TYSABRI® (NATALIZUMAB)
Preauthorization Request
(Preauthorization is not a guarantee of payment)

SECTION I – General Information

Today's Date: / /	☐ New request
Fax completed form to:**1-866-805-4150 toll free**	☐ Re-Authorization

Level of Urgency:

Standard Request (Routine Care)—Care/treatment that is not emergent, urgent, or preventive in nature.

Expedited Request—Care/treatment that is emergent or the application of the timeframe for making Standard/Routine or nonlife-threatening care determinations:

- Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state, or
- In the opinion of the practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

For Expedited Request, Please Explain:

SECTION II – Member Information

Patients Name:	Member ID:	**Patient Information**: DOB:__/__/__ Sex: Age: Weight: ☐ lbs. ☐ Kg Will the patient self-administer the requested medication? ☐ Yes ☐ No
Patients Address:	Is CBC primary payer: ☐ Yes ☐ No	

Plan Type:

☐ PPO ☐ POS ☐ KHPC ☐ CHIP (aka Capital Cares 4Kids)

☐ Traditional ☐ Comprehensive ☐ Special Care ☐ Other* _____

NOTE: For all Medicare Advantage products, please contact Prime Therapeutics at https://www.covermymeds.com/main or via phone at 1-866-260-0452.

SECTION III – Provider Information Required

Requesting Provider Name: **Address**:	**Requesting Provider CBC #**_____ **NPI #** _____

Telephone #:	Secure Fax #:
Office Contact Name:	Office Contact Telephone #:
Is the Rendering/Servicing provider different? ☐ No ☐ Yes – Complete rendering provider information below.	
Rendering Provider Name: **Address**: **Telephone:**	**Rendering Provider CBC #**_____ **NPI #** _____
Site of Service: ☐ MD Office ☐ Home Health ☐ Non-hospital affiliated, outpatient infusion center ☐ Hospital affiliated, outpatient infusion center ☐ Other: Specify _____ **Please refer to MP 3.016 for Site of Service requirements.*	**Check all that apply and include all applicable documentation:** ☐ There are contraindications to a less intensive site of care. ☐ A less intensive site of care is not appropriate for the patient's condition. ☐ Patient is being treated with a drug that cannot be administered in a less intensive site of care concurrently. ☐ Less intensive site of care is not available. **Please include all applicable documentation.*

SECTION IV – Preauthorization Requirements and Clinical Criteria

Is the prescriber a specialist in the area of the patient's diagnosis or has the prescriber consulted with a specialist in the area of the patient's diagnosis? ☐ Yes Specialty: _____ ☐ No

☐ New to therapy ☐ Continuing therapy*: Initial start __/__/__ ☐ Reinitiating therapy: Last treatment __/__/__ *Please include documentation for changes in dose.	**Route of Administration:** ☐ Intravenous (IV) ☐ Injection (Sub Q or IM) ☐ Oral (PO) or Enteral ☐ Other: Specify _____
HCPC Code(s):	**Diagnosis Code(s)**:
Medication requested:	**Indication:**

Does the patient have late stage metastatic disease? ☐ Yes ☐ No

For patients with late stage metastatic disease (Stage IV), please refer to MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions for additional guidance.

Type of drug requested: ☐ Brand name ☐ Generic ☐ Biosimilar ☐ Other: Specify _____

Initial start date of therapy: __/__/__	Anticipated date of **next administration:** __/__/__

Dosing period for request: Start Date: __/__/__ End Date __/__/__	**Dosing Information:** Dose: Strength: Frequency: Quantity requested per month:

<u>Attach documentation demonstrating the medical necessity of the requested drug.</u> Please list all reasons for selecting the requested medication, strength, dosing schedule, and quantity over alternatives (e.g., contraindications, allergies, history of adverse drug reactions to alternatives, lower dose has been tried, information supporting dose over FDA max.)
Has the patient had **medical testing** completed for use of this drug? (labs, imaging) ☐ Yes ☐ No Results:_____
Is drug being requested for an "**off label" indication**? ☐ Yes ☐ No If yes, please see Medical Policy 2.103 and include any applicable documentation.
Please list any previous medications that were **<u>tried and failed</u>**. Include reason for discontinuation (intolerance, hypersensitivity, inadequate response etc.). Please attach documentation. Drug(s) and strength: Documentation of failure:
☐ **Tysabri® (natalizumab)**

Patient is at least 18 years of age □ Yes □ No

Prescriber and patient must be enrolled in and meet the conditions of the TOUCH program □ Yes □ No

Will not be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents□ Yes □ No

Patient must not have a systemic medical condition resulting in significantly compromised immune system function □ Yes □ No

COMPLETE BELOW FOR RELEVANT DIAGNOSIS

Multiple Sclerosis

Patient has been diagnosed with a relapsing form of multiple sclerosis [i.e. relapsing remitting disease (RRMS)*, active secondary progressive disease (SPMS)**, or clinically isolated syndrome (CIS) □ Yes □ No

Confirmed diagnosis of MS as documented by laboratory report (i.e. MRI) □ Yes □ No

Used as single agent therapy□ Yes □ No

Crohns Disease

Patient has moderate to severe active disease □ Yes □ No

Physician has assessed baseline disease severity utilizing an objective measure/tool □ Yes □ No

Documented trial and failure on ONE oral immunosuppressive therapy for at least 3 months, unless use is contraindicated, such as corticosteroids, methotrexate, azathioprine, and/or 6-mercaptopurine □ Yes □ No

Documented trial and failure on ONE TNF-Inhibitor therapy for at least 3 months, unless contraindicated, such as infliximab, certolizumab, or adalimumab □ Yes □ No

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

Renewal Criteria (If applicable, complete the following in addition to the above)

Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions/antibody formation, hepatotoxicity, signs or symptoms of progressive multifocal leukoencephalopathy (PML), herpes infections (including herpes encephalitis and meningitis and acute retinal necrosis), immunosuppression, infections (including pneumonias, pneumocystis carinii pneumonia, pulmonary mycobacterium avium intracellulare, bronchopulmonary aspergillosis, herpes, urinary tract infections, gastroenteritis, vaginal infections, tooth infections, tonsillitis, etc.), thrombocytopenia, etc. □ Yes □ No

Multiple Sclerosis

Continuous monitoring of response to therapy indicates a beneficial response* [manifestations of increased MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)] □ Yes □ No

Crohns Disease

Initial renewal only:

Clinical response and remission of disease is seen by 12 weeks □ Yes □ No

Second renewal only:

Patient has been tapered off of oral corticosteroids within six months of starting Tysabri□ Yes □ No

Disease response 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 □ Yes □ No

therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score.]

All subsequent renewals:

Patient does not require additional steroid use that exceeds three months in a calendar year to control their Crohn's disease□ Yes □ No

Disease response 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 [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score. □ Yes □ No

Please use a separate form for each drug.

To fill out form type or write using blue or black ink

Please fax this form to: 1-866-805-4150

Telephone: 1-800-471-2242

Prior authorization is not a guarantee of payment; benefits and eligibility will apply at the time of claim adjudication.