Effective Date **6/1/2024**
Coverage Policy Number **IP0538**

Deucravacitinib

Table of Contents

Related Coverage Resources

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. 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.

Overview

This policy supports medical necessity review for deucravacitinib (**Sotyktu™**).

Coverage for deucravacitinib (Sotyktu) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

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

Medical Necessity Criteria

Deucravacitinib (Sotyktu) is considered medically necessary for the treatment of Plaque Psoriasis when the individual meets ALL of the following criteria:

1. 18 years of age or older
2. Body Surface Area (BSA) of greater than 5%, OR BSA less than 5% and there is involvement of the scalp, face, the palms and soles, or genitals
3. Documentation of **ONE** of the following:

A. Failure to **ONE** of the following, unless contraindicated or intolerant:
   i. Topical therapy (for example, topical corticosteroids, topical vitamin D analogs, Tazorac)
   ii. Systemic therapy (for example, methotrexate, cyclosporine, Soriatane)
   iii. Phototherapy
B. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Plaque Psoriasis

4. Medication is prescribed by, or in consultation with, a dermatologist
5. Non-Preferred Product Criteria is met, refer to the below table [Individual and Family Plans only]:

Individual and Family Plans
Documentation of failure, contraindication, or intolerance to **THREE** of the following: A. **Adalimumab Product:** (**Adalimumab-adaz/Hyrimoz** (by Sandoz/Novartis)**, Adalimumab – adbm/Cyltezo**, **Adalimumab-ryvk/Simlandi**, or **Humira** [by AbbVie]) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Cosentyx** [requires prior authorization] D. **Enbrel** [requires prior authorization] E. **Otezla** [requires prior authorization] F. **Skyrizi SC** [requires prior authorization] G. **Stelara SC** [requires prior authorization] H. **Tremfya** [requires prior authorization]

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.

Reauthorization Criteria

Continuation of deucravacitinib (Sotyktu) is considered medically necessary for Plaque Psoriasis when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Deucravacitinib should not be administered in combination with a biologic or with a targeted synthetic DMARD used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events with combinations and lack of data supportive of additional efficacy.

2. **Concurrent use with Other Potent Immunosuppressants, Including Methotrexate.** Co-administration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated.

Background

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]

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.

Appendix

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Adalimumab products (Humira, biosimilars)	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√[#]	--
Skyrizi Subcutaneous	--	--	√	√	√[^]	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√[^]	√[^]
Stelara Intravenous	--	--	--	--	√[#]	√[#]

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; [^] Maintenance dosing only; [#] Induction dosing only.

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
Janus Kinases Inhibitors							
Olumiant	√	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√[#]	√	--	√	--	√
Xeljanz oral solution	--	√[#]	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							
Zeposia	--	--	--	--	--	--	√

Tyrosine Kinase 2 Inhibitor							
Sotyktu	--	--	--	--	--	√	--

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; # Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

Indicated in polyarticular JIA.