DRUG DETERMINATION POLICY

Title: DDP-10 Otezla

Effective Date: 07/30/2019

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 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

A. Plaque Psoriasis (PP).

1. Age: at least 18 years.

2. Prescriber: dermatologist or rheumatologist.

3. Diagnosis and severity: moderate to severe chronic Plaque Psoriasis.

    a. Duration: chronic Plaque Psoriasis greater than six months.

    b. Severity:

        i. Body surface area (BSA): at least 10% OR

ii. 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).

4. Other therapies: failed or had significant adverse effects to two local therapies and one systemic therapy.

   a. Local therapies (minimum duration of four months.): topical (steroids, vitamin D, coal tar, dithranol), phototherapy, photo-chemotherapy.

   b. Systemic therapies (minimum duration of four months): cyclosporine, methotrexate.

5. Dosage regimen.

   a. Otezla oral (apremilast): titrate from 10mg daily over six days to 30mg twice daily; adjust for Creatinine Clearance <30 ml/minute.

6. Approve.

   a. Initial: six months.

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

B. Psoriatic arthritis (PA).

1. Age: at least 18 years.

2. Prescriber: rheumatologist or dermatologist.

3. Diagnosis and severity: active psoriatic arthritis with at least five swollen and at least five plus tender joints.

4. Other therapies contraindicated, failed or had significant adverse effects from one of the treatment categories below:

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

   b. Axial disease, enthesitis, dactylitis & uveitis: NSAIDs (four months).

5. Dosage regimen:

   a. Otezla oral (apremilast): titrate from 10mg daily over six days to 30mg twice daily; adjust for Creatinine Clearance <30 ml/minute.

6. Approval.

   a. Initial: six months.

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

C. Exclusions.

1. Combination with biologics agents, including TNF Inhibitors or interleukin Inhibitors.

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, 2019
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:

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%) • URI (≥5%) • Pregnancy category C	• Neuropsychiatric effects (depression / suicidal thoughts) • Weight loss • Renal function - adjust dose for CrCl < 30 ml/min • CYP 3A4 substrate - monitor w strong 3A4 inducers (may ↓ serum concen.)	None

7.0 Revision History:

Original Effective Date: 07/24/2015

Next Review Date: 07/22/2020

Revision Date	Reason for Revision
7/16/19	Annual review; removed symbols and abbreviations.