SENTARA COMMUNITY PLAN
(MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Tysabri® (natalizumab) **IV (Pharmacy)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosage:

Multiple Sclerosis, relapsing: 300 mg infused over 1 hour every 4 weeks; limited evidence suggests extended interval infusion (administration every 5 to 8 weeks) may be associated with a lower risk of PML and similar efficacy

Crohn's disease: 300 mg infused over 1 hour every 4 weeks

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied. **(Trials will be verified using pharmacy claims and/or submitted chart notes.)**

❑ DIAGNOSIS – Multiple Sclerosis (MS) Indication

Initial Authorization: 6 months

- ❑ Has the member been approved for Tysabri® previously through the Sentara Health Plans pharmacy department?
  - ❑ Yes ❑ No
- ❑ Member is 18 years of age or older
- ❑ Member and prescriber have enrolled in and meet the conditions of the TOUCH (applicable to Tysabri) or REMS (applicable to Tyruko) programs
- ❑ Member has a documented negative JCV antibody ELISA within the past 6 months
- ❑ The requested product will **NOT** be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents
- ❑ Member is **NOT** immunocompetent
- ❑ Tysabri® will be used as a single therapy
- ❑ Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI)
- ❑ Member has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS)*, active secondary progressive disease (SPMS)**, or clinically isolated syndrome (CIS)***]
- ❑ Member has tried and failed at least **TWO (2)** of the following preferred agents **(verified by chart notes or pharmacy paid claims; check each tried)**

❑ Avonex® (IFN beta-1b)	❑ Betaseron® (IFN beta-1a)	❑ Copaxone® 20mg (glatiramer acetate)
❑ dimethyl fumarate (generic Tecfidera®)	❑ fingolimod (generic Gilenya®)	❑ Kesimpta® (ofatumumab)*Step-edit required
❑ teriflunomide (generic Aubagio®)	❑ Other_____	

- ❑ Provide clinical evidence that the **Preferred** drug(s) will not provide adequate benefit and list pharmaceutical drugs attempted and outcome.

_____

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❑ DIAGNOSIS – Multiple Sclerosis (MS) Indication

Reauthorization: 12 months

- ❑ Member continues to meet all relevant criteria identified in the initial criteria
- ❑ Member has absence of unacceptable toxicity from the drug
- ❑ Member is being continuously monitored for response to therapy that indicates a beneficial response

***Definitive diagnosis of MS with a relapsing-remitting course is based upon BOTH dissemination in time and space. 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)
❑ ≥ 2 clinical attacks; **OR** ❑ 1 clinical attack **AND** one of the following: • MRI indicating simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2-hyperintense or gadolinium-enhancing lesion on follow-up MRIS compared to baseline scan • CSF-specific oligoclonal bands	❑ ≥ 2 lesions; ❑ 1 lesion **AND** one of the following: • Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location • MRI indicating ≥ 1 T2-hyperintense lesions characteristic of MS in ≥ 2 of 4 areas of the CNS (periventricular, juxtacortical, infratentorial, or spinal cord)

**** 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

*****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 even in the CNS
- ❑ Neurologic symptom duration of at least 24 hours, with or without recovery
- ❑ Absence of fever or infection
- ❑ Member is not known to have multiple sclerosis

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****Definitive diagnosis of MS with a primary progressive course is based upon the following:
❑ 1 year of disability progression independent of clinical relapse; **AND** ❑ **TWO** of the following: • ≥ 1 T2-hyperintense lesion characteristic of MS in one or more of the following regions of the CNS: periventricular, cortical or juxtacortical, or infratentorial • ≥ 2 T2-hyperintense lesions in the spinal cord • Presence of CSF-specific oligoclonal bands

❑ DIAGNOSIS – Crohn's Disease (CD) Indication

Initial Authorization: 6 months

- ❑ Member is at least 18 years of age
- ❑ Member has and prescriber have enrolled in and meet the conditions of the TOUCH (applicable to Tysabri) or REMS (applicable to Tyruko) programs
- ❑ Member has a documented negative JCV antibody ELISA test within the past 6 months
- ❑ Product will **NOT** be used in combination with antineoplastic, immunosuppressant, or immunomodulating agent
- ❑ Member is **NOT** immunocompetent
- ❑ Member has moderate to severe active disease
- ❑ The physician has assessed baseline disease severity utilizing an objective measure/tool
- ❑ Member has 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/or 6-mercaptopurine
- ❑ Tysabri will 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
- ❑ Member has trial and failure of **BOTH**:
  - ❑ Infliximab **AND** ❑ Humira®

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❑ DIAGNOSIS – Crohn's Disease (CD) Indication

Initial renewal: 6 months

- ❑ Member has been tapered off of oral corticosteroids within 6 months of starting Tysabri®
- ❑ Member has demonstrated 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.

❑ DIAGNOSIS – Crohn's Disease (CD) Indication

Subsequent renewals: 12 months

- ❑ Member does not require additional steroid use that exceeds 3 months in a calendar year to control their Crohn's disease
- ❑ Member has demonstrated 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.

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy - PropriumRx**

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.