VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Otezla/Otezla XR Prior Authorization Policy
- Otezla® (apremilast tablets – Amgen)
- Otezla XR™ (apremilast extended-release tablets) – Amgen

REVIEW DATE: 05/21/2025; selected revision 08/06/2025, 09/10/2025, 09/24/2025

OVERVIEW

Otezla, an oral phosphodiesterase 4 (PDE4) inhibitor, is indicated for the following uses:[1]
- **Behcet's disease**, in adults with oral ulcers.
- **Plaque psoriasis**, in adults who are candidates for phototherapy or systemic therapy.
- **Plaque psoriasis**, in pediatric patients ≥ 6 years of age and weighing ≥ 20 kg with moderate to severe disease who are candidates for phototherapy or systemic therapy.
- **Psoriatic arthritis**, in adults with active disease.
- **Psoriatic arthritis,** in pediatric patients ≥ 6 years of age and weighing ≥ 20 kg with active disease.

Otezla XR is indicated for the following uses:[1]
- **Behcet's disease**, in adults with oral ulcers.
- **Plaque psoriasis**, in adults who are candidates for phototherapy or systemic therapy.
- **Plaque psoriasis**, in pediatric patients ≥ 6 years of age and weighing ≥ 50 kg with moderate to severe disease who are candidates for phototherapy or systemic therapy.
- **Psoriatic arthritis**, in adults with active disease.
- **Psoriatic arthritis,** in pediatric patients ≥ 6 years of age and weighing ≥ 50 kg with active disease.

Guidelines

Otezla is addressed in guidelines for treatment of inflammatory conditions.
- **Behcet's Disease:** Recommendations for the management of Behcet's disease from the European League Against Rheumatism (2018) mention Otezla as a treatment option for Behcet's disease with mucocutaneous involvement.[7] Other options include topical steroids, colchicine, azathioprine, thalidomide, interferon alpha, and tumor necrosis factor inhibitors (TNFis). TNFis are also listed among the therapeutic options for patients who present with eye involvement, refractory venous thrombosis, arterial involvement, refractory/severe gastrointestinal involvement, nervous system involvement, and/or joint involvement.
- **Plaque Psoriasis:** Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2020) have been published for management of psoriasis with systemic non-biologic therapies.[8] These guidelines list Otezla as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. For treatment of moderate to severe psoriasis in adults, Otezla has a similar level of evidence and strength of recommendation as methotrexate. Additionally, data support use of methotrexate in combination with other systemic therapies for psoriasis,[4,8] whereas there is no strong evidence supporting combination use of Otezla with other systemic therapies or with phototherapy.[4] Pediatric guidelines were published by the American Academy of Dermatology and the National Psoriasis Foundation (2020).[11] These guidelines list traditional systemic therapies (e.g., methotrexate, cyclosporine, acitretin) and biologics as options for treatment of moderate to severe plaque psoriasis. There was insufficient data in pediatric patients to make recommendations for Otezla.

- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology (2019) recommend TNFis over other biologics and Otezla for use in treatment-naïve patients with psoriatic arthritis and in those who were previously treated with an oral therapy.[6]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Otezla/Otezla XR. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Otezla/Otezla XR as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Otezla/Otezla XR to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Prescriber Attestation: Prescriber attestation is required to confirm that Otezla/Otezla XR will not be administered in combination with a biologic (refer to Appendix) or with another targeted synthetic oral small molecule drug (refer to Appendix) used for an inflammatory condition. This is noted in the criteria as **[attestation required]**, signaling that the provider must confirm prior to approval. Attestation may include verbal, written, or electronic confirmation.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Otezla/Otezla XR is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Behcet's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has oral ulcers or other mucocutaneous involvement; AND
     - **iii.** Patient has tried at least ONE other systemic therapy; AND
       Note: Examples of systemic therapies include colchicine, systemic corticosteroids, azathioprine, thalidomide, interferon alpha, tumor necrosis factor inhibitors (e.g., an adalimumab product [Humira, biosimilars], an etanercept product [Enbrel, biosimilars], Cimzia [certolizumab pegol subcutaneous injection], Simponi [golimumab subcutaneous injection], Simponi Aria [golimumab intravenous infusion], or an infliximab product [Remicade, biosimilars]).
     - **iv.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist; OR
   - **B)** Patient is Currently Receiving Otezla/Otezla XR. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient has been established on therapy for at least 4 months; AND
       Note: A patient who has received < 4 months of therapy or who is restarting therapy should be considered under criterion A (Initial Therapy).
     - **ii.** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Otezla/Otezla XR); AND
       Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); ulcer depth, number, and/or lesion size.

iii. Compared with baseline (prior to initiating Otezla/Otezla XR), patient experienced an improvement in at least one symptom, such as decreased pain or improved visual acuity (if ophthalmic manifestations).

2. Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 6 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) If Otezla is being requested, the patient weighs ≥ 20 kg; OR

b) If Otezla XR is being requested, the patient weighs ≥ 50 kg; AND

iii. Patient meets ONE of the following (a or b):

a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR

Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, or acitretin tablets. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. Refer to Appendix for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND

iv. The medication is prescribed by or in consultation with a dermatologist; OR

B) Patient is Currently Receiving Otezla/Otezla XR. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on therapy for at least 4 months; AND

Note: A patient who has received < 4 months of therapy or who is restarting therapy with the requested drug should be considered under criterion A (Initial Therapy).

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND

iii. Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

3. Psoriatic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of following (i, ii, and iii):

i. Patient is ≥ 6 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) If Otezla is being requested, the patient weighs ≥ 20 kg; OR

b) If Otezla XR is being requested, the patient weighs ≥ 50 kg; AND

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist; OR

B) Patient is Currently Receiving Otezla/Otezla XR. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on the requested drug for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Otezla/Otezla XR); OR

Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index

(CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating Otezla/Otezla XR), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Otezla/Otezla XR is not recommended in the following situations:

1. **Ankylosing Spondylitis.** Current evidence does not support use of Otezla/Otezla XR in ankylosing spondylitis. In a published, double-blind, placebo-controlled, Phase III study, patients (n = 490) were randomized in a 1:1:1 ratio to treatment with Otezla 30 mg twice daily, Otezla 20 mg twice daily, or placebo.[9] At Week 16, the change from baseline in the primary endpoint (Assessment of the Spondyloarthritis international Society 20 [ASAS20] response) was not statistically significantly different between the Otezla and placebo groups.

2. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug [attestation required].** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix). Concurrent therapy is not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
   Note: Conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) may be used concurrently with this medication.

3. **Rheumatoid Arthritis.** Current evidence does not support use of Otezla/Otezla XR in rheumatoid arthritis. A multicenter, double-blind, Phase II study (n = 237) randomized patients in a 1:1:1 ratio to treatment with Otezla 20 mg twice daily, Otezla 30 mg twice daily, or placebo.[10] All patients were required to take a stable dose of methotrexate throughout the study. At Week 16, a similar proportion of patients in all treatment groups achieved an American College of Rheumatology (ACR) 20 response (28%, 34%, and 35%, respectively). At Week 16, patients who were non-responders, defined as patients with a swollen joint count and tender joint count that had not improved by at least 20%, were required to enter early escape (patients who were receiving placebo were transitioned to Otezla 20 mg twice daily and patients receiving Otezla continued on the assigned therapy for an additional year). At Week 24, all patients who received placebo were similarly transitioned to Otezla. At Weeks 24 and 52, both doses of Otezla were associated with generally similar changes versus placebo, including ACR 20, ACR 50, and ACR 70. A subset of patients underwent magnetic resonance imaging evaluation; however, no significant difference in response rate was observed at Week 16. The study was terminated early; data were not analyzed at Year 2 as originally planned.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/07/2023
Early Annual Revision	**Plaque Psoriasis**: Expanded age requirement from ≥ 18 to ≥ 6 years of age.	05/08/2024
Selected Revision	**Plaque Psoriasis:** In the Note, psoralen plus ultraviolet A light (PUVA) was removed from the examples of traditional systemic therapies. An additional Note was added that a 3-month trial of PUVA counts as a traditional systemic therapy. **Conditions Not Recommended for Approval:** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).	09/11/2024
Annual Revision	No criteria changes.	05/21/2025
Selected Revision	**Psoriatic Arthritis:** Expanded age requirement from ≥ 18 to ≥ 6 years of age.	08/06/2025
Selected Revision	The title of the policy was changed from Inflammatory Conditions – Otezla Prior Authorization Policy to Inflammatory Conditions – Otezla/Otezla XR Prior Authorization Policy. **Behcet's Disease:** Otezla XR was added with the same criteria as Otezla. **Plaque Psoriasis and Psoriatic Arthritis:** Otezla XR was added with the same criteria as Otezla. For Otezla, a requirement was added that patient weighs ≥ 20 kg, and for Otezla XR, the patient weighs ≥ 50 kg.	09/10/2025
Selected Revision	**Policy Statement:** This was updated to define prescriber attestation and describe its use to confirm that Otezla/Otezla XR will not be administered concurrently with a biologic or with another targeted synthetic oral small molecule drug used for an inflammatory condition. **Conditions Not Recommended for Approval:** For "concurrent use of Otezla or Otezla XR with a biologic or with a targeted synthetic oral small molecule drug", a requirement was added that the prescriber must attest that Otezla or Otezla XR will not be administered in combination with a biologic or with another targeted synthetic oral small molecule drug used for an inflammatory condition.	09/24/2025

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars)	Inhibition of IL-12/23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsA, PsO
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	AS, nr-axSpA, PsA, PsO
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla®/Otezla XR™ (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.