



Tysabri

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ **Date:** _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ☐ Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ☐ Same as Referring Provider ☐ Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ *kg*

Patient Height: _____ *cm*

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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Exception Criteria Questions:

A. The preferred products for your patient's health plan are Entyvio, Simponi Aria, Skyrizi and Stelara. Can the patient's treatment be switched to one of the preferred products?

- ☐ Yes, Entyvio, *Please obtain Form for preferred product and submit for corresponding PA.*
- ☐ Yes, Simponi Aria, *Please obtain Form for preferred product and submit for corresponding PA.*
- ☐ Yes, Skyrizi, *Please obtain Form for preferred product and submit for corresponding PA*
- ☐ Yes, Stelara, *Please obtain Form for preferred product and submit for corresponding PA*
- ☐ No, *Continue to Question B*

B. Is this request for continuation of therapy with the requested product?

- ☐ Yes, *Continue to Question C*
- ☐ No, *Continue to Question D*

C. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program?

- ☐ Yes, *Continue to Question D*
- ☐ No, *Skip to Site of Service Questions*
- ☐ Unknown, *Continue to Question D*

D. What is the diagnosis?

- ☐ Psoriatic Arthritis, *Continue to Question E*
- ☐ Plaque Psoriasis, *Continue to Question F*
- ☐ Rheumatoid arthritis, Ankylosing spondylitis, Polyarticular juvenile idiopathic arthritis, *Skip to Question G*
- ☐ Crohn's disease, Ulcerative colitis, *Skip to Question H*
- ☐ Other, *Skip to Site of Service Questions*

E. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to Simponi aria, Skyrizi and Stelara? **Action Required: If 'Yes', attach supporting chart note(s)**

- ☐ Yes, *Skip to Site of Service Questions*
- ☐ No, *Skip to Site of Service Questions*

F. Did the patient have a documented inadequate response, intolerable adverse event or contraindication to Skyrizi and Stelara? **Action Required: If 'Yes', attach supporting chart note(s)**

- ☐ Yes, *Skip to Site of Service Questions*
- ☐ No, *Skip to Site of Service Questions*

G. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to Simponi Aria? **Action Required: If 'Yes', attach supporting chart note(s)**

- ☐ Yes, *Skip to Site of Service Questions*
- ☐ No, *Skip to Site of Service Questions*

H. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to Entyvio, Skyrizi, and Stelara? **Action Required: If 'Yes', attach supporting chart note(s)**

- ☐ Yes, *Continue to Site of Service Questions*
- ☐ No, *Continue to Site of Service Questions*

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Site of Service Questions:

- A. Where will this drug be administered?
- ☐ Ambulatory surgical, *skip to Clinical Criteria Questions*
 - ☐ Home infusion, *skip to Clinical Criteria Questions*
 - ☐ Off-campus Outpatient Hospital, *Continue to B*
 - ☐ On-campus Outpatient Hospital, *Continue to B*
 - ☐ Physician office, *skip to Clinical Criteria Questions*
 - ☐ Pharmacy, *skip to Clinical Criteria Questions*
- B. Is the patient less than 14 years of age?
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to C*
- C. Is this request to continue previously established treatment with the requested medication?
- ☐ Yes – This is a continuation of an existing treatment, *Continue to D*
 - ☐ Yes – This is a continuation request, however a gap in therapy of greater than 2 doses has occurred, **ACTION REQUIRED: Please attach supporting clinical documentation. Skip to Clinical Criteria Questions**
 - ☐ No – This is a new therapy request (patient has not received requested medication in the last 6 months), **ACTION REQUIRED: Please attach supporting clinical documentation. Skip to Clinical Criteria Questions**
- D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to E*
- E. Does the patient have laboratory confirmed natalizumab antibodies? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to F*
- F. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to G*
- G. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to H*
- H. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to I*
- I. Are **all** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? **ACTION REQUIRED: If Yes, please attach supporting documentation.**
- ☐ Yes, *continue to Clinical Criteria Questions*
 - ☐ No, *continue to Clinical Criteria Questions*

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Criteria Questions:

1. Will the requested drug be used in combination with any other disease modifying multiple sclerosis (MS) agents (Note: Ampyra and Nuedexta are not disease modifying), immunosuppressants, or tumor necrosis factor (TNF) inhibitors (e.g., adalimumab, infliximab)?

☐ Yes, *Continue to 2*

☐ No, *Continue to 2*

2. What is the diagnosis?

☐ Relapsing forms of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse), *Continue to 12*

☐ Clinically isolated syndrome of multiple sclerosis, *Continue to 12*

☐ Crohn's disease, *Continue to 3*

☐ Other, please specify: _____, *No further questions*

3. Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)?

☐ Yes, *Continue to 4*

☐ No, *Continue to 4*

4. Is the patient an adult (18 years of age or older)?

☐ Yes, *Continue to 5*

☐ No, *Continue to 5*

5. Will the requested drug be prescribed by or in consultation with a gastroenterologist?

☐ Yes, *Continue to 6*

☐ No, *Continue to 6*

6. Is this request for continuation of therapy with the requested drug?

☐ Yes, *Continue to 7*

☐ No, *Continue to 10*

7. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

☐ Yes, *Continue to 10*

☐ No, *Continue to 8*

☐ Unknown, *Continue to 10*

8. Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission.

☐ Yes, achieved or maintained remission **ACTION REQUIRED:** *Submit supporting documentation, Continue to 16*

☐ Yes, achieved or maintained a positive clinical response, *Continue to 9*

☐ None of the above, *No further questions*

9. Which of the following has the patient experienced an improvement in from baseline? **ACTION REQUIRED:** Please attach chart notes or medical record documentation supporting positive clinical response to therapy.

☐ Abdominal pain or tenderness **ACTION REQUIRED:** *Submit supporting documentation, Continue to 16*

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- ☐ Diarrhea **ACTION REQUIRED:** Submit supporting documentation, Continue to 16
- ☐ Body weight **ACTION REQUIRED:** Submit supporting documentation, Continue to 16
- ☐ Abdominal mass **ACTION REQUIRED:** Submit supporting documentation, Continue to 16
- ☐ Hematocrit **ACTION REQUIRED:** Submit supporting documentation, Continue to 16
- ☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** Submit supporting documentation, Continue to 16
- ☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) **ACTION REQUIRED:** Submit supporting documentation, Continue to 16
- ☐ None of the above, Continue to 16

10. Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for moderately to severely active Crohn's disease (excluding receiving the drug via samples or a manufacturer's patient assistance program)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy.

- ☐ Yes, Continue to 11
- ☐ No, Continue to 11

11. Has the patient been tested for anti-JCV (John Cunningham virus) antibodies?

- ☐ Yes, Continue to 16
- ☐ No, Continue to 16

12. Will the requested drug be prescribed by or in consultation with a neurologist?

- ☐ Yes, Continue to 13
- ☐ No, Continue to 13

13. Is this a request for continuation of therapy?

- ☐ Yes, Continue to 15
- ☐ No, Continue to 14

14. Has the patient been tested for anti-JCV (John Cunningham virus) antibodies?

- ☐ Yes, No Further Questions
- ☐ No, No Further Questions

15. Has the patient achieved or maintained a positive clinical response by experiencing disease stability or improvement while receiving the requested drug?

- ☐ Yes, No Further Questions
- ☐ No, No Further Questions

16. Does the prescribed dose exceed 300 mg?

- ☐ Yes, Continue to 17
- ☐ No, Continue to 17

17. Is the prescribed frequency more frequent than one dose every 4 weeks?

- ☐ Yes, Continue to 18
- ☐ No, Continue to 18

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18. What is the requested product?

☐ Tysabri, *No further questions*

☐ Tyruko, *No further questions*

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X _____

Prescriber or Authorized Signature

Date (mm/dd/yy)

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