STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB	HUMIRA	24800		GPI-10 (6627001500)	

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?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for Humira 40mg/0.4mL OR 40mg/0.8mL with a quantity limit of #2 per 28 days.**

   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?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days for all of the following:**
   - **Humira 10mg/0.2mL**
   - **Humira 10mg/0.1mL**
   - **Humira 20mg/0.4mL**
   - **Humira 20mg/0.2mL**
   - **Humira 40mg/0.8mL**
   - **Humira 40mg/0.4mL**

   If no, continue to #3.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

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

   If yes, **approve for 6 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #4.

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

   If yes, **approve for 6 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, continue to #6.
   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and is switching to the requested drug
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, or face

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 month 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 OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 month 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, OR 40mg/0.4mL, OR 20mg/0.4mL, OR 20mg/0.2mL with a quantity limit of #2 per 28 days.**

   If no, continue to #8.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 month for ONE of the following as requested:**
     - **Humira 40mg/0.8mL Pen Ulcerative Colitis Starter Package: #6 pens.**
     - **Humira 80 mg/0.8 mL Ulcerative Colitis Starter Package: #3 pens.**
     - **Humira 80mg/0.8mL Pen Pediatric UC Starter Package: #4 pens.**
     - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 pens/syringes.**
   - **Approve for 5 months for ONE of the following as requested (enter a start date of 3 days before the end date of the first approval):**
     - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
     - **Humira 80mg/0.8mL: #2 per 28 days.**
     - **Humira 20mg/0.4mL OR 20mg/0.2mL: #4 per 28 days.**

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 month 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 the requested agent as follows (enter a start date of 3 days before the end date of the first approval):**
     - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
     - **Humira 80mg/0.8mL: #2 per 28 days.**

   If no, continue to #10.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an ophthalmologist
    - The patient does NOT have isolated anterior uveitis

    If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
    - **For age 2 to 17 years, approve with a quantity limit of #2 per 28 for all of the following:**
      - **Humira 10mg/0.2mL**
      - **Humira 10mg/0.1mL**
      - **Humira 20mg/0.4mL**
      - **Humira 20mg/0.2mL**
      - **Humira 40mg/0.8mL**
      - **Humira 40mg/0.4mL**
    - **For age 18 years and above, please enter two authorizations as follows:**
      - **Approve for 1 month 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 OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

    If no, do not approve.
    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for approval:
    A. You have ONE of the following diagnoses:
       1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
       2. Psoriatic arthritis (PsA: a type of skin and joint condition)
       3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
       4. Ankylosing spondylitis (AS: a type of joint condition)
       5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
       6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
       7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
       8. Moderate to severe hidradenitis suppurativa (a type of skin condition)
       9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You had a trial of or contraindication (harmful for) to ONE or more forms of standard therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and are switching to the requested drug
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the face, hands, feet, or genital area

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. The medication is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do not have isolated anterior uveitis (a different type of eye inflammation)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADALIMUMAB

GUIDELINES FOR USE (CONTINUED)

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 criterion 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 or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #3.

3. Is the request for Humira 40mg dosed **every week OR Humira 80mg dosed every other 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 or GPI-14 for the requested agent with the following quantity limits:**
   - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
   - **Humira 80mg/0.8mL: #2 per 28 days.**

   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 or GPI-14 for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.

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RENEWAL CRITERIA (CONTINUED)

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 or GPI-14 for Humira 10mg/0.1mL, OR 10mg/0.2mL, OR 20mg/0.2mL, OR 20mg/0.4mL, OR 40mg/0.4mL, OR 40mg/0.8mL with a quantity limit of #2 per 28 days.**

   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 or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #6.

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 or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   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 or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #8.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

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

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL, OR 40mg/0.4 mL, OR 20mg/0.4mL, OR 20mg/0.2mL with a quantity limit of #2 per 28 days.**

   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 or GPI-14 for the requested agent as follows:**
   - **Humira 40mg/0.8mL OR Humira 40mg/0.4mL: #4 per 28 days.**
   - **Humira 80mg/0.8mL: #2 per 28 days.**
   - **Humira 20mg/0.4mL OR Humira 20mg/0.2mL: #4 per 28 days.**

   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 or GPI-14 for the requested agent as follows:**
    - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
    - **Humira 80mg/0.8 mL: #2 per 28 days.**

    If no, continue to #11.

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 or GPI-14 for Humira 10mg/0.1mL, OR 10mg/0.2mL, OR 20mg/0.2mL, OR 20mg/0.4mL, OR 40mg/0.8mL, OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (a type of skin condition)
   9. Non-infectious intermediate posterior and panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. If you are requesting Humira 40mg weekly dosing OR Humira 80mg every other week dosing, we require you have tried at least a 3-month of Humira 40mg every other week

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have 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

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have 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 denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

G. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have not experienced treatment failure, defined as ONE of the following:
      a. You have development of new inflammatory chorioretinal or retinal vascular lesions (eye tumors)
      b. A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on how bad eye inflammation is)
      c. A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best visual acuity achieved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/03
Client Approval: 05/23
P&T Approval: 04/23