Deucravacitinib (SOTYKTU)
Criteria for Use
April 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are checked, the patient will NOT qualify.

- ☐ Uncontrolled active infection, including undrained abscess (however, deucravacitinib may be started / restarted once the infection is controlled).
- ☐ Untreated latent or active tuberculosis infection.
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.[1] Deucravacitinib may be initiated after starting antiviral prophylaxis.[1] (Consider hepatitis B virus [HBV] screening. Safety is unknown in patients with current or past HBV infection.)
- ☐ Untreated active hepatitis C. (Consider hepatitis C virus screening. Safety is unknown in patients with current or past hepatitis C infection.)
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with deucravacitinib. (Safety of this drug is unknown in patients with HIV seropositivity.)
- ☐ Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer, unless the treating dermatologist and oncologist agree that risk-benefits favor using the drug.
- ☐ Severe hepatic impairment (Child-Pugh C)
- ☐ Concomitant therapy with other potent immunosuppressants.
- ☐ Concomitant live or live-attenuated vaccines or administration of non-live or live vaccines less than 2 weeks before initiation of deucravacitinib.[2]

Inclusion Criteria

ALL of the following criteria must be met:

- ☐ Diagnosis of moderate to severe plaque psoriasis.
- ☐ Prescribed and monitored by a VA / VA Community Care dermatologist or locally designated psoriasis expert.
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay (IGRA).
- ☐ Completed liver enzyme tests.

- ☐ **Methotrexate** monotherapy is medically inadvisable, not tolerated, or inadequate (NO treatment benefit after 3 months, of which at least 2 months is at the standard target dose of 15–25 mg ONCE WEEKLY PO/SC/IM, or inadequate response after 6 months).
- ☐ **Phototherapy** is medically inadvisable, unavailable, unfeasible, or inadequate (i.e., NO treatment benefit after 12 treatments or inadequate response after 24 treatments).
- ☐ **Three targeted systemic antipsoriatic drugs (≥ 1 drug per class)** are medically inadvisable, not tolerated, or not adequate: Inhibitors of TNF, IL-17 (ixekizumab preferred), IL-23 (e.g., risankizumab), IL-12/23 (ustekinumab) or PDE-4 (apremilast).

Additional Inclusion Criteria

Select if appropriate.

- ☐ If HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive: A GI[3] / liver or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- ☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.

Other Justification

- ☐ _____

Footnotes

1. Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.
2. When possible, vaccinations should be updated before the patient initiates deucravacitinib. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with deucravacitinib, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.
3. GI, Gastrointestinal

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for deucravacitinib.

<table>
<tr><th>Section</th><th>Criterion</th><th>Issues for Consideration</th></tr>
<tr><td rowspan="3">Inclusion Criteria</td><td>Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay (IGRA).</td><td>Routine TB retesting is not required for prescription renewals. Retesting in high-risk patients should be considered, such as patients in highly endemic areas for TB.</td></tr>
<tr><td>Methotrexate monotherapy is medically inadvisable, not tolerated, or inadequate(NO treatment benefit after 3 months, of which at least 2 months is at the standard target dose of 15–25 mg ONCE WEEKLY PO/SC/IM, or inadequate response after 6 months)</td><td>Refer to Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders under Clinical Recommendations at PBM INTRAnet .
Use lower than target doses if limited by toxicity.</td></tr>
<tr><td>Phototherapy is medically inadvisable….</td><td>Reasons for phototherapy being medically inadvisable include (and are not limited to) CONFIRMED (preferably by a written biopsy report) history of skin cancer, melanoma or strong likelihood of developing them (e.g., Fitzpatrick skin type I or II = pale skin, easily sunburns).</td></tr>
<tr><td rowspan="2">Additional Inclusion Criteria</td><td>Apremilast is medically inadvisable,…</td><td rowspan="2">Adequate trials of drugs and reasons for being medically inadvisable
<table>
<tr><th>Class</th><th>Adequate Trial</th><th>Reasons for Being Medically Inadvisable
(include and are not limited to)</th></tr>
<tr><td>PDE4 Inhibitor
Apremilast</td><td>NO treatment benefit after 4 months or inadequate response after 6 months</td><td>Too low likelihood of lesion clearance for disease severity* AND patient is averse to injections; or unacceptable risk of weight loss, depression, or suicidality.
* More effective alternatives to small molecules (apremilast or deucravacitinib) are TNF inhibitors, IL-17A inhibitors, IL-23 inhibitors, and IL-12/23 inhibitors.</td></tr>
<tr><td>TNF Inhibitor</td><td>NO response after 12 weeks with ONE TNFI; inadequate response after 12-week trials of TWO TNFIs for total 24 weeks; or loss of initial response</td><td>Heart failure, demyelinating disease, multiple sclerosis in first-degree relative, lupus, recurrent infections, serious infections, etc.</td></tr>
<tr><td>IL-17A Inhibitor
(i.e., ixekizumab [preferred] or secukinumab)</td><td>NO response after 12 weeks, inadequate partial response after 24 weeks, or loss of initial response</td><td>Inflammatory bowel disease and severe or recurrent Candida infections</td></tr>
<tr><td>IL-23 Inhibitor
(e.g., risankizumab, guselkumab, tildrakizumab)</td><td>NO response after 16 weeks, inadequate partial response after 34 weeks, or loss of initial response)</td><td>Liver cirrhosis in patients with comorbid Crohn’s disease</td></tr>
</table></td></tr>
<tr><td>Three of the following classes of antipsoriatic biologics (≥ 1 drug per class) are medically inadvisable, not tolerated, or not adequate: Inhibitors of TNF, IL-17 (ixekizumab preferred), IL-23 (e.g., risankizumab), or IL-12/23 (ustekinumab).</td></tr>
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Section	Criterion	Issues for Consideration
		IL-12/23 Inhibitor Ustekinumab: NO response after 16 weeks, inadequate partial response after 32 weeks, or loss of initial response: History of noninfectious pneumonia (e.g., interstitial pneumonia, eosinophilic pneumonia, cryptogenic organizing pneumonia).
		Injections Aversity to injections or, if applicable, barriers to in-clinic administration (e.g., travel) should be adjudicated case by case as a reason why a given biologic is medically inadvisable.
Additional Inclusion Criteria	If HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive, a GI / liver or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.	In patients who are HBsAg-negative but **anti-HBc-positive**, the presence of antibody to hepatitis B surface antigen (anti-HBs) does not guarantee protection against HBV reactivation, and the available evidence is insufficient to support the use of anti-HBs titers in deciding whether to give antiviral prophylaxis. Management depends on the patient's risk of HBV reactivation. [Reddy K, et al. American Gastroenterological Association Institute Guideline on the Prevention and Treatment of Hepatitis B Virus Reactivation During Immunosuppressive Drug Therapy. Gastroenterology. 2015;148(1):215–219. doi: https://doi.org/10.1053/j.gastro.2014.10.039 Ekpanyapong S, Reddy KR. Hepatitis B Virus Reactivation: What Is the Issue, and How Should It Be Managed? Clin Liver Dis. 2020 Aug;24(3):317-333. doi: 10.1016/j.cld.2020.04.002.]

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Contact: Francine Goodman, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)