

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Adalimumab Biosimilars

#### 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
- \* 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

**Formulary preferred: High-concentration^^ adalimumab-atto (Amjevita)**

**Initiation (new start) criteria:** Formulary high-concentration^^ adalimumab-atto (Amjevita) 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
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

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3. Prescriber is a rheumatologist and patient has a diagnosis of rheumatoid arthritis/inflammatory arthritis
  - Patient has tried and failed/intolerant to at least 1 of the following:
    - Methotrexate
    - Hydroxychloroquine
    - Sulfasalazine
    - Leflunomide
4. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis
  - Patient has failed an adequate trial<sup>^</sup>, 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])
5. Prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthritis
6. Prescriber is a rheumatologist and patient has a diagnosis of juvenile idiopathic arthritis
  - Patient has failed an adequate trial<sup>^</sup>, has an intolerance to, or has a contraindication to methotrexate
7. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease or ulcerative colitis
8. Prescriber is a uveitis specialist and patient has a diagnosis of iridocyclitis/uveitis

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Formulary high-concentration<sup>^^</sup> adalimumab-atto (Amjevita) will be covered on the prescription drug benefit when the following criteria are met:

1. Prescriber is a dermatologist, gastroenterologist, rheumatologist, or uveitis specialist

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**Non-formulary preferred: adalimumab-bwwd (Hadlima)**

**Initiation (new start) criteria:** Non-formulary **adalimumab-bwwd (Hadlima)** 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<sup>^</sup> of phototherapy (unless documented by prescriber phototherapy not appropriate)
  - Patient has failed an adequate trial<sup>^</sup>, 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<sup>^^</sup> or low-concentration<sup>\*\*</sup> adalimumab-atto (does not include injection site reaction)  
**OR** patient has failed an adequate trial<sup>^</sup> of high-concentration<sup>^^</sup> or low-concentration<sup>\*\*</sup> adalimumab-atto
2. Prescriber is a dermatologist and patient has a diagnosis of hidradenitis suppurativa
  - Patient has failed an adequate trial<sup>^</sup>, 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<sup>^^</sup> or low-concentration<sup>\*\*</sup> adalimumab-atto (does not include injection site reaction)  
**OR** patient has failed an adequate trial<sup>^</sup> of high-concentration<sup>^^</sup> or low-concentration<sup>\*\*</sup> adalimumab-atto

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## CRITERIA FOR DRUG COVERAGE

### Adalimumab Biosimilars

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
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
5. Prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthritis
  - 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

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### Adalimumab Biosimilars

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

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary **adalimumab-bwwd (Hadlima)** 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<sup>^^</sup> or low-concentration<sup>\*\*</sup> adalimumab-atto (does not include injection site reaction)  
**OR**
  - Patient has tried at least 3 months of high-concentration<sup>^^</sup> or low-concentration<sup>\*\*</sup> adalimumab-atto and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

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### Adalimumab Biosimilars

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 (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
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 (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
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 (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

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## CRITERIA FOR DRUG COVERAGE

### Adalimumab Biosimilars

Non-formulary non-preferred: adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-afzb, adalimumab-aqvh, low-concentration\*\* adalimumab-atto, adalimumab-fkjp, or adalimumab-ryvk

**Initiation (new start) criteria:** Non-Formulary adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-afzb, adalimumab-aqvh, low-concentration\*\* adalimumab-atto, adalimumab-fkjp, or adalimumab-ryvk 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<sup>^</sup> of phototherapy (unless documented by prescriber phototherapy not appropriate)
  - Patient has failed an adequate trial<sup>^</sup>, 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<sup>^^</sup> adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial<sup>^</sup> of high-concentration<sup>^^</sup> adalimumab-atto
  - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial<sup>^</sup> of adalimumab-bwwd
2. Prescriber is a dermatologist and patient has a diagnosis of hidradenitis suppurativa
  - Patient has failed an adequate trial<sup>^</sup>, 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<sup>^^</sup> adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial<sup>^</sup> of high-concentration<sup>^^</sup> adalimumab-atto
  - Patient has a documented allergic reaction to adalimumab-bwwd (does not include injection site reaction) **OR** patient has failed an adequate trial<sup>^</sup> of adalimumab-bwwd

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## CRITERIA FOR DRUG COVERAGE

### Adalimumab Biosimilars

3. Prescriber is a rheumatologist and patient has a diagnosis of rheumatoid arthritis/inflammatory arthritis
  - Patient has tried and failed/intolerant to at least 1 of the following:
    - Methotrexate
    - Hydroxychloroquine
    - Sulfasalazine
    - Leflunomide
  - Patient has a documented allergic reaction to high-concentration^^ adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-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
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
  - Patient has a documented allergic reaction to high-concentration^^ adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-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
5. Prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthritis
  - Patient has a documented allergic reaction to high-concentration^^ adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of high-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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### Adalimumab Biosimilars

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

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### Adalimumab Biosimilars

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-Formulary **adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-afzb, adalimumab-aqvh, low-concentration\*\* adalimumab-atto, adalimumab-fkjp, or adalimumab-ryvk** 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^^ adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
  - Patient has tried at least 3 months of high-concentration^^ adalimumab-atto AND 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/spondyloarthritis, or juvenile idiopathic arthritis
  - Patient has a documented allergic reaction to high-concentration^^ adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**
  - Patient has tried at least 3 months of high-concentration^^ adalimumab-atto AND 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^^ adalimumab-atto AND adalimumab-bwwd (does not include injection site reaction) **OR**  
Patient has tried at least 3 months of high-concentration^^ adalimumab-atto AND adalimumab-bwwd and experienced persistent new or worsening symptoms of disease as documented with objective findings by the prescriber

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