Adalimumab (Humira®)	**Place of Service** **Self-Administration** – *May be covered under the pharmacy benefit* **Office Administration** **HCPCS: J0135** per 20 mg

Condition(s) listed in policy (*see criteria for details*)

- Crohn's disease
- Hidradenitis suppurativa
- Polyarticular juvenile idiopathic arthritis
- Plaque psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis
- Spondyloarthritis
- Ulcerative colitis
- Uveitis, noninfectious intermediate, posterior, and panuveitis

AHFS therapeutic class: Disease-Modifying Anti-rheumatic Agent

Mechanism of action: Adalimumab, a recombinant DNA-derived human immunoglobulin G1 (IgG1) monoclonal antibody specific for human tumor necrosis factor (TNF; TNF-α), is a biologic response modifier and is a disease-modifying anti-rheumatic drug (DMARD).

(1) Special Instructions and Pertinent Information

Humira is managed under the Outpatient Pharmacy Benefit. If the patient has a prescription drug benefit, please contact Blue Shield Pharmacy Services to obtain a prior authorization.

To submit a request to the medical benefit, please submit clinical information for prior authorization review via fax, including medical rationale why the patient cannot self-administer Humira in the home.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Humira® (adalimumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Crohn's disease

1. Disease is moderate to severe, **AND**
2. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors)

Covered Doses

Adults: subcutaneous injection

- Initial dose (Day 1): 160 mg (given in one day or split over two consecutive days)
- Second dose two weeks later (Day 15): 80 mg
- Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week
- Maintenance dose escalation request (to 40 mg weekly) will be covered if the following is met:
    1. Patient either flared or had a loss in response after at least one maintenance dose, and
    2. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors)

Pediatrics: subcutaneous injection

Weight	Day 1 and 15	Starting on Day 29
17 kg (37 lbs) to less than 40 kg (88 lbs)	Day 1: 80 mg Day 15: 40 mg	20 mg every other week
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 15: 80 mg	40 mg every other week

Coverage Period

6 months each authorization

ICD-10:

K50.00-K50.119, K50.80-K50.819, K50.90-K50.919

Hidradenitis suppurativa

1. Recommended by a Dermatologist, **AND**
2. Patient has a diagnosis of moderate to severe hidradenitis suppurativa as evidenced by Hurley stage II or III disease *(see section 5 table 2)*, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors)

Covered Doses

Adults: subcutanous injection

- Initial dose (Day 1): 160 mg (given in one day or split over two consecutive days)
- Second dose two weeks later (Day 15): 80 mg
- Third (Day 29) and subsequent doses: 40 mg every week or 80 mg every other week

Adolescents 12 years of age and older: subcutaneous injection

Weight	

30 kg (66 lbs) to less than 60 kg (132 lbs)	Day 1: 80 mg Day 8 and subsequent doses: 40 mg every other week
60 kg (132 lbs) and greater	Day 1: 160 mg (given in one day or split over two consecutive days) Day 15: 80 mg Day 29 and subsequent doses: 40 mg every week or 80 mg every other week

Coverage Period
1st authorization: 12 weeks
Reauthorization: 6 months each authorization following clinical response to therapy

ICD-10:
L73.2

Plaque psoriasis

1. Age ≥ 18 years of age, **AND**
2. Recommended by a dermatologist or rheumatologist, **AND**
3. Documentation of one of the following:
    a. Baseline PASI of 10 or more prior to starting targeted immunomodulator, OR
    b. Baseline BSA (body surface area) affected is 3% or more prior to starting targeted immunomodulator, OR
    c. Sensitive area is involved (i.e., groin, face, etc.) OR
    d. Disease is otherwise debilitating

AND

4. Inadequate response or intolerable side effect, or contraindication to one of the following:
    a. Methotrexate, cyclosporine (Neoral®), acitretin (Soriatane®), OR
    b. PUVA or UVB treatment

AND

5. Not being used with another targeted biologic

Covered Doses
Up to 80 mg subcutaneous injection x 1, followed by 40 mg every other week
OR
Up to 40 mg every week when there is documentation that current treatment with Humira 40 mg every 2 weeks is ineffective.

Coverage Period
Initial: 24 weeks
Reauthorization: Yearly if meets the following:

1. Not being used in combination with other targeted biologics, AND
2. One of the following:
    a. Improvement in PASI score from baseline, OR
    b. Improvement in BSA from baseline, OR
    c. Decrease in sensitive area disease severity, OR
    d. Decrease in debilitating disease severity

ICD-10:
L40.0-L40.9

Polyarticular juvenile idiopathic arthritis

1. Recommended by a rheumatologist, **AND**
2. Inadequate response or intolerable side effect with one disease modifying anti-rheumatic drug (DMARD) *(see section 5)* or patient has a medical justification why methotrexate cannot be used, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors)

Covered Doses

Weight	Given as a subcutaneous injection
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

Coverage Period
6 months each authorization

ICD-10:
M08.00-M08.40

Psoriatic arthritis

1. Recommended by a rheumatologist, **AND**
2. Inadequate response or intolerable side effect with one disease modifying anti-rheumatic drugs (DMARD) (*see section 5*)**,** or patient has a medical reason why methotrexate, leflunomide, or sulfasalazine cannot be used, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors, Otezla)

Covered Doses
Up to 40 mg subcutaneous injection every other week

Coverage Period
6 months each authorization

ICD-10:
L40.50-L40.59

Rheumatoid arthritis

1. Disease is moderate to severe, **AND**
2. Diagnosed or recommended by a rheumatologist, **AND**
3. Inadequate response, intolerable side effect, or contraindication to methotrexate, **AND**

4. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors, Xeljanz)

Covered Doses
Initial: Up to 40 mg subcutaneous injection every other week

Coverage Period
6 months each authorization

ICD-10: (X=0-9)
M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

<u>Spondyloarthritis</u>

1. Recommended by a rheumatologist, **AND**
2. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors), **AND**
3. One of the following:
    a. Patient unable to use NSAIDs due to history of GI bleed or ulcer, or
    b. For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI), or
    c. For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy

Covered Doses
40 mg subcutaneous injection given every other week

Requests for dose greater than 40 mg every other week for the treatment of spondyloarthritis <u>are not covered</u>. Efficacy with greater than 40 mg every other week has not been studied.

Coverage Period
6 months each authorization

ICD-10:
M45.0-M45.9, M48.8X1-M48.8X9

Ulcerative colitis

1. Disease is moderate to severe, **AND**
2. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors)

Covered Doses

Adults: subcutaneous injection

- Initial dose (Day 1): 160 mg (given in one day or split over two consecutive days)
- Second dose two weeks later (Day 15): 80 mg
- Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week

Pediatrics: subcutaneous injection

Weight	Days 1 through 15	Starting on Day 29
20 kg (44 lbs) to less than 40 kg (88 lbs)	Day 1: 80 mg Day 8: 40 mg Day 15: 40 mg	40 mg every other week or 20 mg every week
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 8: 80 mg Day 15: 80 mg	80 mg every other week or 40 mg every week

* Continue the recommended pediatric dosage in patients who turn 18 years of age and who are well-controlled on their Humira regimen.

Coverage Period

6 months each authorization

ICD-10:

K51.00-K51.019, K51.20-K51.219, K51.30-K51.319, K51.40-K51.419
K51.50-K51.519, K51.80-K51.819, K51.90-K51.919

Uveitis: noninfectious intermediate, posterior, and panuveitis

1. Diagnosed or recommended by an ophthalmologist (prescriber does not have to be an ophthalmologist), **AND**
2. Inadequate response, intolerable side effect, or contraindication to systemic corticosteroids, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors)

Covered Doses

Adult: subcutaneous injection

Up to 80 mg subcutaneous injection for the initial dose, followed by 40 mg every other week starting one week after initial dose.

Pediatric: subcutaneous injection

Weight	
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week

30 kg (66 lbs) and greater	40 mg every other week

Coverage Period
6 months each authorization

ICD-10:
H44.111-113, H44.119, H30.001 - H30.049, H30.101 - H30.149, H30.90 - H30.93

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Humira® (adalimumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Combination use with other targeted immunomodulators

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

Pens

- 40 mg/0.8 mL (2 pens), NDC: 0074-4339-02
- 40 mg/0.4 mL (2 pens), NDC: 0074-0554-02

Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa

- 40 mg/0.8 mL (6 pens), NDC: 0074-4339-06
- 40 mg/0.4 mL (6 pens), NDC: 0074-0554-06
- 80 mg/0.8 mL (3 pens), NDC: 0074-0124-03

Psoriasis/Uveitis Starter Package

- 40 mg/0.8 mL (4 pens), NDC: 0074-4339-07
- 40 mg/0.4 mL (4 pens), NDC: 0074-0554-04
- 80 mg/0.8 mL and 40 mg/0.4 mL (3 pens), NDC: 0074-1539-03

Prefilled Syringe Carton

- 40 mg/0.8 mL (2 syringes), NDC: 0074-3799-02
- 40 mg/0.4 mL (2 syringes), NDC: 0074-0243-02
- 20 mg/0.4 mL (2 syringes), NDC: 0074-9374-02
- 20 mg/0.2 mL (2 syringes), NDC: 0074-0616-02
- 10 mg/0.2 mL (2 syringes), NDC: 0074-6347-02
- 10 mg/0.1 mL (2 syringes), NDC: 0074-0817-02

Pediatric Crohn's Disease Starter Package

- 40 mg/0.8 mL (6 syringes), NDC: 0074-3799-06
- 80 mg/0.8 mL (3 syringes), NDC: 0074-2540-03

- 40 mg/0.8 mL (3 syringes), NDC: 0074-3799-03
- 80 mg/0.8 mL and 40 mg/0.4 mL, (2 syringes), NDC: 0074-0067-02

Single-Use Institutional Use Vial Carton
- 40 mg/0.8 mL, (One vial), NDC: 0074-3797-01

DMARD examples:
- Auranofin (Rid aura®)
- Azathioprine (Imuran®)
- Cyclosporine (Neoral®)
- Hydroxychloroquine (Plaquenil®)
- Methotrexate (Rheumatrex®)
- D-Penicillamine (Cuprimine®)
- Sulfasalazine (Azulfidine®)
- Leflunomide (Arava®)

Hurley Stage Definition for Hidradenitis Suppurativa Disease Severity

Hurley Stage I	Solitary or multiple, isolated abscess formation without scarring or sinus tracts
Hurley Stage II	Recurrent abscesses, single or multiple widely separated lesions, with sinus tract formation
Hurley Stage III	Diffuse or broad involvement, with multiple interconnected sinus tracts and abscesses.

(6) References

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- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Feuerstein JD, Isaacs KL, Schneider Y et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology 2020;158:1450–1461
- Fraenkel, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research 2021; 73: 924-939. Available at https://www.rheumatology.org.
- Humira (adalimumab) [Prescribing Information]. North Chicago, IL: AbbVie Inc. 2/2021.
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- Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018;113:481-517.
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- Ward MM, Deodhar A, Gensler LS, Dubreuil M. et al. Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71:1599–613

(7) Policy Update

Dates of last review: 4Q2022
Date of next review: 4Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee