Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Adalimumab (Humira)

Notes:

- Quantity Limits: Yes
- ^Adequate trial is defined as the following:
  - Phototherapy – 8 weeks
  - Systemic non-biologics for psoriasis – 6 weeks
  - Topical/oral antibiotics – 8 weeks
  - Adalimumab biosimilars – 3 months
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ^^ High-concentration adalimumab-atto includes:
  - 10 mg/0.2 mL syringe
  - 20 mg/0.2 mL syringe
  - 40 mg/0.4 mL pen or syringe
  - 80 mg/0.8 mL pen
- ** Low-concentration adalimumab-atto includes:
  - 40 mg/0.8 mL pen or syringe

Initiation (new start) criteria: Non-formulary **adalimumab (Humira)** will be covered on the prescription drug benefit when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
   - Patient has failed an adequate trial^ of phototherapy (unless documented by prescriber phototherapy not appropriate)
   - Patient has failed an adequate trial^, or patient has an allergy or intolerance* to at least 1 of the following:
     - Methotrexate
     - Cyclosporine
     - Acitretin
   - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
   - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

2. Prescriber is a dermatologist and patient has a diagnosis of hidradenitis suppurativa
    - Patient has failed an adequate trial^, or patient has an allergy or intolerance* to, the following (or contraindication to all):
        - Topical clindamycin 1%
        - Oral antibiotic
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
    - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

3. Prescriber is a rheumatologist and patient has a diagnosis of rheumatoid arthritis/inflammatory arthritis
    - Patient has tried and failed/intolerant to as least 1 of the following:
        - Methotrexate
        - Hydroxychloroquine
        - Sulfasalazine
        - Leflunomide
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
    - Patient has tried and failed/intolerant to infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
    - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

4. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
    - Patient has failed an adequate trial^, has an intolerance to, or has a contraindication to methotrexate (methotrexate not required if patient has dactylitis [inflammation of finger or toe] and/or enthesitis [inflammation of the entheses])
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
    - Patient has tried and failed/intolerant to infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
    - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

5. Prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthropathy
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
    - Patient has tried and failed/intolerant to infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
    - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

6. Prescriber is a rheumatologist and patient has a diagnosis of juvenile idiopathic arthritis
    - Patient has failed an adequate trial^, has an intolerance to, or has a contraindication to methotrexate
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
    - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

7. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
    - Patient has tried and failed/intolerant to infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
    - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

8. Prescriber is a uveitis specialist and patient has a diagnosis of iridocyclitis/uveitis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-concentration^^ or low-concentration** adalimumab-atto
    - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial^ of adalimumab-bwwd

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Criteria for *current Kaiser Permanente members* who were previously approved for adalimumab (Humira): Non-formulary **(Humira)** will be covered on the prescription drug benefit when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis or hidradenitis suppurativa
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

2. Prescriber is a rheumatologist and patient has a diagnosis of rheumatoid arthritis/inflammatory arthritis, psoriatic arthritis, ankylosing spondylitis/spondyloarthropathy, or juvenile idiopathic arthritis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

4. Prescriber is a uveitis specialist and patient has a diagnosis of iridocyclitis/uveitis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

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CRITERIA FOR DRUG COVERAGE
Adalimumab (Humira)

Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **adalimumab (Humira)** will be covered on the prescription drug benefit when the following criteria are met:

1. Prescriber is a dermatologist and patient has a diagnosis of psoriasis or hidradenitis suppurativa
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

2. Prescriber is a rheumatologist and patient has a diagnosis of rheumatoid arthritis/inflammatory arthritis, psoriatic arthritis, ankylosing spondylitis/spondyloarthropathy, or juvenile idiopathic arthritis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

3. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

4. Prescriber is a uveitis specialist and patient has a diagnosis of iridocyclitis/uveitis
    - Patient has a documented allergic reaction to high-concentration^^ or low-concentration** adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of high-concentration^^ or low-concentration** adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber **AND**
    - Patient has tried at least 3 months of adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber