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

Reference #
3452-D

POLICY Document for SIMPONIA ARIA

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) • **Cimzia** (certolizumab pegol)	• **Inflectra** (infliximab-dyyb) • **Orencia** (abatacept) • **Renflexis** (infliximab-abda)

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

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**

Reference #
3452-D

*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

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

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

Reference #
3452-D

Section 2: Clinical Criteria

STANDARD MEDICARE PART B MANAGEMENT

SIMPONI ARIA (golimumab)

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.

FDA-Approved Indications

1. Treatment of adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate
2. Treatment of active psoriatic arthritis in patients 2 years of age and older
3. Treatment of adult patients with active ankylosing spondylitis
4. Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

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. Rheumatoid arthritis

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

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

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**

Reference #
3452-D

1. Simponi Aria will be used in combination with methotrexate unless the member has a clinical reason to avoid methotrexate (e.g., breastfeeding, renal or hepatic impairment, previous intolerance to methotrexate)
2. The member meets one of the following:
   a. 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
   b. The member had an inadequate response to methotrexate
   c. The member has a clinical reason to avoid therapy with methotrexate (e.g., hepatic or renal impairment)

B. Psoriatic arthritis (PsA)
Authorization of 24 months may be granted for treatment of active psoriatic arthritis.

C. Ankylosing spondylitis (AS)
Authorization of 24 months may be granted tor treatment of active ankylosing spondylitis.

D. Polyarticular juvenile idiopathic arthritis (pJIA)
Authorization of 24 months may be granted for treatment of active polyarticular juvenile idiopathic arthritis.

III. CONTINUATION OF THERAPY

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:

A. The member is currently receiving therapy with Simponi Aria
B. Simponi Aria is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy

REFERENCES:

SECTION 1

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; June 2019.
2. Avsola [package insert]. Thousand Oaks, CA: Amgen; December 2019.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
4. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceutical America, Inc.; May 2019.
5. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2018.
6. Inflectra [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; June 2019.
7. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; March 2019.
8. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2018.

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

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**

Reference #
3452-D

9. Renflexis [package insert]. Kenilworth, NJ. Merck &Co., Inc; October 2019.
10. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
11. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2019.

SECTION 2

1. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2020.

© 2020 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.