Multiple sclerosis (MS) is a chronic, inflammatory, demyelinating disease of the central nervous system that is thought to be autoimmune in nature. In addition to demyelination, axonal and neuronal damage occur in this disease. In recent years, MS has received significant focus from health plans and those who manage drug benefits. MS affects nearly 400,000 individuals in the United States, and the majority of those affected by the disease have relapsing-remitting MS (RRMS). RRMS is characterized by clearly defined attacks, or relapses, of worsening neurological function with periods of partial to complete recovery between each attack. This form of MS occurs more often in women than men, with disease onset typically occurring between the ages of 20 and 50 years. Ultimately, patients with RRMS experience an accumulation of central nervous system damage and associated cognitive and physical disability progression. With the widespread use of disease-modifying therapies (DMTs), health plans have observed improved clinical outcomes for MS together with increasing associated pharmacy-related expenses.

Prior to the 1993 launch of interferon beta-1b (IFNβ-1b), the first approved DMT for MS, there were only a few drugs available to treat the disease, with most emphasis on the treatment of exacerbations. Health plans were not overly concerned with managing the cost of care associated with this illness. However, over the past 2 decades, several additional DMTs have been developed to reduce relapse rates, improve short-term functionality, and modify the overall disease course. In 2010, prior to the launch of fingolimod, the first oral agent for the treatment of MS, there were 7 injectable DMTs on the market: once-weekly intramuscular IFNβ-1a (Avonex, Biogen Idec), 3-times weekly subcutaneous (SC) IFNβ-1a (Rebif, EMD Serono), alternating daily SC IFNβ-1b (Betaseron, Bayer Healthcare Pharmaceuticals; Extavia, Novartis), once-daily SC glatiramer acetate (GA; Copaxone, Teva Pharmaceutical Industries), once-monthly intravenous natalizumab (Tysabri, Biogen Idec and Elan Pharmaceuticals), and 4-times yearly mitoxantrone (Novantrone, Immunex). Among these therapies, IFNβ formulations and GA have generally been regarded as the mainstays of first-line treatment of MS.

Fingolimod represents only the first of many new agents for the treatment of MS. Over the next 5 years, additional MS treatments may be introduced, including laquinimod, teriflunomide, dimethyl fumarate (BG-12), alemtuzumab, PEGylated interferon beta-1a, daclizumab, and ocrelizumab. If approved by the U.S. Food and Drug Administration, these new agents will broaden the available MS treatment options, but they will also likely create management issues for health plans. MS agents often account for a significant portion of a health plan's specialty drug budget, and this expenditure is expected to increase as new agents come to market. Health plans must balance access to these new MS agents with the needs of patients, clinical outcomes, and the overall cost of care associated with those outcomes. Balancing the known effectiveness and safety of existing MS therapies with the relative unknowns of some of the new agents will challenge drug benefit managers. Additionally, the potential for combination therapy with existing agents and newer drugs will become a reality, and health plans must be equipped to evaluate not only new therapies, but also new therapeutic combinations. These challenges are further complicated by issues such as patient adherence, persistence, and side effects. With the evolving MS treatment options, there is increased need for better information on comparative clinical outcomes, long-term safety, drug tolerability, cost-effectiveness, newer imaging techniques, and adherence and persistence. This information will be critical as health plans evaluate MS risk-benefit considerations and develop cost-effectiveness information and clinical management strategies to improve adherence and patient outcomes. Selecting therapy for patients with MS will become more complex over the next few years with the introduction of new therapies, some of which have unique safety considerations.

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