United Healthcare Community Plan

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

Tysabri ® (natalizumab) and Biosimilars

If the following information is not complete, correct, or legible, the SA process can be delayed.

Please use one form per member.

Physician Administered Drug: This form is only to be used for members obtaining the medication from a pharmacy through billing the pharmacy benefit at point-of-sale. Please reference Appendix B: Physician Administered Drug Criteria for members/providers that will obtain the medication through the medical benefit.

MEMBER INFORMATION

Last Name: _____

First Name: _____

Medicaid ID Number: _____

Date of Birth: _____

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name: _____

First Name: _____

NPI Number: _____

Phone Number: _____

Fax Number: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION

For an initial request for Multiple Sclerosis, complete the following to receive a 6-month approval:

1. Is the member at least 18 years of age? **AND**

   ☐ Yes ☐ No

2. Has the prescriber and member enrolled in and meet the conditions of the TOUCH (applicable to Tysabri) or REMS (applicable to Tyruko) programs? **AND**

   ☐ Yes ☐ No

3. Has the member had a JCV antibody test completed within the past 6 months and been counseled on the risks and benefits of treatment? **AND**

   ☐ Yes ☐ No

4. Will the requested product not be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents? **AND**

   ☐ Yes ☐ No

5. Is the member immunocompetent? **AND**

   ☐ Yes ☐ No

6. Will the requested product be used as a single agent therapy? **AND**

   ☐ Yes ☐ No

7. Does the member have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**

   ☐ Yes ☐ No

8. Does the member have a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS)*, active secondary progressive disease (SPMS)**, or clinically isolated syndrome (CIS)***]?

   ☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For a renewal request for Multiple Sclerosis, complete the following to receive a 12-month approval:

Multiple Sclerosis Renewal Request:

1. Does the member continue to meet the relevant criteria identified in the initial criteria? **AND**

   ☐ Yes ☐ No

2. Does the member have an absence of unacceptable toxicity from the drug? **AND**

   ☐ Yes ☐ No

3. Has the member been continuously monitored for response to therapy and had a beneficial response?

   ☐ Yes ☐ No

For an initial request for Crohn's Disease, complete the following questions to receive a 6-month approval:

1. Is the member at least 18 years of age? **AND**

   ☐ Yes ☐ No

2. Has the prescriber and member enrolled in and meet the conditions of the TOUCH (applicable to Tysabri) or REMS (applicable to Tyruko) programs? **AND**

   ☐ Yes ☐ No

3. Does the member have a documented negative JCV antibody ELISA test within the past 6 months? **AND**

   ☐ Yes ☐ No

4. Will the requested product not be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents? **AND**

   ☐ Yes ☐ No

5. Is the member immunocompetent? **AND**

   ☐ Yes ☐ No

6. Does the member have moderate to severe active disease? **AND**

   ☐ Yes ☐ No

7. Has the physician assessed baseline disease severity utilizing an objective measure and tool? **AND**

   ☐ Yes ☐ No

8. Does the member have a documented trial and failure on ONE oral immunosuppressive therapy for at least 3 months, unless use is contraindicated, such as corticosteroids, methotrexate, azathioprine, and 6-mercaptopurine? **AND**

   ☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

9. Does the member have a documented trial and failure two of the preferred Cytokine and CAM antagonist agents for Crohn's Disease (see Cytokine and CAM Antagonists on the PDL)? **AND**

   ☐ Yes ☐ No

10. Will the requested product be used as single agent therapy [Not used concurrently with another biologic drug or immunosuppressant (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate, etc.) used for Crohn's Disease?

    ☐ Yes ☐ No

For a renewal request for Crohn's Disease, complete the following questions:

1. Initial renewal only (6-month approval):

   a. Has the member been tapered off of oral corticosteroids within 6 months of starting the requested product? **AND**

      ☐ Yes ☐ No

   b. Has the disease responded as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool?

      ☐ Yes ☐ No

2. Subsequent renewals (12-month approval):

   a. Does the member not require additional steroid use that exceeds 3 months in a calendar year to control their Crohn's disease? **AND**

      ☐ Yes ☐ No

   b. Has the disease responded as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool?

      ☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

***Definitive diagnosis of MS with a relapsing-remitting course is based upon:**
• Dissemination in space (see below) **AND** one or more of the following:
  ○ Positive cerebrospinal fluid (CSF) (e.g., presence of oligoclonal bands or kappa free light chain index)
  ○ Positive central vein sign (CVS) (e.g., presence of six or more lesions with CVS; if fewer than 6 white matter lesions are seen on MRI, the number of CVS positive lesions should outnumber the CVS negative lesions)
  ○ Dissemination in time (DIT) (see below)
  ○ Presence of lesions in at least four of five CNS anatomical locations; **OR**
• Lesions present in one CNS site (including members with 12 months or longer progression from onset) **AND** one or more of the following:
  ○ CSF positivity and CVS positivity
  ○ CSF positivity and paramagnetic rim lesion (PRL) positivity (e.g., presence of one or more PRL)
  ○ DIT (see below) and CVS positivity
  ○ DIT (see below) and PRL positivity
Unless contraindicated, MRI should be obtained (even if criteria are met).	

Dissemination In Time **(Development/appearance of new CNS lesions over time)**	**Dissemination In Space** **(Development of lesions in distinct anatomical locations within the CNS; multifocal)**
▪ ≥ 2 clinical attacks; **OR** ▪ Simultaneous presence of gadolinium enhancing and non-enhancing lesions at any time; **OR** ▪ A new T2-hyperintense or gadolinium enhancing lesion on follow-up MRI	▪ MRI indicating typical lesions in ≥ 2 of 5 areas of the CNS (optic nerve, intracortical or juxtacortical, periventricular, infratentorial, or spinal cord); **OR** ▪ In members with progressive disease (patients with 12 months or longer progression from onset), two spinal cord lesions

****Active secondary progressive MS (SPMS) is defined as the following:**
▪ Expanded Disability Status Scale (EDSS) score ≥ 3.0; **AND** ▪ Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in members with EDSS ≤ 5.5 or increase by 0.5 in members with EDSS ≥ 6); **AND** – ≥ 1 relapse within the previous 2 years; **OR** – Member has gadolinium-enhancing activity **or** new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

***Definitive diagnosis of CIS is based upon ALL of the following:
▪ A monophasic clinical episode with member-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS ▪ Neurologic symptom duration of at least 24 hours, with or without recovery ▪ Absence of fever or infection; **AND** ▪ Member is not known to have multiple sclerosis

Prescriber Signature (Required) **Date**

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; incomplete forms will delay the SA process.

Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services.

Fax this form to 1-866-940-7328

Pharmacy PA Call Center 1-800-310-6826