TUMOR NECROSIS FACTOR ALPHA (TNF) INHIBITORS

Included Products: Avsola (infliximab-axxq), Cimzia (certolizumab-pegol), Enbrel (etanercept), Hadlima (adalimumab-bwwd), Inflectra (infliximab-dyyb), Remicade (infliximab), Renflexis (infliximab-adba), Simlandi (adalimumab-ryvk), Simponi Aria (golimumab), Yusimry (adalimumab-aqvh), generic Cyltezo 10mg and 20mg doses (generic only – adalimumab-adbm)

Created: 03/10/2022 *Revised*: 11/14/2024 Reviewed: 11/14/2024 *Updated*: 12/01/2024

Infliximab, Cimzia, and Simponi Aria are nonformulary for outpatient benefit. Prior authorization required on medical benefit.

Note: Avsola and Inflectra are preferred infliximab products. Remicade, Renflexis, and all other Remicade biosimilars require a clear reason Avsola and Inflectra cannot be used.

All Diagnoses			
Initial Criteria: All Diagnoses		If yes	If no
1.	Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?	Continue to #2.	Do not approve.
2.	Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?	Continue to renewal criteria for the submitted diagnosis.	Continue to #3.
3.	Has the risk of infections been addressed by the	Continue to #4.	Do not approve.

	following? a. Initial testing for latent TB and treatment, if necessary, before starting therapy. b. No current active infection at initiation of therapy. c. Risks and benefits documented in cases of chronic or recurrent infection		
4.	Has the treatment been initiated by or is an appropriate specialist currently supervising it? a. Ankylosing Spondylitis and Axial Spondyloarthritis: Rheumatologist b. Crohn's Disease: Gastroenterologist c. Hidradenitis Suppurativa: Dermatologist d. Juvenile Idiopathic Arthritis: Rheumatologist e. Plaque Psoriasis: Dermatologist f. Psoriatic Arthritis: Dermatologist or Rheumatologist g. Rheumatoid Arthritis: Rheumatologist h. Ulcerative Colitis: Gastroenterologist i. Uveitis: Ophthalmologist or Rheumatologist	Continue to #5	Do not approve.
5.	Is the requested agent to be used in combination with another biologic or Otezla?	Do not approve.	Continue to #6.
6.	Is the request for Avsola or Inflectra?	Continue to #11.	Continue to #7.
7.	Is the request for a non-preferred infliximab product (such as Remicade or Renflexis)?	Do not approve.	Continue to #8.
8.	Is the member under the age of 21 or does the member have contraindications to infliximab?	Continue to #9.	Do not approve.
9.	Is the request for adalimumab biosimilar?	Continue to #11.	Continue to #10.

10.	Has the member failed or have contraindication to adalimumab biosimilar?	Continue to #11.	Do not approve.
11.	Proceed to specific criteria for the submitted indication.		

Ankylosing Spondylitis and Axial Spondyloarthritis

Initial Criteria		If yes	If no
1.	Does the member have ankylosing spondylitis or axial spondyloarthritis (radiographic or non-radiographic)? Diagnosis is definitive if the following are met: a. Back pain and stiffness for more than 3 months AND b. Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive.	Continue to #2.	Do not approve.
2.	Does the member have moderate to severe active disease at baseline, as evidenced by an objective test such as the BASDAI?	Continue to #3.	Do not approve.
3.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #5.	Continue to #4.
4.	Has the member tried and failed conventional therapy with both of the following: a. At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless	Continue to #5.	Do not approve.

	contraindicated, and b. Physical therapy/exercise program		
5.	Is the request for infliximab?	Approve for 12 months	Approve for 6 months.
Renewal Criteria		If yes	If no
1.	Does the member have significant improvement in signs and symptoms of AS/SpA and/or functioning, such as ASAS40 or 2-point improvement in BASDAI?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Crohn's Disease

Initial Criteria		If yes	If no
1.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #3.	Continue to #2.
2.	Does the member have moderate to severe Crohn's disease?	Continue to #3.	Do not approve..
3.	Is the request for infliximab?	Approve for 12 months.	Approve for 6 months.
Renewal Criteria		If yes	If no
1.	Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?	Continue to #2.	Do not approve.

2.	Approve for 12 months.		

Hidradenitis Suppurativa

Note: The following criteria for hidradenitis suppuritiva is for infliximab infusions. Adalimumab would require all this AND a reason infliximab cannot be used (or previously failed). If a member is already on adalimumab, a change to infliximab will not be required.

Initial Criteria		If yes	If no
1.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #3.	Continue to #2.
2.	Has the member tried and failed a 3 month treatment course of ALL of the following? a. One of the following combination oral antibiotic regimens: - Clindamycin (or another tetracycline) + rifampin - Moxifloxacin + metronidazole + rifampin b. Intralesional corticosteroid injections c. Antiandrogenic hormonal treatments for women (oral contraceptives, metformin, finasteride, or spironolactone) d. Acitretin if not of child-bearing potential	Continue to #3.	Do not approve.
3.	Approve infliximab for 12 months.		
Renewal Criteria		**If yes**	**If no**
1.	Has there been a significant treatment response	Approve for 12	Do not approve.

	as defined as ONE of the following? a. A reduction of 25% or more in the total abscess and inflammatory nodule count; OR b. No increase in abscesses and draining fistulas	months.	

Juvenile Idiopathic Arthritis

Initial Criteria		If yes	If no
1.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #6.	Continue to #2.
2.	Does the member have juvenile idiopathic arthritis with active systemic features of juvenile idiopathic arthritis, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?	Continue to #4.	Continue to #3.
3.	Does the member have juvenile idiopathic arthritis without active systemic features of juvenile idiopathic arthritis?	Continue to #5.	Do not approve.
4.	Has the member tried and failed systemic corticosteroids?	Continue to #5.	Do not approve.
5.	Has the member tried and failed a 3 month trial of methotrexate or leflunomide for at least 3 months (or have a contraindication to both)?	Continue to #6.	Do not approve.
6.	Is the request for infliximab?	Approve for 12	Approve for 6

		months.	months.
Renewal Criteria		If yes	If no
1.	Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Non-infectious Uveitis

Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of non-infectious, intermediate, posterior or panuveitis?	Continue to #2.	Do not approve.
2.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #4.	Continue to #3.
3.	Has the member failed the following? a. Topical glucocorticoids for at least 1 month OR periocular steroid injections, and b. Immunomodulator: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate.	Continue to #4.	Do not approve.
4.	Is the request for infliximab?	Approve for 12 months.	Approve for 6 months.
Renewal Criteria		If yes	If no

1.	Is there documentation that disease activity has been controlled, such as a lack of inflammation, no new inflammatory vascular lesions, no vitreous haze or decreases in visual acuity?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Plaque Psoriasis

Initial Criteria		If yes	If no
1.	Does the member have chronic, moderate to severe plaque psoriasis at baseline with functional impairment and one or more of the following? a. At least 10% body surface area involved b. Hand, foot, face, or mucous membrane involvement	Continue to #4.	Continue to #2.
2.	Is the member under the age of 21?	Continue to #3.	Do not approve. Plaque psoriasis without functional impairment and hand, foot, face, or mucous membrane involvement or affecting 10% or more of body surface area is not covered for treatment by the

			Oregon Health Plan.
3.	Is it medically necessary or medically appropriate to treat the psoriasis due to contributing factors to a comorbid condition or impact on growth, learning, or development?	Continue to #4.	Do not approve based on medical necessity or appropriateness.
4.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #7.	Continue to #5.
5.	Has the member tried and failed high-potency topical corticosteroids, such as augmented betamethasone cream 0.05%, desoximetasone 0.25% cream, or clobetasol AND a non-steroid topical? a.	Continue to #6.	Do not approve.
6.	Has the member tried and failed ONE of the following?: a. An oral DMARD (methotrexate, cyclosporine, or acitretin) OR b. Phototherapy	Continue to #7	
7.	Is the request for infliximab?	Approve for 12 months.	Approve for 6 months.
Renewal Criteria		If yes	If no
1.	Has the member experienced a clinically significant response, such as PASI-75 (75% improvement) and/or is there evidence of functional improvement?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Psoriatic Arthritis

Initial Criteria		If yes	If no
1.	Does the member have psoriatic arthritis based on at least 3 out of 5 of the following? a. Psoriasis (1 point for personal or family history, 2 points for current) b. Psoriatic nail dystrophy c. Negative test result for RF d. Dactylitis (current or history) e. Radiological evidence of juxta-articular new bone formation	Continue to #2.	Do not approve.
2.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #4.	Continue to #3.
3.	Has the member failed or have contraindications to conventional management with all of the following? a. NSAIDs, and b. Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.	Continue to #4.	Do not approve..
4.	Is the request for infliximab?	Approve for 12 months.	Approve for 6 months.
Renewal Criteria		If yes	If no
1.	Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Rheumatoid Arthritis

Initial Criteria		If yes	If no
1.	Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?	Continue to #2.	Do not approve.
2.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #5.	Continue to #3.
3.	Has the member tried and failed or have contraindications to methotrexate dosed at least 20mg per week for at least 8 weeks?	Continue to #4.	Do not approve.
4.	Has the member tried and failed or have contraindications to the following: leflunomide, hydroxychloroquine, or sulfasalazine?	Continue to #5.	Do not approve.
5.	Is the requested product being prescribed along with at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless contraindicated?	Continue to #6.	Do not approve.
6.	Is the request for infliximab?	Approve for 12 months.	Approve for 6 months.
Renewal Criteria		**If yes**	**If no**
1.	Has the member experienced 20% or greater improvement in tender joint count and swollen	Continue to #2.	Do not approve.

	joint count?		
2.	Approve for 12 months.		

Ulcerative Colitis

Initial Criteria		If yes	If no
1.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #3.	Continue to #2.
2.	Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria? a. Moderate = greater than or equal to 4 stools daily. b. Severe = greater than or equal to 6 bloody stools daily and evidence of toxicity such as fever, anemia, elevated ESR, or tachycardia.	Continue to #3.	Do not approve.
3.	Is the request for infliximab?	Approve for 12 months.	Approve for 6 months.
Renewal Criteria		**If yes**	**If no**
1.	Has the member demonstrated a significant response including the following? a. Decrease in bloody stools per day and/or b. Elimination of signs of toxicity	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Quantity Limits

Enbrel:

- **Four syringes per 28 days all strengths.**
- **Exceptions:**

» New starts:

– Moderate to severe plaque psoriasis: Eight syringes per 28 days are

authorized for the initial 3 month approval.

Adalimumab biosimilar and Humira:

- **Two syringes per 28 days all strengths.**
- **Exceptions:**

» New starts:

– Crohn's Disease or ulcerative colitis: 6 syringes for a 28 day supply at initiation will be authorized.

– Moderate to severe plaque psoriasis: 3 syringes for a 28 day supply at initiation will be authorized.

– Ulcerative colitis: 6 syringes for a 28 day supply at initiation will be authorized.

– Uveitis: 6 syringes for a 28 day supply at initiation will be authorized.

– Hidradenitis suppurativa: 6 syringes for a 28 day supply at initiation will be authorized followed by 4 syringes every 28 days after that.

Simponi Aria:

- **2mg/kg every 8 weeks.**
- **Exceptions:**

» Rheumatoid arthritis: 2mg/kg on weeks 0 and 4 at initiation will be authorized (4 doses over 6 months).

REFERENCES

- 2019 Update of the American College of Rheumatology/Spondylitis Association of America/ Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis
- ACG Clinical Guideline: Management of Crohn's Disease in Adults (2018)
- European S1 guideline for the treatment of hidradenitis suppurativa/acne inversa
- North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations (2019)

» Part 1: diagnosis and evaluation

» Part 2: medical management

- 2013 Update of the 2011 ACR Recommendations for the Treatment of Juvenile Idiopathic Arthritis
- 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis
- Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities (2019)
- Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics (2019)
- 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
- 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
- ACG Clinical Guideline: Ulcerative Colitis in Adults (2019)

AAO Uveitis Guidelines: Immunomodulatory Therapy (2018)