brochstein
Hearing Officer
Board of Hearings

cc: [redacted]