PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Inflammatory Conditions Preferred Specialty Management Policy for FLEX Formulary

* For Non-Preferred adalimumab products, refer to the *Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy for FLEX Formulary*.

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OVERVIEW

Several products are available for use in inflammatory conditions such as rheumatoid arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis.[1-20] This policy involves the use of the products listed above.

The FDA-approved indications for each product listed in this policy are documented in Appendix A. For more information on criteria within a Prior Authorization program by specific condition refer to the respective standard *Prior Authorization Policy*.

POLICY STATEMENT

For all medications, this program requires the patient to meet the respective standard *Prior Authorization Policy* criteria. Additionally, this program requires trial(s) of the Preferred Product(s) according to the table below when clinically appropriate, prior to the approval of the Non-Preferred Products. There are also situations when trials of Non-Preferred Products will be considered; see criteria below. Other details of the program are as follows:

- **Continuation of Therapy:** Approval for a patient continuing therapy with a **Non-Preferred** subcutaneous or oral Product must be supported with verification, noted in the criteria as either **[verification in prescription claims history required]** or, if not available, as **[verification by prescriber required]**.
  - If the patient has at least 130 days of prescription claims history on file, claims history must support that the patient has received the Non-Preferred Product for the specified period of time (90 or 120 days) within a 130-day look-back period; OR
  - When 130 days of the patient's prescription claim file is unavailable for verification, the prescriber must verify that the patient has been receiving the Non-Preferred Product for a specified period of time (90 or 120 days), AND that the patient has been receiving the Non-Preferred Product via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to the Non-Preferred Product).
  - For a patient continuing therapy, other conditions may also apply. Refer to criteria below.
- **Approval Duration:** All approvals for continuation of therapy for Preferred and Non-Preferred Products are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other Products, noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

Automation: None.

Preferred and Non-Preferred Products.[¥]

[¥] For Non-Preferred Products, refer to the *Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy for FLEX Formulary*; RA – Rheumatoid arthritis; [^] A trial of more than one adalimumab product counts as ONE Preferred Product; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Nonradiographic axial spondyloarthritis; PsA – Psoriatic arthritis; CD – Crohn's disease; UC – Ulcerative colitis; SC – Subcutaneous; [#] Pen and syringe; PJIA – Polyarticular juvenile idiopathic arthritis; [*] The prescriber must provide written documentation supporting the trial of Preferred Products, noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts; PSM – Preferred Specialty Management.

RECOMMENDED EXCEPTION CRITERIA

REFERENCES

1. Actemra® subcutaneous injection [prescribing information]. South San Francisco, CA: Genentech; March 2021.
2. Cimzia® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; March 2021.
3. Cosentyx® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; June 2020.
4. Enbrel® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; June 2023.
5. Humira® subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; February 2021.
6. Inflectra™ intravenous injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; August 2020.
7. Kevzara™ subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron/sanofi Aventis; April 2018.
8. Kineret® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Swedish Orphan Biovitrium; December 2020.
9. Orencia® subcutaneous injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; June 2020.
10. Otezla® tablets [prescribing information]. Thousand Oaks, CA: Amgen; December2021.
11. Remicade® intravenous injection [prescribing information]. Malvern, PA: Janssen Biotech; May 2020.
12. Renflexis® intravenous injection [prescribing information]. Whitehouse Station, NJ: Merck/Samsung Bioepsis; March 2021.
13. Rituxan® intravenous injection [prescribing information]. South San Francisco, CA: Genentech; September 2020.
14. Siliq™ subcutaneous injection [prescribing information]. Bridgewater, NJ: Valeant; June 2020.
15. Simponi® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; September 2019.
16. Simponi™ Aria® intravenous injection [prescribing information]. Horsham, PA: Janssen Biotech; February 2021.
17. Stelara® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; December 2020.
18. Taltz® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; March 2021.
19. Tremfya™ subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; July 2020.
20. Xeljanz®/Xeljanz XR tablets/extended release tablets [prescribing information]. New York, NY: Pfizer; October 2020.
21. Ilumya™ subcutaneous injection [prescribing information]. Whitehouse Station, NJ: Sun/Merck; April 2021.
22. Rinvoq® tablets/Rinvoq LQ oral solution [prescribing information]. North Chicago, IL: AbbVie; April 2024.
23. Zeposia® capsules [prescribing information]. Summit, NJ: Celgene; May 2021.
24. Sotyktu™ tablets [prescribing information]. Princeton, NJ: Bristol Myers Squibb; September 2022.
25. Velsipity® tablets [prescribing information]. New York, NY: Pfizer; October 2023.
26. Omvoh™ intravenous infusion and subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; October 2023.
27. Entyvio® subcutaneous injection and intravenous infusion [prescribing information]. Lexington, MA: Takeda; September 2023.
28. Zymfentra™ subcutaneous injection [prescribing information]. Yeonsu-gu, Incheon: Celltrion; October 2023.

APPENDIX A

Table 1. Approved TNFis for Targeted Indications.[*]

TNFis – Tumor necrosis factor inhibitors; [*] Refer to the selected standard *Inflammatory Conditions Prior Authorization Policies* for the specific patient population approved for each indication; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis; [^] Maintenance dosing only.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.[*]
IL – Interleukin; [*] Refer to the selected standard *Prior Authorization Policies* for the specific patient population approved for each indication; nr-axSpA – Non-radiographic spondyloarthritis; [^] Maintenance dosing only; [#] Induction dosing only.

Table 3. Approved Oral tsDMARDs for Targeted Indications.[*]
tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; [*] Refer to the selected standard *Prior Authorization Policies* for the specific patient population approved for each indication; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Nonradiographic axial spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis; [#] Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.[*]
[*] Refer to the selected standard *Prior Authorization Policies* for the specific patient population approved for each indication; ^ Indicated in polyarticular and systemic JIA; [#] Indicated in polyarticular JIA; [¥] Maintenance dosing only.