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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 04/16/2020

Inebilizumab

FDA approval: Anticipated June 2020

HCPCS: J3590

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by on in consultation with a neurologist
 - d. Must have had at least one attack needing rescue therapy within the last year
 - e. Must have an Expanded Disability Status Scale score of less than or equal to 7.5
 - f. Must not be used in combination with Soliris or other medication to treat neuromyelitis optica
 - g. Trial and failure, contraindication, OR intolerance to the preferred products as listed in BCBSM/BCN's medical utilization management drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: FDA approved dosing
 - b. Initial Authorization Period: 6 months
 - c. Renewal Criteria: Decrease in the number of relapses since starting therapy
 - d. Renewal Authorization Period: 1 year

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. FDA approved indication / Diagnosis

- a. Indicated as first-line monotherapy treatment for patients with neuromyelitis optica spectrum disorder (NMOSD)

**Please refer to most recent prescribing information.*

B. Background Information

- a. Neuromyelitis optica spectrum disorders are inflammatory disorders of the central nervous system characterized by severe, immune-mediated demyelination and axonal damage mainly of the optic nerves and spinal cord
- b. NMOSD is thought to be primarily mediated by the humoral immune system and the autoantibody, aquaporin-4 (AQP4) which is released by B-cells and plasmablasts
- c. Serum anti-AQP4 levels have been shown to correlate with disease activity and decrease after immunosuppressive therapy remaining low during remissions
- d. Prevalence of NMOSD in various studies ranges from 0.5 to 10 per 100,000 with a median age of onset from 32 to 41 years
- e. Hallmark features include acute attacks of bilateral or rapidly sequential optic neuritis or transverse myelitis which can result in blindness or paralysis of limbs
- f. Attacks typically occur over a couple days with recovery over weeks to months
- g. Ninety percent of cases are relapsing
- h. No American treatment guidelines are available for neuromyelitis optica spectrum disorders
- i. The European Federation of Neurological Societies published guidelines for the diagnosis and management of neuromyelitis optica in 2010
- j. The European guidelines recommend azathioprine plus prednisone or rituximab as first-line therapy to prevent attacks
- k. Second-line therapy includes cyclophosphamide, mitoxantrone, methotrexate, IVIG, mycophenolate mofetil, and intermittent plasma exchange
- l. Long term treatment options should be initiated as soon as the diagnosis is made to prevent attacks and reduce the risk of permanent disability, but evidence from randomized-controlled trials for any particular medication is lacking

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

- a. Dosing: 300 mg by IV infusion on days 1 and 15 then every 6 months thereafter

**Please refer to most recent prescribing information.*

F. How supplied

- a. Unknown at this time

References:

1. Wilson R, Makuch M, Kienzler AK, et al. Condition-dependent generation of aquaporin-4 antibodies from circulating B cells in neuromyelitis optica. *Brain*. April 2018; 141(4): 1063–74.
2. Cree BAC, Bennett JL, Kim HJ, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOMentum): a double-blind, randomized placebo-controlled phase 2/3 trial. *Lancet*. 2019 Oct 12; 394(10206): 1353 – 63.
3. Soliris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2019.
4. VielaBio. Potential first-line therapy for patients with NMOSD and other diseases sharing the autoantibody pathway. Available at: <https://vielabio.com/product-candidates/inebilizumab/>. Accessed on February 18, 2020.
5. Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in aquaporin-4 positive neuromyelitis optica spectrum disorder. *NEJM*. 2019 May 3. Doi: 10.1056/NEJMoa1900866.
6. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. *EJN*. 2010; 17: 1019 – 32.
7. Sherman E and Han MH. Acute and chronic management of neuromyelitis optica spectrum disorder. *Curr Treat Options Neurol*. 2015; 17(11): 48 – 62.

Policy History		
#	Date	Change Description
1.0	Effective Date: 4/16/2020	Preliminary drug review

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.