Pharmacy Benefit Determination Policy

Policy Subject: Otezla	**Dates:**
Policy Number: SHS PBD46	**Effective Date:** June 24, 2015
Category: Anti-psoriatic Agent	**Revision Date** July 30, 2018
Policy Type: ☐ **Medical** ☒ **Pharmacy**	**Approval Date:** August 22, 2018
Department: Pharmacy	**Next Review Date:** August 2019
Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	PHP: Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Otezla through the Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

J-code

Clinical Determination Guidelines:

Document the following with chart notes

A. Plaque Psoriasis (PP)
   1. Age: ≥ 18yrs.
   2. Prescriber: Dermatologist or Rheumatologist
   3. Diagnosis & severity: Mod-severe chronic PP
      a. Duration: chronic PP > 6 months
      b. Severity
         - Body surface area (BSA): ≥ 10% OR
         - Severe at localized sites and associated w significant functional impairment (e.g. involvement of high-impact and difficult to treat sites such as the face, scalp, palms, soles, flexures & genitals)
   4. Other therapies: Failed or had significant adverse effects of 2 of category a; 1 of b
      a. Local therapies (4 mons.): Topical (steroids, vit. D. coal tar, dithranol), phototherapy, photochemotherapy
      b. Systemic therapies (4 mons.): Cyclosporine, MTX
   5. Dosage regimen
      a. Otezla oral (apremilast): 30mg 2x daily, then 5-day 10/mg/day titration; adjust for CrCl <30.
   6. Approve
      a. Initial: 6 mons.
      b. Reapproval: ↓or sustained ↓ in disease activity, as shown by ↓ in BSA affected

B. Psoriatic arthritis (PA)
   1. Age: ≥ 18 yrs.
   2. Prescriber: Rheumatologist or Dermatologist
   3. Diagnosis & severity: Active psoriatic arthritis w ≥5 swollen & ≥ 5+ tender joints
   4. Other therapies: Failed or to significant adverse effects from1 from the appropriate category below:
      a. Peripheral disease: DMARD therapy (4 mons.) - Methotrexate, leflunomide, sulfasalazine
      b. Axial disease, enthesitis, dactylitis & uveitis: NSAIDs (4 mons.)
   5. Dosage regimen:
      a. Otezla oral (apremilast): 30 mg 2x daily, then 5-day 10mg/day titration; adjust for CrCl < 30 ml/min
   6. Approval
      a. Initial: 6 mons.
      b. Re-approval: ↓ or sustained ↓ in disease activity as shown by ↓in both the swollen & tender joint counts.

C. Exclusions
   1. Combo w biologics agents, including TNF Inhibitors or IL-R Inhibitors

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

References and Resources:

1. Otezla® (apremilast) Package Insert. Celgene Corporation. 2014 Sept.
2. Lexicomp Online® , Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc.;Otezla, accessed July, 2018
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.

Approved By:

8/22/18

Peter Graham, MD – PHP Executive Medical Director Date

8/22/18

Kurt Batteen - Human Resources Date