JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP022
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		Review Date	04/19/2023
	Subject **Tysabri**	*Revision Date*	02/22/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Tysabri

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I. POLICY

Tysabri (natalizumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

Tysabri may be approved for patients who meet the following:

Treatment of Relapsing multiple sclerosis (MS)

1. Patient is 18 years of age or older
2. Documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, progressive-relapsing MS [PRMS])
3. Patient has had inadequate response, or intolerance with two or more formulary (oral or subcutaneous) products from different therapeutic classes indicated for treatment of MS (at least 1-month trial per medication)
    i. If documentation has been provided showing the patient has aggressive, severe disease, a trial and failure with formulary alternatives will not be required
4. Patient has had anti-JCV antibody testing
5. Prescriber is, or in consultation with, a neurologist
6. Both the patient and prescriber are enrolled in the Tysabri REMS program

Induction and Maintenance of remission of moderate- to- severe Crohn's Disease (CD)

1. Patient is 18 years of age or older
2. Documented diagnosis of moderate-to-severe Crohn's Disease
3. Patient has had inadequate response, or intolerance with at least one agent from each of the following drug categories: aminosalicylates, corticosteroids, and immunomodulators
4. Patient has had inadequate response, or intolerance with at least TWO different TNF-alpha inhibitors (at least a 2-month trial per medication)
5. Patient has had anti-JCV antibody testing

6. Prescriber is, or in consultation with, a gastroenterologist
7. Both the patient and prescriber are enrolled in the Tysabri REMS program

III. AUTHORIZATION PERIOD/LIMITATIONS

- Initial approval will be limited to 3 months of therapy
- Continuation of therapy may be approved in 12-month intervals with documentation showing a beneficial response to treatment, evidence by:
  - Reduction in physical signs and symptoms
  - For MS: reduction, or stabilization of lesions per MRI data
  - For CD: reduction of daily chronic oral corticosteroids, and prolonged clinical remission and mucosal healing

IV. EXCLUSIONS

Tysabri will **not** be covered for the following:

- Patients with chronic progressive MS
- Patients with ulcerative colitis
- Patients who have or have had progressive multifocal leukoencephalopathy (PML)
- Patients with active infections, or immune-compromised
- Patient less than 18 years of age
- Concomitant use with other immunosuppressants, or disease-modifying agents
- Any indications that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

- **MS**: 300 mg infused over 1 hour every 4 weeks
- **CD**: 300 mg infused over 1 hour every 4 weeks.
  - Tysabri should be discontinued if therapeutic benefit is not observed within the initial 12 weeks of therapy.
  - If the patient is on chronic oral corticosteroids: discontinue Tysabri if the patient cannot be tapered off of oral corticosteroids within 6 months of therapy initiation with Tysabri

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Tysabri 300MG/15mL SOLN Injection, natalizumab, 1 mg	J2323

VII. REFERENCES

1. Tysabri [Prescribing Information]. Cambridge, MA. Biogen Inc.; 2018 April
2. Sandborn WJ, Colombel JF, Enns R, et al; International Efficacy of Natalizumab as Active Crohn's Therapy (ENACT-1) and the Evaluation of Natalizumab as Continuous Therapy (ENACT-2) Trial Groups. Natalizumab induction and maintenance therapy for Crohn's disease. N Engl J Med. 2005;353(18):1912-1925.
3. Targan SR, Feagan BG, Fedorak RN, et al; International Efficacy of Natalizumab in Crohn's Disease Response and Remission (ENCORE) Trial Group. Natalizumab for the treatment of active Crohn's disease: Results of the ENCORE Trial. Gastroenterology. 2007;132(5):1672-1683.
4. Goodin DS, Cohen BA, O'Connor P, et al. Assessment: The use of natalizumab (Tysabri) for the treatment of multiple sclerosis (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2008;71(10):766-773.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
12/19/18	Policy Creation
01/15/2020	No policy changes- presented policy for USFHP adoption effective 3/1/2020
11/10/2021	Removed Priority Partners as an applicable LOB
02/22/2023	Updated authorization guidance

Review Date: 12/19/2018, 01/15/2020

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