Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Tysabri (natalizumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Tysabri (natalizumab)

APPROVAL CRITERIA

Requests for Tysabri (natalizumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease); **AND**
II. Individual has had an inadequate response to or is unable to tolerate, alternative treatments for MS; **AND**
III. Individual is enrolled in and meeting all conditions of the MS Touch Prescribing Program;

OR

IV. Individual has a diagnosis of moderate to severe Crohn's disease (CD) with evidence of inflammation and is using Tysabri for induction and maintenance of clinical response and remission; **AND**
V. Individual has had an inadequate response to or is unable to tolerate conventional CD therapies and inhibitors of TNF-α; **AND**
VI. Individual is enrolled in and met all conditions of the CD Touch Prescribing Program.

Tysabri (natalizumab) may not be approved for the following:

I. All other indications not included above; **OR**
II. Individual is using to treat primary progressive multiple sclerosis; **OR**
III. Individual is using to treat non-active secondary progressive multiple sclerosis; **OR**
IV. Individual is currently responsive to and tolerating another treatment for multiple sclerosis or Crohn's disease; **OR**
V. Individual has a current or prior history of progressive multifocal leukoencephalopathy (PML); **OR**
VI. Individual has a medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, lymphoma or organ transplantation; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

VII. Concurrent use with chronic antineoplastics, immunosuppressants (for example, azathioprine) or TNF- α inhibitors; **OR**

VIII. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif and Tecfidera); **OR**

IX. Individual has positive test results for anti- John Cunningham virus (JCV) antibodies.

Note: Tysabri has a black box warning for progressive multifocal leukoencephalopathy (PML). Tysabri increases the risk of PML, an opportunistic viral infection of the brain that usually leads to death or severe disability. Risk factors for the development of PML include duration of therapy, prior use of immunosuppressants, and presence of anti-JCV antibodies. Monitor patients and withhold Tysabri immediately at the first sign or symptom suggestive of PML. Because of the risk of PML, Tysabri is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS) called the TOUCH Prescribing Program.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 22, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: June 11, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 20, 2019.
5. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Subcommittee of the American Academy of Neurology. *Neurology*. 2018; 90: 777-788. Available from https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: July 20, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
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