Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2414394
Decision Date:	11/25/2024	**Hearing Date:**	11/20/2024
Hearing Officer:	David Jacobs		

Appearance for Appellant:
[redacted]

Appearance for MCO:
John Shinn, Outside Counsel
Dr. David Dohan, Medical Director
Nicole Dally, Program 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:	11/25/2024	**Hearing Date:**	04/17/2024
MCO Reps.:	John Shinn, Dr. David Dohan, Nicole Dally	**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 September 17, 2024, [redacted] [redacted] a MassHealth managed care organization ("MCO"), denied the appellant's internal Standard Appeal for coverage of a MILD (Minimally Invasive Lumbar Decompression) procedure (Exhibit 1). The appellant filed this appeal in a timely manner on September 19, 2024 (Exhibit 2). Denial of assistance by a managed care contractor is grounds for appeal (130 CMR 610.032(B).)

Action Taken by the MCO

[redacted] denied the appellant's medical procedure because it considers the MILD procedure to be "investigational (unproven) and experimental."

Issue

The appeal issue is whether [redacted] 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 [redacted] a MassHealth MCO. [redacted] appeared telephonically on behalf of [redacted] Testimony was primarily provided by [redacted] medical director for [redacted] testified as follows:

The appellant is a [redacted] member. The member is appealing the denial of coverage of a MILD (Minimally Invasive Lumbar Decompression) procedure. The request was denied on 9/12/24 by [redacted] Health Plan as the service is considered experimental/investigational and therefore, not medically necessary and excluded from coverage. The denial states:

> The services you requested do not meet the guidelines above because [redacted] Health Plan considers the requested procedure/test to be investigational (unproven) and experimental in clinical trials and therefore not a covered benefit. 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. (Exhibit 4, pg. 11).

On September 10, 2024, the case was referred to third party orthopedic surgeon who reviewed the treatment plan utilizing the MILD procedure and provided a utilization review of his findings (Exhibit 4, pgs. 45-112). [redacted] emphasized that the third-party organization that was used receives less than 5% of their income from [redacted] and has no incentive to approve or deny any procedure. The orthopedic surgeon found the following:

"Yes, the prospective coverage of a MILD (Minimally Invasive Lumbar Decompression) procedure is considered experimental or investigational for this member based on the Noncovered Investigational Services list and the definition of experimental/investigational included in this case. There are no relevant peer-reviewed studies that would suggest that this technology is proven safe and effective for this member" (Exhibit 4, pg. 12). [redacted] added that the primary issues are with the methodology and the length of the studies done on the MILD procedure. He argues the studies did not utilize proper control groups and have no data for the long-term effectiveness of the procedure.

The appellant was represented telephonically at the hearing by [redacted] a patient access specialist. She read the following into the record:

> The [appellant] is [redacted] years old and has suffered from spinal stenosis, lumbar region with neurogenic claudication for several years. MRI results from [redacted] 2024, shows disc bulge and moderate facet arthropathy with ligamentum flavum infolding at L4-L5. As well as, moderate to severe spinal canal stenosis centrally and in the bilateral lateral recesses and moderate bilateral neural foramen stenosis, left worse than right.
>
> [The appellant] has tried and failed non-operative treatments including:
> • Physical Therapy
> • Epidural Steroid Injections
> • Pain Medications
> • Physician Directed Home Exercises
>
> Despite these interventions, the patient's pain has escalated over time. His pain affects his mobility, specifically his standing and walking tolerance has declined steadily. Based on the patient's medical history and the treatment algorithm for Lumbar Spinal Stenosis, [redacted] believes the patient is an excellent candidate for the MILD Procedure. Image-guided Minimally invasive lumbar decompression using the MILD tool kit initially received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2006, with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions.
>
> MILD is an FDA-cleared, safe, outpatient, minimally invasive, durable, and therapeutic procedure that treats Lumbar Spinal Stenosis. MILD decompresses the spinal canal by removing small portions of lamina and hypertrophic ligamentum flavum, which helps restore space in the spinal canal. The restoration of space reduces pressure on the nerves, improves mobility, and reduces pain. The procedure is performed through a 5.1-mm treatment portal (smaller than the size of a baby aspirin) via a posterior approach using live fluoroscopy, which provides constant visualization of the treatment area throughout the procedure. A key safety feature is the minimally invasive design of the procedure itself, which doesn't require general anesthesia, implants, or stitches, and is typically performed in less than an hour.
>
> Over a decade's worth of robust data is available to validate the safety and long-term effectiveness of the MILD Procedure:

• 16 clinical studies conducted at leading interventional pain institutions across the United States
• 30+ peer-reviewed journal articles published to date, including Level 1, 2-year data from the CMS-approved MiDAS ENCORE study
• 88% of mild patients avoided back surgery for at least 5 years while experiencing significant symptom relief.
• Clinically demonstrated equivalent safety profile to epidural steroid injections (ESIs)
• No major device-related complications reported in any clinical trial
• Adverse event rate less than 0.1% in all commercial cases
• Proven to be the superior treatment for neurogenic claudication compared to current standard of care (ESI)
– Level-1 evidence from CMS-approved study

There is also clinically proven long-term efficacy:

MiDAS ENCORE Study at 2 Years
The results of all primary and secondary efficacy-outcome measures achieved significant clinically meaningful Improvement:
• 72% of patients saw a clinically significant improvement in function
• No surgery or reoperation in 94.4% of patients
• 95% of patients with 5 or more comorbidities presented higher response rates than the ENCORE population as a whole

In addition, the procedure is endorsed in the 2018 MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment
• MILD is the only image-guided technique meeting the CMS definition of PILD, Percutaneous Image-Guided Lumbar Decompression, and as such, the acronym PILD will refer to the *mild* procedure for the purposes of this section.
• Based on a systematic review of the available literature for PILD, the consensus committee has determined that there is sufficient support to warrant Level 1 evidence using the USPSTF (United States Preventive Services Task Force) criteria.

Also, there is data from the MOTION Study at 1 Year
1-year data for patients receiving the mild Procedure plus conventional medical management (CMM) vs CMM-Alone include:
• 16-point composite ODI mean improvement
• more than 250% improvement in walking time compared to baseline prior to the procedure

• Only 5.8% of mild patients underwent a subsequent lumbar spine intervention
• 0% device- or procedure-related adverse or serious adverse events reported in either group

The benefits of the MILD procedure include being less complicated and less expensive than other more invasive spine surgeries, with far less complications and risks. It's in the patient's best interests to exhaust more conservative treatments like MILD, prior to considering a serious, invasive spinal surgery.

The patient meets the medical necessity guidelines, and the procedure is appropriately indicated for him. All patients should have the right to exhaust all available conservative treatments before making the decision to move forward with a more complicated and higher risk surgery like an open spine procedure. The MILD Procedure offers an excellent treatment option to address Lumbar spinal stenosis in a safe, and minimally invasive way. For these reasons we respectfully request that the denial of coverage for the mild procedure be overturned. We understand that there is a non-coverage policy in place, but for the patient's specific situation, we are requesting that an exception be granted, and coverage be allowed for him to undergo the mild procedure at this time.

In response, [redacted] testified that the referenced studies do not show long-term results for the MILD procedure. For long-term efficacy, the primary study used by the appellant is the MiDAS ENCORE study which was published after only 2 years. [redacted] does not find 2 years to be long enough to study the long-term effectiveness of the MILD procedure. The hearing officer then asked the appellant representative if she believed it was unreasonable for a medical professional to consider 2 years to be not long enough to consider the long-term effectiveness of the MILD procedure. She responded that she was unqualified to make such a judgement as she has no medical training, but that [redacted] the company that offers the MILD procedure, considers 2 years to be long-term study.

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 [redacted] a managed care organization administering MassHealth benefits.

2) The appellant is [redacted] and has suffered from spinal stenosis, lumbar region with neurogenic claudication for several years. This condition has escalated with time and causes pain that affects his mobility.

3) On September 10, 2024, an initial request for coverage of the MILD procedure was submitted to [redacted]

4) On September 10, 2024, an independent orthopedic surgeon who is board certified completed a utilization review consultation.

5) On September 12, 2024, the initial denial letter was sent to the member.

6) On September 17, 2024, the provider requested an expedited appeal.

7) On September 17, 2024, a [redacted] Medical Director upheld the denial of the request for coverage of the MILD procedure.

8) On September 18, 2024, an expedited denial letters sent to member and provider along with member rights and board of hearing request form.

9) On September 19, 2024, the appellant filed an external appeal with the Board of Hearings.

10) The utilization review report concludes that "the prospective coverage of a MILD (Minimally invasive lumbar decompression) procedure, is considered experimental or investigational for this member based on the Noncovered Investigational Services list and the definition of experimental/investigational included in this case. There are no relevant peer-reviewed studies that would suggest that this technology is proven safe and effective for this member."

11) For the long-term effectiveness of the MILD procedure, the appellant primarily relies on a MiDAS ENCORE study that was published after two years of study. [redacted] takes issue with the length of study as not being long enough to prove that MILD is safe and effective for the appellant.

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 a managed care organization if the member has exhausted all remedies available through the contractor's internal appeal process. (130 CMR 508.010.)

MassHealth and MCOs cover only those services that are 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)). The [redacted] Member Handbook also includes this restriction. (See Exhibit 5, pgs. 24, 92.)

This appeal issue here is whether the requested medical procedure is "experimental." 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).)

There is no clearly defined standard of review in the regulations for deciding when medical care is "experimental." [redacted] has developed a non-arbitrary process by which it regularly reviews the state of evidence regarding medical advancements. The [redacted] medical director credibly testified that [redacted] utilized a third-party, non-biased orthopedic surgeon to review the MILD procedure and found it to be experimental. Furthermore, the [redacted] medical director made a credible medical argument that despite all the studies done on the MILD procedure, none have been done on the long-term benefits of the procedure. The 2-year study the appellant provided was found not long enough for [redacted] to believe the long-term benefits of the MILD are known, thus making the procedure still experimental. The only counterargument the appellant representative offered is

that the makers of the MILD procedure considered the duration of the study long enough to determine long-term benefits. However, the hearing officer finds such an argument to be self-serving by the manufacturer and that [redacted] and the orthopedic surgeon are more credible to believe that 2 years is not long enough to determine the long-term benefits of a medical procedure. Furthermore, it is found that it is reasonable for [redacted] to find a medical procedure to be experimental if its long-term benefits are not yet known. As such it is found that [redacted] was within its discretion to find the MILD procedure to be experimental, and therefore not "medically necessary."

For these reasons, this appeal is DENIED.

Order for [redacted] Health Plan

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.

David Jacobs
Hearing Officer
Board of Hearings

cc:

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

[redacted]