Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

TYSABRI® (natalizumab)

GPI CODING:

62405050001320

DESCRIPTION:

Tysabri is a monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to delay the progression of disability and reduce the frequency of clinical exacerbations. It is also approved for the treatment of moderate to severe active Crohn's disease with evidence of inflammation. It is known as an alpha-4 integrin antagonist, and belongs to a new selective adhesion molecule (SAM) inhibitor class.
Tysabri has been FDA approved via a limited distribution system as monotherapy (not to be used in combination with other immune system modifying drugs) for those with Crohn's disease or relapsing multiple sclerosis who have not responded to or cannot tolerate other treatments and who meet the criteria of the TOUCH™ distribution system Prescribing Program.
Please note: This guideline addresses only the use of Tysabri and is not intended to apply to the treatment of Multiple Sclerosis by Beta Interferons (interferon beta 1-a [Avonex®, Rebif®], interferon beta 1-b [Betaseron®]) or Glatiramer Acetate (Copaxone®). The use of Tysabri® in conjunction with these agents is currently contraindicated by the FDA.

APPROVAL DURATION:

Approval duration: 6 months

CRITERIA FOR TYSABRI

I. Member has a diagnosis of relapsing forms of Multiple Sclerosis (MS) and meets all of the following:
   A. Member is 18 years of age or older **AND**
   B. Member has had a gadolinium–enhanced MRI scan of the brain and, when indicated, cerebrospinal fluid analysis to help differentiate potential future MS symptoms from PML as required by the FDA **AND**
   C. Member has had a trial and failure of at least one other treatment for MS OR is contraindicated to all treatments for MS (Beta Interferons [Avonex, Rebif], interferon beta 1-b [Betaseron] AND Glatiramer Acetate [Copaxone] AND fingolimod [Gilenya], AND teriflumonide [Aubagio]) **AND**
   D. Tysabri will be used as monotherapy **AND**
   E. Member is not currently on other immune system modifying drugs such as antineoplastics, immunosuppressants or immunomodulators **AND**
   F. Member does not have a medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, or lymphoma or organ transplantation **AND**
   G. Member does not have current or prior history of progressive multifocal leukoencephalopathy (PML), **AND**
   H. Member is enrolled in and meets all conditions of the MS TOUCH® (Multiple Sclerosis Tysabri Outreach: Unified Commitment to Health) Prescribing Program

II. Member has a diagnosis of moderate to severe active Crohn's disease with evidence of inflammation and meets all of the following:
   A. Member is 18 years of age or older **AND**
   B. Member has had an inadequate response or is unable to tolerate conventional therapies (sulfasalazine, mesalamine products, corticosteroids, immunosuppressants [6-mercaptopurine, azathioprine, cyclosporine, or methotrexate]) **AND**
   C. Member has had an inadequate response or is unable to tolerate Remicade AND Humira **AND**
   D. Tysabri is not used concomitantly with immunosuppressants (6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) **AND**
   E. Member does not have a medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, or lymphoma or organ transplantation **AND**
   F. If the member is on chronic oral corticosteroids, steroid tapering should begin as soon as a therapeutic benefit of Tysabri has occurred **AND**
   G. If oral corticosteroids cannot be tapered within six months of starting therapy, Tysabri must be discontinued **AND**
   H. If the member has not experienced therapeutic benefit by 12 weeks of induction therapy, Tysabri must be discontinued **AND**
   I. Member does not have current or prior history of progressive multifocal leukoencephalopathy (PML) **AND**
   J. Member is enrolled in and meets all conditions of the CD TOUCH® (Crohn's Disease Tysabri Outreach: Unified Commitment to Health) Prescribing Program

III. Prescribers should determine every six months whether individuals should continue on treatment
IV. After 2 years, prescribers should evaluate the risk of developing progressive multifocal leukoencephalopathy (e.g. tested for presence of anti- JC virus antibodies, current or past use of immunosuppressants such as methotrexate, mitoxantrone, mycophenolate).