This policy applies to the following:

	Standard Opt-in	✓	ACSF	✓	VF		Marketplace
	Standard Opt-in NTMB	✓	PDPD		MMT		Medical Benefit
	Standard Opt-out		Generics First				Medical Benefit: Managed Medicaid

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EXCEPTIONS CRITERIA

DISEASE-MODIFYING ANTIRHEUMATIC DRUGS FOR AUTOIMMUNE CONDITIONS

PREFERRED PRODUCTS FOR ANKYLOSING SPONDYLITIS: COSENTYX, ENBREL AND HUMIRA

PREFERRED PRODUCTS FOR CROHN'S DISEASE: PRIMARY: HUMIRA SECONDARY: STELARA

PREFERRED PRODUCTS FOR PSORIASIS: HUMIRA, OTEZLA, SKYRIZI, STELARA AND TALTZ

PREFERRED PRODUCTS FOR PSORIATIC ARTHRITIS: COSENTYX, ENBREL, HUMIRA AND OTEZLA

PREFERRED PRODUCTS FOR RHEUMATOID ARTHRITIS: ENBREL, HUMIRA, KEVZARA, ORENCIA (SC)/ORENCIA CLICKJECT AND XELJANZ/XELJANZ XR

PREFERRED PRODUCTS FOR ULCERATIVE COLITIS: HUMIRA, SIMPONI

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 adult 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

Indication	Primary Preferred Product	Secondary Preferred Product	Targeted Product(s)
Plaque psoriasis	• **Humira** (adalimumab) • **Otezla** (apremilast) • **Skyrizi** (risankizumab-rzaa) • **Stelara** (ustekinumab) • **Taltz** (ixekizumab)	• **None**	• **Cimzia** (certolizumab pegol) • **Cosentyx** (secukinumab) • **Enbrel** (etanercept) • **Ilumya** (tildrakizumab-asmn) • **Inflectra** (infliximab-dyyb) • **Renflexis** (infliximab-abda) • **Siliq** (brodalumab) • **Tremfya** (guselkumab)

This policy applies to the following:

	Standard Opt-in	✓	ACSF	✓	VF		Marketplace
	Standard Opt-in NTMB	✓	PDPD		MMT		Medical Benefit
	Standard Opt-out		Generics First				Medical Benefit: Managed Medicaid

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Ankylosing spondylitis	• **Cosentyx** (secukinumab) • **Enbrel** (etanercept) • **Humira** (adalimumab)	• **None**	• **Cimzia** (certolizumab pegol) • **Inflectra** (infliximab-dyyb) • **Renflexis** (infliximab-abda) • **Simponi** (golimumab)
Psoriatic arthritis	• **Cosentyx** (secukinumab) • **Enbrel** (etancercept) • **Humira** (adalimumab) • **Otezla** (apremilast)	• **None**	• **Cimzia** (certolizumab pegol) • **Inflectra** (infliximab-dyyb) • **Orencia/Orencia Clickject** (abatacept) • **Renflexis** (infliximab-abda) • **Simponi** (golimumab) • **Stelara** (ustekinumab) • **Taltz** (ixekizumab) • **Xeljanz/Xeljanz XR** (tofacitinib)
Rheumatoid arthritis	• **Enbrel** (etanercept) • **Humira** (adalimumab) • **Kevzara** (sarilumab) • **Orencia (SC)/Orencia Clickject** (abatacept) • **Xeljanz/Xeljanz XR** (tofacitinib)	• **None**	• **Actemra** (tocilizumab) • **Cimzia** (certolizumab pegol) • **Inflectra** (infliximab-dyyb) • **Kineret** (anakinra) • **Olumiant** (baricitinib) • **Orencia (IV)** (abatacept) • **Renflexis** (infliximab-abda) • **Simponi** (golimumab)
Crohn's disease	• **Humira** (adalimumab)	• **Stelara** (ustekinumab)	• **Cimzia** (certolizumab pegol) • **Entyvio** (vedolizumab) • **Inflectra** (infliximab-dyyb) • **Renflexis** (infliximab-abda)
Ulcerative colitis	• **Humira** (adalimumab) • **Simponi** (golimumab)	• **None**	• **Entyvio** (vedolizumab) • **Inflectra** (infliximab-dyyb) • **Renflexis** (infliximab-abda) • **Xeljanz/Xeljanz XR** (tofacitinib)

Abbreviations: IV = intravenous; SC = subcutaneous

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. Ankylosing spondylitis
   1. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Cosentyx, Enbrel, and Humira)
   2. 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
   3. The requested product is Cimzia and member is currently pregnant or breastfeeding

B. Crohn's disease

This policy applies to the following:

	Standard Opt-in	✓	**ACSF**	✓	**VF**		**Marketplace**
	Standard Opt-in NTMB	✓	**PDPD**		**MMT**		**Medical Benefit**
	Standard Opt-out		**Generics First**				**Medical Benefit: Managed Medicaid**

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1. Member has a documented inadequate response or intolerable adverse event with the primary preferred product (Humira) and with the secondary preferred product (Stelara), unless there is a documented clinical reason to avoid Humira (see Appendix)
2. 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
3. The requested product is Cimzia and member is currently pregnant or breastfeeding

C. Psoriatic arthritis
1. Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products (Cosentyx, Enbrel, Humira, and Otezla); unless there is a documented clinical reason to avoid Enbrel and Humira (see Appendix)
2. 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
3. The requested product is Cimzia and member is currently pregnant or breastfeeding

D. Plaque psoriasis
1. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Humira, Otezla, Skyrizi, Stelara, Taltz); unless there is a documented clinical reason to avoid Humira (see Appendix)
2. 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
3. The requested product is Cimzia and member is currently pregnant or breastfeeding

E. Rheumatoid arthritis
1. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Enbrel, Humira, Kevzara, Orencia (subcutaneous)/Orencia ClickJect, and Xeljanz/Xeljanz XR); unless there is a documented clinical reason to avoid Enbrel and Humira (see Appendix)
2. 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
3. The requested product is Cimzia and member is currently pregnant or breastfeeding

F. Ulcerative colitis
1. Member has had a documented inadequate response or intolerable adverse event with at least one of the preferred products (Humira, Simponi), unless there is a documented clinical reason to avoid Humira and Simponi (see Appendix)
2. 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

III. Appendix: Clinical reasons to avoid a preferred TNF inhibitor(s)

- History of demyelinating disorder
- History of congestive heart failure
- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- Risk of lymphoma

REFERENCES

This policy applies to the following:

	Standard Opt-in	✓	**ACSF**	✓	**VF**		**Marketplace**
	Standard Opt-in NTMB	✓	**PDPD**		**MMT**		**Medical Benefit**
	Standard Opt-out		**Generics First**				**Medical Benefit: Managed Medicaid**

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