Brodalumab (SILIQ)
Criteria for Use
February 2022

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. Also refer to the Psoriasis and Psoriatic Arthritis Treatment Guide available at PBM INTRAnet.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive brodalumab.

- ☐ Active, serious, systemic or localized infection, including undrained abscess (however, brodalumab 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] Brodalumab may be initiated after starting antiviral prophylaxis.
- ☐ HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.[1] Brodalumab may be initiated after starting antiviral prophylaxis.[2]
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with brodalumab.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of brodalumab.
- ☐ History of suicidal ideation or behavior or risk factors for suicide (e.g., depression, bipolar disorder) – relative contraindication, when potential risks outweigh benefits; available only through the restricted SILIQ REMS Program.
- ☐ Crohn's disease.

Inclusion Criteria for Plaque Psoriasis

All of the following criteria must be met:

- ☐ Meets the requirements of the SILIQ REMS Program. See information at PBM INTRAnet: Special Handling Drugs.
- ☐ Brodalumab is prescribed and monitored by a VA / VA Community Care dermatologist or locally designated psoriasis expert.
- ☐ Brodalumab is prescribed at the FDA-approved dose for plaque psoriasis.
- ☐ Patient is an adult with chronic (≥ 6 months) moderate to severe plaque psoriasis (including involvement of nails only).
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].
- ☐ Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).[3]
- ☐ Current or past completion of hepatitis C screening. Brodalumab may be initiated while waiting for test results.
- ☐ For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.
- ☐ **Methotrexate** monotherapy is medically inadvisable, not tolerated, or not adequate.
- ☐ **Phototherapy** is medically inadvisable, inadequate, not available or not feasible.
- ☐ **Tumor necrosis factor inhibitor (TNFI)** therapy is medically inadvisable, not tolerated, or not adequate (i.e., NO response to ONE TNFI after 3 months, partial response to 3-month trials of TWO TNFIs = total 6 months, or loss of initial response).
- ☐ **Interleukin-17A inhibitor** (i.e., ixekizumab [preferred] or secukinumab) is medically inadvisable, not tolerated or not adequate (i.e., NO response after 12 weeks, inadequate partial response after 24 weeks, or loss of initial response).
- ☐ **Interleukin-23 inhibitor** (e.g., guselkumab, risankizumab-rzaa, or tildrakizumab-asmn) is medically inadvisable, not tolerated or not adequate (i.e., NO response after 12 weeks, inadequate partial response after 24 weeks, or loss of initial response).
- ☐ **Ustekinumab** is medically inadvisable, not tolerated or not adequate (i.e., NO response after 16 weeks, inadequate partial response after 32 weeks, or loss of initial response.

Footnotes

[1] Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.

[2] Consult a hepatologist or infectious diseases expert for advice on whether to start antiviral prophylaxis to prevent HBV reactivation.

[3] Anti-HBs may help to identify patients who require initial or booster vaccination (anti-HBs titers >= 10 IU/L are generally considered protective) or HBsAg-negative patients without past vaccination who have occult HBV from past infection (anti-HBs positive and lost anti-HBc).

Supplemental Information

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

Section	Criterion	Issues for Consideration
Exclusion Criteria	HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.[1] Brodalumab may be initiated after starting antiviral prophylaxis.[2]	In patients who are HBsAg-negative but anti-HBc-positive, the presence of antibody to hepatitis B surface antigen (antiHBs) 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.* Consultation with a local hepatologist or infectious diseases expert is recommended to advise on whether to initiate prophylactic antiviral therapy or perform preemptive monitoring with deferred prophylactic therapy. * 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
Inclusion Criteria	Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).	Anti-HBs may help to identify patients who require initial or booster vaccination (anti-HBs titers >= 10 IU/L are generally considered protective) or HBsAg-negative patients without past vaccination who have occult HBV from past infection (anti-HBs positive and lost anti-HBc).
	Tumor necrosis factor inhibitor (TNFI) therapy is medically inadvisable….	TNFI may be medically inadvisable for reasons that include but are not limited to heart failure, demyelinating disease, multiple sclerosis in first-degree relative, lupus, recurrent infections, serious infections, etc.
	Methotrexate monotherapy is medically inadvisable, not tolerated, or not adequate.	Refer to *Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders* under Clinical Recommendations at PBM INTRAnet. Inadequate response to methotrexate refers to NO treatment benefit after 3 months, of which at least 2 months is at the standard target dose; or inadequate partial response after 6 months. **Target Doses**: Methotrexate: 15–25 mg ONCE WEEKLY orally, subcutaneously, or intramuscularly. Use lower doses if limited by toxicity.
	Phototherapy is medically inadvisable, inadequate….	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). Inadequate phototherapy refers to NO treatment benefit after 12 treatments or inadequate partial response after 24 treatments.
	Interleukin-17A inhibitor (i.e., ixekizumab [preferred] or secukinumab) is medically inadvisable….	IL-17A inhibitors may be medically inadvisable for reasons that include but are not limited to Crohn's disease, ulcerative colitis, or recurrent or severe Candida infections. Brodalumab, an IL-17 *receptor* A inhibitor, may be medically inadvisable for the same reasons.
	Ustekinumab is medically inadvisable….	Ustekinumab may be medically inadvisable for reasons that include but are not limited to history of noninfectious pneumonia (e.g., interstitial pneumonia, eosinophilic pneumonia, cryptogenic organizing pneumonia).

Revisions:

- February 2022. Removed HCV exclusion criterion; added “total” before anti-HBc under inclusion criteria; changed inclusion criterion from “Completed HCV screening” to “Current or past completion of HCV screening…”; added footnote 2; added Supplemental Information section; moved selected footnotes to Supplemental Information; added pregnancy-related exclusion and inclusion criteria.

Original: April 2020. Extracted brodalumab from Anti-Interleukin Biologics in PsO and PsA CFU. Reformatted for Cerner. Updated infection screening.

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