U.S. FOOD & DRUG ADMINISTRATION

ICD-10 Coordination & Maintenance Committee Meeting

Multiple Sclerosis Phenotypes

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TEAM

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DISCLAIMER

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This presentation reflects the views of the authors and do not necessarily represent FDA's views or policies.

MULTIPLE SCLEROSIS

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- Immune-mediated disease of the central nervous system characterized by inflammatory demyelination with axonal transection
- Chronic condition with a variable course

McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review. *JAMA.* 2021;325(8):765–779

DIAGNOSIS

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- Based on a combination of clinical, imaging, and laboratory evidence
  - 2017 McDonald criteria
- Defined by the demonstration of dissemination of MS disease characteristics in space (DIS) and time (DIT)
  - DIS refers to the presence of lesions in distinct CNS anatomical locations
  - DIT refers to the development of new lesions over time

Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. Lancet Neurol. 2018 Feb;17(2):162-173.

McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review. *JAMA.* 2021;325(8):765–779

PHENOTYPES

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- Relapsing-Remitting Multiple Sclerosis (RRMS)
- Secondary Progressive Multiple Sclerosis (SPMS)
  - Active
  - Non-active
- Primary Progressive Multiple Sclerosis (PPMS)

Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. Neurology. 2014 Jul 15;83(3):278-86.

APPROVED THERAPIES

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- Several classes of drugs and biologics, with varying mechanisms of action and routes of administration, are approved to treat RRMS and active SPMS
  - Including interferons, glatiramer acetate, teriflunomide, sphingosine-1-phosphate receptor modulators, fumarates, cladribine, and monoclonal antibodies targeting different immune system components
- As of today, only one product (biologic) is approved for the treatment of PPMS
  - This monoclonal antibody targeting CD20-expressing B cells is also approved to treat RRMS and active SPMS

McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review. *JAMA*. 2021;325(8):765–779

CURRENT CODING

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Currently, there is only one ICD-10-CM code for MS (G35), which does not inform about the MS phenotype

Current coding for Multiple Sclerosis

CHAPTER 6: Diseases of the nervous system (G00-G99)

Demyelinating diseases of the central nervous system (G35-G37)

G35 Multiple sclerosis
- Disseminated multiple sclerosis
- Generalized multiple sclerosis
- Multiple sclerosis NOS
- Multiple sclerosis of brain stem
- Multiple sclerosis of cord

ICD-10-CM (cdc.gov)

OBJECTIVE OF THE REQUEST

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Distinguish between the different MS phenotypes

- Improve the design and interpretation of investigations using real-world data to:
  - Investigate safety signals for treatments approved to treat MS, including those for newly approved treatments
  - Compare safety and effectiveness of treatments approved to treat MS
  - More accurately evaluate MS disease progression and long-term prognosis in population-based epidemiological studies
  - Make inferences at the phenotype level

- Disease management and healthcare utilization decision-making

PROPOSED CODING

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- Consistent with the recent revamping of U.S. package insert (USPI) indications performed by the FDA for all approved MS drugs and biologics

- Provides a broad separation between PPMS and other phenotypes, a fundamental clinical distinction with therapeutic and prognostic implications

- Allows the use of real-world data from electronic healthcare databases for regulatory research of safety and effectiveness of approved MS drugs and biologics

ACKNOWLEDGMENTS

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