SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Tumor Necrosis Factor (TNF) Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
Revised Date:	October 5, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐ Existing Criteria ☒ Revision of Existing Criteria ☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Tumor necrosis factor (TNF) inhibitors are agents that bind to the TNF alpha receptor and interfere with cytokine binding. The interference of TNF inhibits the cytokine driven inflammatory response and helps alleviate the symptoms of several auto-immune disorders. Although these agents interact with the same biological target and pathway, the structure and mechanism of action of these agents vary. There are multiple agents in this class, and while there is a great deal of overlap in their indications, there are also unique indications for each. Each agent is administered through either the subcutaneous route or intravenous route, depending on the indication. These agents display a wide range of potentially serious adverse effects, including infusion reactions, neutropenia, infection, heart failure, malignancy, and the development of autoantibodies against the agent leading to decreased efficacy over time. The TNF inhibitors are commonly reserved for participants with moderate-to-severe disease after failure to control disease progression with first line therapies.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Enbrel®	• **Adalimumab**
• Humira®	• **Amjevita™**
• Infliximab	• Avsola®
• Renflexis®	• Cimzia®
	• **Cyltezo®**
	• **Hadlima™**
	• **Hulio®**
	• **Hyrimoz®**
	• **Idacio®**
	• Inflectra®
	• Remicade®
	• Simponi®
	• Simponi ARIA®
	• **Yuflyma®**

	• **Yusimry™**

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Targeted Immune Modulators, Tumor Necrosis Factor (TNF) Inhibitors
- Age range: All appropriate MO HealthNet participants aged 18 years or older unless indicated otherwise

Approval Criteria

- Documented compliance on current therapy **OR**
- Failure to achieve desired therapeutic outcomes with trial on 2 preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Reference Product	Biosimilars	Indications for Reference Product
Humira® (Adalimumab)	• **Adalimumab** • **Amjevita™** • **Cyltezo®** • **Hadlima™** • **Hulio®** • **Hyrimoz®** • **Idacio®** • **Yuflyma®** • **Yusimry™**	• Ankylosing spondylitis • Crohn's disease (aged 6 or older) • Hidradenitis suppurativa (aged 12 or older) • Juvenile idiopathic arthritis (aged 2 or older) • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis (aged 5 or older) • Uveitis (aged 2 or older)
Cimzia® (certolizumab pegol)		• Ankylosing spondylitis • Crohn's disease • Non-radiographic axial spondyloarthritis • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis
Enbrel® (Etanercept)		• Ankylosing spondylitis • Plaque psoriasis (aged 4 or older) • Polyarticular juvenile idiopathic arthritis (aged 2 or older) • Psoriatic arthritis • Rheumatoid arthritis
Simponi®,Simponi ARIA® (Golimumab)		• Ankylosing spondylitis • Juvenile idiopathic arthritis (aged 2 or older) – Simponi ARIA only • Psoriatic arthritis (Simponi ARIA aged 2 or older) • Rheumatoid arthritis • Ulcerative colitis – Simponi only
Avsola® Inflectra® Remicade® Renflexis®		• Ankylosing spondylitis • Crohn's disease (aged 6 or older) • Plaque psoriasis • Psoriatic arthritis

Reference Product	Biosimilars	Indications for Reference Product
(Infliximab)		• Rheumatoid arthritis • Ulcerative colitis (aged 6 or older)

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: Targeted Immune Modulators, Tumor Necrosis Factor Alpha Inhibitors”, Gainwell Technologies; Last updated April 14, 2023.
- Evidence-Based Medicine Analysis: “Targeted Immune Modulators (Biologics – DMARDS [IL-6, TNF, IL-17A Antibody/IL-17 RA & IL-23/IL-12, JAK Inhibitors, CAPs agents, Select/Other Agents])”. UMKC-DIC; March 2023.
- Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Vol. 73, No. 7, July 2021, pp 924–939. DOI 10.1002/acr.24596.
- Amjevita (adalimymab-atto) [package insert]. Thousand Oaks, CA: Amgen, Inc; April 2023.
- Avsola (infliximab-axxq) [package insert]. Thousand Oaks, CA: Amgen, Inc; September 2021.
- Cimzia (certolizumab pegol) [package insert]. Smyrna, GA: UCB Inc; December 2022.
- Enbrel (etanercept) [package insert]. Thousand Oaks, CA: Immunex Corporation; June 2022.
- Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc; February 2021.
- Inflectra (infliximab-dyyb) [package insert]. New York, NY: Pfizer Inc; June 2021.
- Remicade (infliximab) [package insert]. Horsham, PA: Janssen Biotech, Inc; October 2021.
- Renflexis (infliximab-abda) [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; January 2022.
- Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc; September 2019.
- Simponi ARIA (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc; February 2021.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.