



Drug Coverage Policy

Effective Date 11/01/2024
Coverage Policy Number IP0671
Policy Title Sotyktu Prior
Authorization Policy

Inflammatory Conditions – Sotyktu Prior Authorization Policy

- Sotyktu™ (deucravacitinib tablets - Bristol Myers Squibb)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Sotyktu, a tyrosine kinase 2 (TYK2) inhibitor, is indicated for treatment of moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy.¹ Limitation of use: Sotyktu is not recommended in combination with potent immunosuppressants.

Guidelines

Guidelines have not been updated to address Sotyktu. Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.² These guidelines list all the biologics approved at the time of publication as agents that may be used as monotherapy for adults with moderate to severe psoriasis. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara [ustekinumab subcutaneous injection]) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.³

Medical Necessity Criteria

POLICY STATEMENT

Prior Authorization is required for benefit coverage of Sotyktu. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sotyktu as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sotyktu to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

NOTE: This product also requires the use of preferred products before approval of the requested product. Refer to the respective *Inflammatory Conditions Preferred Specialty Management Policy for Individual and Family Plans (PSM002)* for additional preferred product criteria requirements and exceptions.

Sotyktu is considered medically necessary when the following are met:

FDA-Approved Indication

- 1. Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
 - i.** Patient is \geq 18 years of age; AND
 - ii.** Patient meets ONE of the following (a or b):
 - a)** Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples of one traditional systemic agent include methotrexate, cyclosporine, or acitretin tablets. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.
 - b)** Patient has a contraindication to methotrexate, as determined by the prescriber; AND
 - iii.** The medication is prescribed by or in consultation with a dermatologist.
 - B) Patient is Currently Receiving Sotyktu.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

- i. Patient has been established on therapy for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
- ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
- iii. Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.
- 2. Concurrent use with Other Potent Immunosuppressants, Including Methotrexate.¹** Co-administration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated.

References

1. Sotyktu™ tablets [prescribing information]. Princeton, NJ: Bristol Myers Squibb; September 2022.
2. 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.
3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol.* 2015;29(12):2277-2294.

Revision Details

| Type of Revision | Summary of Changes | Date |
|------------------|--------------------|------------|
| New | New policy | 11/01/2024 |

The policy effective date is in force until updated or retired.

APPENDIX

| | Mechanism of Action | Examples of Indications* |
|---|----------------------------------|---|
| Biologics | | |
| Adalimumab SC Products (Humira®, biosimilars) | Inhibition of TNF | AS, CD, JIA, PsO, PsA, RA, UC |
| Cimzia® (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, nr-axSpA, PsO, PsA, RA |
| Etanercept SC Products (Enbrel®, biosimilars) | Inhibition of TNF | AS, JIA, PsO, PsA, RA |
| Infliximab IV Products (Remicade®, biosimilars) | Inhibition of TNF | AS, CD, PsO, PsA, RA, UC |
| Zymfentra® (infliximab-dyyb SC injection) | Inhibition of TNF | CD, UC |
| Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC |
| | | IV formulation: AS, PJIA, PsA, RA |
| Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA |
| | | IV formulation: PJIA, RA, SJIA |
| Kevzara® (sarilumab SC injection) | Inhibition of IL-6 | RA |
| Orencia® (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator | SC formulation: JIA, PSA, RA |
| | | IV formulation: JIA, PsA, RA |
| Rituximab IV Products (Rituxan®, biosimilars) | CD20-directed cytolytic antibody | RA |
| Kineret® (anakinra SC injection) | Inhibition of IL-1 | JIA [^] , RA |
| Omvo® (mirikizumab IV infusion, SC injection) | Inhibition of IL-23 | UC |
| Stelara® (ustekinumab SC injection, ustekinumab IV infusion) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| Siliq® (brodalumab SC injection) | Inhibition of IL-17 | PsO |
| Cosentyx® (secukinumab SC injection; secukinumab IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, nr-axSpA, PsO, PsA |
| | | IV formulation: AS, nr-axSpA, PsA |
| Taltz® (ixekizumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA |
| Bimzelx® (bimekizumab-bkzx SC injection) | Inhibition of IL-17A/17F | PsO |
| Ilumya® (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |
| Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23 | SC formulation: CD, PSA, PsO, UC |
| | | IV formulation: CD, UC |
| Tremfya® (guselkumab SC injection, guselkumab IV infusion) | Inhibition of IL-23 | SC formulation: PsA, PsO, UC |
| | | IV formulation: UC |
| Entyvio® (vedolizumab IV infusion, vedolizumab SC injection) | Integrin receptor antagonist | CD, UC |
| Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs | | |
| Otezla® (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |

| | | |
|---|--|-------------------------------|
| Cibinqo™ (abrocitinib tablets) | Inhibition of JAK pathways | AD |
| Olumiant® (baricitinib tablets) | Inhibition of JAK pathways | RA, AA |
| Litfulo® (ritlecitinib capsules) | Inhibition of JAK pathways | AA |
| Leqselvi® (deuruxolitinib tablets) | Inhibition of JAK pathways | AA |
| Rinvoq® (upadacitinib extended-release tablets) | Inhibition of JAK pathways | AD, AS, nr-axSpA, RA, PsA, UC |
| Rinvoq® LQ (upadacitinib oral solution) | Inhibition of JAK pathways | PsA, PJIA |
| Sotyktu® (deucravacitinib tablets) | Inhibition of TYK2 | PsO |
| Xeljanz® (tofacitinib tablets/oral solution) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| Xeljanz® XR (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, UC |
| Zeposia® (ozanimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |
| Velsipity® (etrasimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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