



Louisiana

deucravacitinib (Sotyktu™)

Policy # 00811

Original Effective Date: 12/12/2022

Current Effective Date: 12/11/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider deucravacitinib (Sotyktu™)† for the treatment of adult patients with plaque psoriasis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for deucravacitinib (Sotyktu) will be considered when the following criteria are met:

- Patient has a diagnosis of moderate to severe plaque psoriasis; AND
- Patient is 18 years of age or older; AND
- Patient has a negative tuberculosis (TB) test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- Sotyktu is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira®)† or etanercept (Enbrel®)† OR other drugs such as tofacitinib (Xeljanz/XR®)† or apremilast (Otezla®)†; AND
- Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% BSA with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia); AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: adalimumab (Humira), etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara®)†, secukinumab (Cosentyx®)†, guselkumab (Tremfya™)†, or

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risankizumab (Skyrizi[™])[‡] unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).

- Patient has failed to respond to an adequate trial of one of the following treatment modalities:
 - Ultraviolet B; or
 - Psoralen positive Ultraviolet A; or
 - Systemic therapy (e.g., methotrexate [MTX], cyclosporine, acitretin).

(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of deucravacitinib (Sotyktu) when any of the following criteria are not met to be **not medically necessary****:

- Patient has failed treatment with at least TWO of the following products after at least TWO months of therapy with each product: adalimumab (Humira), etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara), secukinumab (Cosentyx), guselkumab (Tremfya), or risankizumab (Skyrizi)
- Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% BSA with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
- Patient has failed to respond to an adequate trial of one of the following treatment modalities:
 - Ultraviolet B; or
 - Psoralen positive Ultraviolet A; or
 - Systemic therapy (e.g., MTX, cyclosporine, acitretin).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of deucravacitinib (Sotyktu) when patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational**.*

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Background/Overview

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. TYK2 is a member of the janus kinase (JAK) family, however the exact mechanism linking the inhibition of TYK2 to the drug's effectiveness is not currently known. Sotyktu is available in 6 mg tablets and is dosed 6 mg orally once daily.

Plaque Psoriasis

Psoriasis is a common skin condition that is caused by an increase in production of skin cells. It is characterized by frequent episodes of redness, itching and thick, dry silvery scales on the skin. It is most commonly seen on the trunk, elbows, knees, scalp, skin folds and fingernails. This condition can appear suddenly or gradually and may affect people of any age; it most commonly begins between the ages of 15 and 35. Psoriasis is not contagious. It is an inherited disorder related to an inflammatory response in which the immune system produces too much tumor necrosis factor-alpha (TNF-alpha). It may be severe in immunosuppressed people or those who have other autoimmune disorders such as rheumatoid arthritis. Treatment is focused on control of the symptoms and prevention of secondary infections. Lesions that cover all or most of the body may be acutely painful and require hospitalization. The body loses vast quantities of fluid and becomes susceptible to severe secondary infections that can involve internal organs and even progress to septic shock. Typical treatments for severe cases of plaque psoriasis include ultraviolet therapy or systemic therapies such as MTX or cyclosporine. Newer biologic therapies are also approved for the treatment of plaque psoriasis.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Sotyktu is approved for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical

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practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy and safety of Sotyktu 6 mg once daily were assessed in two multicenter, randomized, double-blind, placebo- and active-controlled clinical trials, PSO-1 and PSO-2, which enrolled subjects 18 years of age and older with moderate to severe plaque psoriasis who were eligible for systemic therapy or phototherapy. Subjects had a body surface area (BSA) involvement of $\geq 10\%$, a Psoriasis Area and Severity Index (PASI) score ≥ 12 , and a static Physician's Global Assessment (sPGA) ≥ 3 (moderate or severe). In PSO-1 and PSO-2, efficacy was assessed in 1,684 subjects randomized to either Sotyktu (6 mg orally once daily), placebo, or Otezla (30 mg orally twice daily). Both trials assessed the responses at Week 16 compared to placebo for the two co-primary endpoints: 1) proportion of subjects who achieved a sPGA score of 0 (clear) or 1 (almost clear) with at least a 2-grade improvement from baseline; 2) the proportion of subjects who achieved at least a 75% improvement in PASI scores from baseline (PASI 75). In PSO-1, 54% of subjects in the Sotyktu group, 7% in the placebo group, and 32% in the Otezla group achieved an sPGA response of 0 or 1 at Week 16. At Week 16, 58% of subjects in the Sotyktu group, 13% of subjects in the placebo group, and 35% in the Otezla group achieved a PASI 75. In PSO-2, 50% of subjects in the Sotyktu group, 9% in the placebo group, and 34% in the Otezla group achieved an sPGA response of 0 or 1 at Week 16. At Week 16, 53% of subjects in the Sotyktu group, 9% of subjects in the placebo group, and 40% in the Otezla group achieved a PASI 75.

References

1. Sotyktu [package insert]. Bristol-Myers Squibb. Princeton, New Jersey. September 2022.

Policy History

Original Effective Date: 12/12/2022

Current Effective Date: 12/11/2023

11/03/2022 Medical Policy Committee review

11/09/2022 Medical Policy Implementation Committee approval. New policy.

11/02/2023 Medical Policy Committee review

11/08/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged

Next Scheduled Review Date: 11/2024

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***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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