

SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL 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 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

Tysabri (natalizumab) and Biosimilars (Medical)

Drug Requested: (check box below that applies)

Tysabri® (natalizumab) IV

Tyruko® (natalizumab-sztn) IV

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: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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

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.)

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❑ Diagnosis: Multiple Sclerosis (MS) Indication

Initial Authorization: 6 months

- ❑ Has the member been approved for requested medication previously through the Sentara Health Plans medical department?
 - ❑ Yes ❑ No
- ❑ Member is 18 years of age or older
- ❑ Member and prescriber have enrolled in and meet the conditions of the TOUCH/REMS program
- ❑ Member has had a JCV test completed within the past 6 months and been counseled on the risks and benefits of treatment
- ❑ Requested product will **NOT** be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents
- ❑ Member is **NOT** immunocompromised
- ❑ Requested product will be used as 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)	❑ 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:**

- **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)
<ul style="list-style-type: none"> ❑ ≥ 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 	<ul style="list-style-type: none"> ❑ 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 (members with 12 months or longer progression from onset), two spinal cord lesions

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**** 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

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/REMS program
- 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** immunocompromised
- Requested product will be used as single agent therapy
- Member has moderate to severe active disease
- 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
- Member has trial and failure of **BOTH**:

<input type="checkbox"/> adalimumab-adbm (Boehringer Ingelheim) OR Hadlima [®] (adalimumab-bwwd)	<input type="checkbox"/> Pyzchiva [®] syringe/vial OR Starjemza [™] (Requires trial and failure of a preferred TNF-alpha inhibitor)
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DIAGNOSIS – Crohn’s Disease (CD) Indication

Initial renewal: 6 months

- Member has experienced a clinical response within 12 weeks
- Member has been tapered off of oral corticosteroids within 6 months of starting the requested product
- 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 has not required 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: Please check applicable box below.

- Location/site of drug administration:** _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health’s definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member’s ability to regain maximum function.

*****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.****