DRUG DETERMINATION POLICY

Title: DDP-10 Otezla

Effective Date: 8/23/23

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Otezla is a specialty drug indicated for specific diagnoses and is associated with adverse effects. These criteria were developed and implemented to ensure the use of standard therapies prior to Otezla, as well as, use for indicated diagnoses.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. General Considerations

A. Appropriate medication use [must meet one listed below]:

1. FDA approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Non-FDA approved: Compendium support (Lexicomp™) for use of a drug for a non-FDA approved indication or dosage regimen.

2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

B. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

C. Exclusion: Concomitant therapy with other biologics or immune modulators.

D. Adherence to requested medication required for re-approval: consistent fill history (at least 80% of days covered) electronically or verbally from the pharmacy.

II. Plaque Psoriasis [must meet all listed below]:

A. Age: at least 18 years.

B. Diagnosis and severity: moderate to severe chronic plaque psoriasis.

1. Duration: chronic plaque psoriasis greater than six months.

2. Severity [must meet one listed below]:

a. Body surface area (BSA): at least ten percent.

b. Severe at localized sites and associated with significant functional impairment (e.g., involvement of high-impact and difficult to treat sites such as the face, scalp, palms, soles, flexures, and genitals).

C. Other therapies: Trials of two local therapies and one systemic therapy listed below are required unless all are contraindicated. Trial must result in an inadequate response after four consecutive months of use per medication or severe adverse reaction.

1. Local therapies: topical (steroids, vitamin D, coal tar, dithranol), phototherapy, photo-chemotherapy.

2. Systemic therapies: cyclosporine, methotrexate.

D. Dosage regimen.

1. Otezla (apremilast): titrate from 10mg by mouth daily over six days to 30mg by mouth twice daily; adjust for creatinine clearance below 30 ml/minute.

E. Approval.

1. Initial: six months.

2. Re-approval: reduced or sustained decrease in disease activity as shown by reduction in BSA affected.

III. Psoriatic arthritis [must meet all listed below]:

A. Age: at least 18 years.

B. Diagnosis and severity: active psoriatic arthritis.

C. Other therapies: Trial of one from the appropriate category below is required unless all are contraindicated. Trial must result in an inadequate response after four consecutive months of use per medication or severe adverse reaction.

1. Peripheral disease: Disease-Modifying Anti-Rheumatic Drug (DMARD) therapy: methotrexate, leflunomide, sulfasalazine.

2. Axial disease, enthesitis, dactylitis, and uveitis: non-steroidal anti-inflammatory drugs (NSAIDs).

D. Dosage regimen:

1. Otezla (apremilast): titrate from 10mg by mouth daily over six days to 30mg by mouth twice daily; adjust for creatinine clearance below 30ml per minute.

E. Approval.

1. Initial: six months.

2. Re-approval: one year; reduced or sustained decrease in disease activity, as shown by reduction in BSA affected or arthritis.

4.0 References, Citations & Resources:

1. Otezla® (apremilast) Package Insert. Celgene Corporation. 2014 Sept.
2. Lexicomp Online® , Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc.;Otezla, accessed July, 2021
3. Efficacy of apremilast in the treatment of moderate to severe psoriasis: a randomized controlled trial. Lancet 2012;380:738-46.
4. Long-term (52-week) Results of a Phase III Randomized, Controlled Trial of Apremilast in Patients with Psoriatic Arthritis. J Rheumatol 2015;42(3):479-488.
5. British Association of Dermatologists guidelines for the biological therapy for psoriasis 2017;177(3):628-36.
6. Clinical Practice Guidelines for the treatment of patients with axial spondyloarthritis and psoriatic arthritis. Madrid, (Spain): Spanish Society of Rheumatology (SER);2015.

5.0 Appendices:

See page 4

6.0 Revision History:

Original Effective Date: 07/24/2015

Next Review Date: 07/28/2022

Revision Date	Reason for Revision
7/19	Annual review; removed symbols and abbreviations.
6/20	Annual review; removed prescriber type, changed other therapies language, replaced abbreviations, approved by P&T Committee 8/26/20.
6/21	Annual review; clarified criteria instructions, added appropriate use section, reformatting
7/22	Annual review; no substantive changes
6/23	Annual review; fixed formatting, updated other therapies language, added general considerations section - appropriate medication use and concomitant biologics excluded moved, added no sample use, adherence requirement for renewal

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Otezla® (apremilast)	• Weight loss (10-14%) • Diarrhea (8-17%) • Nausea (7-17%) • Headache (≥5%) • Upper respiratory infection (≥5%) • Pregnancy Category C	• Neuropsychiatric effects (depression / suicidal thoughts) • Weight loss • Renal function - adjust dose for creatinine clearance below 30 ml/min • CYP 3A4 substrate - monitor with strong 3A4 inducers (may reduce serum concentration)	None