BlueCross BlueShield
Federal Employee Program

TYSABRI (natalizumab), TYRUKO (natalizumab-sztn)*

*This medication is included in this policy but is not available on the market as of yet)

Pre – PA Allowance

None

Prior – Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
    a. Used as monotherapy
    b. **NOT** used in combination with another MS disease modifying agent

2. Crohn's Disease (CD)
    a. Moderately to severely active
    b. Inadequate treatment response, intolerance, or contraindication to **ALL** of the following:
        i. Conventional Crohn's disease therapies
        ii. TNF inhibitors
    c. **NOT** used in combination with immunosuppressants or TNF inhibitors

AND ALL of the following for **ALL** indications:

a. Patient does **NOT** have or have had progressive multifocal leukoencephalopathy (PML)
b. Patient will be monitored for any new sign or symptom that may be suggestive of PML
    i. Medication will be withheld at the 1st sign or symptom suggestive of PML
c. Patient does **NOT** have significantly compromised immune system function.
d. **NOT** given concurrently with live vaccines
e. **Tysabri ONLY:** Patient must be enrolled in and meet all conditions of the TOUCH Prescribing Program

f. **Tyruko ONLY:** Patient must be enrolled in and meet all conditions of the Tyruko REMS Program

Prior – Approval Limits

Duration 4 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Relapsing Multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
   a. Used as monotherapy
   b. **NOT** used in combination with another MS disease modifying agent

2. Crohn's Disease (CD)
   a. **NOT** used in combination with immunosuppressants or TNF inhibitors
   b. Patient has experienced therapeutic benefit by 12 weeks of induction therapy

AND ALL of the following for **ALL** indications:

a. Patient does not have progressive multifocal leukoencephalopathy (PML)
b. **NO** concurrent therapy with systemic corticosteroids
c. **NO** evidence of jaundice or liver injury
d. **NO** development of opportunistic infections
e. **NO** development of herpes infections
f. **NOT** given concurrently with live vaccines
g. **Tysabri ONLY:** Patient must be enrolled in and meet all conditions of the TOUCH Prescribing Program
h. **Tyruko ONLY:** Patient must be enrolled in and meet all conditions of the Tyruko REMS Program

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Prior – Approval *Renewal* Limits

Duration 12 months