

Apremilast in Psoriatic Arthritis

Criteria for Use

March 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 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 a mental health consultant concurs with apremilast treatment

Inclusion Criteria

All of the following criteria must be met:

- Prescribed and monitored by a VA/VA Community Care rheumatologist, dermatologist, or locally designated expert.
- Has nonsevere or predominantly **oligoarticular peripheral inflammatory disease** and a definite or provisional diagnosis of active **psoriatic arthritis**. (Apremilast is ineffective for joint erosions and axial disease.)
- A **conventional synthetic immunomodulator** (methotrexate, leflunomide or sulfasalazine) is medically inadvisable, not tolerated, or not adequate after 12 weeks.
- Tumor necrosis factor inhibitor (TNFI)** therapy is medically inadvisable.

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

Supplemental Information

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

Section	Criterion	Issues for Consideration
Inclusion Criteria	A conventional synthetic immunomodulator (methotrexate, leflunomide or sulfasalazine) is medically inadvisable, not tolerated, or not adequate after 12 weeks.	<p>Refer to <i>Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders</i> under Clinical Recommendations at PBM INTRANet.</p> <p>Adequate trial of methotrexate: NO or partial treatment benefit after 12 weeks at doses of 15–25 mg/wk (or lower if limited by toxicity). In inadequate responders to oral methotrexate, consider switching to subcutaneous methotrexate.</p> <p>For other immunomodulators: NO or partial treatment benefit after 12 weeks at recommended doses (or lower if limited by toxicity).</p>
	Tumor necrosis factor inhibitor (TNFI) therapy is medically inadvisable.	<p>A prior trial of TNFI therapy is not required but TNFI therapy should be recommended if it is medically advisable.</p> <p>Treatment options for TNFI inadequate responders include switching to a second TNFI, another biologic, or tofacitinib rather than apremilast monotherapy.</p> <p>Options for TNFI nonresponders include switching to another biologic or tofacitinib rather than apremilast monotherapy.</p> <p>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.</p> <p>Aversity to injections or barriers to in-clinic administration (e.g., travel) should be adjudicated case by case as a reason why a TNFI is medically inadvisable.</p>

Prepared: March 2023. Separated the June 2020 criteria for apremilast by individual indications and reformatted for Cerner. No substantial changes to content.

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