CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Sotyktu (deucravacitinib)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Sotyktu is a tyrosine kinase 2 inhibitor initially approved by the FDA in 2022. It is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Sotyku is the first drug in its class to gain FDA approval for any condition. The approval of Sotyktu was based on results from the Phase 3 POETYK PSO-1 and POETYK PSO-2 clinical trials, both of which compared Sotyktu head-to-head with Otezla 30 mg twice daily as well as with placebo. In both studies, Sotyktu outperformed Otezla and placebo on two commonly used measures for assessing skin clearing: Psoriasis Area and Severity Index (PASI) and static Physician's Global Assessment (sPGA).

Sotyktu (deucravitinib) will be considered for coverage when the following criteria are met:

Plaque Psoriasis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of moderate to severe plaque psoriasis; AND
4. Member has tried and failed to respond to treatment with at least one of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
5. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
6. Member has a negative tuberculosis test within the last 12 months.
7. **Dosage allowed/Quantity limit:** Administer one tablet (6mg) once daily. Quantity Limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Sotyktu (deucravacitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/27/2022	New policy for Sotyktu created.

References:

1. Sotyktu [prescribing information]. Princeton, New Jersey: Bristol-Myers Squibb Company; September 2022.
2. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. J Am Acad Dermatol. 2020; S0190-9622(20)32288-X.
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. 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.
5. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. J Am Acad Dermatol. 2019;81(3):775-804.
6. Menter A, Cordoro KM, Davis DM, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol 2020; 82:161-201.
7. ClinicalTrials.gov. Identifier: NCT02307513. A Phase 3 Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Apremilast (CC-10004) in Subjects with Active Behcet's Disease. Available at: https://clinicaltrials.gov/ct2/show/NCT02307513?term=BCT-002&rank=2.

Effective date: 04/01/2023
Revised date: 09/27/2022