

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Upadacitinib 15 mg extended-release (Rinvoq 15 mg ER)

Notes:

- Quantity Limits: Yes
- Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ^ Adequate trial is defined as the following:
 - Topical corticosteroids – 8 weeks
 - Topical calcineurin inhibitors – 6 weeks
 - Phototherapy – 8 weeks
 - Atopic dermatitis systemic medications – 6 weeks
 - Biologics for inflammatory bowel disease – 12 weeks

Initiation (new start) criteria and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

Non-formulary **upadacitinib 15 mg extended-release (Rinvoq 15 mg ER)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. 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 tried and failed/intolerant to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Patient has tried and failed/intolerant to all of the following:
 - Tofacitinib (criteria based)
 - Baricitinib (criteria based)
2. 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 (methotrexate not required if patient has dactylitis [inflammation of finger or toe] and/or enthesitis [inflammation of the entheses])
 - Patient has tried and failed/intolerant to at least 1 of the following:

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- Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Patient has tried and failed/intolerant to or has a contraindication to secukinumab product (criteria based)
 - Patient has tried and failed/intolerant to tofacitinib (criteria based)
3. Prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthritis
- Patient has tried and failed/intolerant to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Patient has tried and failed/intolerant to secukinumab (criteria based)
 - Patient has tried and failed/intolerant to tofacitinib (criteria based)
4. Prescriber is a gastroenterologist and patient has a diagnosis of ulcerative colitis or Crohn's disease
- Patient has tried and failed/intolerant to at least 1 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
5. Prescriber is a dermatologist and patient has a diagnosis of moderate to severe atopic dermatitis
- Patient is at least 12 years of age and weights at least 40 kilograms
 - Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to the following medications
 - At least 1 medium to super-potent/ultrahigh potency topical corticosteroid
 - At least 1 topical calcineurin inhibitor
 - Patient has tried and failed narrow-band ultraviolet B (NB-UVB) phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to at least 1 of the following systemic medications (or contraindication to all)
 - Azathioprine

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- Cyclosporine
- Methotrexate
- Mycophenolate
- Patient has tried and failed/intolerant to tralokinumab-ldrm (criteria based) OR dupilumab (criteria based)
- Patient is NOT currently on a Janus kinase inhibitor (oral or topical) or biologic (tralokinumab-ldrm or dupilumab) for atopic dermatitis

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **upadacitinib 15 mg extended-release (Rinvoq 15 mg ER)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a rheumatologist and patient has a diagnosis of rheumatoid arthritis/inflammatory arthritis, prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis, prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthritis, OR prescriber is a gastroenterologist and patient has a diagnosis of ulcerative colitis or Crohn's disease
 - Patient has responded to upadacitinib treatment as determined by prescriber
2. Prescriber is a dermatologist and patient has a diagnosis of moderate to severe atopic dermatitis
 - Patient has responded to upadacitinib treatment as determined by prescriber
 - Patient is NOT currently on a Janus kinase inhibitor (oral or topical) or biologic (tralokinumab-ldrm or dupilumab) for atopic dermatitis