ADALIMUMAB

Generic	Brand	HICL	GCN	Exception/Other
ADALIMUMAB	HUMIRA	24800		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID for Humira 40mg/0.4mL syringe/pen OR 40mg/0.8mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is 2 years of age or older
   - Documentation of the patient's current weight

   If yes, **approve for 6 months by GPID with a quantity limit of #2 syringes/pens per month based on patient weight as follows:**
   - **If 10kg to <15kg in weight: Approve Humira 10mg/0.2mL syringe OR 10mg/0.1mL syringe.**
   - **If 15kg to <30kg in weight: Approve Humira 20mg/0.4mL syringe OR 20mg/0.2mL syringe.**
   - **If 30kg or heavier: Approve Humira 40mg/0.8mL pen/syringe OR 40mg/0.4mL pen/syringe.**
     APPROVAL TEXT: See approval text on the next page.

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INITIAL CRITERIA (CONTINUED)

APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to an NSAID

   If yes, **approve for 6 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to at least ONE of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   - The patient is 18 years of age or older

   If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**
   - **Approve for 1 fill for Humira 40mg/0.8mL Psoriasis Starter Package with a quantity of #4 pens OR for Humira Psoriasis Starter Package (contains one 80 mg/0.8 mL pen and two 40 mg/0.4 mL pens) with a quantity limit of #3 pens.**
   - **Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

   If no, continue to #6.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient is 6 years of age or older

   If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**
   - **Approve for 1 fill for Humira 40mg/0.8mL Crohn's Disease Starter Package with a quantity limit of #6 pens, OR for Humira 40mg/0.8mL Pediatric Crohn's Starter Package with quantity limit of either #3 syringes or #6 syringes, OR for Humira 80mg/0.8mL Pediatric Crohn's Disease Starter Package with a quantity limit of #3 syringes, OR for Humira Pediatric Crohn's Disease Starter Package (contains one 40mg/0.4mL syringe and one 80mg/0.8mL syringe) with a quantity limit of #2 syringes, OR for Humira 80 mg/0.8 mL Crohn's Disease Starter Package with a quantity limit of #3 pens.**
   - **Approve for 5 months for Humira 40mg/0.8mL syringe/pen, OR Humira 40mg/0.4mL syringe/pen, OR Humira 20mg/0.4mL syringe, OR Humira 20mg/0.2mL syringe with a quantity limit of #2 syringes/pens per month.**

   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient is 18 years of age or older

   If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**
   - **Approve for 1 fill for Humira 40mg/0.8mL Pen Ulcerative Colitis (UC) Starter Package with a quantity limit of #6 pens OR for Humira 80 mg/0.8 mL Ulcerative Colitis Starter Package with a quantity limit of #3 pens.**
   - **Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and is 12 years of age or older?

   If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**
   - **Approve for 1 fill for Humira 40mg/0.8mL Pen Starter Package for Hidradenitis Suppurativa (HS) with a quantity limit of #6 pens OR for Humira 80 mg/0.8 mL Hidradenitis Suppurativa Starter Package with a quantity limit of #3 pens.**
   - **Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #4 syringes/pens per month.**

   If no, continue to #9.

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INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with an ophthalmologist
   - The patient is 2 years of age or older
   - The patient does **NOT** have isolated anterior uveitis
   - Documentation of the patient's current weight if between 2 to 17 years of age

   If yes, **approve for a total of 6 months by GPID as follows:**
   - **For age 2 to 17 years, approve with a quantity limit of #2 syringes/pens per month based on patient weight as follows:**
     - **If 10kg to <15kg in weight: Approve Humira 10mg/0.2mL syringe OR 10mg/0.1mL syringe.**
     - **If 15kg to <30kg in weight: Approve Humira 20mg/0.4mL syringe OR 20mg/0.2mL syringe.**
     - **If 30kg or heavier: Approve Humira 40mg/0.8mL pen/syringe OR 40mg/0.4mL pen/syringe.**
   - **For age 18 years and above, please enter two authorizations as follows:**
     - **Approve for 1 fill for Humira 40mg/0.8mL Uveitis Starter Package with a quantity limit of #4 pens OR for Humira Uveitis Starter Package (contains one 80 mg/0.8 mL pen and two 40 mg/0.4 mL pens) with a quantity limit of #3 pens.**
     - **Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**

   APPROVAL TEXT: Renewal for Uveitis requires that the patient has not experienced treatment failure, defined as development of new inflammatory chorioretinal or retinal vascular lesions, a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade, or a worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved.

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, or moderate to severe hidradenitis suppurativa, or non-infectious intermediate, posterior and panuveitis. The following criteria must also be met:
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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

For patients with moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval requires:
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least ONE of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 2 years of age or older
- Documentation of the patient's current weight

For patients with psoriatic arthritis (PsA), approval requires:
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least ONE of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 of years of age or older

For patients with ankylosing spondylitis (AS), approval requires:
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient had a previous trial of or contraindication to an NSAID

For patients with moderate to severe plaque psoriasis (PsO), approval requires:
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least ONE of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient is 18 years of age or older

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe Crohn's disease (CD), approval requires:
- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least ONE of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older

For patients with moderate to severe ulcerative colitis (UC), approval requires:
- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least ONE of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older

For patients with moderate to severe hidradenitis suppurativa (HS), approval requires:
- The patient is 12 years of age or older

For patients with non-infectious intermediate, posterior and panuveitis, approval requires:
- Therapy is prescribed by or given in consultation with an ophthalmologist
- The patient is 2 years of age or older
- The patient does NOT have isolated anterior uveitis
- Documentation of the patient's current weight if between 2 to 17 years of age

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for Humira 40mg dosed **every other week** and has the following criteria been met?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   If no, continue to #3.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

3. Is the request for Humira 40mg dosed **every week** and have **ALL** of the following criteria been met?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of at least a 3-month regimen of Humira 40mg dosed every other week

   If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #4 syringes/pens per month.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID for Humira 10mg/0.1mL syringe, OR Humira 10mg/0.2mL syringe, OR Humira 20mg/0.2mL syringe, OR Humira 20mg/0.4mL syringe, OR Humira 40mg/0.4mL syringe/pen, OR Humira 40mg/0.8mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   If no, continue to #6.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

   If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen, OR Humira 40mg/0.4 mL syringe/pen, OR Humira 20mg/0.4mL syringe, OR Humira 20mg/0.2mL syringe with a quantity limit of #2 syringes/pens per month.**
   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**
   If no, continue to #10.

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS)?

    If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #4 syringes/pens per month.**
    If no, continue to #11.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criteria?
    - The patient has not experienced treatment failure, defined as **ONE** of the following criteria:
      - Development of new inflammatory chorioretinal or retinal vascular lesions
      - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
      - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID for Humira 10mg/0.1mL syringe, OR Humira 10mg/0.2mL syringe, OR Humira 20mg/0.2mL syringe, OR Humira 20mg/0.4mL syringe, OR Humira 40mg/0.8mL syringe/pen, OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.**

    If no, do not approve.
    RENEWAL DENIAL TEXT: The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, moderate to severe hidradenitis suppurativa, or non-infectious intermediate, posterior and panuveitis for renewal. The following criteria must also be met:
    Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:
    - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
    - Requests for Humira weekly dosing requires that the patient had a trial of at least a 3-month regimen of Humira 40mg every other week

    Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis requires:
    - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

    Renewal for the diagnosis of psoriatic arthritis requires:
    - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

    Renewal for the diagnosis of ankylosing spondylitis requires:
    - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

Renewal for the diagnosis of moderate to severe plaque psoriasis requires:
- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

Renewal for the diagnosis of non-infectious intermediate, posterior and panuveitis requires:
- The patient has not experienced treatment failure, defined as **ONE** of the following criteria:
  - Development of new inflammatory chorioretinal or retinal vascular lesions
  - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
  - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Humira.

REFERENCES

- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 05/03
Client Approval: 11/19
P&T Approval: 10/19