This policy applies to the following:

✓	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

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EXCEPTIONS CRITERIA

DISEASE-MODIFYING ANTIRHEUMATIC DRUG PRODUCTS

SELF-ADMINISTERED PREFERRED PRODUCTS FOR ANKYLOSING SPONDYLITIS: COSENTYX, ENBREL AND HUMIRA

SELF-ADMINISTERED PREFERRED PRODUCTS FOR CROHN'S DISEASE: HUMIRA AND STELARA (SC)

SELF-ADMINISTERED PREFERRED PRODUCTS FOR PSORIASIS: COSENTYX, ENBREL, HUMIRA, OTEZLA, SKYRIZI, STELARA (SC), AND TREMFYA

SELF-ADMINISTERED PREFERRED PRODUCTS FOR PSORIATIC ARTHRITIS: COSENTYX, ENBREL, HUMIRA, OTEZLA, STELARA (SC), TREMFYA, AND XELJANZ/XELJANZ XR

SELF-ADMINISTERED PREFERRED PRODUCTS FOR RHEUMATOID ARTHRITIS: PRIMARY: ENBREL, HUMIRA, RINVOQ, AND XELJANZ/XELJANZ XR; SECONDARY: KEVZARA

SELF-ADMINISTERED PREFERRED PRODUCTS FOR ULCERATIVE COLITIS: HUMIRA, STELARA (SC), AND XELJANZ/XELJANZ XR

PHYSICIAN-ADMINISTERED PREFERRED PRODUCTS: REMICADE, 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. For psoriasis, this program applies to all adult members requesting treatment with a targeted product. For all other indications, 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.

This policy applies to the following:

✓	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

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Table 1. Self-administered disease-modifying antirheumatic drugs for autoimmune conditions

Indication	Primary Preferred Product	Secondary Preferred Product	Targeted Product(s)
Ankylosing spondylitis	• **Cosentyx** (secukinumab) • **Enbrel** (etanercept) • **Humira** (adalimumab)	• **None**	• **Cimzia syringe** (certolizumab pegol) • **Simponi** (golimumab) • **Taltz** (ixekizumab)
Crohn's disease	• **Humira** (adalimumab) • **Stelara (SC)** (ustekinumab)	• **None**	• **Cimzia syringe** (certolizumab pegol)
Plaque psoriasis	• **Cosentyx** (secukinumab) • **Enbrel** (etanercept) • **Humira** (adalimumab) • **Otezla** (apremilast) • **Skyrizi** (risankizumab-rzaa) • **Stelara (SC)** (ustekinumab) • **Tremfya** (guselkumab)	• **None**	• **Cimzia syringe** (certolizumab pegol) • **Siliq** (brodalumab) • **Taltz** (ixekizumab)
Psoriatic arthritis	• **Cosentyx** (secukinumab) • **Enbrel** (etanercept) • **Humira** (adalimumab) • **Otezla** (apremilast) • **Stelara (SC)** (ustekinumab) • **Tremfya** (guselkumab) • **Xeljanz/Xeljanz XR** (tofacitinib)	• **None**	• **Cimzia syringe** (certolizumab pegol) • **Orencia (SC)/Orencia Clickject** (abatacept) • **Simponi** (golimumab) • **Taltz** (ixekizumab)
Rheumatoid arthritis	• **Enbrel** (etanercept) • **Humira** (adalimumab) • **Rinvoq** (upadacitinib) • **Xeljanz/Xeljanz XR** (tofacitinib)	• **Kevzara** (sarilumab) **(after 2 primary preferred products)**	• **Actemra (SC)** (tocilizumab) • **Cimzia syringe** (certolizumab pegol) • **Kineret** (anakinra) • **Olumiant** (baricitinib) • **Orencia (SC)/Orencia Clickject** (abatacept) • **Simponi** (golimumab)
Ulcerative colitis	• **Humira** (adalimumab) • **Stelara (SC)** (ustekinumab) • **Xeljanz/Xeljanz XR** (tofacitinib)	• **None**	• **Simponi** (golimumab)

Abbreviation: SC = subcutaneous

This policy applies to the following:

✓	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

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Table 2. Physician-administered disease-modifying antirheumatic drugs for autoimmune conditions

Preferred Products	Targeted Products
• **Remicade** (infliximab) • **Simponi Aria** (golimumab) • **Stelara (IV)** (ustekinumab)[2]	• **Actemra (IV)** (tocilizumab) • **Avsola** (infliximab-axxq) • **Cimzia lyophilized powder** (certolizumab pegol) • **Entyvio** (vedolizumab)[1] • **Ilumya** (tildrakizumab-asmn) • **Inflectra** (infliximab-dyyb) • **Orencia (IV)** (abatacept) • **Renflexis** (infliximab-abda)

1. Only applies to use for Crohn's Disease (CD); Entyvio is not to be targeted for ulcerative colitis (UC)
2. Stelara IV is indicated for a one-time induction dose for CD and UC.

Abbreviation: IV = intravenous

II. EXCEPTION CRITERIA

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

A. Coverage for a self-administered targeted product, see Table 1 above, is provided when any of the following criteria is met:
   1. Plaque psoriasis
      a. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Cosentyx, Enbrel, Humira, Otezla, Skyrizi, Stelara, Tremfya), unless there is a documented clinical reason to avoid TNF inhibitors
      b. Requested product is Cimzia syringe and member is currently pregnant or breastfeeding
   2. Rheumatoid arthritis
      a. The requested product is Kevzara and member has a documented inadequate response or intolerable adverse event with at least two of the preferred products (Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR)
      b. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Enbrel, Humira, Kevzara, Rinvoq, Xeljanz/Xeljanz XR), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix)
      c. Requested product is Cimzia syringe and member is currently pregnant or breastfeeding.
      d. 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. Ankylosing spondylitis
      a. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Cosentyx, Enbrel, Humira), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix)
      b. Requested product is Cimzia syringe and member is currently pregnant or breastfeeding
      c. 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
   4. Ulcerative colitis
      a. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Humira, Stelara, Xeljanz/Xeljanz XR)

This policy applies to the following:

✓	**Standard Opt-in**		**PDPD**		**Marketplace**		**Medical Benefit**		**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

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   b. 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
5. Psoriatic arthritis[24]
   a. Member has a documented inadequate response or intolerable adverse event with six of the preferred products (Cosentyx, Enbrel, Humira, Otezla, Stelara, Tremfya, Xeljanz/Xeljanz XR) unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix)
   b. Requested product is Cimzia syringe and member is currently pregnant or breastfeeding
   c. 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
6. Crohn's disease
   a. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Humira, Stelara) indicated for the condition being treated
   b. Member is currently pregnant or breastfeeding
   c. 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

B. Coverage for a physician-administered targeted product, see Table 2 above, is provided when any of the following criteria is met:
1. For Avsola, Inflectra, and Renflexis, when member meets both of the following:
   a. Member has a documented intolerable adverse event with preferred product, Remicade, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
   b. Member has a documented inadequate response or intolerable adverse event with Simponi Aria and Stelara where the product's indications overlap
2. For Cimzia lyophilized powder, when any of the following criteria are met:
   a. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Remicade, Simponi Aria, and Stelara) where the product's indications overlap.
   b. Member is currently pregnant or breastfeeding
   c. 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, unless the request is for psoriasis
3. For all other targeted products, when any of the following criteria are met:
   a. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Remicade, Simponi Aria, and Stelara) where the product's indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (Appendix)
   b. 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 unless the request is for psoriasis
   c. The requested product is Entyvio for ulcerative colitis

IV. 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
- Risk of lymphoma

This policy applies to the following:

✓	**Standard Opt-in**		**PDPD**		**Marketplace**		**Medical Benefit**		**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

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