

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Adalimumab-bwvd (Hadlima)

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-atto – 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 finger or toe) and/or enthesitis (inflammation of the entheses)
- Gastroenterology High Risk Classification:
 - Crohn's disease: at least one of the following - extensive anatomical involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricture and/or penetrating behavior
 - Ulcerative colitis: at least one of the following - extensive colitis, deep ulcers, age < 40 years, high CRP and ESR, history of hospitalization, *C. difficile* infection, CMV infection

Initiation (new start) criteria: Non-formulary **adalimumab-bwvd (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 adalimumab-atto (does not include injection site reaction) **OR** patient has failed an adequate trial^ of 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

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

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7. Prescriber is a gastroenterologist, and patient is 17 years of age or younger with a diagnosis of Crohn's disease or ulcerative colitis (if patient is 18 and older, see #8 or #9)
 - 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

8. Prescriber is a gastroenterologist, and patient is 18 years of age or older with a diagnosis of Crohn's disease
 - If patient is LOW risk:
 - Patient has tried and failed/intolerant to the following:
 - Prednisone or budesonide
 - At least 1 of the following: azathioprine, mercaptopurine, 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
 - If patient is HIGH risk:
 - Patient has tried and failed/intolerant to the following:
 - 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

9. Prescriber is a gastroenterologist, and patient is 18 years of age or older with a diagnosis of ulcerative colitis
 - If patient is LOW risk:
 - Patient has tried and failed/intolerant to the following:
 - Prednisone
 - At least 1 of the following: mesalamine product (oral or rectal), sulfasalazine
 - At least 1 of the following: azathioprine, mercaptopurine, 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
 - If patient is HIGH risk:

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- 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
10. 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

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Criteria for current Kaiser Permanente members who were previously approved for adalimumab-bwwd (Hadlima): 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 adalimumab-atto (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
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 adalimumab-atto (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
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 (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
4. 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 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

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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 adalimumab-atto (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
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 (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
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 (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
4. 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 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

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