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 ENTYVIO

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

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. FDA-Approved Indications

1. Ulcerative colitis (UC)

Adult patients with moderately to severely active UC

2. Crohn's disease (CD)

Adult patients with moderately to severely active CD

B. Compendial Uses

Immune checkpoint inhibitor-related toxicity

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. Moderately to severely active ulcerative colitis (UC)

Authorization of 24 months may be granted for treatment of moderately to severely active ulcerative colitis.

B. Moderately to severely active Crohn's disease (CD)

© 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

Authorization of 24 months may be granted for treatment of moderately to severely active Crohn's disease.

C. Immune checkpoint inhibitor-related toxicity

Authorization of 1 month may be granted for the treatment of immune checkpoint inhibitor-related diarrhea or colitis in members who have had an inadequate response to systemic corticosteroids or who have a clinical reason to avoid these medications.

III. CONTINUATION OF THERAPY

A. Immune checkpoint inhibitor-related 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 Entyvio

2. Entyvio is being used to treat an indication enumerated in Section II

3. The member is receiving benefit from therapy

REFERENCES:

© 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 1

Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; June 2019.

Avsola [package insert]. Thousand Oaks, CA: Amgen; December 2019.

Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.

Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceutical America, Inc.; May 2019.

Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2018.

Inflectra [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; June 2019.

Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; March 2019.

Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2018.

Renflexis [package insert]. Kenilworth, NJ. Merck &Co., Inc; October 2019.

Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.

Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2019.

SECTION 2

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; March 2020.

2. Kornbluth A, Sachar D, and the Practice Parameters Committee of the American College of Gastroenterology. Ulcerative Colitis Practice Guidelines in Adults. Am J Gastroenterol. 2010; 105:501–523. Available at http://s3.gi.org/physicians/guidelines/UlcerativeColitis.pdf. Accessed January 25, 2017.

3. Lichtenstein GR, Hanauer SB, Sandborn WJ, and the Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. Am J Gastroenterol. 2009. Available at http://s3.gi.org/physicians/guidelines/CrohnsDiseaseinAdults2009.pdf. Accessed January 26, 2017.

4. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.

© 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

5. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 05, 2020.

6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450

© 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.