

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Certolizumab (Cimzia)

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

Initiation (new start) criteria: Non-formulary **certolizumab (Cimzia)** 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 non-biologic DMARD:
 - Methotrexate
 - Sulfasalazine
 - Hydroxychloroquine
 - Leflunomide
 - Patient has tried and failed/intolerant to at least 2 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
 - Patient has tried and failed/intolerant to or contraindication to all of the following:
 - Tocilizumab (criteria based)
 - Abatacept (criteria based)
 - OR patient is a female trying to conceive, or currently pregnant or breastfeeding
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 2 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
 - Patient has tried and failed/intolerant to or contraindication to all of the following:

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- Secukinumab (criteria based)
 - Apremilast (criteria based)
 - Abatacept (criteria based) (unless documented by prescriber that patient has active psoriasis requiring biologic treatment)
 - Guselkumab (criteria based)
 - Risankizumab-rzaa (criteria based)
 - OR patient is a female trying to conceive, or currently pregnant or breastfeeding
3. Prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthritis
- Patient has tried and failed/intolerant to at least 3 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
 - Golimumab (criteria based)
 - Patient has tried and failed/intolerant to or contraindication to secukinumab (criteria based)
 - OR patient is a female trying to conceive, or currently pregnant or breastfeeding
4. Prescriber is a gastroenterologist and patient has a diagnosis Crohn's disease
- Patient has tried and failed/intolerant to or contraindication to all of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Vedolizumab
5. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
- Patient has tried and failed/intolerant to or has contraindication to all of the following:
 - Secukinumab (criteria based)
 - Guselkumab (criteria based)
 - Risankizumab-rzaa (criteria based)
 - Ustekinumab (criteria based)
 - Ixekizumab (criteria based)
 - Patient has tried and failed/intolerant to at least 2 of the following:

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- Adalimumab product (criteria based)
- Etanercept (criteria based)
- Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **certolizumab (Cimzia)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- See below, for “Continued use criteria for patients stable on the medication”

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **certolizumab (Cimzia)** 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 non-biologic DMARD:
 - Methotrexate
 - Sulfasalazine
 - Hydroxychloroquine
 - Leflunomide
 - Patient has tried and failed/intolerant to at least 2 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
 - Patient has tried and failed/intolerant to or contraindication to all of the following:
 - Abatacept (criteria based)
 - Tocilizumab (criteria based)
 - OR patient is a female trying to conceive, or currently pregnant or breastfeeding
2. Prescriber is a dermatologist or rheumatologist and patient has a diagnosis of psoriatic arthritis

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- 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 2 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
 - Patient has tried and failed/intolerant to or contraindication to all of the following:
 - Secukinumab (criteria based)
 - Apremilast (criteria based)
 - Abatacept (criteria based) (unless documented by prescriber that patient has active psoriasis requiring biologic treatment)
 - Guselkumab (criteria based)
 - Risankizumab-rzaa (criteria based)
 - OR patient is a female trying to conceive, or currently pregnant or breastfeeding
3. Prescriber is a rheumatologist and patient has a diagnosis of ankylosing spondylitis/spondyloarthritis
- Patient has tried and failed/intolerant to at least 3 of the following:
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
 - Golimumab (criteria based)
 - Patient has tried and failed/intolerant to or contraindication to secukinumab (criteria based)
 - OR patient is a female trying to conceive, or currently pregnant or breastfeeding
4. Prescriber is a gastroenterologist and patient has a diagnosis of Crohn's disease
5. Prescriber is a dermatologist and patient has a diagnosis of psoriasis
- Patient has tried and failed/intolerant to or has contraindication to all of the following:

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- Guselkumab (criteria based)
- Risankizumab-rzaa (criteria based)
- Ustekinumab (criteria based)
- Ixekizumab (criteria based)
- Patient has tried and failed/intolerant to at least 2 of the following:
 - Adalimumab product (criteria based)
 - Etanercept (criteria based)
 - Infliximab product (unless documented by prescriber that patient is unable to attend infusion appointments)

Continued use criteria for patients stable on the medication: Non-formulary **certolizumab (Cimzia)** 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, psoriatic arthritis, or ankylosing spondylitis/spondyloarthritis AND
 - If initial approval was due to female patient trying to conceive, pregnant, or breastfeeding; patient is still trying to conceive, is still pregnant, or is still breastfeeding
2. Prescriber is a gastroenterologist and patient has a diagnosis Crohn's disease
3. Prescriber is a dermatologist and patient has a diagnosis of psoriasis