VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Sotyktu Prior Authorization Policy
- Sotyktu™ (deucravacitinib tablets – Bristol Myers Squibb)

**REVIEW DATE:** 10/01/2025; selected revision 03/11/2026, 03/18/2026

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## OVERVIEW

Sotyktu, a tyrosine kinase 2 (TYK2) inhibitor, is indicated for the following uses:[1]

- Treatment of moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy. Limitation of use: Sotyktu is not recommended in combination with potent immunosuppressants.
- Treatment of active **psoriatic arthritis** in adults.

## Guidelines

*Psoriasis*

Joint guidelines from the American Academy of Dermatology (AAD) and National Psoriasis Medical Board have not been updated to include Sotyktu. In 2019, guidelines were published for the management of psoriasis with biologics.[2] These guidelines list all the biologics approved at the time of publication as agents that may be used as monotherapy for adults with moderate to severe psoriasis. The 2020 AAD and National Psoriasis Medical Board guidelines for management of psoriasis with systemic non-biologic therapies provide recommendations for several medications including methotrexate, cyclosporine, acitretin, as well as apremilast (Otezla®).[3]

Guidelines from the European Dermatology Forum (2025) include Sotyktu and recommend as second-line therapy for most patients requiring systemic treatment when there is inadequate response, contraindication, or intolerance to conventional systemic agents (e.g., methotrexate, cyclosporine, acitretin).[4]

*Psoriatic Arthritis*

Guidelines from the American College of Rheumatology have not been updated to include Sotyktu. ACR (2019) recommends 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.[5]

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Sotyktu. All approvals are 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 Sotyktu as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sotyktu to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sotyktu is recommended in those who meet the following criteria:

**FDA-Approved Indication**

1. **Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** 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 one traditional systemic agent 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 or Otezla (apremilast tablets)/Otezla XR (apremilast extended-release tablets). Refer to Appendix for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic or Otezla (apremilast tablets)/Otezla XR (apremilast extended-release tablets) for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
       - **b)** According to the prescriber, the patient has a contraindication to methotrexate; AND
     - **iii.** Patient will not be taking Sotyktu concurrently with other potent immunosuppressants, including methotrexate; AND
     - **iv.** The medication is prescribed by or in consultation with a dermatologist; OR
   - **B)** Patient is Currently Receiving Sotyktu. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient has been established on therapy for at least 3 months; AND
       Note: A patient who has received < 3 months of therapy or who is restarting therapy is reviewed 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 initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning; AND
     - **iv.** Patient will not be taking Sotyktu concurrently with other potent immunosuppressants, including methotrexate.

2. **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 BOTH of the following (i and ii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist; OR
   - **B)** Patient is Currently Receiving Sotyktu. 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 Sotyktu); 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 Sotyktu), 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 Sotyktu is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** 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 for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

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

## REFERENCES

1. Sotyktu™ tablets [prescribing information]. Princeton, NJ: Bristol Myers Squibb; March 2026.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
4. Nast A, Spuls PI, Dressler C, et al. EuroGuiDerm guideline for the systemic treatment of psoriasis vulgaris. Updated February 2025. Available at: https://www.guidelines.edf.one/guidelines/psoriasis-guideline. Accessed on: March 9, 2026.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 09/13/2023 |
| Selected Revision | **Plaque Psoriasis:** For a patient currently taking Sotyktu, the timeframe for established on therapy was changed from 90 days to 3 months. | 03/27/2024 |
| 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.<br>**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. | 10/09/2024 |
| Annual Revision | **Plaque Psoriasis:** For Initial Therapy, in the Note, a 3-month trial or prior intolerance to Otezla (apremilast tablets) or Otezla XR (apremilast extended-release tablets) was added as an exception to the requirement for a trial of one traditional systemic agent for psoriasis. For Initial Therapy, the requirement "patient has a contraindication to methotrexate, as determined by the prescriber" was modified to "according to the prescriber, the patient has a contraindication to methotrexate".<br>**Conditions Not Recommended for Approval:** For concurrent use with a biologic or with a targeted synthetic oral small molecule drug, the Note was removed stating "this does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication." | 10/01/2025 |
| Selected Revision | **Psoriatic Arthritis:** This new condition for approval was added to the policy.<br>**Appendix:** Otezla XR (apremilast extended-release tablets) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecular Drugs. | 03/11/2026 |
| Selected Revision | **Conditions Not Recommended for Approval:** Concurrent use with other potent immunosuppressants, including methotrexate, was removed.<br>**Plaque Psoriasis:** For initial therapy and for patients currently receiving Sotyktu, the requirement that the patient will not be taking Sotyktu concurrently with other potent immunosuppressants, including methotrexate, was added. | 03/18/2026 |

## 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, JIA, 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, biosimilars; Actemra SC, biosimilars) | 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, PsO, PsA, 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®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Otezla XR™** (apremilast extended-release 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, PsA |
| **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.