Original Effective Date: 02/25/2023
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Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C24672-A

Sotyktu (deucravacitinib)

PRODUCTS AFFECTED

Sotyktu (deucravacitinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Plaque psoriasis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:
1. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA

label
AND

2. Member is not on concurrent treatment or will not be used in combination with TNF-inhibitors, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
3. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

B. MODERATE TO SEVERE PLAQUE PSORIASIS:
1. Documented diagnosis of moderate to severe psoriasis (BSA ≥ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
   AND
2. (a) Documentation of treatment failure or serious side effects to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
   OR
   (b) Documentation of treatment failure to Phototherapy for ≥3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation. Provider to submit documentation of duration of treatment, dates of treatment, or number of sessions.
   OR
   (c) Documentation of contraindication to systemic therapy and phototherapy
   NOTE: Contraindications to phototherapy include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time.
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. PLAQUE PSORIASIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., serious infection, elevated liver enzymes)
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
6mg once daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Antipsoriatic - Systemic

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to*

receive more than one prior authorization annually of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.

(b) This section does not apply to:

(1) opioids, benzodiazepines, barbiturates, or carisoprodol;

(2) prescription drugs that have a typical treatment period of less than 12 months;

(3) drugs that:

(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and

(B) must have specific provider assessment; or

(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Sotyktu is a tyrosine kinase 2 inhibitor indicated for the treatment of moderate to severe plaque psoriasis. Sotyktu is a part of the Janus Kinase family and prevents downstream activation of signal transducers and activators of transcription and subsequent cytokine pathways.

Plaque psoriasis is a T-lymphocyte mediated inflammatory skin autoimmune disorder characterized by recurrent exacerbations and remissions. Psoriasis is characterized by patches of raised reddish skin covered with a silvery-white scale that may itch or burn and sometimes be painful. Triggers for psoriasis include cold weather, infection, stress and injury to the skin. If left untreated this disease can have a negative effect on the patient's mental health and put them at a higher risk for skin cancer.

Current treatment guidelines for moderate to severe plaque psoriasis include systemic agents like methotrexate, Xeljanz, and Otezla which can be used in combination with topical agents such as clobetasol or triamcinolone cream/ointment and phototherapy. If this treatment is ineffective, biologic response modifiers can be used as first line treatment (i.e., Humira, Stelara). Given Sotyktu's recent FDA approval, this medication is not yet referenced in the current psoriasis treatment guidelines.

The landmark trial for FDA approval of Sotyktu was "Deucravacitinib versus placebo and apremilast (Otezla) 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". This study included adults 18 years of age or older with moderate to severe plaque psoriasis for 6 months or more prior to screening. Moderate to severe plaque psoriasis was defined as psoriasis area and severity index (PASI) ≥12 and the static Physician's Global Assessment (sPGA) ≥3 and a body surface involvement ≥10%. This study excluded patients with infection, other immunodeficiencies, and patients with significant medical history or concurrent diseases such as mental health illness, certain cardiovascular conditions and other unstable clinical conditions. The two primary endpoints in this study were PASI response rates ≥75% reduction from baseline to week 16 and an sPGA score of 0 or 1 from baseline to week 16 comparing deucravacitinib versus placebo. The mean age in this study was 47 years old, 68% of subjects were male and 87% were white. At baseline, subjects had a median affected body surface area of 20%, a median PASI score of 19 and 80% of patients had an sPGA score of 3. In POETYK PSO-1, 40% of subjects had received prior phototherapy, 42% were naive to any systemic therapy, 41% received prior non-biologic systemic treatment, and 35% had received prior biologic therapy. 666 patients in this study were randomized 2:1:1, 332 people received deucravacitinib 6mg by mouth daily, 166 people received placebo, and 168 people received Otezla 30mg twice daily. At week 16, 58.4% of participants (n=193) in the deucravacitinib achieved PASI 75, compared to 12.7% and 35.1% in the placebo and Otezla group, respectively. SPGA responses of 0 or 1 were received in 53.6% (n=178) of patients in the deucravacitinib group, compared to 7.2% in the placebo group and 32.1% in the Otezla group. Adverse effects reported were similar to those in the placebo and Otezla groups, the most common adverse events experienced from deucravacitinib included nasopharyngitis and upper respiratory infection. Another pivotal trial that earned Sotyktu FDA approval was POETYK PSO-2. POETYK PSO-1 and PSO-2 trials studied the same primary outcomes,

however a few key differences were noted. POETYK PSO-2 had more participants and included a randomized withdrawal and retreatment period after week 24.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Sotyktu (deucravacitinib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Sotyktu (deucravacitinib) include: Known hypersensitivity to deucravacitinib or any of the excipients in Sotyktu, concurrent use with live vaccines.

OTHER SPECIAL CONSIDERATIONS:
Sotyktu may increase the risk of infection and elevate liver enzymes and triglycerides. Cases of rhabdomyolysis and malignancy including lymphomas were reported in the clinical trial.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Sotyktu TABS 6MG

REFERENCES

1. Sotyktu (deucravacitinib) tablets, for oral use [prescribing information]. New York, New York: Bristol Myers Squibb; September 2022.
2. Armstrong, A. W., et al. (2022). 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. Journal of the American Academy of Dermatology, S0190-9622(22)02256-3.
3. Menter, A., et al. (2019). Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology, 80(4), 1029– 1072.
4. Menter, A., Gelfand, J., Connor, C., Armstrong, A., Cordoro, K., & Davis, D. et al. (2020). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. Journal Of The American Academy Of Dermatology, 82(6), 1445-1486. doi: 10.1016/j.jaad.2020.02.044
5. Elmets, C., Lim, H., Stoff, B., Connor, C., Cordoro, K., & Lebwohl, M. et al. (2019). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. Journal Of The American Academy Of Dermatology, 81(3), 775-804. doi: 10.1016/j.jaad.2019.04.042

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Appendix References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity FDA-Approved Uses	Q4 2023
NEW CRITERIA CREATION	Q1 2023