Adalimumab (Humira®) is a recombinant human IgG1 monoclonal antibody that blocks tumor necrosis factor (TNF). TNF is a naturally occurring cytokine that plays a role in inflammatory and immune responses. Elevated TNF levels can cause inflammation and joint destruction in individuals with rheumatoid arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, and psoriatic arthritis. Adalimumab (Humira®) binds to TNF-alpha, blocks its interaction with surface TNF receptors, and causes surface lysis (breakdown), leading to decreased inflammation and joint destruction. Adalimumab (Humira®) does not bind to or inactivate TNF-beta. Adalimumab (Humira®) also modulates biological responses that are induced or regulated by TNF, including changes in the levels of adhesion molecules responsible for leukocyte migration. Adalimumab (Humira®) decreases C-reactive protein, erythrocyte sedimentation rate, IL-6, and matrix metalloproteinases MMP-1 and MMP-3.

Adalimumab (Humira®) is approved when any of the following inclusion criteria is met:

- Documentation of a diagnosis of moderate to severe Rheumatoid Arthritis, Ankylosing Spondylitis or Psoriatic Arthritis and ALL of the following:
  - Patient is an adult (≥ 18 years)
  - Medication is being recommended and prescribed by a rheumatologist
  - Patient had at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to ALL of the following DMARDs:
- Methotrexate
- Hydroxychloroquine
- Leflunomide
- Azathioprine
- Sulfasalazine
- Etanercept (Enbrel®)
  - Patient is not on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
  - Patient does not have active infections or sepsis
  - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
  - Patient does not have active malignancy

- Documentation of a diagnosis of moderate to severe Juvenile Idiopathic Arthritis (JIA) and ALL of the following:
  - Patient is ≥ 4 years old
  - Medication is being recommended and prescribed by a rheumatologist
  - Patient had at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to ALL of the following DMARDs:
    - Methotrexate
    - Hydroxychloroquine
    - Leflunomide
    - Azathioprine
    - Sulfasalazine
    - Etanercept (Enbrel®)
  - Patient is not on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
  - Patient does not have active infections or sepsis
  - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
  - Patient does not have active malignancy

- Documentation of a diagnosis of moderate to severe chronic Plaque Psoriasis and ALL of the following:
  - Patient is an adult (≥ 18 years)
  - Medication is being recommended and prescribed by a dermatologist
  - Patient had at least a 30 day trial and failure with ONE of the following drugs OR contraindication to ALL of the following drugs:
    - Topical Calcipotriene containing products
    - Topical Anthralin
    - Topical Steroids
    - Topical immunomodulators (Elidel®, Protopic®)
    - Topical retinoids
    - Efudex
    - Etanercept (Enbrel®)
  - Patient is not on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
  - Patient does not have active infections or sepsis
  - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
  - Patient does not have active malignancy
• Documentation of a diagnosis of Crohn’s Disease and ALL of the following:
  ○ Patient is an adult (≥ 18 years old)
  ○ Medication is being recommended and prescribed by a gastroenterologist
  ○ Patient had at least a 30 day trial and failure with Infliximab (Remicade®) OR at least a 30 day trial and failure with one drug from any TWO of the following groups OR contraindication to ALL of the following groups:
    ▪ Corticosteroids: Budesonide (Entocort® EC), Prednisone, Hydrocortisone, Methylprednisolone
    ▪ Aminosalicylates: Sulfasalazine, Mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®), Olsalazine (Dipentum®, Balsalazide (Colazal™)
    ▪ Immunomodulators: Azathioprine, 6-mercaptopurine, Cyclosporine, Sirolimus (Prograf®), Methotrexate
    ▪ Antibiotics: Metronidazole or Fluoroquinolones
  ○ Patient is not on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
  ○ Patient does not have active infections or sepsis
  ○ Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
  ○ Patient does not have active malignancy

Policy Guideline Exclusion

For a diagnosis of moderate to severe Rheumatoid Arthritis, Ankylosing Spondylitis or Psoriatic Arthritis, **Adalimumab (Humira®)** is denied when **any** of the following exclusion criteria is present:

• Patient is less than 18 years old
• Medication is not being prescribed by a rheumatologist
• Patient does not have at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) or contraindication to ALL of the following DMARDs:
  ○ Methotrexate
  ○ Hydroxychloroquine
  ○ Leflunomide
  ○ Azathioprine
  ○ Sulfasalazine
  ○ Etanercept (Enbrel®)
• Patient is on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
• Patient has active infections or sepsis
• Patient has not been evaluated using tuberculin skin test
• Patient has active or latent tuberculosis
• Patient has active malignancy

For a diagnosis of moderate to severe Juvenile Idiopathic Arthritis (JIA), **Adalimumab (Humira®)** is denied when **any** of the following exclusion criteria is present:

• Patient is less than 4 years old
• Medication is not being prescribed by a rheumatologist
• Patient does not have at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) or contraindication to ALL of the following DMARDs:
  ○ Methotrexate
  ○ Hydroxychloroquine
For a diagnosis of moderate to severe chronic Plaque Psoriasis, **Adalimumab (Humira®)** is denied when **any** of the following exclusion criteria is present:

- Patient is less than 18 years old
- Medication is not being prescribed by a dermatologist
- Patient does not have at least a 30 day trial and failure with ONE of the following drugs OR contraindication to ALL of the following drugs:
  - Topical Calcipotriene containing products
  - Topical Anthralin
  - Topical Steroids
  - Topical immunomodulators (Elidel®, Protopic®)
  - Topical retinoids
  - Efudex
  - Etanercept (Enbrel®)
- Patient is on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
- Patient has active infections or sepsis
- Patient has not been evaluated using tuberculin skin test
- Patient has active or latent tuberculosis
- Patient has active malignancy

For a diagnosis of Crohn’s Disease, **adalimumab (Humira®)** is denied when **any** of the following exclusion criteria is present:

- Patient is less than 18 years old
- Medication is not being prescribed by a gastroenterologist
- Patient does not have at least a 30 day trial and failure with Infliximab (Remicade®) OR at least a 30 day trial and failure with one drug from any TWO of the following groups OR contraindication to ALL of the following groups:
  - Corticosteroids: Budesonide (Entocort® EC), Prednisone, Hydrocortisone, Methylprednisolone
  - Aminosalicylates: Sulfasalazine, Mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®), Olsalazine (Dipentum®), Balsalazide (Colazal™)
  - Immunomodulators: Azathioprine, 6-mercaptopurine, Cyclosporine, Sirolimus (Prograf®), Methotrexate
  - Antibiotics: Metronidazole or Fluoroquinolones
- Patient is on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
- Patient has active infections or sepsis
- Patient has not been evaluated using tuberculin skin test
- Patient has active or latent tuberculosis
● Patient has active malignancy

### Policy List of Applicable Drugs

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>Humira</td>
<td>adalimumab</td>
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### Dosing and Administration

Refer to the specific manufacturer’s prescribing information for administration and dosage details, contraindications, and Black Box warnings.

### Policy References


Effectiveness Review Project [available at http://derp.ohsu.edu/about/final-products.cfm


Policy Link to Related Policies
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