UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2297-5
Program	Prior Authorization/Medical Necessity
Medication	Sotyktu™ (deucravacitinib)
P&T Approval Date	1/2023, 4/2023, 7/2023, 7/2024, 10/2024
Effective Date	1/1/2025

1. Background:

Sotyktu is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Limitations of Use:
Not recommended for use in combination with other potent immunosuppressants.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. **Initial Authorization**

a. **Sotyktu** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

(2) **One** of the following:

(a) **All** of the following:

i. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

ii. History of failure to **one** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
c. Tazarotene
d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
e. Anthralin
f. Coal tar

-AND-

iii. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab)]

-OR-

(c) **Both** of the following:

i. Patient is currently on Sotyktu therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Sotyktu*

-AND-

(3) Patient is not receiving Sotyktu in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Olumiant (baricitinib), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Siliq (brodalumab), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)]

-AND-

(4) Prescribed by or in consultation with a dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sotyktu** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Sotyktu therapy

-AND-

(2) Patient is not receiving Sotyktu in combination with another targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Ilumya (tildrakizumab), Olumiant (baricitinib), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Siliq (brodalumab), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

1. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022
2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.

7. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
8. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
9. 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;80:1029-72.

Program	Prior Authorization/Medical Necessity - Sotyktu (deucravacitinib)
Change Control	
1/2023	New program
4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote "For a list of preferred adalimumab products please reference drug coverage tools."
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
7/2024	Annual review. Updated step therapy criteria requirements. Updated state mandate foot note.
10/2024	Removed step through preferred products. Added continuation of therapy to initial criteria. Removed preferred adalimumab footnote. Updated examples with no change to clinical intent.