Humira (adalimumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Humira 10 mg/0.2 mL prefilled syringe	2 syringes per 28 days
Humira 10 mg/0.1 mL prefilled syringe	2 syringes per 28 days
Humira 20 mg/0.2 mL prefilled syringe¥	2 syringes per 28 days
Humira 20 mg/0.4 mL prefilled syringe¥	2 syringes per 28 days
Humira 40 mg/0.8 mL prefilled pen/syringe#*^§†‡ ¥◊@¶	2 pens/syringes per 28 days
Humira 40 mg/0.4 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Humira (adalimumab) 80 mg/0.8 mL prefilled pen∞*†‡◊@¶	2 pens per 28 days∞
Humira (adalimumab) pediatric Ulcerative Colitis starter pack 80 mg/0.8 mL prefilled syringe◊	1 pack (28 day supply, one time fill)
Humira pediatric Crohn's Disease starter pack 80 mg/0.8 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Humira pediatric Crohn's Disease starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Humira pediatric Crohn's Disease starter pack 40 mg/0.8 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Humira Crohn's Disease/Ulcerative Colitis/ Hidradenitis Suppurativa starter pack 80 mg/0.8 mL prefilled pen†*@	1 pack (28 day supply, one time fill)
Humira Crohn's Disease/Ulcerative Colitis/ Hidradenitis Suppurativa starter pack 40 mg/0.4 mL prefilled pen†*@	1 pack (28 day supply, one time fill)
Humira Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack 40 mg/0.8 mL prefilled pen†*@	1 pack (28 day supply, one time fill)
Humira Psoriasis/Uveitis/adolescent Hidradenitis Suppurativa starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled pen^‡@	1 pack (28 day supply, one time fill)
Humira Psoriasis/Uveitis/adolescent Hidradenitis Suppurativa starter pack 40 mg/0.4 mL prefilled pen^‡@	1 pack (28 day supply, one time fill)

Humira Psoriasis/Uveitis/adolescent Hidradenitis Suppurativa starter pack 40 mg/0.8 mL^‡@	1 pack (28 day supply, one time fill)

Override Criteria

†Initiation of therapy for pediatric Crohn's Disease (CD): Depending on individual's weight, may approve one (1) pediatric or adult Crohn's Disease starter pack **OR** up to four (4) additional 40 mg pens or syringes **OR** up to a total of three (3) 80 mg pens in the first month (28 days) of treatment.

#In the treatment of Rheumatoid Arthritis (RA): May approve up to four (4) syringes or pens (40mg) (up to an additional two (2) syringes or pens every 28 days if the individual is unable to take concomitant methotrexate.

*Initiation of therapy for adult Crohn's Disease (CD) or Ulcerative Colitis (UC) or Hidradenitis Suppurativa (HS): May approve one (1) Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack **OR** up to four (4) additional 40 mg pens or syringes **OR** up to a total of three (3) 80 mg pens in the first month (28 days) of treatment.

^Initiation of therapy for Plaque Psoriasis (Ps) (psoriasis vulgaris): May approve one (1) Psoriasis starter pack **OR** up to two (2) additional 40 mg pens or syringes **OR** up to one (1) 80 mg pen in the first month (28 days) of treatment.

§ Maintenance therapy for Hidradenitis Suppurativa (HS): May approve up to two (2) additional 40 mg pens or syringes per each 28 days.

@ Initiation of therapy for adolescent Hidradenitis Suppurativa (HS): Depending on individual's weight, may approve one (1) adolescent or adult Hidradenitis Suppurativa starter pack **OR** up to four (4) additional 40 mg pens or syringes **OR** up to a total of three (3) 80 mg pens in the first month (28 days) of treatment.

‡Initiation of therapy for Uveitis (UV): May approve one (1) Uveitis starter pack **OR** up to 2 (two) additional 40 mg pens or syringes **OR** up to one (1) 80 mg pen in the first month (28 days) of treatment.

¥In the treatment of Ulcerative Colitis (UC): May approve up to 4 (four) syringes, autoinjectors, or pens (40mg) [up to an additional 2 (two) syringes, autoinjectors, or pens] every 28 days for individuals 5-17 years of age weighing at least 40 kg (88 lbs)Δ. May approve up to 4 (four) syringes, autoinjectors, or pens (20mg) [up to an additional 2 (two) syringes, autoinjectors, or pens] every 28 days for individuals 5-17 years of age weighing 20 kg (44 lbs) to 40 kg (88 lbs) Δ.

◊Initiation of therapy for pediatric Ulcerative Colitis (UC): Depending on individual's weight, may approve one (1) pediatric Ulcerative Colitis starter pack **OR** up to five (5) additional 40 mg pens or syringes **OR** up to a total of four (4) 80 mg pens in the first month (28 days) of treatment.

[∞]Requests for 80mg/ 0.8 mL pen for maintenance dosing require clinical review. Initial requests for maintenance treatment of up to 2 pens per 28 days may be approved if the following criteria are met[Δ]:

I. Individual has a diagnosis of Rheumatoid Arthritis (RA); **AND**
II. Individual is unable to take concomitant methotrexate;
OR
III. Individual has a diagnosis of Hidradenitis Suppurativa (HS);
OR
IV. Individual has a diagnosis of Ulcerative Colitis (UC); **AND**
V. Individual is 5 to 17 years of age; **AND**
VI. Individual weighs at least 40 kg (88 lbs).

[Δ]*Individuals with UC who initiated therapy at age 17 or below and who are **well controlled** on 20 to 40 mg every week or 80 mg every other week regimen may continue therapy.*

[¶]For individuals requesting escalated dosing for CD or UC, up to one 40 mg syringe/pen/autoinjector per week **OR** one 80 mg syringe every 2 weeks (i.e. four 40 mg syringes/pens/autoinjectors or two 80 mg syringes per month) may be approved if the following criteria are met:

A. Individual has been treated with standard maintenance dosing (i.e. 40 mg every 2 weeks) for *at least* 8 doses or 16 weeks; **AND**
B. The increased dosing is being prescribed by or in consultation with a gastroenterologist;
AND
C. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR**
D. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber;
AND
E. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
F. Requested dosing does not exceed up to one 40 mg syringe/pen/autoinjector per week OR one 80 mg syringe every 2 weeks (i.e. four 40 mg syringes/pens/autoinjectors or two 80 mg syringes per month).

Initial approval duration for increased dosing for CD or UC: 16 weeks

[¶]Requests for continued escalated dosing for CD and UC may be approved if the following criteria are met:

A. Requested dosing does not exceed up to one 40 mg syringe/pen/autoinjector per week OR one 80 mg syringe every 2 weeks (i.e. four 40 mg syringes/pens/autoinjectors or two 80 mg syringes per month); **AND**
B. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
C. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**

D. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for CD or UC: 6 months

¶For CD or UC, Increased dosing may not be approved for the following:
A. Individual has had no response to adalimumab at standard maintenance dosing (i.e. 40 mg every 2 weeks); **OR**
B. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

APPROVAL CRITERIA

Initial requests for Humira (adalimumab) may be approved for the following:

I. Crohn's disease (CD) when each of the following criteria are met:
   A. Individual is 6 years of age or older with moderate to severe CD; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]);

OR

II. Ulcerative colitis (UC) when each of the following criteria are met:
   A. Individual is 5 years of age or older with moderate to severe UC; **AND**
   B. 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 [such as thiopurines]);

OR

III. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual must be 18 years of age or older with moderate to severe RA;
   AND
   B. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021);
   OR
   C. 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);

OR

IV. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. 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);

OR

V. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [non-biologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate)] (ACR 2019).

OR

VI. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual must be 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)];

OR

VII. Plaque psoriasis (Ps) (psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2019):
      1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) of body surface area (BSA);
         OR
      2. Plaque Ps (psoriasis vulgaris) involving 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

   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

OR

VIII. Non-infectious uveitis (UV) when each of the following criteria are met:
   A. Individual has chronic, recurrent, treatment-refractory or vision-threatening disease; **AND**
   B. 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)].

OR

IX. Hidradenitis suppurativa (HS) when each of the following criteria are met:
   A. Individual is 12 years of age or older; **AND**
   B. Individual has moderate to severe HS (Hurley stage II or Hurley stage III disease); **AND**
   C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as oral

antibiotics);

OR

X. Sarcoidosis when each of the following criteria are met (Sweiss 2014):
   A. Individual is 18 years of age or older; **AND**
   B. Individual has chronic, progressive, treatment-refractory disease; **AND**
   C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids; **AND**
   D. 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).

Continuation requests for Humira (adalimumab) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Humira (adalimumab) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
III. If initiating therapy, 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); **OR**
IV. When the above criteria are not met and for all other indications.

Note:
TNFi have black box warnings for serious infections and malignancy. Individuals treated with TNFi are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated prior to TNFi use. Risks and benefits of TNFi should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

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