Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2313708
Decision Date:	5/2/2024	**Hearing Date:**	January 30, 2024
Hearing Officer:	Brook Padgett	**Record Open:**	March 01, 2024

Appellant Representative:

Pro se

MassHealth MCO Representative:

Kay George, Fallon Health
Manager of Appeals

Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street, 6th floor
Quincy, MA 02171

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	MCO Prior Authorization 130 CMR 450.204
Decision Date:	5/2/2024	**Hearing Date:**	January 30, 2024
MCO Rep.:	K. George	**Appellant Rep.:**	Pro se
Hearing Location:	Springfield		

Authority

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

Jurisdiction

The Appellant received a notice from Fallon Health Navicare Senior Care Options (FH or FHP) [a MassHealth managed care agent] dated December 14, 2023 denying his request for "[p]ercutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under direct image guidance (e.g. fluoroscopic, CT) with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic, lumbar (GPT 0275T) at Berkshire Medical Center from November 1, 2023 to February 1. 2024" (Exhibit 1). The Appellant appealed this action timely on December 27, 2023. (130 CMR 610.015(B); Exhibit 2). Denial of a request for prior authorization is valid grounds for appeal (130 CMR 610.032).

Action Taken by MassHealth MCO

FHP denied Appellant's prior authorization request for a Percutaneous Laminotomy/Laminectomy via an Image-Guided Minimally Invasive Decompression procedure.

Issue

Did Fallon Health correctly deny the Appellant's request?

Summary of Evidence

A representative from FH testified that on October 26, 2023, FH received a request from the Appellant's physician for coverage of a Percutaneous Laminotomy/Laminectomy[1] via an Image-Guided Minimally Invasive Decompression (GPT 0275T) procedure to reduce back pain. The request was sent to an external Orthopedic Surgeon who has expertise in spine surgery. After review, the surgeon indicated this procedure is not yet proven safe and effective and is considered experimental/investigational according to Centers for Medicare and Medicaid Services (CMS), FH's criteria, and MassHealth guidelines for medical necessity (130 CMR 450.204). On November 09, 2023, FH denied the requested procedure. The Appellant filed an internal appeal of the denial with FH on November 09, 2023. On December 14, 2023, the denial was reviewed by FH and upheld. The Appellant appealed the FH denial of the internal appeal to the MassHealth Board of Hearings on December 27, 2023. FH testified that FH denied the request for GPT 0275T because: 1. the procedure has not been shown by the scientific literature to be equivalent to standard treatments for lumbar spinal stenosis; 2. The procedure is not considered standard of care for the Appellant's diagnosis (standard treatment would be a lumbar laminectomy with an open procedure); 3. There are clinically appropriate and evidence-based alternative treatments i.e. lumbar laminectomy; and 4. CMS National Coverage Determination (NCD) criteria has not been met as this service/procedure may be considered medically necessary only for Medicare patients currently enrolled in a clinical trial. FH submitted into evidence the Appellant's final review packet. (Exhibit 4).

The Appellant testified that the procedure is part of his treatment plan for diagnosis of spinal stenosis. The Appellant stated he has severe low back and pain radiating down his leg which worsens when lifting, standing, bending and twisting. The pain makes it very difficult to do ordinary daily activities. The Appellant stated he has been receiving injections; however the injections are no longer giving him relief and he has had to use a walker and cane to ambulate. The Appellant argued his doctor has recommended this procedure and believes it is medically necessary. (Exhibit 5).

[1] **Laminectomy and laminotomy** are related procedures in which a surgeon removes bone from the spine. Laminectomy: Is a common procedure that removes part of the lamina, the bony "roof" of the spinal canal. The extent of bone removal depends on the situation: in some cases, only part of one side of one lamina is removed. In a more extensive removal, the surgeon may remove both sides of several laminae. Common reasons for a laminectomy are to relieve pressure on the spinal cord and nerve roots caused by spinal stenosis or to grant the surgeon access to the spinal canal to remove a tumor or vascular malformation. Laminotomy: Is like a laminectomy in which only a small amount of the lamina is removed. A laminotomy is performed to remove a herniated disc during a microdiscectomy or to allow the surgical treatment of a synovial cyst. Columbia University Irving Medical Center.

At the Appellant's request the hearing record remained open until March 01, 2024, for the Appellant to provide evidence that the clinical benefit of percutaneous lumbar laminectomy procedures has been shown by the scientific literature to be equivalent to standard treatments for lumbar spinal stenosis; and until April 01, 2024 for FH to respond to any additional submission. (Exhibit 5).

On January 30, 2024, the Appellant submitted an email from a nurse practitioner (NP) referring to a website explaining the *mild®*[2] procedure stating that effective February 16, 2017 coverage for the procedure has been granted by Medicaid under NCD 150.13, and material from Vertos Medical supplier of the *mild®* Device Kit.(Exhibit 6).

FH responded on March 29, 2024 stating that after review of the submitted documents, the Appellant did not provide evidence through scientific literature of the clinical benefit of procedure GPT 0275T or that it is equivalent to standard treatments for lumbar spinal stenosis. The Appellant submitted documents from a NP who requested the procedure, and from Vertos, the company that markets and distributes the Vertos Medical *mild®* Device Kit, which includes the specialized arthroscopic surgical equipment related to the procedure and not a true reflection of scientific literature verifying the procedure as standard treatment of lumbar spinal stenosis. FH continued to deny the procedure because the CMS, NCD and Fallon Health's Experimental and Investigational Clinical Coverage Criteria have not been met. In addition, the Medical Necessity criteria per 130 CMR 450.204 is not met because this procedure is considered medically necessary only for Medicare patients currently enrolled in a clinical trial and there is no evidence the Appellant is part of clinical trial. (Exhibit 7).

On April 08, 2024, the Appellant submitted a Request for Reconsideration of Appeal #2413708. (Exhibit 8). The Appellant's submission was received outside of the record open period and prior to a decision on the matter so the submission was not considered as part of the record or substantively addressed in this decision.[3]

Findings of Fact

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

1. The Appellant is a member of FH, a MassHealth MCO. (Exhibit 4 and Testimony).

2. On October 26, 2023, FH received a request from the Appellant's physician for coverage of a Percutaneous Laminotomy/Laminectomy via an Image-Guided Minimally Invasive Decompression procedure (GPT 0275T) to reduce the Appellant's back pain. (Exhibit 4).

[2] *mild®*, is proprietary technology consisting of outpatient procedure to restore space in the spinal canal through a small incision.

[3] If the appellant disagrees with the MassHealth Board of Hearings decision, he has the right to appeal to Superior Court in accordance with Chapter 30A of the Massachusetts General Laws within 30 days after the receipt of the decision.

3. On November 09, 2023, the request was denied as FH considers the procedure experimental/investigational; not the standard of care for the Appellant's diagnosis; there are other clinically appropriate and evidence-based alternative treatments; and CMS, NCD criteria considers this service/procedure medically necessary only for Medicare patients currently enrolled in a clinical trial. (Exhibit 4).

4. On December 14, 2023, an internal review by FH upheld the denial. (Exhibit 4).

5. On December 27, 2023, the Appellant appealed the FH denial of the internal appeal to the MassHealth Board of Hearings. (Exhibit 2).

6. The hearing record remained open until March 01, 2024 for the Appellant to provide evidence that the clinical benefit of GPT 2075T has been shown, by the scientific literature, to be equivalent to standard treatments for lumbar spinal stenosis. (Exhibit 5).

7. On January 30, 2024, the Appellant submitted an email from an NP referring to a website explaining the *mild®* and material from Vertos Medical, supplier of the *mild®* Device Kit. (Exhibit 6).

Analysis and Conclusions of Law

MassHealth regulations at 130 CMR 508.001(A)(1) address member participation in a MassHealth managed care organization (MCO) as follows:

> MassHealth members who are younger than 65 years old, except those MassHealth members who are receiving services from the Department of Children and Families (DCF) or the Department of Youth Services (DYS) or who are receiving Title IV-E adoption assistance described in 130 CMR 522.003: *Adoption Assistance and Foster Care Maintenance*, those MassHealth members who may voluntarily choose to enroll in the Primary Care Clinician (PCC) Plan or a MassHealth-contracted managed care organization (MCO) as described in 130 CMR 508.001(A)(3), and those excluded from participation as described in 130 CMR 508.004, must enroll in the PCC Plan or a MassHealth-contracted MCO available for their coverage types.

130 CMR 508.006 addresses the members' right to a fair hearing as follows:

> Members 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);
> (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.

The Appellant submitted a prior authorization request to FH for a Percutaneous Laminotomy/Laminectomy via an Image-Guided Minimally Invasive Decompression procedure or GPT 0275T to reduce his back pain. The FH handbook lists a number of services that FH considers experimental/investigational (and therefore noncovered) because they do not meet FH's Technology Assessment Criteria. FH excludes coverage of experimental/investigational procedures due to their lack of reliable or detailed clinical evidence of superior clinical outcomes. The HP handbook lists GPT 2075T as excluded from coverage as it is considered experimental/investigational and not yet proven safe and effective for lumbar spinal stenosis. FH maintains that the standard treatment for the Appellant's condition would be a lumbar laminectomy.[4]

All services covered by MassHealth must meet the medical necessity requirements set forth in 130 CMR 433.00 and in 130 CMR 450.204. For items covered by MassHealth for which there is no MassHealth item-specific medical necessity guideline, and for which there is a Medicare Local Coverage Determination (LCD) indicating Medicare coverage of the item under at least some circumstances, the provider must demonstrate medical necessity of the item consistent with the Medicare LCD. However, if the provider believes the procedure is medically necessary even though it does not meet the criteria established by the local coverage determination, the provider must demonstrate medical necessity under 130 CMR 450.204.

Regulations at 130 CMR 450.204 describe medical necessity, as follows:

> The MassHealth agency will not pay a provider for services that are not medically necessary and may impose sanctions on a provider for providing or prescribing a service or for admitting a member to an inpatient facility where such service or admission is 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, 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

[4] Lumbar laminectomy, also called open decompression, is a surgical procedure performed to treat the symptoms of central spinal stenosis or narrowing of the spinal canal. The surgery involves removal of all or part of the lamina (posterior part of the vertebra) to provide more space for the compressed spinal cord and/or nerve roots. Lumbar laminectomy is typically considered after nonsurgical treatments such as physical therapy, medications, and/or epidural steroid injections have been tried for a period of 8 to 12 weeks without improvement.

pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007, or 517.007.

(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.)

In this instance the standard of care for an individual with the Appellant's condition is a lumbar laminectomy. Since the Appellant has another medical service which is comparable in effect, available, and suitable for the Appellant's condition, and the requested procedure is not the standard of care for the Appellant's condition, his request fails to meet either the first or second prong of MassHealth medical necessity criteria at 130 CMR 450.204 A(2) and (B).

While the Centers for Medicare & Medicaid Services (CMS) has determined that Percutaneous image-guided lumbar decompression (PILD) can be covered by Medicare for beneficiaries with Lumbar Spinal Stenosis (LSS), it is only for those who are enrolled in an approved clinical study trial.[5] The Appellant did not provide any proof that he is a participant in a required clinical trial, and, as a result, the procedure would not covered under CMS.

The Appellant's request for GPT 2705T has not been shown by the scientific literature to be equivalent to standard treatments for lumbar spinal stenosis and is therefore considered experimental/investigational for the Appellant's diagnosis[6]. The standard of care for lumbar spinal stenosis is a lumbar laminectomy which is comparable in effect, available, and suitable for the Appellant's condition, therefore GPT 2075T fails to meet the MassHealth medical necessity criteria. Finally, the Appellant is not a participant in a clinical trial, therefore the requested procedure is not covered by CMS.

Percutaneous Laminotomy/Laminectomy via an Image-Guided Minimally Invasive Decompression (GPT 2075T) is not an FHP covered service and does not meet the MassHealth medical necessity guidelines therefore the appeal must be DENIED.

[5] When provided in a clinical study under section 1862(a)(1)(E) through Coverage with Evidence Development (CED) Effective for services performed on or after January 09, 2014 Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis | CMS

[6] 433.451: Surgery Services: Introduction…(B) Nonpayable Services. The MassHealth agency does not pay for (1) any experimental, unproven, cosmetic, or otherwise medically unnecessary procedure or treatment;… (4) services billed under codes listed in Subchapter 6 of the Physician Manual as not payable; (5) services otherwise identified in MassHealth regulations at 130 CMR 433.000 or 450.000 as not payable… (130 CMR 433.451(B)(1), (4), (5)).

Order for MCO

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.

Brook Padgett
Hearing Officer
Board of Hearings

cc: MassHealth/MCO representative: Fallon Health, Member Appeals and Grievances, 10 Chestnut Street, Worcester, MA 01608

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