

**Office of Medicaid
BOARD OF HEARINGS**

Appellant Name and Address:

[REDACTED]

Appeal Decision:	Denied	Appeal Number:	2513243
Decision Date:	12/31/2025	Hearing Date:	December 03, 2025
Hearing Officer:	Brook Padgett		

Appellant Representatives:

[REDACTED]


MCO/MassHealth Representatives:

John Shea, Esq., Mirick
Carl Carlson, MD, Fallon Vice President
Mark Cloutier, Fallon
Tim Nolan, Fallon Prior Authorization 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:	MCO – Diagnostic Testing
Decision Date:	12/31/2025	Hearing Date:	December 03, 2025 ¹
MCO/MassHealth Reps.:	J. Shea, Esq. C. Carlson, MD M. Cloutier T. Nolan	Appellant Reps.:	
Hearing Location:	Telephonic		

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 dated September 05, 2025 from Fallon Health, a MassHealth Managed Care Organization (MCO)², informing the appellant that it had reviewed its decision to deny coverage for medication Tibsovo (ivosidenib) 250 mg tablet. The notice states that the appellant's Fallon plan allows coverage of a drug only when it is used for a medically accepted indication. Tibsovo is approved for Acute Myelogenous Leukemia (AML), Relapsed or Refractory Myelodysplastic Syndrome (MDS) and Cholangiocarcinoma. The submitted documentation indicates the requested drug is not approved for use in individuals under  years of age and there is no recognized off-label uses for this medication. (130 CMR 508.000; Exhibit 1). The appellant filed timely with the Board of Hearings on September 11, 2025. (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 A hearing was originally scheduled for October 22, 2025; however, the appellant and/or his representatives failed to attend the hearing. After evidence of good cause was submitted, the hearing was rescheduled for December 03, 2025.

² Fallon Health is a MassHealth MCO contractor as defined by regulations at 130 CMR 610.004 and described in regulations at 130 CMR 508.000.

Action Taken by MCO

Fallon Health, a MassHealth MCO, denied the appellant's request for the prescription drug Tibsovo.

Issue

Was Fallon Health correct in denying the appellant's request?

Summary of Evidence

The representatives from Fallon testified that the appellant, through his doctors, submitted a request for the drug Tibsovo³ for the treatment of [REDACTED]. Fallon denied this request on August 20, 2025. The appellant requested a review of the denial. Fallon submitted the denial to MES Per Review Services which upheld the action on August 27, 2025. Fallon again denied the appellant's request on September 05, 2025. Fallon argued Tibsovo is only FDA approved for certain blood cancers in adults (AML, relapsed or refractory MDS, and cholangiocarcinoma (bile duct cancer)). Since the appellant's diagnosis is [REDACTED] the use of Tibsovo is considered off label. The representatives argued that there are no peer-reviewed studies or supporting clinical trial data for Tibsovo's use in [REDACTED] or for the specific age group of a [REDACTED]. Due to the limited information available, the use of Tibsovo for the treatment of [REDACTED] is considered theoretical and indirect (no testing or trials regarding [REDACTED] with only a single case report with a related disorder [REDACTED]). Because of this lack of evidence, Fallon classifies the medication as investigational or experimental and not covered under MassHealth guidelines. The representatives maintain that the potential risks of the drug, such as fatigue (which the appellant already experiences), and the possibility of serious side effects (like [REDACTED]), outweigh the unproven benefits in this case. The typical treatment for this condition is supportive care (pain medication) and surgical removal of tumors when they cause problems. Fallon submitted into evidence the appellant's notices and medical evidence. (Exhibit 4).

The appellant's representatives testified that the appellant was diagnosed with [REDACTED] at the age of [REDACTED] and has a confirmed IDH1 mutation.⁷ The appellant has had multiple surgical procedures

³ A targeted IDH1 therapy. It is a drug that is intended to block the pathway associated with the IDH1 mutation, potentially slowing tumor growth and reducing pain.

⁴ An extremely rare non-hereditary disorder characterized by the growth of multiple cartilaginous tumors (enchondromas) and can cause vascular anomalies. It can transform into a chondrosarcoma, a rare type of cancer that usually begins in the bones.

⁵ A related but different condition involving multiple enchondromas and blood vessel abnormalities (vascular tumors).

⁶ A condition in which the body's immune system attacks the nerves. It can cause weakness, numbness or paralysis.

⁷ A specific genetic mutation (Isocitrate Dehydrogenase 1) found in the appellant's tumors. The mutation is part of a cellular pathway that contributes to the disease and tumor growth. The appellant's representatives assert Tibsovo targets this mutation.

and removal of multiple enchondroma.⁸ Recently, the appellant has been having increasing pain which is difficult for a [REDACTED] to express, but is visible to his care providers and evidenced by the change in the appellant's functionality. The appellant's most recent MRI (July 11, 2025) confirmed the disease is progressing. The appellant has innumerable osseous lesions⁹ throughout his entire skeleton resulting growth disturbance and bone deformities. A number of lesions have increased in size in comparison to previous study. As a result, the representatives maintain the appellant needs to start treatment with Tibsovo, as it is a targeted IDH1 inhibitor. The representatives argue the [REDACTED] is one of the few centers in the [REDACTED] that specializes in the diagnosis and treatment of vascular malformations. BCH has a multidisciplinary program and have extensive experience with medical treatment for rare conditions.

The representatives acknowledge that there are currently no FDA-approved therapies and no open prospective clinical trials investigating the potential effect and benefits of medical therapies for patients with vascular anomalies affected by the IDH1 mutation. Due to the reported efficacy of Tibsovo in targeting IDH1 mutation in patients with AML, for which this medication has received FDA approval, BCH believes there is a high likelihood that Tibsovo may achieve a reduction in the appellant's tumor growth, help control and reduce his symptoms, and reduce his potential risk for malignancy. They believe the downstream effect of inhibiting the mutation will tremendously help with his pain and improve his daily life. Because there is no standard of care for rare and serious vascular anomalies, in the absence of an approved therapies for patients such as the appellant, the off-label drug use is a necessity. The appellant's condition is not just a growth disorder; it is driven by a specific genetic mutation (IDH1). The appellant's team, comprising pediatric hematology/oncology and vascular anomaly specialists, believes that using Tibsovo, a drug that specifically targets this known mutation, is medically necessary and is the best chance for treatment.

The record was left open for the submission of BCH letters of August 14, 2025 and August 20, 2025, as well the research article *Disruption of the HIF-1 pathway in individuals with [REDACTED]* [REDACTED] PLOS Genetics, <https://doi.org/10.1371/journal.pgen.1010504>, and Progress Notes dated August 14, 2025. (Exhibit 5).

Findings of Fact

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

1. The appellant is [REDACTED] and is diagnosed with [REDACTED] (Testimony; Exhibit 1).

⁸ Benign (non-cancerous) bone tumors that can grow and, in rare conditions like [REDACTED] transform into malignant (cancerous) tumors (chondrosarcoma) The presence and growth of these tumors cause pain and the loss of mobility.

⁹ Osseous lesions, also known as bone lesions, refer to areas where the bone has been damaged or has abnormal growth. They can be classified as either benign (non-cancerous) or malignant (cancerous). These lesions can occur in any bone in the body and may present symptoms such as pain, stiffness, or lumps.

2. The appellant is a member of Fallon Health, a MassHealth MCO. (Testimony; Exhibit 1).
3. Fallon submitted a prior authorization request for payment for the drug Tibsovo for the treatment of the appellant's [REDACTED] (Testimony; Exhibit 4).
4. Tibsovo is only FDA approved for the treatment of certain blood cancers in adults. (Testimony; Exhibit 4).
5. On August 20, 2025, Fallon denied the appellant's prior authorization request (Level 1 denial) for payment for the drug Tibsovo for the treatment of [REDACTED] as the drug is not FDA approved the treatment of [REDACTED] in pediatric patients. (Testimony; Exhibit 4).
6. On August 27, 2025, the Fallon decision was upheld by MES Peer Review Services. (Exhibit 4).
7. On September 05, 2025, Fallon again denied the request for payment for this drug (Level 2 denial). (Testimony; Exhibit 4).
8. The appellant filed a timely appeal with the Board of Hearings.

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, a member of MassHealth's MCO, Fallon, requested payment for the drug Tibsovo for the treatment of ██████████ Fallon denied the appellant's request at its Level 1 and Level 2 review. The issue is whether Fallon's denial of the requested drug is supported by the regulations, Fallon's policies, and the material facts contained in the hearing record.

The appellant is a ██████████ with ██████████ The appellant has documented IDH1 mutation and he has had multiple enchondromas and has required surgeries to treat his tumors. Currently, he has growing enchondromas with increasing pain and his medical team has prescribed Tibsovo to treat his condition.

It is undisputed that Tibsovo is not FDA approved as a therapy for the treatment of ██████████ Further, there is insufficient evidence to demonstrate that the drug meets the MassHealth or Fallon Health MCO criteria, as there is no supporting evidence or controlled clinical trials supporting its efficacy with the ██████████ in pediatric patients. The single case report referenced did not involve ██████████ and was not a controlled clinical trial – it therefore does not meet the appellant's burden here. The appellant's representatives argue that the authorization of Tibsovo for patients like the appellant would assist in creating the data that is currently missing from the medical community. While this assertion may be true, it falls short of establishing that Tibsovo is currently a safe and effective for the treatment of ██████████ (130 CMR 406.413(B)(5) and (C)(3)).¹⁰

The appellant's representatives have highlighted the appellant's bind here - they cannot generate the necessary data to prove the drug's efficacy for FDA approval unless they can use the drug, and Fallon will not authorize the drug for use because there is no data to prove its effectiveness. While this argument is noted, without FDA approval or peer-reviewed studies or supporting clinical trial data for the use of Tibsovo for the treatment of ██████████ in pediatric patients, this appeal must be denied.

¹⁰ 130 CMR 406.413: Limitations on Coverage of Drugs (B) Drug Exclusions. The MassHealth agency does not pay for the following types of prescription or over-the-counter drugs or drug therapy. (5) Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature. (C) Service Limitations. (3) The MassHealth agency does not pay for any drug prescribed for other than the FDA approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence.

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:

[REDACTED]

[REDACTED]