

Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision:	Denied	Appeal Number:	2410796
Decision Date:	10/22/2024	Hearing Date:	08/15/2024
Hearing Officer:	Mariah Burns	Record Open to:	09/13/2024

Appearance for Appellant:



Appearance for MassHealth:

Phung Luc, R. Ph., Pharm. D., Appeals
Reviewer, MassHealth Drug Utilization Review



*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:	Prior Authorization; Drug Utilization Review
Decision Date:	10/22/2024	Hearing Date:	08/15/2024
MassHealth's Rep.:	[REDACTED]	Appellant's Rep.:	Monika Smith, MA
Hearing Location:	Remote	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 notice dated June 5, 2024, MassHealth denied the appellant's request for prior authorization (PA) seeking coverage of Skyrizi 150 mg/ml Pen. *See* Exhibit 1. The appellant filed this appeal in a timely manner on July 11, 2024. *See* 130 CMR 610.015(B) and Exhibit 2. Denial of a prior authorization request is a valid basis for appeal. *See* 130 CMR 610.032.

Action Taken by MassHealth

MassHealth denied Appellant's PA request for Skyrizi 150 mg/ml Pen.

Issue

The appeal issue is whether MassHealth correctly applied the regulations in denying the appellant's PA request for Skyrizi 150 mg/ml Pen.

Summary of Evidence

The appellant is an adult MassHealth member who was represented at the hearing by a medical assistant from the office of his provider, a physician's assistant. MassHealth was represented by a registered pharmacist from MassHealth's Drug Utilization Review Program. The following is a summary of the testimony and evidence provided at the hearing:

On June 5, 2024, the appellant's provider submitted a prior authorization request seeking approval for coverage of the following medication: Skyrizi 150 mg/ml. The request form, which was specifically designated for "Targeted Immunomodulators," indicated that the medication was prescribed to treat moderate to severe plaque psoriasis, but did not include information about dosage and frequency of the requested medication, nor did it provide documentation of a well-defined clinical rationale for the use of Skyrizi instead of Stelara and Taltz.

The MassHealth representative explained that through its Drug List, MassHealth establishes and publishes medical necessity criteria for drugs that are subject to the agency prior approval. The MassHealth drug list requires that for approval of Skyrizi for treatment of moderate to severe plaque psoriasis, the requesting provider must include the appropriate diagnosis, appropriate dosing, and "clinical rationale for the use of the requested agent instead of Stelara and Taltz..." Exhibit 5 at 27. She reported that this would require clinical documentation indicating that Skyrizi is more efficacious than Stelara or Taltz, because the latter two medications are less expensive than Skyrizi.

On June 5, 2024, MassHealth denied the appellant's request on the basis that the submission did not contain sufficient information to determine medical necessity. The notice informed the provider that they could resubmit the request with additional information, including previous drug trials, dosage, and frequency of administration. The MassHealth representative explained that in preparation for this appeal, MassHealth sent the appellant a letter on July 26, 2024, requesting that the appellant provide documentation of the dose and frequency of Skyrizi prescribed and "documentation of well-defined clinical rationale for the use of Skyrizi instead of Stelara and Taltz." Exhibit 5 at 15. On August 1, 2024, the appellant provided an updated prior authorization request form that included the prescribed dosage and frequency for the appellant's use of Skyrizi, but did not have any clinical documentation regarding Skyrizi's effectiveness as opposed to Stelara or Taltz.

The appellant's representative testified that Skyrizi is the provider's preferred medication in circumstances such as the appellant's. In her experience, Stelara "doesn't seem to work," and she believed that the appellant had tried all previous treatments required of him before requesting Skyrizi. She testified that these requirements by MassHealth were a waste of patients' time and caused more unnecessary suffering. She intimated that the appellant had previous success using Skyrizi to treat his condition.

The record was kept open for the appellant to provide any clinical documentation that would aid in their argument. The MassHealth representative also reported that MassHealth could accept documentation regarding the appellant's stability on Skyrizi along with the dates and duration of his use along with his response to the therapy. The appellant did not submit anything additional during the record open period.

Findings of Fact

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

1. Appellant is a MassHealth member over the age of 21. Exhibit 4.
2. On or about June 5, 2024, the appellant's provider, a physician's assistant, sought MassHealth prior authorization for the following medication on behalf of the appellant: Skyrizi 150 mg/ml to treat moderate to severe plaque psoriasis. Exhibit 5 at 3-11.
3. The PA request form, which was specifically designated for "Targeted Immunomodulators," did not include information about dosage and frequency of the requested medication, nor did it provide documentation of a well-defined clinical rationale for the use of Skyrizi instead of Stelara and Taltz. *Id.*
4. On June 5, 2024, MassHealth denied Appellant's PA request on the basis that the submission did not contain sufficient information to determine medical necessity, and informed the provider that a new PA request could be submitted with additional information, "[p]rescriber may resubmit request with clinical rationale for use and additional clinical documentation (e.g. previous drug trials, dosage, and frequency of administration)." Exhibit 5 at 13.
5. In preparation for the hearing, MassHealth sent the appellant a letter on July 26, 2024, requesting medical documentation of the dose and frequency of Skyrizi prescribed and documentation "of well-defined clinical rationale for the use of Skyrizi instead of Stelara and Taltz. Exhibit 5 at 15.
6. On August 1, 2024, in response to MassHealth's letter, the appellant's provider submitted a new copy of the PA request that included additional information regarding the dose and frequency of the medication. Exhibit 6.
7. As of this decision, neither the appellant nor his representatives have provided documentation showing a clinical rationale for using Skyrizi instead of Stelara and Taltz, nor was any documentation provided showing that the appellant is stable on Skyrizi along with the dates and duration of his use along with his response to the therapy. Exhibit 7.

Analysis and Conclusions of Law

MassHealth does not cover a medical service unless it is “medically necessary.” The threshold considerations for determining whether a service is medically necessary are set forth under 130 CMR 450.204, which states, in full:

450.204: Medical Necessity

(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. ...

(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 MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.

(Emphasis added).

As subsection (D) indicates, MassHealth establishes additional medical necessity criteria throughout its regulations and publications governing specific health-related service-types. For coverage of prescription drugs, MassHealth publishes and routinely updates a “Drug List” - a formulary that identifies whether a covered drug is subject to prior approval and the specific criteria required to establish medical necessity for the drug. *See* 130 CMR 406.422; *see also* 130 CMR 450.303. The criteria used to determine medical necessity is “based upon generally

accepted standards of practice, review of the medical literature, federal and state policies, as well as laws applicable to the Massachusetts Medicaid Program.”¹ Further, the criteria reflect MassHealth’s policy as described in its pharmacy regulations and the reviews conducted by the agency and the DUR board. *See Id.*

As published in its Drug List, MassHealth has imposed the following PA criteria for coverage of Skyrizi (risankizumab-rzaa):

Skyrizi...for moderate to severe plaque psoriasis

- Documentation of the following is required:
 - appropriate diagnosis; **and**
 - appropriate dosing; **and**

....

- For...Skyrizi...clinical rationale for the use of the requested agent instead of Stelara and Taltz...

(Emphasis added). *See* Exhibit 5 at 27; *see also* MassHealth Drug List, Table 5 (www.mass.gov/druglist).

An appellant bears the burden of proof at fair hearings “to demonstrate the invalidity of the administrative determination.” *Andrews v. Division of Medical Assistance*, 68 Mass. App. Ct. 228, 231 (2006). The fair hearing decision, established by a preponderance of evidence, is based upon “evidence, testimony, materials, and legal rules, presented at hearing, including the MassHealth agency’s interpretation of its rules, policies and regulations.” 130 CMR 610.085(A).

Based on the evidence in the record, MassHealth did not err in denying the appellant’s prior authorization request for Skyrizi 150 mg/ml pen. The appellant’s provider did not submit documentation to establish the requisite criteria that there is a scientific, clinical rationale that warrants the use of Skyrizi over the use of Stelara or Taltz. The testimony of the appellant’s representative that Skyrizi is the provider’s preferred treatment, that Stelara “doesn’t seem to work,” and that it is a waste of the patient’s time to have them try other, less expensive treatments, is not sufficient clinical evidence that the other treatments are less effective. The appellant was given time to provide any such documentation after the hearing and failed to do so. All members must comply with the MassHealth regulations for MassHealth to cover a requested medication, without exception. To the extent this claim is a challenge to the legality of the MassHealth PA criteria, it cannot be adjudicated in this hearing decision, but may be pursued via judicial review in accordance with M.G.L. c. 30A.²

¹ *See* <https://mhd1.pharmacy.services.conduent.com/MHDL/>

² The hearing officer must not render a decision regarding the legality of federal or state law including, but not limited to, the MassHealth regulations. If the legality of such law or regulations is raised by the appellant, the hearing officer must render a decision based on the applicable law or regulation as

Based on the foregoing, Appellant did not establish, by a preponderance of the evidence, that MassHealth erred in denying his request for coverage of Skyrizi 150 mg/ml pen. As such, this appeal is hereby DENIED.

The appellant may, at any time, submit a new prior authorization request with the appropriate documentation for consideration.


Order for 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.

Mariah Burns
Hearing Officer
Board of Hearings



MassHealth Representative: Drug Utilization Review Program, ForHealth Consulting at UMass Chan Medical School, P.O. Box 2586, Worcester, MA 01613-2586, 774-455-3200

interpreted by the MassHealth agency. Such decision must include a statement that the hearing officer cannot rule on the legality of such law or regulation and must be subject to judicial review in accordance with 130 CMR 610.092. See 130 CMR 610.082(C)(2) (emphasis added); see also 130 CMR 450.244.