SmartHealth Ascension

Adalimumab

(Humira®) J0135

Covered with prior authorization

Adalimumab (Humira®) may be authorized when the following criteria are met:

FDA-Approved Indications

- Diagnosis of Rheumatoid arthritis (RA); **AND**
- Age 18 years or older with moderate to severe RA; **AND**
    - Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose; **OR**
    - If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **AND**
- Dose
    - Is 40 mg every other week; **OR**
    - For individuals not receiving methotrexate, dose is up to 40 mg every week or 80 mg every other week.

OR

- Diagnosis of Polyarticular juvenile idiopathic arthritis (PJIA); **AND**
- Age is 2 years of age or older with moderate to severe PJIA; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [non-biologic disease modifying antirheumatic drugs (DMARDs) (such as methotrexate)]; **AND**
- Dose is weight-appropriate:
    - 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week; **OR**
    - 15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week; **OR**
    - ≥ 30 kg (66 lbs): 40 mg every other week.

OR

- Diagnosis of Psoriatic arthritis (PsA); AND:
- Age 18 years or older with moderate to severe PsA; **AND**
- Individual has had an inadequate response to, is intolerant of, or has contraindication to conventional therapy [nonbiologic disease modifying antirheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, or leflunomide)]; **AND**
- Dose is 40 mg every other week.

OR

- Diagnosis of Ankylosing spondylitis (AS); **AND**
- Age is 18 years or older with moderate to severe AS; **AND**

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Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or non-biologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine); **AND**
- Dosing is 40 mg every other week.

OR

- Diagnosis of Crohn's disease (CD); **AND**
- Age is 6 years or older with moderate to severe CD; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants); **AND**
- Adult dosing is:
    - Initial dose
        - Day 1: 160 mg; **OR**
        - Days 1 & 2: 80 mg per day for two consecutive days; **AND**
    - Followed by 80 mg two weeks later (Day 15); **AND**
    - Maintenance dose of 40 mg every other week beginning two weeks later (Day 29); **OR**
- Pediatric Dosing is weight-appropriate:
    - 17 kg (37 lbs) to <40 kg (88 lbs):
        - Initial Dose (Day 1): 80 mg; **AND**
        - Followed by 40 mg two weeks later (Day 15); **AND**
        - Maintenance dose of 20 mg every other week beginning two weeks later (Day 29); **OR**
    - ≥ 40 kg (88 lbs) (same as adult dosing):
        - Initial dose
            - Day 1: 160 mg; **OR**
            - Days 1 & 2: 80 mg per day for two consecutive days; **AND**
        - Followed by 80 mg two weeks later (Day 15); **AND**
        - Maintenance dose of 40 mg every other week beginning two weeks later (Day 29).

OR

- Diagnosis of Ulcerative colitis (UC); **AND**
- Age is 5 years or older with moderate to severe UC; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants); **AND**
- Adult dosing is:
    - Initial dose
        - Day 1: 160 mg **OR**
        - Days 1 & 2: 80 mg per day for two consecutive days (160 mg over two consecutive days); **AND**
    - Followed by 80 mg two weeks later (Day 15); **AND**
    - Maintenance dose of 40 mg every other week beginning two weeks later (Day 29); **OR**
- Pediatric Dosing is weight-appropriate:
    - 20 kg (44 lbs) to <40 kg (88 lbs):
        - Initial Dose (Day 1): 80 mg; **AND**

        - Followed by 40 mg one week later (Day 8); **AND**
        - 40 mg one week later (Day 15)**; AND**
            - Maintenance dose of 40 mg every other week beginning two weeks later (Day 29); **OR**
            - Maintenance dose of 20 mg every week beginning two weeks later (Day 29); **OR**
    - ≥ 40 kg (88 lbs):
        - Initial dose
            - Day 1: 160 mg; **OR**
            - Days 1 & 2: 80 mg per day for two consecutive days; **AND**
        - Followed by 80 mg one week later (Day 8); **AND**
        - 80 mg one week later (Day 15); **AND**
            - Maintenance dose of 80 mg every other week beginning two weeks later (Day 29); **OR**
            - Maintenance dose of 40 mg every week beginning two weeks later (Day 29).

OR

- Diagnosis of Plaque psoriasis (Ps) (psoriasis vulgaris); **AND**
- Age is 18 years or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris); **AND**
    - Plaque Ps (psoriasis vulgaris) involves greater than three percent (3%) of body surface area (BSA); **OR**
    - Plaque Ps (psoriasis vulgaris) involves less than or equal to three percent (3%) of BSA involving sensitive areas or areas that significantly impact daily function (such as fingernails, palms, soles of feet, head/neck, or genitalia); **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as methotrexate, acitretin, or cyclosporine); **AND**
- Dosing is: 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

OR

- Diagnosis is Hidradenitis suppurativa (HS); **AND**
- Age is 12 years or older; **AND**
- Individual has moderate to severe HS (Hurley stage II or Hurley stage III disease); **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as oral antibiotics); **AND**
- Adult dosing is:
    - Initial dose
        - Day 1: 160 mg (four 40 mg injections in one day; **OR** two 80 mg injections on day); **OR**
        - Days 1 & 2: 80 mg per day for two consecutive days (160 mg over two consecutive days) (two 40 mg injections per day for two consecutive days or one 80 mg injection per day for two days); **AND**
    - Followed by 80 mg two weeks later (Day 15); **AND**
    - Maintenance dose of 40 mg every week or 80 mg every other week beginning two weeks later (Day 29).

- Adolescent dosing is:
  - 30 kg (66 lbs) to <60 kg (132 lbs):
    - Initial Dose (Day 1): 80 mg; **AND**
    - Followed by 40 mg one week later (Day 8); **AND**
    - Maintenance dose of 40 mg every other week beginning two weeks later (Day 22); **OR**
  - ≥ 60 kg (132 lbs):
    - Initial dose
      - Day 1: 160 mg; **OR**
      - Days 1 & 2: 80 mg per day for two consecutive days; **AND**
    - Followed by 80 mg two weeks later (Day 15); **AND**
      - Maintenance dose of 80 mg every other week beginning two weeks later (Day 29); **OR**
      - Maintenance dose of 40 mg every week beginning two weeks later (Day 29).

OR

- Diagnosis is non-infectious non-infectious intermediate, posterior, and panuveitis uveitis (UV); **AND**
- Individual is 2 years of age and older; **AND**
- Individual has chronic, recurrent, treatment-refractory or vision-threatening disease; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as corticosteroids or immunosuppressive drugs (azathioprine, cyclosporine, or methotrexate)]; **AND**
- Adult Dosing is:
  - 80 mg initial dose; **AND**
  - 40 mg every other week starting one week after initial dose; **OR**
- Pediatric Dosing is weight-appropriate:
  - 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week; **OR**
  - 15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week; **OR**
  - ≥ 30 kg (66 lbs): 40 mg every other week.

AND

- Prescribed by or in consultation with rheumatology, dermatology, or gastroenterology.

OR

Non-FDA Approved Indications

- Diagnosis of sarcoidosis; **AND**
- Age is 18 years or older; **AND**
- Individual has chronic, progressive, treatment-refractory disease; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate or azathioprine).

AND

- Dose is supported by practice standards, standards of care, or protocols.

AND

- Prescribed by or in consultation with rheumatology, dermatology, or gastroenterology.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;
- In combination with other TNF antagonists, apremilast, JAK inhibitors, ozanimod, or other biologic drugs (such as abatacept, anakinra, IL-17 inhibitors, IL-23 inhibitors, ustekinumab, rituximab, tocilizumab, or vedolizumab);
- Continuation of therapy in individuals with ulcerative colitis (UC) without evidence of clinical remission by eight weeks of treatment (Day 57).
- Tuberculosis, other active serious infections, or a history of recurrent infections;
- If individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention-recommended equivalent, to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors).

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

Humira® is a tumor necrosis factor (TNF) blocker indicated for treatment of:

- Rheumatoid Arthritis (RA)
- Juvenile Idiopathic Arthritis(JIA)
- Psoriatic Arthritis (PsA
- Ankylosing Spondylitis (AS)
- Crohn's Disease (CD)
- Ulcerative Colitis (UC)
- Plaque Psoriasis (Ps)
- Hidradenitis Suppurativa (HS)

- Uveitis (UV)

References:

Feuerstein JD, Isaacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
Humira® (adalimumab) label. (2011, December). Accessdata.fda.gov. Retrieved April 23, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125057s417lbl.pdf
Humira® Alternatives Compared. (Updated frequently). Drugs.com. Retrieved April 25, 2022, from https://www.drugs.com/compare/humira®
U.A Food & Drug Administration. (2021, October 18). *FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira® | FDA*. US Food and Drug Administration. Retrieved April 25, 2022, from https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.