SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Tumor Necrosis Factor (TNF) Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	June 17, 2021
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, including rheumatoid arthritis, psoriasis, and ankylosing spondylitis. Although these agents interact with the same biological target and pathway, the structure and mechanism of action of these agents vary. TNF inhibitors have demonstrated equal efficacy to methotrexate (MTX) in treating rheumatoid arthritis and when TNF inhibitors and MTX are used in combination a greater level of efficacy is achieved than either achieves alone. 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, intravenous route, or either 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 first line therapies.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Enbrel®	• Avsola®
• Humira®	• Cimzia®
	• Inflectra®
	• Remicade®
	• Renflexis®
	• Simponi®
	• Simponi ARIA®

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**
- Documented diagnosis of rheumatoid arthritis:
  - Adequate therapeutic trial of methotrexate **OR**
  - Contraindication to methotrexate therapy **OR**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Generic	Brand	Indication
Adalimumab	Humira®	• Ankylosing spondylitis • Crohn's disease (aged 6 or older) • Hidradenitis suppurativa (aged 12 or older) • Plaque psoriasis • Polyarticular juvenile idiopathic arthritis (aged 2 or older) • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis **(aged 5 or older)** • Uveitis (aged 2 or older)
Certolizumab Pegol	Cimzia®	• Ankylosing spondylitis • Crohn's disease • Non-radiographic axial spondyloarthritis • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis
Etanercept	Enbrel®	• Ankylosing spondylitis • Plaque psoriasis (aged 4 or older) • Polyarticular juvenile idiopathic arthritis (aged 2 or older) • Psoriatic arthritis • Rheumatoid arthritis
Golimumab	Simponi®	• Ankylosing spondylitis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis
Golimumab	Simponi ARIA®	• Ankylosing spondylitis • **Juvenile idiopathic arthritis (aged 2 or older)** • Psoriatic arthritis (aged 2 or older) • Rheumatoid arthritis

Generic	Brand	Indication
Infliximab	Remicade®	• Ankylosing spondylitis • Crohn's disease (aged 6 or older) • Juvenile idiopathic arthritis (aged 4 or older) • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis (aged 6 or older)
Infliximab-abda	Renflexis®	• Ankylosing spondylitis • Crohn's disease (aged 6 or older) • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis (aged 6 or older)
Infliximab-axxq	Avsola®	• Ankylosing spondylitis • Crohn's disease (aged 6 or older) • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis (aged 6 or older)
Infliximab-dyyb	Inflectra®	• Ankylosing spondylitis • Crohn's disease (aged 6 or older) • Plaque psoriasis • Psoriatic arthritis • 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

1. Evidence-Based Medicine and Fiscal Analysis: “Targeted Immune Modulators: Tumor Necrosis Factor (TNF) Inhibitors – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
2. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783
3. Evidence-Based Medicine Analysis: “Targeted Immune Modulators (Biologics – DMARDS)”. UMKC-DIC; April 2021.
4. Humira [package insert]. North Chicago, IL: AbbVie Inc; February 2021.
5. Cimzia [package insert]. Smyrna, GA: UCB Inc; September 2019.
6. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; April 2021.
7. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc; September 2019.
8. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc; February 2021.
9. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc; May 2020.
10. Renflexis [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; February 2021.
11. Inflectra [package insert]. New York, NY: Pfizer; June 2019.
12. USPDI, Micromedex; 2021.
13. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.