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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POLICY Document for REMICADE, AVSOLA, INFLECTRA, RENFLEXIS

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
DISEASE-MODIFYING ANTIRHEUMATIC DRUG PRODUCTS

PREFERRED PRODUCTS: ENTYVIO, ILUMYA, 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. 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

	Products	
Preferred	• **Entyvio** (vedolizumab) • **Ilumya** (tildrakizumab-asmn) • **Remicade** (infliximab)	• **Simponi Aria** (golimumab, intravenous) • **Stelara IV** (ustekinumab)*
Targeted	• **Actemra** (tocilizumab) • **Avsola** (infliximab-axxq)	• **Inflectra** (infliximab-dyyb) • **Orencia** (abatacept)

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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	• **Cimzia** (certolizumab pegol)	• **Renflexis** (infliximab-abda)

*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 Avsola, Inflectra and Renflexis, when either of the following criteria are met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. When both of the following criteria are met:
      a. Member has a documented intolerable adverse event with the 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 Entyvio, Ilumya, and Simponi Aria where the product's indications overlap.

B. For Cimzia, when any of the following criteria are met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Remicade, and Simponi Aria where the product's indications overlap
   3. Member is currently pregnant or breastfeeding

C. For all other targeted products, when any of the following criteria are met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, Remicade, and Simponi Aria where the product's indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (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
- Risk of lymphoma

Section 2: Clinical Criteria

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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STANDARD MEDICARE PART B MANAGEMENT

REMICADE (infliximab)

AVSOLA (infliximab-axxq)

INFLECTRA (infliximab-dyyb)

RENFLEXIS (infliximab-abda)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. REMICADE

1. FDA-Approved Indications
   - i. Crohn's disease
     - a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
     - b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
   - ii. Pediatric Crohn's disease
     Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy

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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iii. Ulcerative colitis
Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy

iv. Pediatric ulcerative colitis
Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy

v. Rheumatoid arthritis in combination with methotrexate
Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease

vi. Ankylosing spondylitis
Reducing signs and symptoms in patients with active disease

vii. Psoriatic arthritis
Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function

viii. Plaque Psoriasis
Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
   i. Adult onset Still's disease
   ii. Arthritis/arthropathy in Crohn's disease
   iii. Axial spondyloarthritis
   iv. Behcet's disease
   v. Gastrointestinal tract transplantation organ rejection
   vi. Giant cell arteritis
   vii. Graft versus host disease
   viii. Granulomatosis with polyangiitis
   ix. Hidradenitis suppurativa
   x. Juvenile idiopathic arthritis
   xi. Kawasaki disease
   xii. Necrobiosis lipoidica diabeticorum
   xiii. Pyoderma gangrenosum
   xiv. Rheumatoid arthritis as monotherapy
   xv. Severe, refractory SAPHO syndrome
   xvi. Sarcoidosis
   xvii. Subcorneal pustular dermatosis
   xviii. Synovitis
   xix. Takayasu's arteritis
   xx. Uveitis
   xxi. Immune checkpoint inhibitor toxicity

B. AVSOLA

1. FDA-Approved Indications

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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i. Crohn's disease
   a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease

ii. Pediatric Crohn's disease
Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy

iii. Ulcerative colitis
Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy

iv. Pediatric ulcerative colitis
Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy

v. Rheumatoid arthritis in combination with methotrexate
Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease

vi. Ankylosing spondylitis
Reducing signs and symptoms in patients with active disease

vii. Psoriatic arthritis
Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function

viii. Plaque Psoriasis
Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
Same as Remicade. See Section I.A.2.

C. INFLECTRA

1. FDA-Approved Indications
   i. Crohn's disease
      a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
      b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
   ii. Pediatric Crohn's disease

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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Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy

iii. Ulcerative colitis
Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy

iv. Pediatric ulcerative colitis
Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy

v. Rheumatoid arthritis in combination with methotrexate
Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease

vi. Ankylosing spondylitis
Reducing signs and symptoms in patients with active disease

vii. Psoriatic arthritis
Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function

viii. Plaque Psoriasis
Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
Same as Remicade. See Section I.A.2.

D. RENFLEXIS

1. FDA-Approved Indications
   i. Crohn's disease
      a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
      b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
   ii. Pediatric Crohn's disease
   Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   iii. Ulcerative colitis
   Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy

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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iv. Pediatric ulcerative colitis
Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy

v. Rheumatoid arthritis in combination with methotrexate
Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease

vi. Ankylosing spondylitis
Reducing signs and symptoms in patients with active disease

vii. Psoriatic arthritis
Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function

viii. Plaque Psoriasis
Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
Same as Remicade. See Section I.A.2.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Crohn's disease
Authorization of 24 months may be granted for treatment of Crohn's disease

B. Ulcerative colitis
Authorization of 24 months may be granted for treatment of ulcerative colitis

C. Rheumatoid arthritis
Authorization of 24 months may be granted for treatment of rheumatoid arthritis when any of the following criteria are met:

i. The member has previously received any other biologic disease-modifying anti-rheumatic drug (DMARD) (e.g., Humira) or targeted synthetic DMARD (e.g., Xeljanz) indicated for rheumatoid arthritis.

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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ii. The member had an inadequate response to methotrexate or there is a clinical reason to avoid treatment with methotrexate (e.g., renal or hepatic impairment).

D. Ankylosing spondylitis and axial spondyloarthritis
Authorization of 24 months may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis.

E. Psoriatic arthritis
Authorization of 24 months may be granted for treatment of psoriatic arthritis.

F. Plaque psoriasis
Authorization of 24 months may be granted for treatment of plaque psoriasis.

G. Adult onset Still's disease
Authorization of 24 months may be granted for the treatment of adult onset Still's disease.

H. Arthritis/arthropathy in Crohn's disease
Authorization of 24 months may be granted for the treatment of arthritis or arthropathy in a member with Crohn's disease.

I. Behcet's disease
Authorization of 24 months may be granted for the treatment of Behcet's disease.

J. Gastrointestinal tract transplantation organ rejection
Authorization of 24 months may be granted for the treatment of gastrointestinal tract transplantation organ rejection.

K. Giant cell arteritis
Authorization of 24 months may be granted for the treatment of giant cell arteritis.

L. Graft versus host disease
Authorization of 24 months may be granted for the treatment of graft versus host disease.

M. Granulomatosis with polyangiitis (Wegener's granulomatosis)
Authorization of 24 months may be granted for the treatment of granulomatosis with polyangiitis.

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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N. Hidradenitis suppurativa
Authorization of 24 months may be granted for the treatment of hidradenitis suppurativa.

O. Juvenile idiopathic arthritis
Authorization of 24 months may be granted for the treatment of juvenile idiopathic arthritis.

P. Kawasaki disease
Authorization of 24 months may be granted for the treatment of Kawasaki disease.

Q. Necrobiosis lipoidica diabeticorum
Authorization of 24 months may be granted for the treatment of necrobiosis lipoidica diabeticorum.

R. Pyoderma gangrenosum
Authorization of 24 months may be granted for the treatment of pyoderma gangrenosum.

S. SAPHO syndrome
Authorization of 24 months may be granted for the treatment of SAPHO syndrome.

T. Sarcoidosis
Authorization of 24 months may be granted for the treatment of sarcoidosis.

U. Subcorneal pustular dermatosis
Authorization of 24 months may be granted for the treatment of subcorneal pustular dermatosis.

V. Synovitis
Authorization of 24 months may be granted for the treatment of synovitis.

W. Takayasu's disease
Authorization of 24 months may be granted for the treatment of Takayasu's disease.

X. Uveitis
Authorization of 24 months may be granted for the treatment of uveitis.

Y. Immune Checkpoint Inhibitor Toxicity
Authorization of 1 month may be granted for the treatment of immune checkpoint inhibitor toxicity.

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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III. CONTINUATION OF THERAPY

A. Immune Checkpoint Inhibitor Toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

B. All other indications

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 24 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Avsola, Remicade, Inflectra, or Renflexis
2. The requested medication is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy

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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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