Updated: 03/2018
DMMA Approved: 04/2018

Request for Prior Authorization for Tysabri (natalizumab)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Tysabri (natalizumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Tysabri Prior Authorization Criteria:

For all requests for Tysabri (natalizumab) all of the following criteria must be met:

- Member must be 18 years of age or older
- Member must **NOT** have pre-existing hepatic disease or hepatic impairment defined as ALT or AST at least two times the upper limit of normal
- Provider, member, infusion site, and pharmacy must be enrolled in the TOUCH REMS prescribing program
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of multiple sclerosis (MS) and the following criteria are met:

- Documentation of a diagnosis of relapsing-remitting or relapsing secondary progressive MS
- The drug is given as monotherapy and not in combination with other therapies approved for the treatment of MS
- Must be prescribed by, or in consultation with, a neurologist or a physician that specializes in the treatment of MS
- Patients initiating therapy for the first time must have at least one clinical relapse documented (e.g., functional disability, hospitalization, acute steroid therapy, etc.) during the prior year
- Therapeutic failure or an inadequate response to two or more formulary medications (prior authorization may be required) indicated for the treatment of MS
- Member must have documented Expanded Disability Status Scale (EDSS) score of 5.0 or lower
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation of a clinical response defined as:
        - No increase in their Expanded Disability Status Scale (EDSS) score
        - No relapse rate increase or >1 relapse per year after at least 6 months of treatment

  - No evidence of liver impairment indicated by jaundice or ALT or AST at least two times the upper limit of normal
  - Continued enrollment and submission of requested patient data to TOUCH REMS Prescribing Program
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of moderate to severe Crohn's disease and the following criteria are met:

- Must be prescribed by, or in consultation with, a gastroenterologist
- Documentation of C-reactive protein >2.87 mg/L (evidence of inflammation) and baseline Crohn's Disease Activity Index ≥220 (moderate to severe disease)
- Must have an inadequate response or intolerance/contraindication to at least 2 medications from each of the following classes:
  - Aminosalicylates
  - Immunomodulators
  - TNF-α inhibitors
- **Initial Duration of Approval:** 12 weeks
- **Reauthorization criteria**
  - Documentation of a clinical response (decrease in CDAI from baseline)
  - No evidence of liver impairment indicated by jaundice or ALT or AST at least two times the upper limit of normal
  - Continued enrollment and submission of requested patient data to TOUCH REMS Prescribing Program
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.