

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[^], 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[^], 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^{^^} 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[^] 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
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

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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 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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6. Prescriber is a rheumatologist and patient has a diagnosis of juvenile idiopathic arthritis
 - Patient has failed an adequate trial^{^A}, 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^{^A} of high-concentration^{^^} or low-concentration^{**} 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^{^^} or low-concentration^{**} adalimumab-atto (does not include injection site reaction)
OR patient has failed an adequate trial^{^A} of high-concentration^{^^} or low-concentration^{**} 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^{^^} or low-concentration^{**} adalimumab-atto (does not include injection site reaction)
OR patient has failed an adequate trial^{^A} of high-concentration^{^^} or low-concentration^{**} 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^{^^} 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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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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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[^] 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^{^^} 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
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^{^^} 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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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^{^^} 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/spondyloarthropathy
 - 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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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^{^^} 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
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^{^^} 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
8. Prescriber is a uveitis specialist and patient has a diagnosis of iridocyclitis/uveitis
 - 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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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