

Guselkumab (TREMFA) in Psoriasis

Criteria for Use

October 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 the [PBM INTRAnet](#).

Exclusion Criteria

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

- Active, serious, systemic or localized infection, including undrained abscess (however, guselkumab 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 Guselkumab 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 Guselkumab may be initiated after starting antiviral prophylaxis.²
- Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with guselkumab.
- Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of guselkumab.

Inclusion Criteria for Plaque Psoriasis WITHOUT Psoriatic Arthritis

All criteria must be met:

- Guselkumab is prescribed and monitored by a VA / VA Community Care dermatologist or locally designated psoriasis expert.
- Guselkumab 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. Guselkumab 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 (i.e., 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.
- Phototherapy** is medically inadvisable, not available, not feasible, or inadequate (i.e., NO treatment benefit after 12 treatments or inadequate partial response after 24 treatments).
- 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).

Additional Inclusion Criteria

ONE of the following criteria must be met:

- 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).
- 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 guselkumab.

Section	Criterion	Issues for Consideration
Exclusion Criteria	HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis. Guselkumab 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. <i>Gastroenterology</i> . 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 <i>Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders</i> 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) <i>CONFIRMED</i> (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.
	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) and <u>severe</u> concomitant plaque psoriasis (i.e., guselkumab preferred).

Revisions:

- October 2022. Created separate criteria by indication (i.e., by psoriasis and by psoriatic arthritis). No content changes for psoriasis.
- 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 inclusion criteria.
- January 2021. Added psoriatic arthritis.

Original: April 2020. Extracted from Anti-Interleukin Biologics in PsO and PsA CFU. Changed place in therapy of ustekinumab to be an alternative to IL-17AIs, such as for patients with IBD. Reformatted for Cerner. Revised infection screening.

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