AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Sotyktu	Page:	1 of 3
Effective Date:	5/1/2025	Last Review Date:	11/2023; 4/2024; 4/2025
Applies to:	☐Illinois ☐New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia	☒Florida Kids ☐Michigan ☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Sotyktu under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Treatment of adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Non-Preferred: Sotyktu

Policy/Guideline:

Documentation for all indications:
The patient is unable to take THREE preferred products, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.
THREE preferred products:

- A preferred adalimumab product OR Enbrel
- A preferred ustekinumab product
- Otezla

Documentation:
Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
   2. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Prescriber Specialty:
This medication must be prescribed by or in consultation with a dermatologist.

Criteria for Initial Approval:
Plaque psoriasis (PsO)

A. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Otezla) indicated for treatment of moderate to severe plaque psoriasis.

B. Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:
   1. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   2. At least 10% of body surface area (BSA) is affected.
   3. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
      i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
      ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Continuation of Therapy:
Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

A. Reduction in body surface area (BSA) affected from baseline
B. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

APPENDIX
Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease

2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Approval:
Initial and Renewal Approval: 12 months

Quantity Level Limit: 30 tablets per 30 days

References:

1. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.
2. Armstrong, AW, Gooderham M, Warren RB, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: efficacy and safety results from the 52-week, randomized, double-blinded, placebo-controlled phase 3 POETYK PSO-1 trial. *J AM Acad Dermatol*. 2023;88(1):29-39. doi:10.1016/j.jaad.2022.07.002.
3. Strober B, Thaçi D, Sofen H, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: Efficacy and safety results from the 52-week, randomized, double-blinded, phase 3 Program fOr Evaluation of TYK2 inhibitor psoriasis second trial. *J Am Acad Dermatol*. 2023;88(1):40-51.
4. Menter, A, Gelfand, JM, Connor, C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6): 1445-86.
5. 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.
6. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
7. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 4, 2023 from: https://www.cdc.gov/tb/topic/basics/risk.htm.