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
- **Methotrexate not required if patient has dactylitis (inflammation of finder or toe) and/or enthesitis (inflammation of the entheses)

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 adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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 adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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 adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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 tried and failed/intolerant to or has contraindication to methotrexate**
    - Patient has a documented allergic reaction to adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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 adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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 tried and failed/intolerant to or has contraindication to methotrexate
   - Patient has a documented allergic reaction to adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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 a diagnosis of Crohn's disease or ulcerative colitis
   - Patient has a documented allergic reaction to adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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 adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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

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 adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
   - Patient has tried at least 3 months of 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 adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
   - Patient has tried at least 3 months of 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 adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**

- Patient has tried at least 3 months of 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 adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of 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

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 adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of 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, or juvenile idiopathic arthritis

- Patient has a documented allergic reaction to adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
- Patient has tried at least 3 months of 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 adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of 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 adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
    - Patient has tried at least 3 months of 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