Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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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 forms of multiple sclerosis (MS); **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. Individual is using to treat types of multiple sclerosis other than relapsing forms; **OR**
II. Individual is currently responsive to and tolerating another treatment for multiple sclerosis or Crohn's disease; **OR**
III. Individual has a current or prior history of progressive multifocal leukoencephalopathy (PML); **OR**
IV. Individual has a medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, lymphoma or organ transplantation; **OR**
V. Concurrent use with chronic antineoplastics, immunosuppressants (for example, azathioprine) or TNF- α inhibitors; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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VI. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Tecfidera, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron); **OR**

VII. 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:

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5. Olek MJ, Gonzalez-Scarano F, Dashe JF. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated June 28, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: June 29, 2018.
6. 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 Subcommittee of

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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the American Academy of Neurology. *Neurology*. 2018; 90: 777-788. Available from https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: June 28, 2018.