Policies Repository

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Policy Title	Adalimumab (Humira®)
Policy Number	FS.CLIN.22

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Adalimumab (Humira®) is indicated for the treatment of crohn's disease, moderate to severe rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis (JIA) and moderate to severe plaque psoriasis.

The use of adalimumab (Humira®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

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.

Policy Guideline Inclusion

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

    - 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 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

Brand Name	Generic Name
Humira	adalimumab

Dosing and Administration

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

Policy References

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Policy Link to Related Policies

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