

This policy applies to the following:

Standard Control (SF)	Value (VF)	ACSF Chart (ACSFC)	✓	Medical Benefit	Medicare Part B	Reference # 4957-D
Preferred Drug Plan Design (PDPD)	Managed Medicaid Template (MMT)	SF Chart (SFC)	✓	Medical Benefit: Biosimilars First	Medicare Part B: Biosimilars First	
Advanced Control Specialty (ACSF)	Marketplace (MF)	VF Chart (VFC)		Medical Benefit: Add-on	Medicare Part B: Add-on	
Balanced (BF)	New to Market (NTM)	IVL		Medical Benefit: Managed Medicaid	Aetna Health Exchange (AHE)	

EXCEPTIONS CRITERIA DISEASE-MODIFYING ANTIRHEUMATIC DRUG PRODUCTS

PREFERRED PRODUCTS: ENTYVIO, ILUMYA, SIMPONI ARIA, STELARA IV

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the disease-modifying antirheumatic drug (DMARD) products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with Cimzia vial. For plaque psoriasis, this program applies to all members requesting treatment with a targeted product. For all other indications, this program applies to all members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Product(s)
Preferred*	<ul style="list-style-type: none"> • Entyvio (vedolizumab) • Ilumya (tildrakizumab-asmn) • Simponi Aria (golimumab, intravenous) • Stelara IV (ustekinumab)**
Targeted	<ul style="list-style-type: none"> • Actemra (tocilizumab) • Cimzia (certolizumab pegol) • Orencia (abatacept)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

**Stelara IV is indicated for a one time induction dose for Crohn's disease and ulcerative colitis.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Cimzia, when any of the following criteria are met:

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	Advanced Control Specialty (ACSF)	Marketplace (MF)	VF Chart (VFC)		Medical Benefit: Add-on	Medicare Part B: Add-on	
	Balanced (BF)	New to Market (NTM)	IVL		Medical Benefit: Managed Medicaid	Aetna Health Exchange (AHE)	

1. For prefilled syringe request, member is currently receiving treatment with Cimzia prefilled syringes excluding when the requested targeted product is obtained as samples or via manufacturer’s patient assistance programs, unless the request is for plaque psoriasis.
2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Simponi Aria, and Stelara (IV) where the product’s indications overlap.
3. Member is currently pregnant or breastfeeding.

B. For all other targeted products, when any of the following criteria are met:

1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer’s patient assistance programs.
2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Simponi Aria, and Stelara (IV) where the product’s indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix).

III. Appendix: Clinical reasons to avoid TNF inhibitors

- History of demyelinating disorder
- History of congestive heart failure
- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- History or risk of lymphoma or other malignancy
- History of being a primary non-responder to a TNF inhibitor

REFERENCES

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
3. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceutical America, Inc.; August 2021.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2020.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; December 2021.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2020.