

Apremilast in Plaque 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.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

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

- Concomitant therapy with strong CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin), which may cause loss of efficacy of apremilast.
- Untreated or unstable depression or suicidality unless mental health consultation concurs with apremilast treatment.

Inclusion Criteria

All of the following criteria must be met.

- Prescribed and monitored by a VA/VA Community Care dermatologist or locally-designated expert.
- Diagnosis of plaque psoriasis.
- Phototherapy** is medically inadvisable,¹ not available, not feasible, not tolerated, or not adequate.

Additional Inclusion Criteria

ONE of the following criteria must be met.

- Documented mild to moderate disease AND tried and had an inadequate response to **≥ 3 classes of topical therapies** (≥ 1 month per class) or intolerance unless they were medically inadvisable (then prior trials not required).²
- Documented moderate to severe disease, impaired function or quality of life, or involvement of special areas³ AND **1 conventional immunomodulator**⁴ and **2 classes of targeted immunomodulators**⁵ are medically inadvisable (prior trials not required).^{6,7}

Additional Inclusion Criteria for Patients Who Can Become Pregnant

Select if applicable.

- Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy.

Other Justification

- _____

Footnotes

- 1 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).
- 2 Classes of topical therapies: Corticosteroids, vitamin D analogs (e.g., calcipotriene, calcitriol), calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), retinoids (e.g., tazarotene), PDE4 inhibitors (e.g., roflumilast), and aryl hydrocarbon receptor agonists (e.g., tapinarof)
- 3 Special areas: face, intertriginous, genitals, palms, soles, scalp, nails
- 4 Conventional immunomodulators: e.g., methotrexate.
- 5 Targeted immunomodulators: e.g., TNF inhibitors and IL-17A inhibitors (ixekizumab preferred)
- 6 A prior trial of each therapy is not required but the therapy should be recommended if it is medically advisable.
- 7 Apremilast may be an acceptable alternative therapy when the conventional immunomodulator and targeted immunomodulators are medically inadvisable because of reasons that include and not limited to their risk of immunosuppressive effects such as in patients with malignancy, high risk of tuberculosis (TB), or hepatitis B, hepatitis C, or HIV infection.

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for apremilast in plaque psoriasis.

Section	Criterion	Issues for Consideration
Additional Inclusion Criteria	Documented moderate to severe disease, impaired function or quality of life, or involvement of special areas ³ AND 1 conventional immunomodulator⁴ and 2 classes of targeted immunomodulators⁵ are medically inadvisable (prior trials not required)	For methotrexate, refer to <i>Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders</i> under Clinical Recommendations at PBM INTRAnet .

Prepared: October 2022. Incorporated mild to moderate psoriasis into earlier version for moderate to severe psoriasis. Removed prior requirement for methotrexate that pertained to criteria for use of apremilast in moderate to severe psoriasis.

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