

Special Authorization Criteria for Biologic Drugs



For each disease category specified below, the biologic drugs listed will only be considered for reimbursement if the patient has failed an adequate trial or experienced intolerable side effects to other prior biologic therapies.

DISEASE CATEGORY	BIOLOGIC DRUG
Juvenile Arthritis	Abrilada Actemra IV Amgevita Cosentyx Humira Hadlima Hulio Hyrimoz Idacio Orenzia IV Simlandi Yuflyma Tyenne IV
Rheumatoid Arthritis	Actemra IV Kineret Orenzia IV Rituxan Riximyo Ruxience Truxima Tyenne IV
Crohn's Disease	Entyvio IV Entyvio SC
Ulcerative Colitis	Entyvio IV Entyvio SC Xeljanz and generic tofacitinib
Multiple Sclerosis	Gilenya and generic fingolimod Kesimpta Lemtrada Mavenclad Mayzent Ocrevus Ponvory Tysabri
Non-radiographic axial spondyloarthritis (nr-axSpA)	Taltz
Macular edema secondary to retinal vein occlusion (RVO)	Vabysmo

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The Special Authorization criteria for these biologic drugs for their respective disease categories are as follows:

Juvenile Arthritis

- Abrilada, Amgevita, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma: For therapy in combination with METHOTREXATE, unless intolerable or inappropriate, in patients 2 to 17 years of age with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD, AND who has tried and failed Etanercept or Actemra SC
- Actemra IV, Tyenne IV: For patients ages 2 and older with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week, AND who has tried and failed Cosentyx or Actemra SC or Tyenne SC.
- Cosentyx: For patients ages 6 and older with a confirmed diagnosis of polyarticular juvenile arthritis (juvenile psoriatic arthritis (JPsA) or enthesitis-related arthritis (ERA)) where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND who has tried and failed Actemra SC
- Orencia IV: For patients ages 6 and older with a confirmed diagnosis of juvenile arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 15 mg/week AND at least one other DMARD, AND who have tried and failed Etanercept or Actemra SC

Rheumatoid Arthritis

- Actemra IV, Kineret, Orencia IV, Tyenne IV: For patients with a confirmed diagnosis of rheumatoid arthritis with persistent active disease where the patient has not adequately responded to Methotrexate at a dose equal to or greater than 20 mg/week AND at least one other DMARD (i.e. hydroxychloroquine, leflunomide and/or sulfasalazine) for a period of 3 months, AND who have tried and failed Cimzia or Etanercept or Adalimumab or Simponi or Actemra SC or Infliximab or Orencia SC or Tyenne SC
- Rituxan: For the treatment of patients with rheumatoid arthritis who have tried and failed or could not tolerate at least one or more anti-TNF treatment (e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab) and who are medically unable to use a Rituximab biosimilar. For Rituximab naïve patients, only a Rituximab biosimilar will be approved.
- Riximyo, Ruxience & Truxima: For the treatment of patients with RA; Trial and failure or intolerance to at least one or more anti-TNF treatment e.g. Cimzia or Etanercept or Adalimumab or Simponi or Infliximab.

Crohn's Disease

- Entyvio IV: For patients with Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate or cyclosporine) AND who have tried and failed or experienced intolerant effects to at least ONE of the following: Infliximab, Adalimumab, or Ustekinumab AND are medically unable to use Entyvio SC
- Entyvio SC: For patients with Crohn's disease or patients with moderate to severe Crohn's disease who have failed to respond to corticosteroids AND an immunosuppressant agent (azathioprine, 6-mercaptopurine, methotrexate or cyclosporine) AND who have tried and failed or experienced intolerant effects at least ONE of the following: Infliximab, Adalimumab, or Ustekinumab

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Ulcerative Colitis

- Entyvio IV: For patients with active ulcerative colitis who have failed or are intolerant to oral corticosteroid therapy AND a 5-ASA product or immunosuppressant (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) AND who have tried and failed or experienced intolerant effects to at least TWO of the following: Infliximab, Adalimumab, Simponi SC, Velsipity or Ustekinumab AND are medically unable to use Entyvio SC
- Entyvio SC: For patients with active ulcerative colitis who have failed or are intolerant to oral corticosteroid therapy AND a 5-ASA product or immunosuppressant (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) AND who have tried and failed or experienced intolerant effects to at least TWO of the following: Infliximab, Adalimumab, Simponi SC, Velsipity or Ustekinumab
- Xeljanz and generic tofacitinib: For patients with active ulcerative colitis who have failed or are intolerant to oral corticosteroid therapy AND a 5-ASA product or immunosuppressant (azathioprine, 6-mercaptopurine, methotrexate, or cyclosporine) AND who have failed or have patient-specific contraindication(s) to at least ONE of the following: infliximab, Adalimumab, Simponi SC, Velsipity and Ustekinumab

Multiple Sclerosis

- Gilenya and generic fingolimod: For the treatment of patients 10 year or older with RRMS in patients who have failed or are intolerant to one or more therapies for multiple sclerosis treatments (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera)
- Kesimpta, Ocrevus & Ponvory: For RRMS patients who have had an inadequate response to, or are unable to tolerate, one or more therapies (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera)
- Lemtrada & Mavenclad: For RRMS patients who have had an inadequate response to, or are unable to tolerate, two or more therapies (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera)
- Tysabri: For RRMS patients have had an inadequate response to, or are unable to tolerate, two or more therapies, (e.g. generic Aubagio, Avonex, Betaseron, Glatiramer, Extavia, Plegridy, Rebif, generic Tecfidera) AND have evidence of lesions on their MRI scan, an EDSS value less than 6 AND have had at least one relapse in previous year
- Mayzent: For the treatment of patients with secondary progressive multiple sclerosis with active disease as confirmed by evidence of relapses or imaging features (e.g. lesions of MRI scan, history of relapse in the last two years), have an EDSS score of less than 7 and who have tried and failed, or have intolerance or contraindication to one other agent, e.g. Avonex, Rebif, Extavia, Betaseron

Non-radiographic axial spondyloarthritis (nr-axSpA)

- Taltz: For patients with confirmed diagnosis of severe, active non-radiographic axial spondyloarthritis where symptoms are uncontrolled by NSAIDs AND who have had inadequate response or experienced intolerant effects to Cosentyx

Macular edema secondary to retinal vein occlusion (RVO)

- Vabysmo: For the treatment of macular edema secondary to retinal vein occlusion (RVO) where another anti-VEGF agent (e.g. Ranibizumab or Aflibercept) is contraindicated, not tolerated or ineffective.