Humira® (adalimumab)  
Amjevita (adalimumab-atto) biosimilar

Policy Number: 5.01.504  Last Review: 8/2017  

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Humira® (adalimumab) and biosimilars when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Humira® requires prior authorization through the pharmacy services area. Humira® (adalimumab) is considered medically necessary in the treatment of the following conditions:

Rheumatoid Arthritis

- For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs).
- Humira® (adalimumab) will be considered for coverage at a dosage of 40 mg injected subcutaneously every other week as specified in the product information provided by the manufacturer.

Juvenile Idiopathic Arthritis

- For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 4 and older. Humira can be used alone or in combination with methotrexate.

Psoriatic Arthritis

- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage of, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with DMARDs.
- Humira® (adalimumab) will be considered for coverage at a dosage of 40 mg injected subcutaneously every other week as specified in the product information provided by the manufacturer.

Ankylosing Spondylitis

- Reducing signs and symptoms in patients with active ankylosing spondylitis.
- Humira® will be considered for coverage at a dosage of 40 mg injected subcutaneously every other week as specified in the product information provided by the manufacturer.

Crohn Disease

- For reducing signs and symptoms and inducing and maintaining clinical remission in adult Ipatients with moderately to severely active Crohn’s disease who have had an inadequate response to
conventional therapy. Humira is initiated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response or are intolerant to infliximab.

- Humira® will be considered for coverage at a dosage of 160mg initially at week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), 80mg at week 2, followed by a maintenance dose of 40mg every other week beginning at week 4.

**Plaque Psoriasis**

- For the treatment of adult patients with chronic moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

- Humira® will be considered for coverage at a dosage of 80mg initially at week 0 followed by 40mg every other week starting one week after the initial dose.

**Ulcerative Colitis**

- For inducing and sustaining clinical remission in adults with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine.

- Humira® will be considered for coverage at a dosage of 160mg initially at week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), 80mg at week 2, followed by a maintenance dose of 40mg every other week beginning at week 4.

**Hidradenitis Suppurativa** Approve if the patient meets the following criteria (a and b):

a) The patient has tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin); AND

b) Humira is prescribed by or in consultation with a dermatologist.

**Other Uses with Supportive Evidence**

**Behcet’s Disease.** Approve if the patient meets the following criteria (a and b):

a) The patient meets ONE of the following conditions (i or ii):

i. The patient has tried at least ONE conventional therapy (e.g., systemic corticosteroids, immunosuppressants [azathioprine, MTX, mycophenolate mofetil, tacrolimus, Leukeran® (chlorambucil), cyclophosphamide, or cyclosporine], interferon alfa) or Enbrel or Remicade; OR

ii. The patient has ophthalmic manifestations of Behcet’s disease; AND

b) Humira is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

Recommendations for the use of TNF blockers in ocular inflammatory disorders from the American Academy of Ophthalmology (AAO) [2014] note that Humira may be used as first-line corticosteroid-sparing therapy in patients with ophthalmic manifestations of Behcet’s disease. In three cases, Humira was effective in controlling uveitis in adults with Behcet’s disease who were in remission after receiving Remicade. In another case series, six adults with Behcet’s disease (uveitis [two patients], central nervous system disease [two patients], colitis [one patient], and severe oral ulcers and arthritis [one patient]) in whom immunosuppressive therapy had failed, Humira was effective. These patients had received prior therapy with Remicade which had been discontinued after complete response or acceptable improvement. In a retrospective analysis (n = 11), Humira improved visual acuity and showed a corticosteroid and immunosuppressive sparing effect in ocular Behcet’s disease. Another review found 19 patients treated with Humira for Behcet’s disease, all of whom had refractory disease or experienced AEs to cyclosporine and Remicade. Overall, 17 out of 19 patients improved with Humira. In case reports, it has also been effective for neuro-Behcet’s and for treatment of leg ulcers in Behcet’s disease. EULAR recommendations for the management of Behcet disease include either Remicade or cyclosporine in combination with azathioprine and corticosteroids for refractory eye
involvement. For gastrointestinal or parenchymal involvement, TNF antagonists have been used in resistant and complicated cases.

**Pyoderma Gangrenosum.** Approve if the patient meets the following criteria (a and b):

1. **The patient meets ONE of the following conditions (i or ii):**
   - i. Patient has tried one systemic corticosteroid; OR
   - ii. Patient has tried one other immunosuppressant (e.g., mycophenolate mofetil, cyclosporine) for at least 2 months or was intolerant to one of these agents; AND

2. **Humira is prescribed by or in consultation with a dermatologist.**

Multiple topical and systemic therapies have been used to treat pyoderma gangrenosum. Oral prednisone is the most common initial immunosuppressant medication. Topical therapies (e.g., corticosteroids, immunomodulators) may be applied to the lesion. Other systemic therapies used for treatment of pyoderma gangrenosum include cyclosporine, MTX, azathioprine, cyclophosphamide, mycophenolate mofetil, Remicade, Enbrel, and Humira. In case reports, Humira and other TNF antagonists have been effective in treating pyoderma gangrenosum. In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for previous therapy.

**Sarcoidosis.** Approve if the patient meets the following criteria (a, b, and c):

1. **Patient has tried at least ONE corticosteroid for this condition; AND**

2. **Patient has tried at least one immunosuppressive agent (e.g., MTX, azathioprine, cyclosporine, Leukeran, leflunomide, cyclophosphamide, mycophenolate mofetil), Remicade, chloroquine, or thalidomide; AND**

3. **Humira is prescribed by or in consultation with a pulmonologist, ophthalmologist, or dermatologist.**

Well-controlled studies are not available for any therapies. Steroids are the standard therapy, though long-term use is limited by AEs. Immunosuppressants have shown modest efficacy with the best results available for MTX. High levels of TNF in bronchoalveolar lavage of patients with sarcoidosis have been reported with a decrease in TNF levels following treatment. Recommendations for best practice in the management of pulmonary and systemic sarcoidosis recommend glucocorticoids as first-line therapy. Patients who cannot be weaned to a prednisone-equivalent dose of < 10 mg/day are appropriate candidates for steroid-sparing treatment with cytotoxic agents (e.g., MTX, azathioprine, leflunomide). If these agents fail or cause toxicity, Humira, Remicade, cyclophosphamide, or mycophenolate mofetil are proposed. In a double-blind, placebo-controlled study, Humira was effective in improving clinical lesions and DLQI score in patients with cutaneous sarcoidosis (n = 16). In a prospective study in patients with refractory posterior uveitis (n = 26), intraocular inflammation improved and other indicators of disease activity, including pulmonary lung tests and laboratory tests, improved with Humira. Humira has also been effective in case reports of patients who were refractory to standard therapy. Recommendations for the use of TNF blockers in ocular inflammatory disorders from the AAO (2014) note that Remicade or Humira may be considered as second-line immunomodulatory therapy for patients failing or intolerant of standard immunomodulatory agents (e.g., prednisone and MTX). In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for previous therapy.

**Scleritis or Sterile Corneal Ulceration.** Approve if the patient meets the following criteria (a and b):

1. **The patient has tried ONE other therapy for this condition (e.g., oral, topical [ophthalmic] or IV corticosteroids, MTX, oral NSAIDs, cyclosporine, or other immunosuppressants); AND**

2. **Humira is prescribed by or in consultation with an ophthalmologist.**

Recommendations for the use of TNF blockers in ocular inflammatory disorders from the AAO (2014) mention Humira as an agent that should be considered as a second-line immunomodulatory agent for severe ocular inflammatory conditions including chronic and severe scleritis.
**Undifferentiated Spondyloarthritis (undifferentiated arthritis).** Approve if Humira is prescribed by or in consultation with a rheumatologist.

Patients may present with signs and/or symptoms of inflammatory arthritis but do not meet diagnostic criteria for any specific type of arthritis. If a clinical work-up does not reveal another diagnosis and clinical presentation does not indicate a specific diagnosis, the patient is often diagnosed with a form of undifferentiated arthritis. Over time, a patient with undifferentiated arthritis may progress to meet the diagnostic criteria for another type of inflammatory arthritis. In a randomized, double-blind trial in patients \((n = 185)\) with nonradiographic axial spondyloarthritis (nr-axSpA), treatment response (ASAS 40) was 36% in patients treated with Humira compared with 15% in patients treated with placebo. However, ASAS 40 response rates were higher in patients with short disease durations, elevated CRP, and active inflammation on magnetic resonance imaging (MRI) of the sacroiliac joints. In a double-blind study in patients \((n = 40)\) with peripheral arthritis who did not meet the criteria for AS or PsA, patient global assessment, physician's global assessment, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Ankylosing Spondylitis Disease Activity Score (ASDAS), and erythrocyte sedimentation rate (ESR) were significantly improved at Week 12 in the Humira treatment group compared with placebo \((P < 0.05\) for all comparisons vs. placebo). In a double-blind study conducted at two centers in Germany, 46 patients with active axial spondyloarthritis without radiographically defined sacroiliitis were randomized to placebo or Humira 40 mg EOW for 12 weeks followed by an open-label extension up to Week 52. All patients in the open-label extension received Humira EOW. Patients were refractory to treatment with NSAIDs and had a baseline BASDAI \(\geq 4\). The Humira dosage was increased to every week in ten patients who did not attain ASAS 40 response after 12 weeks of therapy. At Week 12 an ASAS 40 response (primary endpoint) was attained by 54.5% of the patients on Humira compared with 12.5% with placebo \((P = 0.004\) vs. placebo). Efficacy was maintained at Week 52. In the entire study group of 46 patients, 50% of patients attained an ASAS 40 response at Week 52. Of note, trials with ankylosing spondylitis include patients who have radiographic changes in the sacroiliac joints which are the consequences of previous inflammation and may take years to become evident.

**Uveitis (including other posterior uveitides and panuveitis syndromes).** Approve for 1 year if the patient meets the following criteria (a and b):

- **a)** The patient has tried ONE of the following therapies: periocular, intraocular, or systemic corticosteroids; immunosuppressives (e.g., MTX, mycophenolate mofetil, azathioprine, cyclophosphamide, or cyclosporine); AND
- **b)** Humira is prescribed by or in consultation with an ophthalmologist.

Recommendations for the use of TNF blockers in ocular inflammatory disorders from the AAO (2014) note that Humira may be used in patients with uveitis due to various causes (e.g., spondyloarthropathy-associated or human leukocyte antigen [HLA]-B27-associated uveitis, JIA-associated uveitis, and other posterior uveitides and panuveitis syndromes). Humira should be considered second-line in vision-threatening JIA-associated uveitis when MTX has failed or is not tolerated (strong recommendation) and may be used as corticosteroid-sparing treatment for vision-threatening chronic uveitis from seronegative spondyloarthropathy (strong recommendation). Humira may also be considered in other patients who have vision-threatening or corticosteroid-dependent disease who have failed first-line therapies. The recommendations point out that a prospective study evaluated the efficacy of Humira in patients \((n = 31)\) with a variety of uveitic conditions, including patients with idiopathic panuveitis and patients with birdshot chorioretinitis (BSCR), a bilateral posterior uveitis generally treated with systemic immunomodulation. Results showed a 68% response rate to Humira at Week 10 suggesting efficacy. In patients with uveitis, TNF levels are increased in the serum an aqueous humor. An open-label, uncontrolled study \((n = 1,250)\) showed that treatment with Humira reduced the rate of anterior uveitis flares by 51% in adult patients with anterior uveitis and ankylosing spondylitis \((P < 0.001)\). Other open-label studies and case series have demonstrated efficacy of Humira for treatment in a variety of patients with refractory uveitis. Humira has been effective in a small number of children with chronic uveitis (either with rheumatic disease [JIA] or idiopathic) refractory to other therapies. Humira was also
effective in the management of refractory uveitis in adults and has allowed the dose of concomitant immunosuppressives to be reduced.79

**Patient has been Established on Humira for ≥ 90 days.**
For conditions that do not have criteria for Patients Currently Receiving Humira but are indications or conditions addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications and Other Uses with Supportive Evidence), approve Humira for 1 year, if the patient is currently taking Humira for ≥ 90 days. (In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion.)

**When Policy Topic is not covered**
Humira® (adalimumab) is considered investigational when used for all other conditions, including, but not limited to:

**Concurrent Use with a Biologic DMARD or Targeted Synthetic DMARD.** Humira should not be administered in combination with another biologic agent for an inflammatory condition (e.g., TNF antagonists [Cimzia, Enbrel, Remicade, Simponi SC, or Simponi Aria], Actemra, Kineret, Orencia, or RituXan® [rituximab for IV infusion], or Stelara). Combination therapy with two biologic agents is not recommended due to a higher rate of AEs with combinations and/or lack of additive efficacy. Xeljanz should not be used in combination with biologic DMARDs such as Humira. Targeted synthetic DMARDs (e.g., Xeljanz, Otezla) do not have data supporting use in combination with biologic DMARDs. Due to similar safety concerns (i.e., increased risk of AEs) plus no evidence of additive efficacy, targeted synthetic DMARDs should not be used in combination with biologic DMARDs such as Humira. Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Humira.

**Osteoarthritis.** In an open-label trial in 12 patients with moderate to severe erosive/inflammatory osteoarthritis of the hands despite therapy with NSAIDs, 12 weeks of therapy with Humira 40 mg EOW did not significantly improve signs and symptoms (number of tender joints, grip strength, disability, pain, or global disease assessment). Another study randomized patients with radiographic erosive OA of the interphalangeal joints (n = 60) to treatment with Humira 40 mg or placebo EOW for 52 weeks. OA progressed to erosive disease more often in joints with soft-tissue swelling at baseline (14.5% of joints with baseline inflammation treated with placebo [9/62 joints] vs. 3.7% treated with Humira [3/81 joints]; P = 0.009). At Week 52, active disease was similar in both groups, and there was not a statistically significant difference in clinical outcomes, including pain, stiffness, function, number of tender joints or joints with palpable effusion, or maximal grip strength. Larger, long-term, placebo-controlled trials that have a specific efficacy outcome for hand or generalized osteoarthritis are needed.

**Polymyalgia Rheumatica (PMR).** EULAR/ACR guidelines for the management of PMR (2015) strongly recommend against the use of TNF blockers for treatment of PMR. This recommendation is based on lack of evidence for benefit as well as considerable potential for potential harm.

**Considerations**
Although Humira® (adalimumab) has been assigned a HCPCS infusion code, benefits will pay through pharmacy.
This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

**Boxed Warnings**
Humira has boxed warnings concerning risks of serious infection and the risk of malignancy.1 Prior to initiating therapy with Humira, patients should be evaluated for active tuberculosis (TB) infection; periodically during therapy, patients should be assessed for latent TB infection. Patients should also be monitored for signs and symptoms of infection during and after treatment with Humira, and if a serious infection or sepsis develops, Humira should be discontinued. It is also recommended that patients treated with any TNF antagonist should be monitored for malignancies.

**Description of Procedure or Service**
Humira is a recombinant human immunoglobulin G1 (IgG1) monoclonal antibody specific for human tumor necrosis factor alpha (TNFα).1 It neutralizes the biological activity of TNFα and inhibits binding of TNFα with its receptors. TNF, a naturally occurring cytokine, mediates inflammation and modulates cellular immune responses. Increased levels of TNF are found in the synovial fluid of patients with rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS). TNF has an important role in both the pathologic inflammation and the joint destruction that are characteristic of these diseases. Increased levels of TNF are found in psoriasis plaques but the mechanism of action in plaque psoriasis and Crohn’s disease are not known.

**Rationale**
Humira is indicated for the following uses:1

1. To reduce the signs and symptoms, induce major clinical response, inhibit the progression of structural damage, and improve physical function in adult patients with moderately to severely active RA.1-6 Humira can be used alone or in combination with methotrexate (MTX) or other conventional synthetic disease-modifying antirheumatic drugs (DMARDs); AND

2. for reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.1,7 Humira can be used alone or in combination with MTX; AND

3. for reducing the signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with PsA.1,8 Humira can be used alone or in combination with conventional synthetic DMARDs; AND

4. for reducing signs and symptoms in patients with active AS1,9; AND

5. for the treatment of adults with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate1,10-11; AND

6. for reducing signs and symptoms and inducing and maintaining clinical remission in adults with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy1,12-13, including for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to Remicade® (infliximab) injection1,14; AND

7. for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn’s disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-MP, or MTX; AND

8. for inducing and sustaining clinical remission of moderately to severely active ulcerative colitis (UC) in adults who do not respond to corticosteroids or other immunosuppressive drugs such as azathioprine or 6-mercaptopurine.1,15-16 However, efficacy has not been established in patients with UC who have lost response or were intolerant to another TNF inhibitor.1

**Rheumatoid Arthritis (RA) in an Adult**
Humira is indicated for moderate or severe active RA in adults and can be used alone or in combination with MTX or other DMARDs.1 Most patients will have received initial therapy with MTX, another oral
DMARD(s) (e.g., hydroxychloroquine, leflunomide, sulfasalazine, MTX), or combination DMARD therapy (including double or triple therapy). However, current recommendations from the American College of Rheumatology (ACR) [2012] note that patients with early RA (defined as disease duration < 6 months) with important markers of poor prognosis may be started early on a biologic agent such as Humira, either alone or in combination with MTX. The guidelines generally recommend assessment at Month 3 with a general recommendation to switch biologic in patients with a loss or lack of benefit at this assessment. The criteria for patients with contraindications or intolerance to DMARDs are recommended based on the professional opinion of specialized physicians.

Ankylosing Spondylitis (AS)
Humira is indicated for ankylosing spondylitis. According to the Assessment of SpondyloArthritis International Society/European League Against Rheumatism (ASAS/EULAR) 2010 recommendations for AS, all patients should have an adequate trial of at least two nonsteroidal anti-inflammatory drugs (NSAIDs) for pain and stiffness, unless contraindicated. Recommendations for other therapies before receiving Humira (or other TNF blocker therapy) vary according to the manifestations of the disease, level of current symptoms, clinical findings, etc. According to these recommendations, patients with pure axial manifestations do not have to try conventional synthetic DMARDs before anti-TNF agents such as Humira; patients with symptomatic peripheral arthritis should have an insufficient response to at least one local corticosteroid injection, if appropriate; patients with persistent peripheral arthritis should normally have a trial of a DMARD, preferably sulfasalazine; and patients with enthesitis should try appropriate local therapy (e.g., corticosteroid injection in selected cases). In the AS guidelines, it is recommended to assess a patient's response to a TNF blocker after at least 12 weeks of therapy.

Crohn’s Disease in a Patient ≥ 6 Years of Age
Humira is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adults with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy. Humira is also indicated for reducing signs and symptoms and inducing clinical remission in patients if they have also lost response to or are intolerant to Remicade. In pediatric patients with Crohn’s disease, Humira is indicated for reducing signs and symptoms and inducing and maintaining clinical remission patients 6 years of age and older with moderately to severely active disease who have had an adequate response to corticosteroids or immunomodulators such as azathioprine, 6-MP, or MTX. There are also published data supporting the use of Humira for prevention of post-operative recurrence of Crohn’s disease. The American Gastroenterological Association (AGA) has guidelines for Crohn’s disease (2013). For induction therapy, TNF blockers are listed as a strong recommendation for patients with moderately severe Crohn’s disease (moderate-quality evidence). TNF blocker ± thiopurine is also mentioned as an appropriate regimen for maintenance of remission.

Juvenile Idiopathic Arthritis (JIA) [or juvenile rheumatoid arthritis {JRA}] (regardless of type of onset)
Humira is indicated for reducing signs and symptoms of moderately to severely active polyarticular JIA in patients ages 2 and older. The 2011 ACR recommendations for the treatment of JIA propose initial DMARD treatment with MTX in most patients; however, sulfasalazine is recommended for patients with enthesitis-related arthritis and may also be used in certain patients with sacroiliac arthritis. Leflunomide may be an appropriate initial DMARD in certain patients with high disease activity and/or a poor prognosis. Kineret may be used in systemic arthritis and Actemra may be used in systemic and polyarticular juvenile arthritis arthrits. TNF antagonists such as Humira may also be used as second- or third-line treatment for systemic JIA. The criteria for patients starting on Humira concurrently with a conventional synthetic DMARD or for patients with an absolute contraindication MTX, sulfasalazine, or leflunomide are recommended based on the professional opinion of specialized physicians.
Plaque Psoriasis
Humira is indicated for plaque psoriasis.\textsuperscript{1} Guidelines for treatment of plaque psoriasis recommend topical therapy for limited disease.\textsuperscript{32} However, for patients with chronic plaque psoriasis that does not respond to topical therapies or patients with more extensive disease, systemic therapy may be used. The traditional systemic agents for plaque psoriasis are MTX, Soriatane, and cyclosporine. An injectable biologic agent such as Humira is an option for patients who are candidates for phototherapy or systemic therapy, especially those who are intolerant of or unresponsive to traditional systemic agents. In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for previous therapy.

Psoriatic Arthritis (PsA)
Humira is indicated for PsA and can be used alone or in combination with DMARDs.\textsuperscript{1} In clinical trials, Humira was effective in patients with active PsA despite therapy with an NSAID. There are few well-controlled, prospective studies with adequate duration that have evaluated the efficacy of the oral DMARDs.\textsuperscript{33} According to the EULAR recommendations for treatment of PsA (2012), NSAIDs are recommended as first-line treatment.\textsuperscript{34} Recommendations for other therapies before receiving a TNF blocker vary according to the manifestations of the disease, prognostic factors, and efficacy/toxicity of previous therapies. The TNF inhibitors indicated in PsA are equally effective for treatment of PsA, inhibition of radiographic progression, and improving physical function in patients with PsA. The conventional synthetic DMARDs have not been shown to prevent the progression of radiographic (structural) damage or to have significant impact on axial disease, dactylitis, or enthesitis in PsA.\textsuperscript{34-35} This is in contrast with the newer biological DMARDs which have shown efficacy in well-controlled trials in reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with PsA.\textsuperscript{1,34}

Ulcerative Colitis in Adult
Humira is indicated for inducing and sustaining clinical remission of moderately to severely active ulcerative colitis in adults who do not respond to corticosteroids or other immunosuppressive drugs such as azathioprine or 6-mercaptopurine.\textsuperscript{1} Clinical guidelines for the management of pouchitis, published in 2009, and ulcerative colitis practice guidelines from the American College of Gastroenterology (ACG) [2010] indicate that first-line therapy for pouchitis is antibiotic therapy (e.g. metronidazole, ciprofloxacin).\textsuperscript{36-37} Other treatment options include maintenance probiotics, oral or topical budesonide, anti-inflammatory drugs (e.g., mesalamine), or immunosuppressive drugs (e.g., Remicade). A retrospective, open-label, case series demonstrated some efficacy of Humira in patients with pouchitis previously treated with Remicade.\textsuperscript{38} In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for pouchitis.

References
5. Furst DE, Schiff MH, Fleischmann RM, et al. Adalimumab, a fully human anti tumor necrosis factor-alpha monoclonal antibody, and concomitant standard antirheumatic therapy for the


Other References Utilized


Billing Coding/Physician Documentation Information

Humira® (adalimumab) is a pharmacy benefit.

Additional Policy Key Words

5.01.504

Policy Implementation/Update Information

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