STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Cytokine & CAM antagonist criteria
Effective 11/21/2019
Prior Authorization Request Form

Prior Authorization for any agent in this class requires the following criteria to be met. Additional criteria may be required for specific indications; off-label requests require an appeal:

- **Diagnoses Must Accompany All Requests**
- Patient must meet the minimum age recommended by the manufacturer for the FDA-approved indication; **AND**
- Initial treatment plan must be done by, or in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist); **AND**
- A negative tuberculin skin test must be submitted prior to initiation of therapy.
- Off-label use must be appealed to the Medical Director and be accompanied with a letter from the prescriber detailing the clinical rationale for the request.
- *DMARD refers to a non-biologic disease-modifying anti-rheumatic drug and includes such agents as methotrexate (MTX), sulfasalazine, leflunomide, and cyclosporine among other agents).*

THE FOLLOWING INDICATION-SPECIFIC CRITERIA MUST ALSO BE SATISFIED:

- **Ankylosing spondylitis, Plaque Psoriasis and Psoriatic Arthritis:**
  - **Plaque psoriasis**: Preferred agents require evidence of failure after at least 90 days of topical therapy* with two different agents classified as an emollient, corticosteroid, topical retinoid or vitamin D analog. A 90-day trial of one DMARD (or a systemic retinoid such as acitretin) is also required.
    **Topical therapy requirement is waived for moderate-to-severe disease affecting at least 5% of the BSA or crucial body areas such as the hands, feet, face, neck, genitals/groin, or intertriginous areas.*
  - **Psoriatic Arthritis:** Preferred agents require a 90-day trial of one DMARD.
  - **Ankylosing Spondylitis:** Preferred agents require failure of two 30-day trials of NSAIDs.
  - Note: Cosentyx may be authorized only after a 90-day trial of either Humira or Enbrel.
  - Non-preferred agents require 90-day trials of Enbrel, Humira and Cosentyx.
- **Rheumatoid arthritis:**
  - Humira and Enbrel each require a 90-day trial a DMARD.
  - Non-preferred agents require 90-day trials each of one DMARD, and Enbrel and Humira.
- **Juvenile idiopathic arthritis:**
  - Humira and Enbrel each require a 90-day trial of a DMARD.
  - Non-preferred agents require 90-day trials each of one DMARD, and Enbrel and Humira.

- **Crohn's Disease (Adult and Pediatric):**
  - Humira may be authorized upon demonstration of an inadequate response to at least one 14-day trial of corticosteroids or an immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate.
  - In addition to the above criteria, non-preferred agents require a 90-day trial of Humira.

- **Ulcerative Colitis:**
  - Humira may be authorized upon demonstration of an inadequate response to at least a thirty (30) day course of aminosalicylates (e.g. sulfasalazine, mesalamine) requiring treatment for two (2) or more exacerbations using corticosteroids, such as prednisone.
  - In addition to the above criteria, non-preferred agents require a 90-day trial of Humira.

- **Hidradenitis suppurativa:**
  - Humira may be authorized with documentation indicating that the patient has severe disease (Hurley stage III) OR moderate disease (Hurley state II) despite treatment with an oral formulary tetracycline (i.e., doxycycline) OR topical clindamycin.

- **Uveitis:**
  - Humira may be authorized for a diagnosis of non-infectious uveitis and failure to respond to an appropriate trial of oral/topical corticosteroid therapy, unless contraindicated.

Table 1 FDA-approved indications – *(Preferred agents highlighted).* ***Current on 2/22/2019***

		Ankylosing Spondylitis	Plaque Psoriasis	Psoriatic Arthritis	Polyarticular JIA	Rheumatoid Arthritis	Crohn's Disease	Pediatric Crohn's Disease	Ulcerative Colitis	Hidradenitis Suppurativa	Uveitis	Cytokine Release Syndrome	Giant Cell arteritis	Systemic JIA	Periodic Fever Syndromes	Mechanism of Action
Humira	adalinumab	☑	☑	☑	☑ ≥ 2 y	☑	☑ ≥ 6 y	☑	☑	☑ ≥ 12 y	☑ ≥ 2 y					Anti-TNF
Ebrel	etanercept	☑	☑ ≥ 4 y	☑	☑ ≥ 2 y	☑										Anti-TNF
Cosentyx	secukinumab	☑	☑	☑												Anti-IL-17A
Cimzia	certolizumab pegol	☑	☑	☑		☑	☑									Anti-TNF
Remicade	infliximab	☑	☑	☑		☑	☑		☑							Anti-TNF
Renflexis	infliximab	☑	☑	☑		☑	☑		☑							Anti-TNF
Simponi	golimumab	☑	☑	☑					☑							Anti-TNF
Actemra	tocilizumab				☑	☑						☑	☑	☑		Anti-IL-6
Entyvio	vedolizumab						☑		☑							Select. adhesion mol. inhib.
Ilaris	canakinumab													☑	☑	IL-1 Beta Inhibitor
Kevzara	sarilumab					☑										Anti-IL-6
Orencia	abatacept			☑	☑	☑										Select. T-Cell costim. blocker
Otezla	apremilast		☑	☑												PDE-4 Enzyme Inhibitor
Siliq	brodalumab		☑													Anti-IL-17A
Stelara	ustekinumab		☑	☑			☑									Anti-IL-12/23
Taltz	ixekizumab		☑	☑												Anti-IL-17A
Tremfya	guselkumab		☑													Anti-IL-23
Xeljanz	tofacitinib			☑		☑			☑							JAK inhibitor

REFERENCES

1) Lexi-Comp drug monographs for all drugs listed reviewed on 2-22-2019
2) Package Inserts reviewed on 2-22-2019
3) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
4) The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics
5) American College of Rheumatology/Spondylitis Association of America/Spondyloarhtritis Research and Treatment Network 2015 Recommendations for the Treatment of Anykylosing Spondylitis and Noradiographic Axial Spondyloarthritis
6) Crofford *Arthritis Research & Therapy* 2013, 15(Suppl 3):S2
7) J Braun *et al*. 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
8) Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults. A national clinical guideline. Edinburgh (Scotland); Scottish Intercollegiate (SIGN), 2010 Oct (SIGN publication, no. 121 (217 references)
9) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009
10) EDF Guideline for Hidradenitis Suppurativa / Acne Inversa (HS) - S1 Guideline – 2016-2017

Table 1.2 Drugs by Indication - *(Alternate view - Preferred agents highlighted). **Current on 2/22/2019***

	Humira	Ebrel	Cosentyx	Cimzia	Remicade	Renflexis	Simponi	Actemra	Entyvio	Ilaris	Kevzara	Orencia	Otezla	Siliq	Stelara	Taltz	Tremfya	Xeljanz
Ankylosing Spondylitis	☑	☑	☑	☑	☑	☑	☑	☑	☑									
Plaque Psoriasis	☑	☑ ≥ 4 y	☑	☑	☑	☑	☑						☑	☑	☑	☑	☑	
Psoriatic Arthritis	☑	☑	☑	☑	☑	☑	☑					☑	☑		☑	☑		☑
Polyarticular JIA	☑ ≥ 2 y	☑ ≥ 2 y						☑				☑						
Rheumatoid Arthritis	☑	☑		☑	☑	☑		☑			☑	☑						☑
Crohn's Disease	☑ ≥ 6 y			☑	☑	☑			☑						☑			
Pediatric Crohn's Disease	☑																	
Ulcerative Colitis	☑				☑	☑	☑		☑									☑
Hidradentis Suppurativa	☑ ≥ 12																	
Uveitis	☑ ≥ 2 y																	
Cytokine Release Syndrome								☑										
Giant Cell arteritis								☑										
Systemic JIA								☑	☑									
Periodic Fever Syndromes									☑									