Department:	Pharmacy Management	**Original Approval:**	06/06/2018
Policy #:	PM147	**Last Approval:**	12/12/2018
Title:	Cytokine & CAM Antagonists		
Approved By:	UM Committee		

Reviewers may use approved compendia such as Micromedex for determinations on diagnoses not listed below.

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW:

History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Dosing and duration requested -Weight -Age -Medication list (current and past) to include start and end dates of previous trials for all conventional synthetic disease-modifying anti-rheumatic drugs (DMARD)/other small molecule drugs and biologic drugs - Prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, neurologist, oncologist, hematologist or other specialist as indicated.

BACKGROUND

Cytokine and CAM Antagonists	
abatacept (ORENCIA) adalimumab (HUMIRA) anakinra (KINERET) apremilast (OTEZLA) baricitinib (OLUMIANT) brodalumab (SILIQ) canakinumab (ILARIS) certolizumab pegol (CIMZIA) etanercept (ENBREL) golimumab (SIMPONI) guselkumab (TREMFYA) infliximab (REMICADE)	infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA)ixekizumab (TALTZ) rilonacept (ARCALYST) sarilumab (KEVZARA) secukinumab (COSENTYX) tildrakizumab-asmn (ILUMYA) tocilizumab (ACTEMRA) tofacitinib citrate (XELJANZ/ XR) ustekinumab (STELARA) vedolizumab (ENTYVIO)

Cytokines and cell-adhesion molecule (CAM) antagonists are chemical mediators involved in inflammatory processes throughout the body. Medications included in this policy are used to treat a group of diseases that may be caused or worsened by an overactive immune system such as rheumatoid arthritis, psoriasis, and ulcerative colitis. Administration is different for each medication, and may be a subcutaneous injection (SC), intravenous injection (IV), or administered by mouth.

Cytokine and CAM antagonists may be considered medically necessary when **ALL** of the following apply:

- Used for the treatment of moderately to severely active ankylosing spondylitis (AS), Crohn's disease (CD), hidradenitis suppurativa (HS), juvenile idiopathic arthritis (JIA), plaque psoriasis (Ps), psoriatic arthritis (PsA), rheumatoid arthritis (RA), ulcerative colitis (UC), or uveitis (UV)
- History of failure, contraindication or intolerance to conventional therapy
- Documentation of a negative TB skin test

Preferred biologic medications for the treatment of chronic inflammatory conditions include: adalimumab (Humira®) and etanercept (Enbrel®)

DEFINITIONS

Term	Description
Disease modifying anti-rheumatic drugs (DMARDs)	A variety of drugs that work by altering the immune system function to halt the underlying processes that cause certain forms of inflammatory arthritis including rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis.
Conventional therapy	Treatments that are widely accepted and practiced by the medical community
Hidradenitis suppurativa (HS)	A chronic, inflammatory disease affecting sweat glands known as apocrine glands.
Immunomodulator drugs	A class of drugs that modifies or influences the immune system
Immunosuppressive drugs	subclass of immunomodulator drugs that reduce inflammation by affecting the immune system; includes 6-mercaptopurine (6-MP), azathioprine, cyclophosphamide, cyclosporine, methotrexate, and tacrolimus; also referred to as immunosuppressant drugs
Nonsteroidal anti-inflammatory drugs (NSAIDs)	A class of drugs used to treat pain, redness, swelling, and inflammation from conditions including different types of arthritis; includes over-the-counter (OTC) and prescription medicines, such as celecoxib, diclofenac, ibuprofen, indomethacin, meloxicam, naproxen, sulindac, tolmetin, and valdecoxib

INDICATIONS/CRITERIA

Medicaid Members	The medications listed above are included in WA HCA's Single Preferred Drug List with criteria from WA HCA Cytokine & CAM Antagonists Medical policy no. 66.27.00-1
Medicare Members	See MCG 22nd Edition ***Step-utilization of Part D drugs not required.***

Initial Approval:

A. Ankylosing Spondylitis (AS) may be covered when ALL of the following are met:

1. Diagnosis of active ankylosing spondylitis
2. History of failure, contraindication, or intolerance to **ALL** of the following:
    a. Non-steroidal anti-inflammatory drugs (NSAIDs)
    b. Nonbiologic DMARD (e.g., methotrexate, acetretin, or cyclosporine)
3. Not used in combination with **ANY** of the following:
    a. Biologic DMARD
    b. Janus kinase inhibitor
    c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a rheumatologist

Approve for 6 months

A. Crohn's Disease (CD) may be covered when **ALL** of the following are met:

1. Diagnosis of moderately to severely active Crohn's disease
2. History of failure, contraindication, or intolerance to **ALL** of the following:
    a. Conventional therapy
    b. Humira
3. Patient is not receiving in combination with any of the following:
    a. Biologic DMARD
    b. Janus kinase inhibitor
    c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a gastroenterologist

Approve for 6 months

B. **Hidradenitis Suppurativa (HS)** may be covered when **ALL** of the following are met:

1. Diagnosis of moderate to severe hidradenitis suppurativa
2. History of failure, contraindication, or intolerance to **ALL** of the following:
    a. Conventional therapy
    b. Humira
3. Patient is not receiving in combination with any of the following:
    a. Biologic DMARD
    b. Janus kinase inhibitor
    c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a dermatologist

Approve for 6 months

C. **Juvenile Idiopathic Arthritis (JIA)** may be covered when **ALL** of the following are met:

1. Diagnosis of moderately to severely active juvenile idiopathic arthritis
2. History of failure, contraindication, or intolerance to **ALL** of the following:
    a. NSAID or corticosteroid
    b. Greater than or equal to (≥) 1 nonbiologic agent
3. Patient is not receiving in combination with any of the following:
    a. Biologic DMARD
    b. Janus kinase inhibitor
    c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a rheumatologist

Approve for 6 months

D. **Plaque Psoriasis (Ps)** may be covered when **ALL** of the following are met:

1. Diagnosis of moderate to severe chronic plaque psoriasis
2. History of failure, contraindication, or intolerance to the following:
    a. Phototherapy

   b. Other systemic therapies
3. Patient is not receiving in combination with any of the following:
   a. Biologic DMARD
   b. Janus kinase inhibitor
   c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a dermatologist or rheumatologist

Approve for 6 months

E. Psoriatic Arthritis (PsA) may be covered when **ALL** of the following are met:
1. Diagnosis of active psoriatic arthritis
2. History of failure, contraindication, or intolerance to **ALL** of the following
   a. Non-biologic DMARDs
   b. Greater than or equal to (≥) 2 preferred biologic agents
3. Patient is not receiving in combination with any of the following:
   a. Biologic DMARD
   b. Janus kinase inhibitor
   c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a dermatologist or rheumatologist

Approve for 6 months

F. Rheumatoid Arthritis (RA) may be covered when **ALL** of the following are met:
1. Diagnosis of moderately to severely active rheumatoid arthritis
2. History of failure, contraindication, or intolerance to **ALL** of the following:
   a. Greater than or equal to (≥) 1 nonbiologic DMARD
   b. Greater than or equal to (≥) 2 preferred biologic products
3. Patient is not receiving in combination with any of the following:
   a. Biologic DMARD
   b. Janus kinase inhibitor

   c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a rheumatologist

Approve for 6 months

G. Ulcerative Colitis (UC) may be covered when **ALL** of the following are met:
1. Diagnosis of moderately to severely active ulcerative colitis
   a. Greater than or equal to (≥) 18 years of age
2. History of failure, contraindication, or intolerance to conventional therapy
3. Patient is not receiving in combination with any of the following:
   a. Biologic DMARD
   b. Janus kinase inhibitor
   c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a gastroenterologist

Approve for 6 months

H. Uveitis (UV) may be covered when **ALL** of the following are met:
1. Diagnosis of non-infectious uveitis classified as one of the following:
   a. Intermediate
   b. Posterior
   c. Panuveitis
2. History of failure, contraindication, or intolerance to conventional therapy
3. Patient is not receiving in combination with any of the following:
   a. Biologic DMARD
   b. Janus kinase inhibitor
   c. Phosphodiesterase 4 (PDE4) inhibitor
4. Greater than or equal (≥) to FDA-approved age limit
5. Negative TB skin test
6. Prescribed by or in consultation with a rheumatologist or ophthalmologist

Approve for 6 months

I. Reauthorization

May be continued when **ALL** of the following are met:

Documentation of positive clinical response

Approve for 12 months

SPECIAL CONSIDERATIONS

Drug Name	Dose and Quantity Limits
abatacept (ORENCIA)	#4 syringe per 28-day supply
adalimumab (HUMIRA)	Initial authorization (1 time): • RA/PsA/AS/JIA: 80mg for 28-day supply • CD/UC: 240mg for 28-day supply • Ps/UV: 160mg for 28-day supply • HS initial: 240mg for 28-day supply Renewal: • RA/PsA/AS/JIA/CD/UC/Ps/UV: ○ 80mg per 28-day supply • HS: 160mg every week per 28-day supply
anakinra (KINERET)	#1 syringe per day; #28 syringes per 28-day supply
apremilast (OTEZLA)	#60 tablets per 30-day supply
brodalumab (SILIQ)	Initial (1 time): #3 syringe per 28-day supply Renewal: #2 syringe per 28-day supply
canakinumab (ILARIS)	#2 syringe/vial per 28-day supply
certolizumab pegol (CIMZIA)	Initial(1 time): #6 syringe per 28-day supply Renewal: #2 syringes per 28-day supply
etanercept (ENBREL)	Initial Authorization • Ps: 400mg per 28-day supply x3 months • AS/PsA/RA: 200mg per 28-day supply Renewal: • AS/Ps/PsA/RA: 200mg per 28-day supply
guselkumab (TREMFYA)	Initial (1 time): #2 syringes per 28-day supply Renewal: #1 syringe per 56-day supply
ixekizumab (TALTZ)	Initial authorization: • Ps #1: #4 syringe per 28-day supply (1 month) • Ps #2: # 2 syringe per 28-day supply (2 months) • PsA: #3 syringe per 28-day supply (1 month) Renewal: • Ps/PsA: #1 syringe per 28-day supply
rilonacept (ARCALYST)	Initial (1 month): 800mg per 28-day supply Renewal: 640mg per 28-day supply
sarilumab (KEVZARA)	400mg per 28-day supply
secukinumab (COSENTYX)	Initial Authorization (1 time) : • Ps: 1200mg (#8 syringe) per 28-day supply • AS/PsA: 600mg (#4 syringe) per 28-day supply Renewal: • Ps: 600mg (#2 syringe) per 28-days thereafter • AS/PsA: 150mg (#1 syringe) per 28-days thereafter

tocilizumab (ACTEMRA)	#4 syringes per 28-day supply after initial approval
tofacitinib citrate (XELJANZ/ XR)	IR: 10mg per day; #60 tablets per 30-day supply XR: 11mg per day; #30 tablets per 30-day supply
ustekinumab (STELARA)	Initial Authorization (1 time): • <100kg: 45mg/0.5mL per 28-day supply • >100kg: 90mg/1mL per 28-day supply Renewal: • <100kg: 45mg per 84-day supply • >100kg: 90mg per 84-day supply
vedolizumab (ENTYVIO)	Initial: 900mg per 42-day supply Renewal: 300mg per 56-day supply

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References	1. van den Bosch, F. Arthritis associated with gastrointestinal disease. Last updated February 2016. . In: Sieper J. UpToDate, Waltham, MA, 2016. 2. Smith, E, Yazici, Y. Treatment of Behcet's syndrome. Last updated June 2015. In: Merkel P. UpToDate, Waltham, MA, 2016. 3. Hisamatsu, T, Ueno, F, Matsumoto, T, et al. The 2nd edition of consensus statements for the diagnosis and management of intestinal Behcet's disease: indication of anti-TNFalpha monoclonal antibodies. Journal of gastroenterology. 2014 Jan;49(1):156-62. PMID: 23955155 4. Magnano, MD, Chakravarty, EF, Broudy, C, et al. A pilot study of tumor necrosis factor inhibition in erosive/inflammatory osteoarthritis of the hands. The Journal of rheumatology. 2007 Jun;34(6):1323-7. PMID: 17516620

5. Hoffman, GS, Cid, MC, Rendt-Zagar, KE, et al. Infliximab for maintenance of glucocorticosteroid-induced remission of giant cell arteritis: a randomized trial. Annals of internal medicine. 2007 May 1;146(9):621-30. PMID: 17470830
6. Couriel, DR, Saliba, R, de Lima, M, et al. A phase III study of infliximab and corticosteroids for the initial treatment of acute graft-versus-host disease. Biology of blood and marrow transplantation : journal of the American Society for Blood and Marrow Transplantation. 2009 Dec;15(12):1555-62. PMID: 19896079
7. R., B. Granuloma annulare. Last updated November 2015. In: Stratman E. UpToDate, Waltham, MA, 2016.
8. Sandborn, WJ, Colombel, JF, Sands, BE, et al. Abatacept for Crohn's disease and ulcerative colitis. Gastroenterology. 2012 Jul;143(1):62-9 e4. PMID: 22504093
9. Hueber, W, Sands, BE, Lewitzky, S, et al. Secukinumab, a human anti-IL-17A monoclonal antibody, for moderate to severe Crohn's disease: unexpected results of a randomised, double-blind placebo-controlled trial. Gut. 2012 Dec;61(12):1693-700. PMID: 22595313
10. Burns, JC, Best, BM, Mejias, A, et al. Infliximab treatment of intravenous immunoglobulin-resistant Kawasaki disease. The Journal of pediatrics. 2008 Dec;153(6):833-8. PMID: 18672254
11. Son, MB, Gauvreau, K, Burns, JC, et al. Infliximab for intravenous immunoglobulin resistance in Kawasaki disease: a retrospective study. The Journal of pediatrics. 2011 Apr;158(4):644-9 e1. PMID: 21129756
12. Tremoulet, AH, Jain, S, Jaggi, P, et al. Infliximab for intensification of primary therapy for Kawasaki disease: a phase 3 randomised, double-blind, placebo-controlled trial. Lancet. 2014 May 17;383(9930):1731-8. PMID: 24572997
13. Aster, J, Brown, J., Munshi, N. Multicentric Castleman's disease. Last updated January 2015. . In: Freedman A. UpToDate, Waltham, MA, 2016.
14. Van Den Bosch, F, Kruithof, E, Baeten, D, et al. Randomized double-blind comparison of chimeric monoclonal antibody to tumor necrosis factor alpha (infliximab) versus placebo in active spondylarthropathy. Arthritis and rheumatism. 2002 Mar;46(3):755-65. PMID: 11920412
15. Mease, P, Sieper, J, Van den Bosch, F, Rahman, P, Karunaratne, PM, Pangan, AL. Randomized controlled trial of adalimumab in patients with nonpsoriatic peripheral spondyloarthritis. Arthritis Rheumatol. 2015 Apr;67(4):914-23. PMID: 25545240
16. Paramarta, JE, De Rycke, L, Heijda, TF, et al. Efficacy and safety of adalimumab for the treatment of peripheral arthritis in spondyloarthritis patients without ankylosing spondylitis or psoriatic arthritis. *Annals of the rheumatic diseases*. 2013 Nov;72(11):1793-9. PMID: 23139265
17. Reich, K, Ortonne, JP, Gottlieb, AB, et al. Successful treatment of moderate to severe plaque psoriasis with the PEGylated Fab' certolizumab pegol: results of a phase II randomized, placebo-controlled trial with a re-treatment extension. The British journal of dermatology. 2012 Jul;167(1):180-90. PMID: 22413944
18. Mease, P, Genovese, MC, Gladstein, G, et al. Abatacept in the treatment of patients with psoriatic arthritis: results of a six-month, multicenter, randomized, double-blind, placebo-controlled, phase II trial. Arthritis and rheumatism. 2011 Apr;63(4):939-48. PMID: 21128258

19. Judson, MA, Baughman, RP, Costabel, U, et al. Efficacy of infliximab in extrapulmonary sarcoidosis: results from a randomised trial. Eur Respir J. 2008;31:1189-96. PMID: 18256069
20. Baughman, RP, Drent, M, Kavuru, M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement. American journal of respiratory and critical care medicine. 2006 Oct 1;174(7):795-802. PMID: 16840744
21. Pariser, RJ, Paul, J, Hirano, S, Torosky, C, Smith, M. A double-blind, randomized, placebo-controlled trial of adalimumab in the treatment of cutaneous sarcoidosis. Journal of the American Academy of Dermatology. 2013 May;68(5):765-73. PMID: 23276549
22. Brooklyn, TN, Dunnill, MG, Shetty, A, et al. Infliximab for the treatment of pyoderma gangrenosum: a randomised, double blind, placebo controlled trial. Gut. 2006 Apr;55(4):505-9. PMID: 16188920
23. Narshi, CB, Allard, SA. Sustained response to tocilizumab, anti-IL-6 antibody, following anti-TNF-alpha failure in a patient with relapsing polychondritis complicated by aortitis. Rheumatology (Oxford). 2012 May;51(5):952-3. PMID: 22298790
24. Kawai, M, Hagihara, K, Hirano, T, et al. Sustained response to tocilizumab, anti-interleukin-6 receptor antibody, in two patients with refractory relapsing polychondritis. Rheumatology (Oxford). 2009 Mar;48(3):318-9. PMID: 19106169
25. Genovese, MC, Durez, P, Richards, HB, et al. One-year efficacy and safety results of secukinumab in patients with rheumatoid arthritis: phase II, dose-finding, double-blind, randomized, placebo-controlled study. The Journal of rheumatology. 2014 Mar;41(3):414-21. PMID: 24429175
26. Genovese, MC, Durez, P, Richards, HB, et al. Efficacy and safety of secukinumab in patients with rheumatoid arthritis: a phase II, dose-finding, double-blind, randomised, placebo controlled study. Annals of the rheumatic diseases. 2013 Jun;72(6):863-9. PMID: 22730366
27. Barkham, N, Keen, HI, Coates, LC, et al. Clinical and imaging efficacy of infliximab in HLA-B27-Positive patients with magnetic resonance imaging-determined early sacroiliitis. Arthritis and rheumatism. 2009 Apr;60(4):946-54. PMID: 19333933
28. Korhonen, T, Karppinen, J, Paimela, L, et al. The treatment of disc-herniation-induced sciatica with infliximab: one-year follow-up results of FIRST II, a randomized controlled trial. Spine. 2006 Nov 15;31(24):2759-66. PMID: 17108825
29. Korhonen, T, Karppinen, J, Paimela, L, et al. The treatment of disc herniation-induced sciatica with infliximab: results of a randomized, controlled, 3-month follow-up study. *Spine*. 2005 Dec 15;30(24):2724-8. PMID: 16371894
30. Genevay, S, Viatte, S, Finckh, A, Zufferey, P, Balague, F, Gabay, C. Adalimumab in severe and acute sciatica: a multicenter, randomized, double-blind, placebo-controlled trial. Arthritis and rheumatism. 2010 Aug;62(8):2339-46. PMID: 20506391
31. Genevay, S, Finckh, A, Zufferey, P, Viatte, S, Balague, F, Gabay, C. Adalimumab in acute sciatica reduces the long-term need for surgery: a 3-year follow-up of a randomised double-blind placebo-controlled trial. Annals of the rheumatic diseases. 2012 Apr;71(4):560-2. PMID: 21998121

32. Khanna, D, Denton, CP, Jahreis, A, et al. Safety and efficacy of subcutaneous tocilizumab in adults with systemic sclerosis (faSScinate): a phase 2, randomised, controlled trial. Lancet. 2016 Jun 25;387(10038):2630-40. PMID: 27156934
33. Moutsopoulos, NM, Katsifis, GE, Angelov, N, et al. Lack of efficacy of etanercept in Sjogren syndrome correlates with failed suppression of tumour necrosis factor alpha and systemic immune activation. Annals of the rheumatic diseases. 2008 Oct;67(10):1437-43. PMID: 18198195
34. Norheim, KB, Harboe, E, Goransson, LG, Omdal, R. Interleukin-1 inhibition and fatigue in primary Sjogren's syndrome--a double blind, randomised clinical trial. PloS one. 2012;7(1):e30123. PMID: 22253903
35. Uppal, SS, Hayat, SJ, Raghupathy, R. Efficacy and safety of infliximab in active SLE: a pilot study. Lupus. 2009 Jul;18(8):690-7. PMID: 19502264
36. Illei, GG, Shirota, Y, Yarboro, CH, et al. Tocilizumab in systemic lupus erythematosus: data on safety, preliminary efficacy, and impact on circulating plasma cells from an open-label phase I dosage-escalation study. Arthritis and rheumatism. 2010 Feb;62(2):542-52. PMID: 20112381
37. Merrill, JT, Burgos-Vargas, R, Westhovens, R, et al. The efficacy and safety of abatacept in patients with non-life-threatening manifestations of systemic lupus erythematosus: results of a twelve-month, multicenter, exploratory, phase IIb, randomized, double-blind, placebo-controlled trial. Arthritis and rheumatism. 2010 Oct;62(10):3077-87. PMID: 20533545
38. Dick, AD, Tugal-Tutkun, I, Foster, S, et al. Secukinumab in the treatment of noninfectious uveitis: results of three randomized, controlled clinical trials. Ophthalmology. 2013 Apr;120(4):777-87. PMID: 23290985
39. de Menthon, M, Cohen, P, Pagnoux, C, et al. Infliximab or rituximab for refractory Wegener's granulomatosis: long-term follow up. A prospective randomised multicentre study on 17 patients. Clinical and experimental rheumatology. 2011 Jan-Feb;29(1 Suppl 64):S63-71. PMID: 21586199
40. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. [cited 10/30/2013]; Available from: http://ard.bmj.com/content/70/6/896.full
41. 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Initiation and Safety Monitoring of Therapeutic Agents for the Treatment of Arthritis and Systemic Features. [cited 09/13/2013]; Available from: http://www.rheumatology.org/Practice/Clinical/Guidelines/Clinical_Practice_Guidelines/
42. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies. [cited 09/13/2013]; Available from: http://ard.bmj.com/content/71/1/4.abstract
43. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. [cited 09/13/2013]; Available from: http://www.rheumatology.org/Practice/Clinical/Guidelines/Clinical_Practice_Guidelines/

44. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. [cited 09/13/2013]; Available from: http://ard.bmj.com/content/early/2010/05/04/ard.2009.126532.abstract
45. Villiger, PM, Adler, S, Kuchen, S, et al. Tocilizumab for induction and maintenance of remission in giant cell arteritis: a phase 2, randomised, double-blind, placebo-controlled trial. Lancet. 2016 Mar 4. PMID: 26952547
46. Ingram, JR, Woo, PN, Chua, SL, et al. Interventions for hidradenitis suppurativa: a Cochrane systematic review incorporating GRADE assessment of evidence quality. The British journal of dermatology. 2016 Jan 23. PMID: 26801356
47. [Poster] Evaluating optimal medium-term dosing strategy for adalimumab in moderate to severe hidradenitis suppurative based on analysis of integrated results from the PIONEER I and II phase 3, randomized, placebo-controlled trials. North Chicago, IL: AbbVie; 2015
48. Simonini, G, Taddio, A, Cattalini, M, et al. Prevention of flare recurrences in childhood-refractory chronic uveitis: an open-label comparative study of adalimumab versus infliximab. Arthritis care & research. 2011 Apr;63(4):612-8. PMID: 21452272
49. Diaz-Llopis, M, Salom, D, Garcia-de-Vicuna, C, et al. Treatment of refractory uveitis with adalimumab: a prospective multicenter study of 131 patients. United States, 2012. p. 1575-81.
50. Nigrovic, PA. Cryopyrin-associated periodic syndromes and related disorders. . In: UpToDate, Basow DS (Ed). UpToDate, Waltham, MA, 2013.
51. Sanclemente, G, Murphy, R, Contreras, J, Garcia, H, Bonfill Cosp, X. Anti-TNF agents for paediatric psoriasis. The Cochrane database of systematic reviews. 2015 Nov 24(11):CD010017. PMID: 26598969
52. European biotech gets boost as Genmab market value hits $7 billion. [cited 11/20/2015]; Available from: http://www.reuters.com/article/2015/11/17/us-genmab-europe-biotech-idUSKCN0T61RU20151117#7OexUWlSTIozpu79.97
53. Abe, K, Itoyama, Y, Sobue, G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotrophic lateral sclerosis & frontotemporal degeneration. 2014 Dec;15(7-8):610-7. PMID: 25286015
54. Sibley, CH, Plass, N, Snow, J, et al. Sustained response and prevention of damage progression in patients with neonatal-onset multisystem inflammatory disease treated with anakinra: a cohort study to determine three- and five-year outcomes. Arthritis and rheumatism. 2012 Jul;64(7):2375-86. PMID: 22294344
55. Loftus, EV, Jr., Colombel, JF, Feagan, BG, et al. Long-term Efficacy of Vedolizumab for Ulcerative Colitis. J Crohns Colitis. 2017;11:400-11. PMID: 27683800
56. Vermeire, S, Loftus, EV, Jr., Colombel, JF, et al. Long-term Efficacy of Vedolizumab for Crohn's Disease. J Crohns Colitis. 2017;11:412-24. PMID: 27683798
57. Arnett, FC, Edworthy, SM, Bloch, DA, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis and rheumatism. 1988 Mar;31(3):315-24. PMID: 3358796
58. Kay, J, Upchurch, KS. ACR/EULAR 2010 rheumatoid arthritis classification criteria. England, 2012. p. vi5-9.

	59. Felson, DT, Anderson, JJ, Boers, M, et al. American College of Rheumatology. Preliminary definition of improvement in rheumatoid arthritis. Arthritis and rheumatism. 1995 Jun;38(6):727-35. PMID: 7779114 60. Product Information: OTEZLA® oral tablets, apremilast oral tablets. Celgene Corporation (per FDA), Summit, NJ, 2017. 61. Product Information: ILUMYA ™ Subcutaneous injection, tildrakizumab-asmn subcutaneous injection. Merck & Co.Inc (per manufacturer), Whitehouse Station, NJ, 2018	
CFR		
WAC	WAC 284-43-2050	
RCW		
Contract Citation	☒ WAH	
	☒ IMC	
	☒ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
06/06/2018	Created to mirror HCA Policy	Catherine Vu, PharmD
06/14/2018	Approval	UM Committee
09/19/2018	Revisions to match HCA update from 9/7/18	Jennifer Farley, PharmD
12/12/2018	Approval	UM Committee