

Cytokine and CAM Antagonists: Tumor Necrosis Factor (TNF) Inhibitors Utilization Management Criteria

Therapeutic	Cytokine and CAM Antagonists: Tumor Necrosis Factor (TNF) Inhibitors						
Class:							
Non-Preferred	Adalimumab Products Abrilada (Adalimumab-afzb), Adalimumab-adbm (Quallent), Amjevita						
Agents:	(Adalimumab-atto), Hulio (adalimumab-fkjp), Hyrimoz (Adalimumab-adaz), Idacio (Adalimumab-aacf), Simlandi (adalimumab-ryvk), Yuflyma (Adalimumab-aaty), Yusimry (Adalimumab-aqvh), Cyltezo (adalimumab-adbm), adalimumab-adbm (Boehringer Ingelheim brand)						
	Certolizumab Products Cimzia (Certolizumab pegol)						
	Infliximab Products Avsola (Infliximab-aaxq), Inflectra (Infliximab-dyyb), Remicade (Infliximab), Renflexis (Infliximab-abda), Zymfentra (Infliximab-dyyb)						
	Golimumab Products Simponi (Golimumab)						
Preferred Agents:	Adalimumab Products						
	Adalimumab-adaz, Hadlima (Adalimumab-bwwd), Humira (adalimumab) Etanercept Products Enbrel (etanercept) Infliximab Products Infliximab						
Implementation	HIIIAHIAD						
Date:	1/1/2026						
Prepared For:	CT Medicaid						
PDL Status:	Non-preferred						
	The tumor necrosis factor (TNF) alpha inhibitors are monoclonal antibodies that bind to human TNF and inhibit the endogenous activity related to the induction of proinflammatory cytokines, enhancement of leukocyte migration, and activation of neutrophils and eosinophils. Collectively, these agents are approved for a broad range of immune-mediated conditions.						
Purpose:	Adalimumab has the most approved indications, including ankylosing spondylitis, Crohn's disease, hidradenitis suppurativa, plaque psoriasis, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, and uveitis. All agents are administered via subcutaneous injection except for infliximab and golimumab (Simponi Aria®), which are given intravenously. Biosimilars are approved for adalimumab, etanercept, and infliximab, but biosimilar etanercept is not yet marketed.						
	Some warnings and precautions vary among the TNF inhibitors, but all agents have boxed warnings regarding an increased risk for serious infection and malignancy. The						



most commonly reported adverse events include infection and infusion-related and injection site reactions.

Guidelines generally include TNF inhibitors among the agents recommended for either first- or second-line treatment of these agents' approved indications. Few guidelines suggest a preference for specific TNF inhibitors over others.

Table 1. Cytokine and CAM Antagonists: Tumor Necrosis Factor (TNF) Inhibitors

Generic Name	Brand Name				Арр	Route of Administration	Biosimilar Availability						
Generic Name		AS	CD	HS	nr- axSpA	JIA	PsA	PsO	RA	UC	UV		
Adalimumab	Humira®	✓	✓	✓		✓	✓	✓	✓	✓	✓	SC	Yes
Adalimumab-aacf	Idacio®*	✓	✓	✓		✓	✓	✓	✓	✓	✓	SC	N/A
Adalimumab-aaty	Yuflyma®*	✓	√	√		✓	✓	✓	✓	√	✓	SC	N/A
Adalimumab-adaz	Hyrimoz®*	√	✓	√		✓	✓	✓	✓	✓	✓	SC	N/A
Adalimumab- adbm	Cyltezo®*	√	√	√		✓	√	√	✓	√	✓	SC	N/A
Adalimumab-afzb	Abrilada™*	✓	✓	✓		✓	✓	✓	✓	✓	✓	SC	N/A
Adalimumab- aqvh	Yusimry™*	√	√	√		✓	√	√	✓	✓	✓	SC	N/A
Adalimumab-atto	Amjevita®*	✓	✓	✓		✓	✓	✓	✓	✓	✓	SC	N/A
Adalimumab- bwwd	Hadlima™*	√	√	✓		√	√	✓	✓	✓	✓	SC	N/A
Adalimumab-fkjp	Hulio®*	✓	✓	✓		✓	✓	✓	✓	✓	✓	SC	N/A
Adalimumab-ryvk	Simlandi®*	✓	✓	✓		✓	✓	✓	✓	✓	✓	SC	N/A
Certolizumab pegol	Cimzia®	√	√		√	✓	✓	✓	✓			SC	No
Etanercept	Enbrel [®]	✓				✓	✓	✓	✓			SC	No
Golimumab	Simponi®	✓					✓		✓	√		SC	No
Golimumab	Simponi Aria®	√				✓	✓		✓			IV	No
Infliximab	Remicade®	✓	✓				✓	✓	✓	✓		IV	Yes
Infliximab-aaxq	Avsola®±	✓	√				✓	✓	√	✓		IV	N/A
Infliximab-dyyb	Inflectra®±	✓	√				✓	✓	✓	√		IV	N/A
Infliximab-abda	Renflexis®±	✓	✓				✓	✓	✓	✓		IV	N/A
Infliximab-dyyb	Zymfentra™		✓							√		SC	N/A

[±]FDA approved biosimilar to Remicade®

Abbreviations: AS, ankylosing spondylitis; CD, Crohn disease; HS, hidradenitis suppurativa; IV, intravenous; nr-axSpA, non-radiographic axial spondyloarthritis; pJIA, polyarticular juvenile idiopathic arthritis; PsO, psoriasis; PsA, psoriatic arthritis; RA, rheumatoid arthritis; SC, subcutaneous; UC, ulcerative colitis; UV, uveitis.

This table does not differentiate between adult and pediatric indications. In some cases, biosimilars may have indications that differ from their reference products, especially concerning approved age ranges.

^{*}FDA approved biosimilar to Humira®



All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to <u>initiate</u> therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes.

General Approval Criteria:

- Claim is for a preferred agent OR
- Requested agent is NOT used in combination with other targeted immunomodulators AND
- Patient does NOT have active TB, or other active infection prior to initiation AND
- Requested quantity in accordance with FDA approved product labelling AND

Initial Therapy - All the following must be met:

For Non-preferred Adalimumab products

- Prescribed by or in consultation with a specialist familiar with the treated disease state
- Must provide medical reason patient cannot utilize a preferred adalimumab product (e.g. allergy, contraindication, drug interaction, history of intolerance or adverse event, preferred drug is not approved for patient age/weight/indication)

For Non-preferred Infliximab products

- Prescribed by or in consultation with a specialist familiar with the treated disease state
- Must provide medical reason patient cannot utilize preferred infliximab product (e.g. allergy, contraindication, drug interaction, history of intolerance or adverse event, preferred drug is not approved for patient age/weight/indication)

For Zymfentra

- Must provide reason patient cannot utilize intravenous infliximab
- Diagnosis of moderate to severely active ulcerative colitis **OR** moderately to severely active Crohn's disease
- Patient is 18 years and older

For Cimzia

- · Prescribed by or in consultation with a specialist familiar with the treated disease state
- Must provide medical reason patient cannot use a preferred tumor necrosis factor (TNF) Inhibitor (e.g. allergy, contraindication, drug interaction, history of intolerance or adverse event, stable disease where change in therapy risks destabilization, preferred drug is not approved for patient age/weight/indication, previous trial and failure of a preferred TNF product)
- Age restrictions:
 - For Crohn's disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, nonradiographic axial spondyloarthritis, and plaque psoriasis patient is 18 years and older
 - For polyarticular juvenile idiopathic arthritis patient is 2 years and older

For Simponi

- Prescribed by or in consultation with a specialist familiar with the treated disease state
- Must provide medical reason patient cannot use a preferred tumor necrosis factor (TNF) Inhibitor (e.g. allergy, contraindication, drug interaction, history of intolerance or adverse event, stable disease where change in therapy risks destabilization, preferred drug is not approved for patient age/weight/indication, previous trial and failure of a preferred TNF product)
- Age and weight restrictions:
 - For rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis patient is 18 years and older
 - For ulcerative colitis: adults and pediatric patients weighing at least 15 kg



For Simponi Aria

- · Prescribed by or in consultation with a specialist familiar with the treated disease state
- Must provide medical reason patient cannot use a preferred tumor necrosis factor (TNF) Inhibitor (e.g. allergy, contraindication, drug interaction, history of intolerance or adverse event, stable disease where change in therapy risks destabilization, preferred drug is not approved for patient age/weight/indication, previous trial and failure of a preferred product)
- Age restrictions:
 - For rheumatoid arthritis and ankylosing spondylitis patient is 18 years and older
 - For psoriatic arthritis and polyarticular juvenile idiopathic arthritis patient is 2 years and older

Initial PA length: 1 year

Exclusion Criteria: Approval criteria not met

Continuation Therapy: Documentation of continued clinical benefit **AND** Documented compliance on current therapy regimen (*Exceptions: Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred adalimumab and infliximab formulations*)

Continuation Length: 1 year

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Revision History

Date	Version	Revisions
11/7/25	V1	Document approved by DSS