STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of the Department of Insurance and Financial Services

In the matter of:

[redacted]
Petitioner

v **File No. 239888-001**

Health Alliance Plan of Michigan
Respondent

Issued and entered
this 23rd day of October 2025
by Joseph Stoddard
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On September 23, 2025, [redacted], authorized representative for [redacted] (Petitioner), filed with the Director of the Department of Insurance and Financial Services a request for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. The request for review concerns the denial of prior authorization for a prescription drug. On September 30, 2025, the Director accepted the request for review.

The Petitioner receives health care benefits through Health Alliance Plan of Michigan (HAP), a health maintenance organization. The benefits are described in HAP's *Health Maintenance Organization (HMO) Group Subscriber Contract* (the contract). The Director notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP responded on October 10, 2025.

The Director assigned an independent review organization (IRO) to analyze the medical issues in this appeal. The IRO submitted its report to the Director on October 14, 2025.

II. FACTUAL BACKGROUND

The Petitioner has psoriasis which has not responded to aggressive topical therapies and a history of malignant melanoma. Past treatments for management of psoriasis included Enstilar and Vtama. On July 8, 2025, the Petitioner began taking the prescription drug Otezla and showed improvement in their psoriasis symptoms. The Petitioner's physician recommended continued treatment with Otezla and asked

HAP to authorize coverage. HAP denied the request on the basis its criteria for use were not met.

The Petitioner appealed HAP's decision through its internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated August 4, 2025, affirming its coverage denial. The Petitioner now seeks the Director's review of that determination.

III. ANALYSIS

Respondent's Argument

In its final adverse determination, HAP wrote:

> After considering all available evidence, previous decisions and your medication history, the decision is to uphold the original denial for Otezla. HAP's Criteria for Use of Otezla considers diagnosis, disease characteristics, and therapies tried.
>
> The requested use of Otezla is for the treatment of psoriasis (a condition in which skin cells build up and form scales, and itchy, dry patches). You do not meet HAP Criteria for Use of Otezla because the following is not demonstrated:
>
> (1) Medical records must document that 10% or greater of total body surface area is covered with moderate-to-severe psoriasis plaques.
>
> Office visit note dated July 8, 2025, documenting 5% of your body surface area is affected by psoriasis plaques.
>
> (2) Trial (3 months) and failure (medication was not helpful) of acitretin (oral (taken by mouth) medication helpful for management of psoriasis). NOTE: Acitretin is not immunosuppressive and does not affect the immune system.
>
> (3) Trial (3 months) and failure of all HAP preferred specialty medications, for example, Yesintek (Ustekinumab).
>
> PLEASE NOTE: This is not a complete list. Additional formulary medications may need to be tried before coverage can be approved.
>
> NOTE: Infliximab (Renflexis or Inflectra) is available without prior authorization. In addition, Hadlima and Yesintek (ustekinumab) will process at zero copay at Specialty Pharmacy (under the member's Prescription Pharmacy Benefit).
>
> You have previously used medications applied to the skin. Information submitted with the original request indicates you have tried Otezla in the past and would like to try Otezla again. However, the appeal does not include any new or additional documentation that the above criteria have been met to continue use.
>
> The appeal does not include any new or additional documentation that the above criteria have been met.
>
> Therefore, as HAP Criteria for Use of Otezla are not met, the decision is to uphold the original denial for Otezla.

Petitioner's Argument

In a letter submitted with the request for external review, the Petitioner's representative wrote:

> This letter serves as a second appeal for coverage of Otezla 30 mg tablet for our patient, [the Petitioner]. We are appealing the prior authorization denial, which cited unmet clinical criteria and formulary preference requiring trials of alternative treatments. We firmly believe that Otezla is the most appropriate and medically necessary treatment for [the Petitioner]'s unique clinical profile.
>
> [The Petitioner] has been diagnosed with plaque psoriasis (ICD-10: L40), presenting with thick plaques on her elbows and scalp. Her current symptoms include an itch Numeric Rating Scale (NRS) score of 2.0 and a Body Surface Area (BSA) involvement of 4%. She has a documented history of melanoma, which significantly impacts the safety considerations for her systemic treatment options. Prior to this, [the Petitioner] has tried and failed multiple therapies, including topical corticosteroids, Vtama, and topical vitamin D analogs. Despite these efforts, she continues to experience significant symptoms that meaningfully impact her quality of life. Given her history of melanoma, Otezla represents the safest and most appropriate systemic treatment option for her.
>
> The denial cited that [the Petitioner's] current BSA does not exceed 10%. However, it is crucial to note that her BSA has historically been documented as high as 12% on 10/28/2017. Furthermore, her current BSA measurement of 4% reflects the positive effects of ongoing therapy, not an absence of disease activity. [The Petitioner] has demonstrated meaningful improvement and stability while on Otezla, both in the past and at her most recent appointments.
>
> Specifically, just two weeks after restarting Otezla on 7/8/25, [the Petitioner] experienced a 1% reduction in BSA and a 3-point reduction in itch NRS severity (from 5 to 3), as noted at her 7/23/25 appointment. This makes Otezla a critical component of her treatment plan. Discontinuing or switching therapy would place her at unnecessary risk of disease destabilization and diminished quality of life. To optimize long-term outcomes and maintain disease control, continued coverage of Otezla is medically necessary.
>
> The denial was also based on the requirement for trials of alternative treatments, specifically acitretin, Hadlima (adalimumab), Enbrel (etanercept), ustekinumab, and infliximab. The remainder of this letter will outline why these requirements are not clinically appropriate for [the Petitioner]. We kindly request approval for her to continue treatment with Otezla.
>
> ACITRETIN:
>
> Our patient is contraindicated from using acitretin due to concurrent use of other medications metabolized in the liver, which significantly increases the risk of hepatotoxicity and long-term liver damage, as these medications are all hepatotoxic. In addition, acitretin is not considered an appropriate first-line therapy

for this condition. Its reduced efficacy compared to newer systemic agents, combined with the potential for serious adverse events such as infections and organ dysfunction, as well as the requirement for intensive laboratory monitoring, make it an unsuitable step therapy option.

ADALIMUMAB:

In the management of plaque psoriasis, Otezla (apremilast) demonstrates clinically relevant superiority over adalimumab, particularly for patients seeking an oral, non-biologic therapy with established efficacy and a favorable safety profile. In the phase III ESTEEM trials, Otezla achieved a PASI-75 response in 33-41% of patients at week 16. This is a meaningful improvement, especially considering the study population often included those who were biologic-naive or had contraindications to biologic agents. Otezla is specifically FDA-approved for adult patients with plaque psoriasis who are candidates for systemic therapy or phototherapy, and its efficacy is established without the risks of serious infections, malignancies, or TB reactivation associated with adalimumab. Head-to-head data further reinforces Otezla's superiority in safety and patient suitability.

The LIBERATE trial directly compared Otezla and etanercept, another TNF inhibitor, revealing similar PASI- 75 rates at week 16, but Otezla's oral administration and absence of immunosuppressive complications position it as a preferred option for many patients. Unlike adalimumab, Otezla requires no baseline or ongoing lab monitoring, providing significant clinical and logistical advantages. Furthermore, Otezla is guideline endorsed as an appropriate and effective systemic therapy for moderate-to-severe plaque psoriasis, distinguished by its broad labeling and favorable risk/benefit profile. Adalimumab's risk of serious adverse effects, including infection and malignancy, renders it an inferior option, particularly when a safe, non-immunosuppressive, and effective oral therapy is both indicated and available for [the Petitioner].

ENBREL:

Regarding Enbrel, Otezla demonstrates superior clinical utility in long-term efficacy, safety, and guideline positioning. Unlike Enbrel, which has been explicitly downgraded in recent American Academy of Dermatology National Psoriasis Foundation (AAD-NPF) guidelines due to lower sustained PASI outcomes, OTEZLA maintains a strong position based on both regulatory approval and outcome-based performance. In the ESTEEM I and 2 trials, Otezla achieved PASI 75 responses in approximately 33-41 % of patients by week 16 and continued to show durable response through 52 weeks. While these rates may initially appear lower than some biologics, Enbrel has consistently underperformed relative to other systemic agents, notably failing to reach benchmark PASI 90 thresholds in head-to-head trials. Critically, Otezla's oral administration and lack of laboratory monitoring provide a major advantage in patient adherence and long-term tolerability, without compromising safety. Enbrel, by contrast, has been associated with injection site reactions and immunosuppressive risks, making it a less favorable option for patients seeking long-term management without the burden of

biologic-associated monitoring. The CLEAR trial and subsequent studies further confirmed Enbrel's inferior efficacy versus IL-17 and IL-23 agents, which led to its deprioritization in treatment algorithms.

Given Otezla's FDA-approved indication for moderate-to-severe plaque psoriasis in patients eligible for systemic therapy or phototherapy, alongside its superior tolerability and maintenance profile, it is the clinically preferred therapy over Enbrel in this context for [the Petitioner].

INFLIXIMAB:

Otezla also demonstrates consistent, meaningful skin clearance and a favorable safety profile compared to infliximab. In the ESTEEM- I and ESTEEM-2 trials, Otezla achieved PASI-75 responses in 33% and 29% of patients at Week 16, respectively-versus just 5-6% with placebo-confirming statistically robust efficacy in biologic-naive populations. While Otezla is slower than biologic agents in achieving clearance, its oral administration, absence of infusion requirements, and lower immunosuppressive burden support easier, safer outpatient management without the need for infusion centers or intensive monitoring. In contrast, infliximab is associated with higher risks of serious infection, infusion reactions, and indirect cost burdens from IV administration. In a large registry analysis, infliximab carried a significantly greater rate of serious infections requiring hospitalization compared to non-TNF biologics-and Otezla did not increase such risks in similar evaluations. Remicade's intravenous dosing schedule-typically every 6-8 weeks-necessitates repeated infusion visits and exposes patients to infusion-related adverse events, logistical burdens, and higher monitoring costs.

Therefore, for patients with plaque psoriasis who require systemic therapy, Otezla provides a clearly clinically preferable option: the oral PDE-4 mechanism offers proven PASI-75 efficacy by Week 16 with a more manageable safety profile and greater convenience. Remicade's biologic mechanism lacks regulatory differentiation in this context, and its well-characterized disadvantages in infection risk and logistic complexity render it a clinically inferior alternative for first-line systemic therapy in plaque psoriasis for [the Petitioner].

USTEKINUMAB:

Furthermore, Otezla (apremilast) provides a clinically superior option to ustekinumab, particularly in terms of its safety profile, mechanism of action, and regulatory positioning for long-term management. Unlike ustekinumab, OTEZLA is an oral, non-biologic PDE4 inhibitor with no requirement for baseline or ongoing laboratory monitoring, making it notably more suitable for patients requiring systemic therapy without the risks associated with immunosuppressive biologics. The ESTEEM I and 2 trials demonstrated that by week 16, 29- 33% of Otezla-treated patients achieved PASI 75 compared to placebo, with maintained response through week 52 in many cases. These outcomes, combined with its favorable tolerability and lack of contraindications related to infection or malignancy history, position Otezla as a front-line systemic option in appropriate patient populations. Ustekinumab, while approved for psoriasis, underperforms in

> direct comparison due to its immunosuppressive mechanism and associated risks, including serious infections and malignancies-an important distinction for patients requiring sustained therapy.
>
> Moreover, ustekinumab does not offer an efficacy advantage that justifies its injectable route and monitoring burden, particularly in patients with moderate disease or contraindications to biologics. Otezla's oral administration and broad indication-spanning both plaque psoriasis and psoriatic arthritis without limitation to disease severity-further distinguish it as the clinically preferred therapy. Given the safety, administration, and regulatory profile, ustekinumab represents a less appropriate and risk-laden alternative for [the Petitioner].
>
> We believe it is medically necessary for [the Petitioner] to access Otezla 30 mg tablet for the treatment of her condition. Therefore, we kindly urge you to reconsider and approve the coverage for Otezla for [the Petitioner] promptly.

Director's Review

The Director assigned an IRO to evaluate HAP's criteria and help determine whether the prescription drug Otezla is medically necessary for treating the Petitioner's condition. This review is required by section 11(7) of the Patient's Right to Independent Review Act, MCL 550.1911(7).

The IRO reviewer is a physician who is board-certified in dermatology and is in active practice. The IRO reviewer's report included the following analysis and recommendation:

> *1. Are the plan's criteria which denied coverage for the prescription drug Otezla consistent with the standard of care?*
>
> Yes. The plan's criteria for the prescription drug Otezla are consistent with the standard of care. Otezla is considered an effective, safe, systemic drug used to treat plaque psoriasis.
>
> *2. If they are, does the member meet the criteria for coverage such that the prescription drug Otezla is medically necessary?*
>
> Yes. The patient meets criteria for coverage such that the prescription drug Otezla is considered medically necessary.
>
> The patient has tried and failed topical steroids, vitamin D analogs, and VTAMA cream and has failed these topicals. Several months ago, the patient started Otezla and showed clinical improvement. The patient had malignant melanoma on her genitals in 2015, and her provider is recommending a safe systemic drug that does not suppress her immune system. This is appropriate and medically necessary for her. The criteria require her to go on a biologic drug.

***

Reviewer's Clinical Rationale for the Decision:

Otezla is considered the standard of care for patients who have failed topical therapies and medications and need a systemic drug. Otezla is currently recommended by the current national guidelines by the American Academy of Dermatology (AAD) and National Psoriasis Foundation joint guidelines.

The patient has a past history of malignant melanoma on her genitals in 2015 and requires a safe systemic drug that does not suppress her immune system. In patients with invasive malignant melanoma, it is important to have one's immune system intact and well-functioning immunosuppressive drugs, such as TNF inhibitors, can potentially risk the reoccurrence of tumors and should be avoided if at all possible. Otezla is an appropriate and medically necessary drug for this patient.

The IRO reviewer recommended that the Director reverse HAP's denial of coverage.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan,* 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the Director must cite "the principal reason or reasons why the director did not follow the assigned independent review organization's recommendation." MCL 550.1911(18)(b). The IRO's review is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(17).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the prescription drug Otezla is medically necessary, and therefore, is covered under the Petitioner's benefit plan.

IV. ORDER

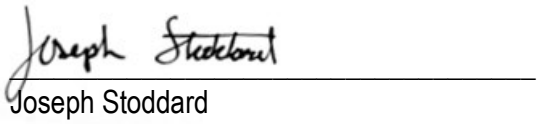
The Director reverses Health Alliance Plan of Michigan's August 4, 2025, final adverse determination. HAP shall immediately authorize coverage for the prescription drug Otezla. See MCL 550.1911(19). Further, HAP shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Office of Appeals and Market Regulation, at this toll-free telephone number: (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the Michigan county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of Appeals and Market Regulation, Post Office Box 30220, Lansing, MI 48909-7720.

Anita G. Fox
Director

For the Director:



Joseph Stoddard
Special Deputy Director