




<b>ISSUE DATE</b> December 27, 2017	<b>EFFECTIVE DATE</b> January 8, 2018	<b>NUMBER</b> *See Below
<b>SUBJECT</b>  Prior Authorization of Cytokine and CAM Antagonists - Pharmacy Services		<b>BY</b>   Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

**New IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at:

[http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages for Cytokine and CAM Antagonists that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Cytokine and CAM Antagonists for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long-term care facilities.

**BACKGROUND:**

The Department of Human Services (DHS) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

*01-17-46	09-17-45	27-17-43	
02-17-41	11-17-41	30-17-42	
03-17-41	14-17-42	31-17-47	
08-17-48	24-17-42	32-17-41	33-17-46

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at  
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

**DISCUSSION:**

Siliq (brodalumab), Kevzara (sarilumab), Dupixent (dupilumab), and Tremfya (guselkumab) are new agents in the Cytokine and CAM Antagonists class on the Department's Preferred Drug List and are designated as non-preferred. In addition, the U.S. Food and Drug Administration recently approved new indications for existing agents in the class. During the September 20, 2017 DUR Board meeting, the DUR Board recommended guidelines to determine medical necessity of Cytokine and CAM Antagonists to address these changes, which were subject to public review and comment, and subsequently approved for implementation by DHS.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Cytokine and CAM Antagonists are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Cytokine and CAM Antagonists) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II  
Cytokine and CAM Antagonists

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**Requirements for Prior Authorization of Cytokine and CAM Antagonists**

A. Prescriptions That Require Prior Authorization

Prescriptions for Cytokine and CAM Antagonists that meet any of the following conditions must be prior authorized:

1. All prescriptions for Cytokine and CAM Antagonists must be prior authorized. See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: <https://papdl.com>
2. A prescription for a preferred or non-preferred Cytokine and CAM Antagonist with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Cytokine and CAM antagonist, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Cytokine and CAM Antagonist for treatment of a condition that is a U.S. Food and Drug Administration (FDA) approved, or a medically accepted, indication

**AND**

2. Is prescribed a dose of the Cytokine and CAM Antagonist appropriate for the beneficiary's age, weight, concurrent medications, liver function, and renal function in accordance with the package labeling

**AND**

3. Is prescribed the Cytokine and CAM Antagonist by, or in consultation with, a specialist (i.e. gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, etc.)

**AND**

4. Is under 21 years of age and is up to date on immunizations in accordance with current Early and Periodic Screening Diagnosis and Treatment (EPSDT) immunization guidelines prior to initiating therapy

**OR**

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

5. Is 21 years of age or older and is up to date on immunizations prior to initiating therapy

**AND**

6. Is not taking any other Cytokine and CAM Antagonist

**AND**

7. Will not be taking a medication that interacts with the prescribed Cytokine and CAM Antagonist as recommended in the package labeling

**AND**

8. Does not have a contraindication to the prescribed Cytokine and CAM Antagonist

**AND**

9. Has documentation of baseline lab results as recommended in the package labeling

**AND**

10. Is prescribed a dose of the Cytokine and CAM Antagonist that is appropriate based on the beneficiary's baseline lab results as recommended in the package labeling

**AND**

11. For a Cytokine and CAM Antagonist associated with an increased risk of infection according to the package labeling:
- a. Was evaluated for active or latent tuberculosis infection documented by either test results (purified protein derivative [PPD] testing) or blood testing

**AND**

- b. Does not have active, severe uncontrolled infection

**AND**

- c. Has documentation of:
  - i. Completion of hepatitis B immunization series

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**OR**

- ii. Hepatitis B screening (sAb/sAg and cAb)

**AND**

- a) If screening results indicate a risk of hepatitis B virus reactivation (HBVr), a follow-up plan to address this risk

**OR**

- b) If negative for hepatitis B, a plan for vaccination against hepatitis B virus

**AND**

- d. Does not have acute hepatitis B

**AND**

- e. Does not have chronic hepatitis B with Child-Pugh class B or C

**AND**

- 12. For Xeljanz (tofacitinib citrate), does not have severe hepatic impairment

**AND**

- 13. For Entyvio (vedolizumab):

- a. Had baseline LFTs and testing for anti-JC virus antibodies

**AND**

- b. Does not have jaundice or elevated transaminases and/or bilirubin

**AND**

- c. Has never taken Tysabri (natalizumab)

**AND**

- 14. For Otezla (apremilast):

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- a. Was evaluated by a psychiatrist in the last 6 months if the beneficiary has a history of prior suicide attempt, bipolar disorder, or major depressive disorder

**OR**

- b. For all others, had a mental health evaluation performed

**AND**

- c. Is being regularly monitored for weight loss

**AND**

15. For Siliq (brodalumab):

- a. Was evaluated by a psychiatrist in the past 6 months if the beneficiary has a history of prior suicide attempt, bipolar disorder, or major depressive disorder

**OR**

- b. For all others, had a mental health evaluation

**AND**

- c. Is prescribed Siliq by a prescriber enrolled in the Siliq REMS Program

**AND**

- d. Is authorized to receive Siliq by the Siliq REMS Program

**AND**

16. For Kevzara (sarilumab), does not have active hepatic disease or hepatic impairment

**AND**

17. For treatment of Crohn's Disease or moderate to severe Ulcerative Colitis, has a diagnosis of Crohn's Disease or Ulcerative Colitis which has remained active despite treatment with one or more of the following therapies:

- a. Aminosalicylates **OR**
- b. Corticosteroids **OR**
- c. Immunomodulators in accordance with current consensus guidelines

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**AND**

18. For treatment of moderate to severe active Rheumatoid Arthritis, has a documented history of therapeutic failure of a three (3) or more month trial of or a documented contraindication or intolerance to:

- a. Methotrexate **OR**
- b. An alternate conventional non-biologic disease-modifying anti-rheumatic drug (DMARD) in accordance with current consensus guidelines

**AND**

19. For treatment of ankylosing spondylitis, or other spondyloarthritis, or a diagnosis of active psoriatic arthritis:

a. Has Axial Disease **AND:**

- i. A documented history of therapeutic failure of one (1) month trial of continuous treatment with two (2) different oral Non-Steroidal Anti-Inflammatory drugs (NSAIDs) (i.e., an oral NSAID taken on a daily basis for one month and a different oral NSAID taken on a daily basis for one month)

**OR**

- ii. A documented contraindication or intolerance to oral NSAIDs

**OR**

b. Has peripheral disease **AND:**

- i. A documented history of therapeutic failure of a one (1) month trial of continuous treatment with two (2) different oral NSAIDs

**OR**

- ii. A documented history of therapeutic failure of an eight (8) or more week trial of optimally-titrated doses of methotrexate **OR** an alternate conventional non-biologic DMARD

**OR**

- iii. A documented contraindication or intolerance to NSAIDs, methotrexate, or an alternate conventional non-biologic DMARD

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**AND**

20. For treatment of chronic moderate to severe Plaque Psoriasis for beneficiaries  $\geq$  18 year of age:

- a. Has a body surface area (BSA):
  - i. Of 5% or more that is affected **OR**
  - ii. Involvement of  $<$  5% in critical areas (palms, soles, genitals or face) that interferes with daily activities

**AND**

- b. Has a documented history of therapeutic failure, contraindication, or intolerance to phototherapy in accordance with current consensus guidelines

**AND**

- c. Has a history of therapeutic failure, contraindication or intolerance to a trial of oral systemic therapy (e.g., methotrexate, cyclosporine, acitretin)

**AND**

21. For the treatment of non-infectious uveitis:

- a. Has a diagnosis of uveitis associated with juvenile idiopathic arthritis or Behçet's disease

**OR**

- b. For a diagnosis of inflammatory uveitis of other etiology, has a documented history of therapeutic failure, contraindication, or intolerance of:

- i. Systemic, topical, intraocular, or periocular corticosteroids

**OR**

- ii. Systemic immunosuppressives

**OR**

- c. Has corticosteroid-dependent uveitis (defined as requiring a daily systemic dose equivalent to 7.5 mg or greater of prednisone in adults for  $\geq$  six (6) weeks) and will be using the requested Cytokine and CAM



MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

Antagonist with the intent of discontinuing or decreasing the dose of the systemic corticosteroid

**AND**

22. For treatment of chronic moderate to severe atopic dermatitis for beneficiaries  $\geq$  18 year of age:

a. Has a documented history of therapeutic failure, contraindication, or intolerance to the following topical pharmacologic treatments:

i. For treatment of the face or skin folds, low-potency topical corticosteroids

**OR**

ii. For the treatment of areas other than the face or skin folds, medium- to high-potency topical corticosteroids

**AND**

iii. Topical calcineurin inhibitors

**AND**

b. Has a documented history of therapeutic failure, contraindication, or intolerance to phototherapy in accordance with current consensus guidelines

**AND**

c. Has a history of therapeutic failure, contraindication, or intolerance to systemic immunosuppressives in accordance with current consensus guidelines (e.g, cyclosporine, azathioprine, methotrexate, mycophenolate mofetil)

**AND**

23. For the treatment of giant cell arteritis:

a. Has a documented history of therapeutic failure, contraindication, or intolerance to methotrexate

**AND**

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- b. Will be using the requested medication in combination with a tapering course of glucocorticoids

**AND**

24. For Cosentyx (secukinumab) has a documented history of therapeutic failure of, or contraindication or intolerance to Humira (adalimumab)

**AND**

25. For a non-preferred Cytokine and CAM Antagonist, has a documented history of therapeutic failure of, or contraindication or intolerance to the preferred Cytokine and CAM Antagonists approved for the beneficiary's indication

**OR**

26. Has a current history (within the past 90 days) of being prescribed the same non-preferred Cytokine and CAM Antagonist

**OR**

27. Does not meet the clinical review guidelines above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary

28. In addition, if a prescription for either a preferred or non-preferred Cytokine and CAM Antagonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits/Daily Dose Limits Chapter.

**FOR RENEWALS OF PRESCRIPTIONS FOR CYTOKINE AND CAM ANTAGONISTS:** The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Cytokine and CAM Antagonists that were previously approved will take into account whether the beneficiary:

1. Had an improvement in disease activity and/or level of functioning

**AND**

2. Has documentation of results of recent lab monitoring as recommended in the package labeling

**AND**

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

3. Is prescribed a dose of the Cytokine and CAM Antagonist appropriate for the beneficiary's age, weight, concurrent medications, and recent lab results as recommended in the package labeling

**AND**

4. Is continued on the prescribed Cytokine and CAM Antagonist based on recent lab results as recommended in the package labeling

**AND**

5. Will not be taking a medication that interacts with the prescribed Cytokine and CAM Antagonist as recommended in the package labeling

**AND**

6. For Xeljanz (tofacitinib citrate), does not have severe hepatic impairment

**AND**

7. For Entyvio (vedolizumab), if baseline testing for anti-JC virus was negative, had repeat testing for anti-JC virus antibodies

**AND**

8. For Otezla (apremilast):
  - a. Has documentation of regular weight monitoring

**AND**

- b. If positive for a history of prior suicide attempt, bipolar disorder, major depressive disorder, continues to receive treatment for that condition

**AND**

9. For Siliq, if positive for a history of prior suicide attempt, bipolar disorder, or major depressive disorder, continues to receive treatment for that condition

**AND**

10. For Kevzara (sarilumab), does not have active hepatic disease or hepatic impairment

**OR**

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

11. Does not meet the clinical review guidelines above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary
12. In addition, if a prescription for either a preferred or non-preferred Cytokine and CAM Antagonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits/Daily Dose Limits Chapter.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. to assess the medical necessity of the request for a prescription for a Cytokine and CAM Antagonist. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

The Department will limit authorization as follows:

1. The U.S. Food and Drug Administration (FDA) maximum recommended therapeutic dose for specific indications for each Cytokine and CAM Antagonist.

References:

1. Kineret [package insert]. Thousand Oaks, CA: Amgen; May 2016.
2. Kyle S, Chandler D, Griffiths CEM, et. al. Guidelines for Anti-Tumor Necrosis Factor in Psoriatic Arthritis; Rheumatology 2005; 44(3): 390-397.
3. Mease PJ, Goffe BS, Diagnosis and Treatment of Psoriatic Arthritis; J AM Acad Dermatol 2005; 52(1): 1-19.
4. Hashkes PJ, Laxer RM, Medical Treatment of Juvenile Idiopathic Arthritis; JAMA 2005; 294(13): 1671-1684.
5. Cimzia [package insert]. Smyrna, GA: UCB, Inc; January 2017.
6. FDA MedWatch Report:  
[http://www.fda.gov/cder/drug/early\\_comm/TNF\\_blockers.htm](http://www.fda.gov/cder/drug/early_comm/TNF_blockers.htm)  
Accessed on January 26, 2009.
7. FDA Alert: Information for Healthcare Professionals:  
[http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF\\_blockersHCP.htm](http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm)

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- Accessed on January 26, 2009.
8. FDA MedWatch Report:  
[http://www.fda.gov/cder/drug/early\\_comm/TNF\\_blockers.htm](http://www.fda.gov/cder/drug/early_comm/TNF_blockers.htm)
  9. FDA Alert: Information for Healthcare Professionals:  
[http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF\\_blockersHCP.htm](http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm)
  10. Menter A, et al. American Academy of Dermatology, Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. 2008.02.039; and Section 4. 2009.03.027
  11. Simponi [package insert]. Horsham, PA; Centocor Ortho Biotech Inc.; June 2017.
  12. Stelara [package insert]. Horsham, PA; Centocor Ortho Biotech Inc.; September 2016.
  13. Actemra [package insert]. Genentech Inc. San Francisco, CA. August 2017.
  14. Beukelman et.al. 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: *Arthritis Care & Research*; 63 (4), 465–482
  15. Saag KG et.al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis and Rheumatology*. 2008;59(6):762.
  16. UpToDate, Tumor necrosis factor-alpha inhibitors: Risk of bacterial, viral, and fungal infections; accessed October 17, 2012.
  17. Lok A, Bonis P. Hepatitis B virus reactivation associated with immunosuppression, UpToDate. Accessed March 7, 2013.
  18. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2015.
  19. Orenzia package insert. Bristol-Myers Squibb, Princeton, NJ: December 2011.
  20. Xeljanz [package insert]. New York, NY: Pfizer Inc.; December 2015.
  21. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2014.
  22. Otezla [package insert]. Summit, NJ: Celgene Corporation; June 2017.
  23. Menter A, et al. American Academy of Dermatology, Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. *Journal of the American Academy of Dermatology* 2011; 65:137-74.
  24. Brown, T. FDA Oks Vedolizumab (Entyvio) for Ulcerative Colitis, Crohn's. *Medscape News*, May 20, 2014.
  25. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2016;68(1):1-25. doi: 10.1002/acr.22783.
  26. Ward MW, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2016;68(2):292-98. doi: 10.1002/art.39298.

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

27. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis.* 2011;70:896-904. doi: 10.1136/ard.2011.151027.
28. Yu DT. Assessment and treatment of ankylosing spondylitis in adults. In: UpToDate. Sieper J (Ed). Waltham, MA: Wolters Kluwer. Updated April 21, 2016. Accessed August 19, 2016.
29. Zochling J, van der Heijde D, Burgos-Vargas R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis.* 2006;65:442-452. doi: 10.1136/ard.2005.041137.
30. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Care Res (Hoboken).* 2013;65(10):1551-63. doi: 10.1002/acr.22087.
31. Kimura Y. Systemic juvenile idiopathic arthritis: treatment. In: UpToDate, Klein-Gitelman M (Ed). Waltham, MA: Wolters Kluwer. Updated September 28, 2015. Accessed June 21, 2016.
32. Weiss PF. Polyarticular juvenile idiopathic arthritis: treatment. In: UpToDate, Klein-Gitelman M (Ed). Waltham, MA: Wolters Kluwer. Updated December 9, 2015. Accessed June 21, 2016.
33. Stoll ML, Cron RQ. Treatment of juvenile idiopathic arthritis: a revolution in care. *Pediatr Rheumatol Online J.* 2014;12:13. doi: 10.1186/1546-0096-12-13.
34. Kimura Y, Beukelman T, Morgan-DeWitt E, et al. Results from the Childhood Arthritis and Rheumatology Research Alliance systemic JIA consensus treatment plans pilot study [abstract]. *Arthritis Rheumatol.* 2015; 67 (suppl 10). <http://acrabstracts.org/abstract/results-from-the-childhood-arthritis-and-rheumatology-research-alliance-systemic-jia-consensus-treatment-plans-pilot-study/>. Accessed June 22, 2016.
35. Vastert SJ, de Jager W, Noordman BJ, et al. Effectiveness of first-line treatment with recombinant interleukin-1 receptor antagonist in steroid-naïve patients with new-onset systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2014;66(4): 1034-43. doi: 10.1002/art.38296.
36. Feldman SR. Treatment of psoriasis. In: UpToDate, Dellavalle RP, Duffin KC (Eds). Waltham, MA: Wolters Kluwer. Updated July 11, 2016. Accessed July 27, 2016.
37. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: UpToDate, Sieper J (Ed). Waltham, MA: Wolters Kluwer. Updated June 14, 2016. Accessed July 25, 2016.
38. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 treatment recommendations for psoriatic arthritis. *Arthritis Rheumatol.* 2016;68(5):1060-71. doi: 10.1002/art.39573.

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

39. Coates LC, Tillett W, Chandler D, et al. The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics. *Rheumatology (Oxford)*. 2013;52(10):1754-7. doi: 10.1093/rheumatology/ket187.
40. Cohen RD, Stein AC. Approach to adults with steroid-refractory and steroid-dependent ulcerative colitis. In: UpToDate; Rutgeerts P (Ed). Waltham, MA: Wolters Kluwer. Updated June 15, 2016. Accessed July 26, 2016.
41. Peppercorn MA, Farrell RJ. Management of severe ulcerative colitis in adults. In: UpToDate; Rutgeerts P (Ed). Waltham, MA: Wolters Kluwer. Updated August 13, 2014. Accessed July 25, 2016.
42. Farrell RJ, Peppercorn MA. Overview of the medical management of severe or refractory Crohn disease in adults. In: UpToDate; Rutgeerts P (Ed). Waltham, MA: Wolters Kluwer. Updated January 14, 2016. Accessed July 25, 2016.
43. Humira [package insert]. North Chicago, IL: AbbVie Inc.; May 2017.
44. Rosenbaum JT. Uveitis: treatment. In: UpToDate; Trobe J (Ed). Waltham, MA: Wolters Kluwer. Updated July 6, 2016. Accessed July 27, 2016.
45. Levy-Clarke G, Jabs DA, Read RW, Rosenbaum JT, Vitale AB, Van Gelder RN. Expert panel recommendations for the use of anti-tumor necrosis factor biologic agents in patients with ocular inflammatory disorders. *Ophthalmology*. 2014;121(3):785-96.e3. doi: 10.1016/j.ophtha.2013.09.048.
46. Ramanan AV, Dick AD, McKay A, et al. A randomised controlled trial of the clinical effectiveness, safety and cost-effectiveness of adalimumab in combination with methotrexate for the treatment of juvenile idiopathic arthritis associated uveitis [abstract]. *Arthritis Rheumatol*. 2015;67(10). <http://acrabstracts.org/abstract/a-randomised-controlled-trial-of-the-clinical-effectiveness-safety-and-cost-effectiveness-of-adalimumab-in-combination-with-methotrexate-for-the-treatment-of-juvenile-idiopathic-arthritis-associated/>. Accessed August 2, 2016.
47. Jabs DA, Rosenbaum JT, Foster CS, et al. Guidelines for the use of immunosuppressive drugs in patients with ocular inflammatory disorders: recommendations of an expert panel. *Am J Ophthalmol*. 2000;130(4):492-513.
48. Vallet H, Seve P, Biard L, et al. Infliximab versus adalimumab in the treatment of refractory inflammatory uveitis: multicenter study from the French Uveitis Network [accepted article February 25, 2016]. *Arthritis Rheumatol*. doi: 10.1002/art.39667.
49. Sanchez-Cano D, Callejas-Rubio JL, Ruiz-Villaverde R, Rios-Fernandez R, Ortego-Centeno N. Off-label uses of anti-TNF therapy in three frequent disorders: Behçet's disease, sarcoidosis, and noninfectious uveitis. *Mediators Inflamm*. 2013;2013:286857. doi: 10.1155/2013/286857.
50. Bansal R, Gupta V, Gupta A. Current approach in the diagnosis and management of panuveitis. *Indian J Ophthalmol*. 2010;58(1):45-54. doi: 10.4103/0301-4738.58471.
51. Arcalyst [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2016.

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

52. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2016.
53. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; 2016.
54. Siliq [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC: February 2017.
55. Kevzara [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC: May 2017.
56. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.: March 2017.
57. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2017.
58. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2017.
59. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med*. 2016;375:2335-48.
60. Weston W, Howe W. Treatment of atopic dermatitis (eczema). In: UpToDate [internet database]. Dellavalle RP, Levy ML, Fowler J, eds. Waltham, MA: UpToDate. Updated July 24, 2017. Accessed August 16, 2017.
61. Spergel JM. Management of severe refractory atopic dermatitis (eczema). In: UpToDate [internet database]. Dellavalle RP, Levy ML, Fowler J, eds. Waltham, MA: UpToDate. Updated February 2, 2015. Accessed August 17, 2017.
62. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71(1):116-32.
63. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014;71(2):327-49.
64. Actemra [package insert]. San Francisco, CA: Genentech, Inc.: May 2017.
65. Hunder GG. Treatment of giant cell (temporal) arteritis. In: UpToDate [internet database]. Trobe J, Matteson EL, eds. Waltham, MA: UpToDate. Updated September 14, 2016. Accessed August 16, 2017.
66. Weyand CM, Fulbright JW, Hunder GG, Evans JM, Goronzy JJ. Treatment of giant cell arteritis: interleukin-6 as a biologic marker of disease activity. *Arthritis Rheum*. 2000;43(5):1041-48.
67. Stone JH, Tuckwell K, Dimonaco S, et al. Trial of tocilizumab in giant-cell arteritis. *N Engl J Med*. 2017;377(4):317-28.
68. Dasgupta B, Borg FA, Hassan N, et al. BSR and BHPR guidelines for the management of giant cell arteritis. *Rheumatology*. 2017;49:1594-97.
69. Roberts J, Clifford A. Update on the management of giant cell arteritis. *Ther Adv Chronic Dis*. 2017;8(4-5):69-79.
70. Bienvenu B, Ly KH, Lambert M, et al. Management of giant cell arteritis: recommendations of the French Study Group for Large Vessel Vasculitis (GEFA). *Rev Med Interne*. 2016;37(3):154-65.
71. Mahr AD, Jover JA, Spiera RF, et al. Adjunctive methotrexate for treatment of giant cell arteritis. *Arthritis Rheum*. 2007;56(8):2789-97.



MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

72. Lok ASF, Bonis PAL. Hepatitis B virus reactivation associated with immunosuppressive therapy. In: UpToDate. Esteban R, ed. Waltham, MA: UpToDate. Updated January 31, 2017. Accessed August 28, 2017.
73. Rajender Reddy K, Beavers KL, Hammond SP, Kim JK, Falk-Ytter YT. American Gastroenterological Association Institute guideline on the prevention and treatment of hepatitis B virus reactivation during immunosuppressive drug therapy. *Gastroenterology*. 2015;148:215-19.
74. Felis-Giemza A, Olesinska M, Swierkocka K, Wiesik-Szewczyk E, Haladyj E. Treatment of rheumatic diseases and hepatitis B virus coinfection. *Rheumatol Int*. 2015;35:385-92.