Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2403132
Decision Date:	6/3/2024	**Hearing Date:**	April 08, 2024
Hearing Officer:	Brook Padgett	**Record Open to:**	May 08, 2024

Appellant Representatives:
Mother/Father

MCO/MassHealth Representatives:
[redacted]

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 Denial of Internal Appeal 130 CMR 450.204
Decision Date:	6/3/2024	**Hearing Date:**	April 08, 2024
MCO/MassHealth Reps.:	[redacted]	**Appellant Rep.:**	Mother/father
Hearing Location:	Worcester MassHealth Enrollment Center		

Authority

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

Jurisdiction

Through a notice dated February 15, 2024 Mass General Brigham Health Plan (MGBHP), a MassHealth MCO[1], informed the appellant that it reviewed his appeal of a denial for Vertebral Body Tethering received on February 14, 2024 and denied the request. (130 CMR 508.000; Exhibit 1). The appellant filed this appeal to the Board of Hearings in a timely manner on March 01, 2024. (130 CMR 610.015(B)(7); Exhibit 2). A MassHealth MCO's decision to deny or provide limited authorization of a requested service, including the type or level of service is valid grounds for appeal. (130 CMR 610.032(B)).

[1] MGBHP is a MassHealth managed care contractor as defined by regulations at 130 CMR 610.004 and described in regulations at 130 CMR 508.000.

Action Taken by MCO

MGBHP, a MassHealth MCO, denied the appellant's request for Vertebral Body Tethering.

Issue

Does the appellant's request for Vertebral Body Tethering meet the medical necessity criteria necessary to be authorized for coverage by MGBHP?

Summary of Evidence

[redacted], Medical Director from MGBHP testified via video conference that the appellant is a member of MGBHP, a MassHealth MCO. [redacted] stated the appellant is a [redacted] year old male with Adolescent Idiopathic Scoliosis involving two progressive curves. On December 05, 2023, the appellant's doctor [redacted] requested authorization for posterior fusion for the upper curve and Vertebral Body Tethering (VBT) for the lower curve. On December 06, 2023 the request was submitted to the Medical Review Institute of America (MRIoA) for review. On December 11, 2023, a partial approval letter was sent to the appellant approving the fusion but denying the VBT as the procedure is considered experimental and investigational. On December 19, 2023, the appellant requested a peer-to-peer review. A peer-to-peer review with the appellant's treating physician was unsuccessful and on December 22, 2023 a peer-to-peer denial letter was issued. On January 22, 2024, the appellant initiated a Level 1 internal appeal. On February 08, 2024, the case was again submitted to the MRIoA and on February 14, 2024 the denial was upheld. On February 15, 2024, the Level 1 internal appeal denial letter was sent to the appellant. The appellant appealed the denial to the MassHealth Board of Hearings on March 01, 2023.

[redacted] stated that while the fusion for the upper curve to treat the appellant's scoliosis meets the Mass General Brigham policy criteria per current medical literature, the VBT of the lower spine does not meet the current standard of care or deemed medically necessary. [redacted] maintained there are no generally accepted standards of care for this hybrid procedure and it is therefore considered experimental and investigational. [redacted] argued the standard treatments for idiopathic scoliosis among children and adolescents who are still growing are conservative, non-surgical treatments such as external bracing to help correct the spinal curvature. For those patients that do not respond to bracing, like the appellant, the standard of care is spinal fusion surgery (placing a rod along the spine). VBT is a process that places anchors and screws in each vertebra along the curved section of the spine. A flexible cord, (a tether), is connected to the screws. Tension is applied to the tether during surgery to compress one side of the spine and to partially correct the curve. Over time, the tether slows the growth on the curved side of the spine and promotes growth on the opposite side. This provides additional correction of the curve as the patient continues to grow. The current medical standard is that VBT can only be used in skeletally immature children as it requires growth to straighten the curved spine. Given the appellant's age of [redacted] and his recorded skeletal maturity of a Sanders

6[2], the procedure would be ineffective and not medically necessary. [redacted] stated patients at Sanders stage 5 to 7 have little growth remaining. MGHBP submitted into evidence the Level 1 denial, and x-rays. (Exhibit 4).

The appellant and his parents attended the hearing and testified he is very interested in VBT because he is concerned about the negative effects that might accompany full fusion surgery for both curves. The appellant is a young man with his whole life ahead of him and does not want to be limited by having a rod in his back. The appellant's parent stated he is a hockey player and fears he will not be able to play if he has to get a rod. The appellant's parents argued that the appellant's doctor has stated this surgery can help the appellant and that it is not experimental. The representative indicated that they only want what is best for the appellant and are requesting the denial be overturned so that MGHBP can cover the requested VBT surgery.

The appellant submitted additional information including a letter dated April 04, 2024 from the treating physician stating a full fusion of both curves would likely involve instrumentation and fusion spanning T2-L2 eliminating motion and function across twelve segments of the appellant's thoracic and lumbar spine. This would likely severely limit his participation in hockey and other sports in the short term and would limit motion and function of his spine for the next [redacted] years. Further, the length of this rigid fusion would negatively impact the overall health of the spine in the long term by transferring forces to the remaining unfused lumbar segments, increasing the risk of premature deterioration of these lumbar segments over time. The physician stated he is recommending Anterior Vertebral Tethering surgery for the appellant's primary curve spanning T6-L1 with a goal of preserving motion and function across these important segments of the spine, and a short fusion across only four segments for the upper thoracic curve which is essentially out of reach of an Anterior Vertebral Tethering procedure. This combination procedure is the best option as it addresses both of his surgical curves. Though the appellant has reached somewhat greater skeletal maturity than many other patients who undergo Anterior Vertebral Tethering, the appellant's treating physician argued he has not found this to be significantly detrimental to the goal of achieving a good or excellent outcome. The physician states he has extensive data over the past 12 years that supports the treatment of scoliosis in this range of skeletal maturity with Anterior Vertebral Tethering surgery with corrections similar to those with greater skeletal immaturity. Additionally, he has found that these more mature patients have fewer complications and less need for revision surgery than those patients with greater skeletal immaturity. He argues that he not only had a great deal of experience with Anterior Vertebral Tethering and fusion surgery over the past two decades but has had significant additional experience with this specific hybrid combination over the past ten years and is quite confident that this is the best option for the appellant. The appellant submitted into evidence office notes, x-rays, Abstracts: Anterior Vertebral Body Tethering for Scoliosis Patients With and Without Skeletal Growth Remaining and Retrospective Review With Minimum 2-Year Follow-Up, Efficacy of Anterior Vertebral Body Tethering in Skeletally Mature Children with Adolescent

[2] Skeletal maturity assessment in Idiopathic Scoliosis is used for the evaluation of deformation progression as well as selecting method of treatment. Sanders Maturity Scale - The Sanders score assesses a child's bone maturity using an x-ray of the left-hand fingers and wrist. Based on a scale of 1-8, the Sanders maturity scale considers level 1 to be slow growth in early adolescence whereas 8 is categorized as full skeletal maturity.

Idiopathic Scoliosis: A Preliminary Report, Articles Investigation performed at [redacted], Vertebral Body Tethering in 49 Adolescent Patients after Peak Height Velocity for the Treatment of Idiopathic Scoliosis: 2–5 Year Follow-Up, treating physician letters of support dated March 01, 2024 and April 04, 2024 (Exhibit 5).

The record was left open until May 08, 2024 for MGHBP to review and respond to the appellant's additional submission. (Exhibit 6).

MGBHP responded within the record open period that after review of the additional submission the conclusion is that VBT remains investigational in skeletally mature patients and therefore the denial is appropriate. MGBHP also submitted the MRIoA review which concluded there is a scarcity of literature to support the use of VBT as the current standard of care. The study that does exist consists of 20 patients and reported the procedure was performed on a small number of skeletally immature patients. The member here is [redacted] years old and a Sanders 6, which denotes skeletal maturity which was confirmed with the peer-to-peer call with the provider. The average age in the study was [redacted]. MRIoA determined there is insufficient literature that the requested hybrid is safe and effective and at least equal in outcomes to a posterior spinal fusion, therefore no current generally accepted standard of care exists for the hybrid procedure. (Exhibit 7).

Findings of Fact

Based on a preponderance of the evidence, I find:

1. MGBHP is a MassHealth managed care provider. (Exhibit 4).

2. The appellant is a [redacted] year old male with Adolescent Idiopathic Scoliosis involving two progressive curves (T1-T6 and T6-L1). (Exhibit 4 and testimony).

3. On December 05, 2024, the appellant's physician submitted to MGBHP a request for prior authorization for fusion surgery for the upper curve and VBT for the lower curve. (Exhibit 4).

4. VBT is a process that places anchors and screws in each vertebra along the curved section of the spine. A flexible cord is connected to the screws. Tension is applied to the tether to compress one side of the spine and to partially correct the curve. Over time, the tether slows the growth on the curved side of the spine and promotes growth on the opposite side. This provides additional correction of the curve as the patient continues to grow. (Exhibit 4).

5. On December 06, 2023, the request was submitted to the MRIoA for review. (Exhibit 4).

6. After MRIoA review, a partial approval letter was sent to the appellant on December 11, 2023, approving the fusion but denying the VBT as the procedure is considered experimental and investigational. (Exhibit 4).

7. The appellant is determined to be skeletally mature and a 6 on the Sanders scale. (Exhibit 4).

8. On January 22, 2024, the appellant initiated a Level 1 internal appeal. (Exhibit 4).

9. On February 08, 2024, the request was again submitted to MRIoA. (Exhibit 4).

10. On February 14, 2024, the case was upheld by MRIoA which determined there is insufficient literature that the requested hybrid (fusion and VBT) is safe and effective or the standard of care for individuals who are skeletally mature. (Exhibit 7).

11. On February 15, 2024, MGBHP upheld the Level 1 internal appeal and a denial letter was sent to the appellant. (Exhibit 1).

12. The appellant appealed the February 15, 2024 denial to the MassHealth Board of Hearings on March 01, 2023. (Exhibit 1).

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 [redacted] 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 is a [redacted] year old male with Adolescent Idiopathic Scoliosis that consists of a 40 degree curve at T1-T6 and a 50 degree curve at T6-L1. On December 05, 2023, the appellant's doctor requested prior authorization for a posterior fusion for the upper curve and VBT for the lower curve. After the request was review by MRIoA and MGBHP, the appellant was approved for spinal fusion for the upper curve, however the VBT was denied for the lower curve because the procedure is considered experimental and investigational and as a result not medically necessary.

MGBHP considers VBT experimental and investigational and not medically necessary for the appellant because the appellant has achieved skeletal maturity and there is a lack of documentation that indicates the hybrid procedure has sufficient effect for individuals who have limited growth potential. This is because VBT relies on the tethering of one side of the spine and allowing the opposite to continue to grow thus straightening the curve.[3] Without continued growth it is uncertain whether the procedure will result in decreasing the curve in any meaningful way. The current standard treatments for idiopathic scoliosis for individuals who do not respond to bracing and are at skeletal maturity is spinal fusion surgery and the surgical implant of a rod along the spine.

Due to the appellant's age, skeletal maturity as well as lack of medical literature on the efficacy of VBT in patients who have met their peak height, I find there is insufficient authoritative evidence that the requested procedure is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure the appellant's condition as required to meet the medical necessity regulations. Since the appellant has not provided sufficient evidence that his request for hybrid fusion VBT surgery is medically necessary[4], the denial is upheld as the procedure is presently considered experimental and investigatory.

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[3] Hueter-Volkmann principle -Subluxation results in decrease of growth of the dorsal length of the scapula (by increasing dorsal pressure) and increase of the ventral length (decrease pressure). (See Exhibit 5).

[4] 130 CMR 450.204 Medical Necessity: 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 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.) (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 acute inpatient hospital admissions are contained in 130 CMR 415.414 **(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).**

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: MCO Representative: Christina Thompson, 399 Revolution Drive, Suite 810, Somerville, MA 02145