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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	October 14, 2022
Subject:	Sotyktu	**Page:**	1 of 7

Last Review Date: March 8, 2024

Sotyktu

Description

Sotyktu (deucravacitinib)

Background
Sotyktu (deucravacitinib) is an inhibitor of tyrosine kinase 2 (TYK2), which is a member of the Janus kinase (JAK) family. Sotyktu binding to TYK2 results in allosteric inhibition of receptor-mediated activation of TYK2 and its downstream activation of Signal Transducers and Activators of Transcription (STATs). The precise mechanism linking inhibition of TYK2 enzyme to therapeutic effectiveness in the treatment of plaque psoriasis is unknown (1).

Regulatory status
FDA-approved indication: Sotyktu is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy (1).

Limitations of Use: (1)
Sotyktu is not recommended for use in combination with other potent immunosuppressants.

Sotyktu has warnings regarding the following: hypersensitivity, infections, tuberculosis, malignancy including lymphomas, rhabdomyolysis, laboratory abnormalities, and immunizations (1).

It is not known whether TYK2 inhibition may be associated with the observed or potential adverse reactions of JAK inhibition. In rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of all-cause mortality were observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. Sotyktu is not approved for use in RA (1).

The safety and effectiveness of Sotyktu in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sotyktu may be considered **medically necessary** if the conditions indicated below are met.

Sotyktu may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:
Moderate-to-severe plaque psoriasis (PsO)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
    a. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate response, intolerance, or contraindication to the other treatment option

2. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
3. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Severe hepatic impairment (Child Pugh C)
3. Used in combination with potent immunosuppressants azathioprine or cyclosporine
4. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
5. Given concurrently with live vaccines

Prior-Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:
Plaque psoriasis (PsO)

AND ALL of the following:

1. Condition has improved or stabilized
2. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Used in combination with potent immunosuppressants azathioprine or cyclosporine

3. Used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
4. Given concurrently with live vaccines

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 90 tablets per 90 days

Duration 12 months

Prior–Approval *Renewal* Limits

Quantity 90 tablets per 90 days

Duration 18 months

Rationale

Summary

Sotyktu (deucravacitinib) is an inhibitor of tyrosine kinase 2 (TYK2), which is a member of the Janus kinase (JAK) family. Sotyktu is indicated for the treatment of moderate-to-severe plaque psoriasis (PsO). The safety and effectiveness of Sotyktu in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Sotyktu while maintaining optimal therapeutic outcomes.

References

1. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.

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Policy History

Date	Action
October 2022	Addition to PA
December 2022	Annual review
September 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant

deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Plaque Psoriasis (PsO)	*must try **TWO** preferred products: Enbrel Humira** Otezla Skyrizi Stelara (SC) Taltz Tremfya	*must try **ONE** preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)