Pharmacy Benefit Determination Policy

`Policy Subject: Interleukin Inhibitors	**Dates:**
Policy Number: SHS PBD49	**Effective Date:** June 24, 2015
Category: Anti-inflammatory biologicals	**Revision Date:** July 30, 2018
Policy Type: ☒ **Medical** ☒ **Pharmacy**	**Approval Date:** February 27, 2019
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 and PHP Insurance & Service Company will cover Preferred Interleukin Inhibitors through the Medical or Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines.

Drugs and Applicable Coding:

J-code: Stelara - J3358 (1u=1mg), Actemra IV - J3262 (1U=1mg); **NDC**: Cosentyx 2 pack syringe - 0078-0639-98 (pen 41)

Clinical Determination Guidelines:

Document the following with chart notes:

I. Inflamatory bowel Disease (IBD)
   A. Crohn's disease (CD)
      1. Age: ≥ 18 years
      2. Prescriber: Gastroenterologist
      3. Diagnosis and severity: Mod-severe active CD disease
      4. Other therapies: Contraindicated, failed or significant adverse effects (one of both below):
         a. Conventional therapies (4 months.): Mesalamine, metronidazole
         b. DMARD (4 months.): Thiopurines (azathioprine/6-MP), MTX
      5. Dosage regimen:
         a. Stelara IV and SC (ustekinumab): Load: ≤55Kg - 260mg; >55-85Kg - 390mg; >85Kg - 520mg IV x 1, then 90 mg SC q 8 wks
      6. Approval
         a. Initial: 6 months.
         b. Re-approval: 1 year.
      7. Exceptions: Skipping the requirements of "*2. Other therapies"* are allowed if patient exhibits severe or fulminant disease (See Appendix III)

II. Rheumatology
- A. Rheumatoid Arthritis (RA)
  1. Age: ≥ 18 years
  2. Prescriber: Rhematologist
  3. Diagnosis and severity: Moderate - severe RA
  4. Other therapies: Contraindicated, failed or had significant adverse events with 2 therapies with different MOA:
     Chronic DMARD (4 months): Leuflonomide or MTX, hydroxychloroquine, sulfasalazine
  5. Dosage regimen
     a. Actemra IV (tocilzumab): 4mg/Kg q 4 weeks; increase to 8mg/Kg with inadequate response (max. 800mg)
  6. Exclude: Actemra subcutaneous (tocilzumab) and Kevzana SC (sarilumab)
     a. All preferred products are contraindicated, failed or resulted in significant adverse effects
     b. Required site of care determined by the health plan
- B. Psoriatic Arthritis (PA)
  1. Age: ≥ 18years
  2. Prescriber: Rhematologist
  3. Diagnosis and severity: Active PA with ≥ 5 swollen and ≥ 5 tender joints
  4. Other therapies: Contraindicated, failed or to significant adverse effects from 2 of the appropriate category below:
     a. Peripheral disease: DMARD therapy (4 months) - Methotrexate, leflunomide, sulfasalazine
     b. Axial disease, enthesitis, dactylitis and uveitis: NSAIDs (4 months)
  5. Exclude: Taltz SC (ixekizumab)
     a. All preferred products are contraindicated, failed or resulted in significant adverse effects
     b. Required site of care determined by the health plan
  6. Dosage regimen:
     a. Cosentyx SC (secukinumab): 300 mg weekly x 5, then 150-300 mg q4 weeks.
     b. Stelara SC (ustekinumab):
        - Standard: 45 mg week 0 and 4, then 45 mg q 12 weeks.
        - Co-morbid mod-severe PP (>100 kg): 90 mg week 0 and 4, then 90 mg q 12 weeks.
  7. Approval:
     a. Initial: 6 months.
     b. Re-approval: 1 year (decreased or sustained reduction in disease activity, as shown by less joints affected)
- C. Ankylosing Spondylitis (AS)
  1. Age: ≥ 18years
  2. Prescriber: Rhematologist
  3. Diagnosis and severity: Active AS
  4. Other therapies: Contraindicated, failed or had significant adverse effects (2 below)
     a. DMARD (4 months.): MTX, leflunomide, sulfasalazine
  5. Dosage regimen:
     a. Cosentyx SC (secukinumab): 150 mg weekly x 5, then 150 mg q4 weeks.
  6. Approval
     a. Initial: 6 months
     b. Re-approval: 1 year. (decreased or sustained reduction in disease activity, as shown by less joints affected)

III. Dermatology

A. Plaque Psoriasis (PP)

1. Age: ≥ 18 years
2. Prescriber: Dermatologist, allergist
3. Diagnosis and severity: Moderate to severe chronic PP
   a. Duration: Chronic PP > 6 months
   b. Severity
      - Body Surface area (BSA): ≥ 10% OR
      - 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: Contraindicated, failed or significant adverse effects with 2 of category a and 1 of b:
   a. Local therapies (4 mons.): Topical (steroids, vit. D analogues, coal tar, dithranol), phototherapy, photochemotherapy,
   b. Systemic therapy (4 mons.): Cyclosporine, MTX
5. Exclude: Taltz SC (ixekizumab), Siliq SC (brodalumab), Tremfya SC (guselkumab) & Ilumya SC (tildrakizumab)
   a. All preferred products are contraindicated, failed or resulted in significant adverse effects
   b. Required site of care determined by the health plan
6. Dosing regimen
   a. Cosentyx SC (secukinumab): 300mg wkly x 5, then 150-300mg q4 wks
   b. Stelara SC (ustekinumab):
      - ≤ 100 kg: 45 mg x 2 wk. 0 & 4, then 45 mg q 12 wks.
      - >100 kg: 90 mg x 2 wk. 0 & 4, then 90 mg q 12 wks.
7. Approval
   a. Initial: 6 months
   b. Re-approval: 1 year (decreased or sustained reduction in disease activity, as shown by less joints affected)

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Appendix I FDA Approved Indications

FDA Approved Indications	Plaque Psoriasis (PP)	Crohn's Disease (CD)	Rheumatoid Arthritis (RA)	Psoriatic Arthritis (PA)	Ankylosis Spondylitis (AS)
Preferred Interleukin Inhibitors					
Actemra IV			X		
Cosentyx SC	X			X	X
Stelara IV/SC	X	X		X	
Excluded Interleukin Inhibitors					
Actemra SC			X		
Kevzara SC			X		
Siliq SC	X				
Talltz SC	X			X	
Tremfya SC	X				
Ilumya SC	X				

Appendix II: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring	REMS
Stelara Ustekinumab IV/SC	• CNS: HA (5%) • Resp.: naso-pharyngitis (27-72%) • Other: Antibody development (6%) • Preg. Risk factor: B	• Infection: TB- Test prior to tx; watch for S/Sx • Misc: S & Sx skin CA (esp w elderly, long therapy, hx PUVA tx)	• Med. Guide must be dispensed with med
Cosentyx secukinumab	• Infection: nasopharyngitis, Candida, herpes, staph skin (29-48%) • Preg. Risk factor: B	• GI: Crohn's flare (0.09%) • Infections: TB Test - pre tx; watch for S/Sx	• Med. Guide must be dispensed with med
Actemra Tocilizumab IV/SC	• Endo/metab: ↑cholesterol (19-20%) • Hepatic: ↑ ALT (≤34%); ↑ AST(≤22%) • Misc: Infusion related Rx (4-16%) • Preg.: Adverse events observed in some animal studies.	• CNS: S & Sx of Deylinating disorder • GI: perforation • Infections: TB test - pre tx • Labs: ALT/AST - pre, 4-8 wks during, then q 3 mons; lipids - pre, 4-8 wks during, then q 6 wks)	• Med. Guide must be dispensed with med

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References and Resources:

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4. Secukinumab in Plaque Psoriasis – results of two phase 3 trials. NEJM 2014; 371:326-338.
5. Ustekinumab induction and maintenance therapy in refractory Crohn's disease. NEJM 2012;367:1519-1528.
6. Comparison of ustekinumab and etanercept for moderate-to-severe psoriasis. NEJM 2010; 362(2):118-28.
7. Ustekinumab inhibits radiographic progression in patients with active psoriatic arthritis: results from the phase 3 PSUMMIT-1 and PSUMMIT-2 trials. Ann Rheum Dis. 2014;73(6):1000-6.
8. 3rd European evidence-based consensus on the diagnosis and management of Crohn's disease 2016: Part 1: Diagnosis and medical management. Journal of Crohn's and Colitis. 2017;11:3-25
9. British Association of Dermatologists guidelines for the biological therapy for psoriasis 2017;177(3):628-36.
10. Clinical Practice Guidelines for the treatment of patients with axial spondyloarthritis and psoriatic arthritis. Madrid, (Spain): Spanish Society of Rheumatology (SER);2015.

Approved By:

2/27/19

Peter Graham, MD – PHP Executive Medical Director — Date

2/27/19

Kurt Bateen - Human Resources — Date