Commercial/Healthcare Exchange PA Criteria

Effective: September 2006

Prior Authorization: Humira

Products Affected: Humira (adalimumab) Subcutaneous Solution

Medication Description: Adalimumab binds specifically to tumor necrosis factor (TNF)-alpha and blocks its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab lyses surface TNF expressing cells in vitro in the presence of complement. Adalimumab does not bind or inactivate lymphotoxin (TNF-beta). Adalimumab also modulates biological responses that are induced or regulated by TNF, including changes in the levels of adhesion molecules responsible for leukocyte migration. Adalimumab decreases C-reactive protein, erythrocyte sedimentation rate, and matrix metalloproteinases MMP-1 and MMP-3

Covered Uses:

1. Treatment of moderate to severe Rheumatoid arthritis
2. Treatment of psoriatic arthritis
3. Treatment of ankylosing spondylitis
4. Treatment of moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy and if they have also lost response to or are intolerant to infliximab.
5. Treatment of moderate to severe plaque psoriasis
6. Treatment of polyarticular idiopathic juvenile (JIA) arthritis
7. Treatment of moderate to severe ulcerative colitis in adults who have had an inadequate response to other immunosuppressants, such as corticosteroids, azathioprine, and 6-mercaptopurine.
8. Treatment of moderate to severe hidradenitis suppurativa
9. Treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

Exclusion Criteria:

1. Concurrent use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD)

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

1. Polyarticular juvenile idiopathic arthritis, panuveitis: 2 years of age and older
2. Crohn's disease: 6 years of age and older
3. Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, ulcerative colitis, Hidradenitis suppura: 18 years of age or older

Prescriber Restrictions: Medication is prescribed by a specialist: rheumatologist, gastroenterologist, or dermatologist

Coverage Duration:

Initial: 3 months

Continuation: 3 years

Other Criteria:
Initiation:
****Note: Clinical criteria incorporated into the Humira quantity limit edit, approve additional quantity (to allow for 40 mg every week) if the patient has a diagnosis of Hidradenitis Suppurativa OR a diagnosis of Rheumatoid Arthritis in patients not receiving concomitant methotrexate.***

Dosing Limitations:
Subcutaneous Adult Dosage Regimen (Rheumatoid Arthritis)
1. ***The recommended dose is 40mg every other week.***

Subcutaneous Adult Dosage Regimen (Psoriatic arthritis)
1. ***The recommended dose is 40 mg every other week.***

Subcutaneous Adult Dosage Regimen (Ankylosing spondylitis)
1. ***The recommended dose is 40mg every other week.***

Subcutaneous Adult Dosage Regimen (Plaque Psoriasis)
1. ***The recommended dose is initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.***

Subcutaneous Adult Dosage Regimen (Ulcerative colitis and Crohn's disease)
1. ***The recommended dose is 160 mg initially on Day 1 (given in one day or split over two consecutive days), followed by 80 mg two weeks later, then 40mg every other week beginning on day 29***

Subcutaneous Pediatric Dosage Regimen (Crohn's disease)
1. ***The recommended dose in patients weighing 17kg to less than 40kg is 80mg on day 1, then 40mg on day 15, then 20mg every other week starting on day 29.***
2. ***The recommended dose in patients weighing 40kg or greater is 160mg on day 1, then 80mg on day 15, then 40mg every other week starting on day 29.***

Subcutaneous Adult Dosage Regimen (Hidradenitis suppurativa)
1. ***The recommended dose is an initial dose of 160 mg (given in one day or split over two consecutive days), followed by 80 mg two weeks later, then 40mg every week beginning on day 29.***

Subcutaneous Adolescent Dosage Regimen (Hidradenitis suppurativa)
1. ***The recommended dose for patients weighing 30kg to less than 60kg is 80mg on day 1, then 40mg on day 8, then 40mg every other week thereafter.***
2. ***The recommended dose for adolescent patients weighing 60kg or greater is 160 mg initially on Day 1 (given in one day or split over two consecutive days), then 80mg on day 15, then 40mg every week beginning on day 29***

Subcutaneous Adult Dosage Regimen (Panuveitis)
1. ***The recommended dose is initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.***

<u>Subcutaneous Pediatric Dosage Regimen</u> (Panuveitis)

1. ***The recommended dose in patients weighing 10kg to less than 15 kg is 10 mg every other week.***
2. ***The recommended dose in patients weighing 15kg to less than 30kg is 20 mg every other week.***
3. ***The recommended dose in patients weighing greater than or equal to 30kg is 40mg every other week***

<u>Subcutaneous Pediatric Dosage Regimen</u> (Polyarticular juvenile idiopathic arthritis)

1. ***The recommended dose in patients weighing 10kg to less than 15 kg is 10 mg every other week.***
2. ***The recommended dose in patients weighing 15kg to less than 30 kg is 20 mg every other week.***
3. ***The recommended dose in patients weighing greater than or equal to 30kg is 40mg every other week***

Rheumatoid Arthritis, Psoriatic Arthritis, or JIA:

- The patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
- Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine).

Ankylosing Spondylitis

- The patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 therapy

Crohn's Disease

- Patient is experiencing a severe exacerbation; **AND**
- Patient has had a previous trial with, contraindication to, or intolerance to at least ONE form of conventional therapy including: aminosalicylates (e.g. mesalamine and sulfasalazine), immunomodulators (i.e. azathioprine) or corticosteroids; OR
- Crohn's disease is steroid dependent and unable to be weaned or patient has Crohn's related fistulas

Plaque Psoriasis

- Humira is being prescribed by a dermatologist; AND
- Patient has chronic (greater than or equal to 1 year) plaque psoriasis; AND
- Patient has minimum body surface area involvement with plaque psoriasis of $\geq$ 10%; AND
- Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed.*

Ulcerative Colitis

- Humira is being prescribed by a gastroenterologist; AND
- Patient has clinically diagnosed ulcerative colitis; AND
- Patient has had an inadequate response to other immunosuppressants, such as corticosteroids, azathioprine, and 6-mercaptopurine.

Hidradenitis Suppurativa

- The patient has tried ONE other therapy (e.g., intralesional or oral corticosteroids [such as triamcinolone, prednisone], systemic antibiotics [for example, clindamycin, dicloxacillin, erythromycin], isotretinoin); AND
- Humira is prescribed by or in consultation with a dermatologist.

Panuveitis

- Patient is diagnosed with non-infectious intermediate, posterior and panuveitis, excluding diagnosis with isolated anterior uveitis; AND
- Individual has chronic, recurrent, treatment-refractory OR vision-threatening disease; AND
- Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]).

*ConnectiCare does not consider alcohol use to be a clinical reason to use Humira over methotrexate.

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Humira as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References:

1. Humira [package insert], Abbott Laboratories, North Chicago, IL 60064.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	09/2006
2	Update	Update	Coverage Duration: Continuation Update to 3 years	07/01/2019

3	Update	CCI adopted EH Template CCI P&T Review History:9/06, 6/07, 3/08, 6/08, 9/09,9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 8/16, 11/16, 11/17, 11/18 CCI Revision Record:6/07, 1/08, 2/08, 10/12, 10/13, 9/14, 10/15, 2/16, 8/16, 8/17, 1/19	All	7/3/2019
4	Update	Removed DMARD requirement from AS diagnosis	Other Criteria	7/22/2019
5	Update	Added Dosing Limitations according to FDA label Updated age restriction on Hidradenitis Suppurativa to 12 years of age to match FDA label	Other Criteria Age restrictions	5/5/2020
6	Update	Addition of *Note on quantity limit edits	Other Criteria	6/2/2020