

**CENTER FOR HEALTH  
INFORMATION AND ANALYSIS**

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**MANDATED BENEFIT REVIEW OF H.B. 800  
SUBMITTED TO THE 189<sup>TH</sup> GENERAL COURT:  
AN ACT PROMOTING CONTINUITY OF CARE  
FOR MULTIPLE SCLEROSIS TREATMENT**

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## BENEFIT MANDATE OVERVIEW:

### H.B. 800: AN ACT PROMOTING CONTINUITY OF CARE FOR MULTIPLE SCLEROSIS TREATMENT

#### HISTORY OF THE BILL

The Committee on Financial Services referred House Bill (H.B.) 800, “An Act promoting continuity of care for multiple sclerosis treatment,” sponsored by Rep. Bradley of Hingham in the 189<sup>th</sup> General Court, to the Center for Health Information and Analysis (CHIA) for review.<sup>1</sup> Massachusetts General Laws, Chapter 3, Section 38C requires CHIA to review and evaluate the potential fiscal impact of a mandated benefit bill referred to the agency by a legislative committee.

#### WHAT DOES THE BILL PROPOSE?

The bill provides for continuity of coverage for treatment of multiple sclerosis:

- It requires carriers to cover a disease-modifying prescription drug for treatment of multiple sclerosis (MS) that the patient has already been prescribed and has been taking; it would apply to an MS patient entering or already in the carrier’s membership.
- It provides that these benefits shall not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other disease-modifying prescription drug for multiple sclerosis provided by the insurer.

#### MEDICAL EFFICACY OF H.B. 800

Multiple sclerosis (MS) is an unpredictable, frequently disabling disease of the central nervous system in which the immune system attacks the protective sheath (myelin) that surrounds, insulates, and protects nerve fibers. There is no cure for MS, but treatments can expedite recovery from attacks, modify the course of the disease, and manage symptoms. Disease-modifying drug therapy (DMT) is at the core of MS treatment, and is administered with the goals of reducing the frequency and severity of relapses and slowing the progression of disability. Research supports initiation of DMT early in the course of the disease, and patients who adhere to DMT experience better quality of life and lower risk of relapse.

Once a patient is managed effectively on a DMT, clinical literature supports continuing that DMT, except in prescribed circumstances. To the extent enactment of H.B. 800 would reduce the risk that patients would not be able to continue using an effective treatment, it would promote the health of the relevant population.

#### CURRENT COVERAGE

No current Massachusetts law requires coverage, or comparable cost-sharing, for continued treatment with a given DMT for current or new members. However, in a survey of carriers conducted for this analysis, carriers reported covering most available DMT. All surveyed carriers reported using both a tiered system to manage pharmacy benefits and “step therapy”<sup>i</sup> before covering non-preferred drugs. Carriers reported that their policies allow members to waive step therapy if the prescribing provider requests it as medically necessary, and carriers would consider covering a DMT drug not on their formularies on a case-by-case basis if the member’s healthcare provider requested an exception for medical necessity. When such an exception is granted, the member pays the highest tier cost-sharing.

<sup>i</sup> Most carriers use a three-tier formulary system where Tier 1, the tier with the lowest patient cost sharing, includes generic drugs, Tier 2 includes the carrier’s “preferred” brands, and Tier 3, the tier with the highest patient cost sharing, includes the carrier’s “non-preferred” brands.

## **COST OF IMPLEMENTING THE BILL**

Requiring coverage for this benefit by fully-insured health plans would result in an average annual increase, over five years, to the typical member's monthly health premiums of between \$0.02 (0.004%) and \$0.10 (0.021%), with the most likely value at approximately \$0.04 (0.008%). This increase is driven by the requirement that carriers must immediately cover any DMT drug for MS a new member had already been taking, regardless of the drug's status with respect to its formulary. The carrier would no longer have discretion to require new members who have already been taking a particular DMT drug to change to an alternative that is less expensive to the carrier.

The Massachusetts Division of Insurance and the Commonwealth Health Insurance Connector Authority are responsible for determining any potential state liability associated with the proposed mandate under Section 1311 of the Affordable Care Act (ACA).

## **PLANS AFFECTED BY THE PROPOSED BENEFIT MANDATE**

H.B. 800 provides for continued coverage of medications for multiple sclerosis for all commercially fully-insured health plans offered pursuant to Massachusetts General Laws, including general indemnity, Blue Cross Blue Shield, HMO coverage, as well as plans, both fully- and self-insured, sponsored by the Group Insurance Commission (GIC) for the benefit of public employees and their dependents. The proposed mandate would apply to members covered under the relevant plans issued in Massachusetts by the relevant Massachusetts-licensed carriers.

## **PLANS NOT AFFECTED BY THE PROPOSED BENEFIT MANDATE**

Self-insured plans (i.e., where the employer or policyholder retains the risk for medical expenses and uses a third-party administrator or insurer only to provide administrative functions), except for those provided by the GIC, are not subject to state-level health insurance mandates. State benefit plan mandates do not apply to Medicare and Medicare Advantage plans, the benefits of which are qualified by Medicare. State mandates also do not apply to federally-funded plans including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employee's Health Benefit Plan. In addition, Massachusetts benefit plan mandates do not apply to Massachusetts residents covered by plans governed by other states. The bill as drafted does not address Medicaid/MassHealth.

## MEDICAL EFFICACY ASSESSMENT

Massachusetts House Bill (H.B.) 800,<sup>2</sup> as submitted in the 189<sup>th</sup> General Court, requires commercial fully-insured health plans and plans sponsored by the Group Insurance Commission (GIC), to provide “coverage for a disease-modifying prescription drug for treatment of multiple sclerosis that the individual has already been prescribed and has already been taking.” It also requires that the benefits for the disease-modifying prescription drug “shall not be subject to any greater deductible, coinsurance, copayments or out-of-pocket limits than any other disease-modifying prescription drug for multiple sclerosis provided by the insurer.”

M.G.L. c. 3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service, and describe the potential impact of a mandated benefit on the quality of patient care and the health status of the population.

## MULTIPLE SCLEROSIS

Multiple sclerosis (MS) is an unpredictable and frequently disabling disease of the central nervous system—the brain and spinal cord—in which the immune system attacks the fatty protective sheath (myelin sheath) that surrounds, insulates, and protects nerve fibers.<sup>3,4</sup> When any part of the myelin sheath or nerve fiber is damaged or destroyed, nerve pulses traveling to and from the spinal cord are slowed or blocked.<sup>5</sup> This causes a wide variety of symptoms, depending on the amount of nerve damage and on which nerves are affected.<sup>6</sup> The “multiple” in MS refers to the many places in which myelin is lost, and “sclerosis” refers to the scars that form in the areas without myelin.<sup>7</sup> There is no cure for MS, but treatments can expedite recovery from attacks, modify the course of the disease, and manage symptoms.<sup>8</sup>

## MULTIPLE SCLEROSIS SYMPTOMS AND DIAGNOSIS

Most people who develop MS experience their first symptoms between the ages of 20 and 40.<sup>9</sup> Typical initial presentations include blurred or double vision, red-green color distortion, or even blindness in one eye.<sup>10</sup> Most MS patients develop muscle weakness in their extremities, which can lead to difficulty with coordination and balance.<sup>11</sup> MS symptoms can be severe, producing partial or complete paralysis.<sup>12</sup> Other symptoms may include transitory abnormal sensory feelings such as numbness, prickling, or complaints of “pins and needles”.<sup>13</sup> Some individuals may experience pain, speech impediments, tremors, and dizziness.<sup>14</sup> Hearing loss is an occasional symptom.<sup>15</sup> Approximately half of all patients with MS experience cognitive symptoms.<sup>16</sup> These symptoms include difficulties with concentration, attention, or memory, and poor judgment.<sup>17</sup> Depression is a common feature of MS.<sup>18</sup>

Although patients experience a wide variety of symptoms, the disease may take one of four courses (“types” or “phenotypes”).<sup>19</sup> The name of each course describes how the disease presents:<sup>20</sup>

- Relapsing-Remitting Multiple Sclerosis (RRMS) is the phenotype diagnosed in most people with MS (80 percent). Individuals with RRMS go through periods of symptoms (relapse) followed by absence of symptoms (remission).<sup>21</sup>
- Secondary Progressive Multiple Sclerosis (SPMS) is characterized by initial RRMS that suddenly begins to worsen without periods of remission.
- Progressive-Relapsing Multiple Sclerosis (PRMS) is the rarest type of MS, and it is characterized by a steady worsening of the disease with superimposed attacks.
- Primary Progressive Multiple Sclerosis (PPMS) is characterized by a steady increase in disability without attacks. The U.S. Food and Drug Administration (FDA) has approved no medications for the treatment of PPMS. This is because PPMS is characterized by nerve degeneration rather than inflammation, and disease-modifying treatments work primarily by reducing inflammation in the central nervous system.<sup>22</sup>

MS affects approximately 400,000 people in the United States;<sup>23</sup> an estimated 90 per 100,000 people have the disease.<sup>24</sup> However, the Centers for Disease Control and Prevention (CDC) does not require U.S. physicians to report new cases, and the symptoms of MS can be completely invisible.<sup>25</sup> Therefore, the prevalence of MS can only be estimated and may not be accurate.<sup>26</sup>

When considering MS as a potential diagnosis, the clinician must rule out other potential causes of the patient's symptoms.<sup>27</sup> An MS diagnosis requires a neurological exam and an extensive patient history, with detailed probing into any past neurological events. No single biological marker can diagnose MS.<sup>28</sup> A diagnostic workup typically begins with an MRI of the brain, with additional MRI studies related to specific symptoms.<sup>29</sup> A diagnosis of MS requires evidence of damage in two separate areas of the central nervous system which occurred at least one month apart.<sup>30</sup> A lumbar puncture or spinal tap is used to rule out other disease processes and help confirm an MS diagnosis.<sup>31</sup>

## DISEASE-MODIFYING THERAPY FOR MS

While no cure for MS exists, disease-modifying therapies (DMTs) have been shown to be effective in limiting the number of relapses, preventing new inflammatory lesions, and reducing the progression of disability.<sup>32,33</sup> Additionally, clinical trials have demonstrated that starting a DMT within three months of a first event decreases the risk of conversion to clinically-definite MS.<sup>34</sup> Currently the FDA has approved 13 disease-modifying agents. (See Appendix A.) Interferon injectibles and glatiramer acetate have long-established efficacy and have served as the primary DMTs since the 1990's, and they are the first-line treatments for RRMS, the most common phenotype.<sup>35</sup>

Since early 2010, many new drug therapies have been introduced, expanding treatment options for a disease that previously had very few.<sup>36</sup> Appendix B summarizes the efficacy findings and safety issues for approved DMTs; highlights of recent efficacy evaluations of the newer products follow.

In a review of the safety and efficacy of five new agents and one new dosage formulation, peginterferon beta 1a and high-dose glatiramer acetate were found to be effective, while reducing the burden (frequency) of administration.<sup>37</sup> Three new oral agents were found to have varying efficacy in reducing annualized relapse rates, compared with a placebo, of 48 to 55 percent (Fingolimod), 22 to 36 percent (teriflunomide), and 44 to 53 percent (dimethyl fumarate). Alemtuzumab, a biologic agent given over a 2-year span, reduced annualized relapse rates by 55 percent in previously-untreated patients and by 49 percent in patients relapsing on prior DMTs.<sup>38</sup> Adverse effects emerging during treatment were common with all drug treatments, including liver toxicity, infections, and neuropathy (see Appendix B for more detail).<sup>39</sup> In one recent large drug class review of disease-modifying drugs for MS,<sup>ii</sup> evidence was presented that interferon beta-1a IM (Avonex®) was less effective than interferon beta-1a SC (Rebif®) and interferon beta-1b (Betaseron®) for preventing relapse in RRMS.<sup>40</sup> However, in other outcomes and other populations, direct evidence was lacking or little difference was observed in the safety and effectiveness among the disease-modifying drugs.<sup>41</sup>

DMTs vary in routes and frequency of administration, tolerability and likelihood of treatment adherence, common adverse effects, risk of major toxicity, and pregnancy-related risks.<sup>42</sup> To establish a logical and safe treatment plan for each individual patient, these variables, as well as the benefit-risk profiles of each drug, must be carefully considered by the clinician and patient.<sup>43</sup>

## CONTINUITY OF TREATMENT

Numerous studies document the importance of taking MS disease-modifying agents regularly to achieve optimal outcomes.<sup>44,45,46</sup> In a large multicenter observational study in patients with RRMS, MS patients who adhered to their treatment with disease-modifying agents reported better quality of life and fewer neuropsychological issues than non-adherent patients.<sup>47</sup> In a systematic literature review, researchers found a greater risk of MS relapse or progression among patients who did not adhere to DMT compared to those who adhered.<sup>48</sup> In a retrospective study of patients taking interferon-beta therapy for MS, patients who adhered to treatment tended to have a lower risk of relapse over three years than did non-adherent patients.<sup>49</sup> In a study of 114 subjects with RRMS, researchers found that subjects who missed an injection had a fourfold chance of having a relapse.<sup>50</sup> Study authors have cited better quality of life, lower risk of relapse, and fewer hospitalizations and emergency room visits as benefits of adherence.<sup>51</sup>

ii Drugs studied for safety and efficacy included Glatiramer acetate (Copaxone®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1 (Betaseron®, Extavia®), mitoxantrone (Novantrone®), and natalizumab (Tysabri®).



In a review of current treatment strategies for MS, the authors advise that changes in disease-modifying therapy should be considered in specific situations, such as a suboptimal response to treatment, intolerable side effects, laboratory tests indicating reduced effectiveness of treatment, or the presence of certain antibodies under special circumstances.<sup>52</sup>

With the introduction of new DMTs, treatment decisions have become more complex. In a review of DMT selection and use for patients with MS, the author noted that the major goal of DMT therapy is to “balance perceived efficacy and tolerability in a specific patient with the relative impact of the disease activity and adverse events of quality of life.”<sup>53</sup> These factors are specific to each patient and how that patient’s characteristics and preferences interact with the benefits and risks of each drug.

By requiring coverage for members transitioning from one insurance plan to another, and prohibiting a carrier from discontinuing coverage, for an MS DMT when the member is actively using it, H.B. 800 reduces the risk that a member will experience a gap in treatment due to coverage or other non-clinical reasons.

## CONCLUSION

Disease-modifying therapy is at the core of MS treatment and is administered with the goals of reducing the frequency and severity of relapses, reducing the rate of nerve damage, and slowing the progression of disability. Research supports initiation of DMT early in the course of the disease, and patients who adhere to their DMT experience better quality of life and lower risk of relapse. Since 2010, the number and use of disease-modifying therapies has grown, with new mechanisms of action and expanded options for route and frequency of administration, and therapeutic approaches to MS are expected to continue to grow and evolve as researchers gain a better understanding of the pathogenesis of MS and the influence of environmental factors.<sup>54</sup> DMTs have numerous common side effects and carry many warnings. Choosing the right DMT for an individual depends on balancing many factors, including chances of adherence based on lifestyle. Once a patient is being managed effectively on a DMT, clinical literature supports continuation of that DMT except in prescribed circumstances. To the extent enactment of H.B. 800 would reduce the risk that patients would not be able to continue using an effective treatment, it would promote the health of the relevant population.

## APPENDIX A: ROUTE OF ADMINISTRATION AND COMMON SIDE EFFECTS OF MS DISEASE-MODIFYING THERAPIES<sup>55,56</sup>

Treatment (Chemical Name)	Route of Administration	Most Common Side Effects <sup>iii</sup>
Lemtrada® (alemtuzumab)	Intravenous infusion	Rash, headache, fever, nasal congestion, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infections, hives, itching, thyroid gland disorders, fungal infection, pain in joints, extremities and back, diarrhea, vomiting, flushing. Infusion reactions (including nausea, hives, itching, insomnia, chills, flushing, fatigue, shortness of breath, changes in the sense of taste, indigestion, dizziness, pain) also common while the medication is being administered and for 24 hours after infusion.
Tecfidera® (dimethyl fumarate)	Orally twice a day	Flushing (sensation of heat or itching and a blush on the skin), gastrointestinal issues (nausea, diarrhea, abdominal pain).
Gilenya® (fingolimod)	Orally once a day	Headache, flu, diarrhea, back pain, liver enzyme elevations, sinusitis, abdominal pain, pain in extremities and cough.
Glatopa® (glatiramer acetate)	Subcutaneously (under the skin) once a day	Injection site reactions (redness, pain, swelling).
Copaxone® (glatiramer acetate)	Subcutaneously once a day, three times a week	Injection site reactions (redness, pain, swelling), flushing, shortness of breath, rash, chest pain.
Avonex® (interferon beta-1a)	Intramuscularly (into a large muscle) once a week	Headache, flu-like symptoms (chills, fever, muscle pain, fatigue, weakness), injection site pain and inflammation.
Rebif® (Interferon beta-1a)	Subcutaneously three times per week	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness, headache), injection site reactions (redness, pain, swelling).
Betaseron® (interferon beta-1b)	Subcutaneously every other day	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness) following injection, headache, injection site reactions (swelling, redness, pain), injection site skin breakdown, low white blood count.
Extavia® (Interferon beta-1b)	Subcutaneously every other day	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness) following injection, headache.
Novantrone® (mitoxantrone)	Intravenous infusion	Nausea, hair loss, menstrual change, upper respiratory infection, urinary tract infection, mouth sores, irregular heartbeat, diarrhea, constipation, back pain, sinusitis, headache, blue-green urine.
Tysabri® (natalizumab)	Intravenous infusion	Headache, fatigue, joint pain, chest discomfort, urinary tract infection, lower respiratory tract infection, gastroenteritis, vaginitis, depression, pain in extremity, abdominal discomfort, diarrhea, rash.
Plegridy® (peginterferon beta-1a)	Subcutaneously every 14 days	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness, headache, itching). Injection site reactions (swelling, redness, pain).
Aubagio® (teriflunomide)	Orally once a day	Headache, hair thinning, diarrhea, nausea, abnormal liver tests.

iii In addition to common side effects, each disease modifying therapy has additional warnings. See Appendix B.

## APPENDIX B: CLINICAL EFFICACY AND SAFETY ISSUES FOR MS DISEASE-MODIFYING THERAPY<sup>57</sup>

Treatment	Clinical efficacy in placebo-controlled phase III trials <sup>iv</sup>	Safety issues
Alemtuzumab 12 mg/d intravenously for five days followed by 12 mg/d intravenously for three days one year after the first course	49%-55% reduction of ARR over two years compared to subcutaneous interferon beta 1a 42% reduction of progression of disability at two years compared to subcutaneous interferon beta 1a	Infusion associated reactions; cytokine release syndrome; lymphopenia; infections; autoimmune thyroiditis; thrombocytopenic purpura; glomerulonephritis
Dimethyl fumarate 240 mg orally twice a day	44%-53% reduction of ARR over two years 38% reduction of progression of disability at two years	Lymphopenia; progressive multifocal leukoencephalopathy
Fingolimod 0.5 mg orally every day	48%-54% reduction of ARR over two years 30% reduction of progression of disability at two years	Bradycardias after first dose; lymphopenia; viral infections (VZV); macular edema; hepatotoxicity; hypertension
Glatiramer acetate 20 mg subcutaneously every day	29% reduction of ARR over two years (RRMS) 45% risk reduction of conversion to CDMS at three years (CIS) No statistically significant effect on disability progression	Cutaneous necrosis; anaphylaxis (rare)
Interferon beta 1b 250 mcg subcutaneously every other day	34% reduction of annualized relapse rate (ARR) over two years (RRMS) 50% risk reduction of conversion to CD MS at two years (CIS) No statistically significant effect on disability progression	Hepatotoxicity; myelotoxicity; autoimmune thyroiditis; microangiopathy; epileptic seizures (rare)
Interferon beta 1a 30 mcg intramuscularly once a week	18% reduction of ARR over two years (RRMS) 44% risk reduction of conversion to CD MS at two years (CIS) No statistically significant effect on disability progression	Same as above
Interferon beta 1a 44 mcg subcutaneously three times a week.	32% reduction of ARR over two years (RRMS) 45% risk reduction of conversion to CD MS at two years (CIS) 30% reduction of progression of disability at two years (RRMS)	Same as above
Mitoxantrone 12 mg/m <sup>2</sup> intravenously every three months or 8 mg/m <sup>2</sup> intravenously every month	65% reduction of relapse risk over two years (mostly in RRMS) 66% reduction of risk of disability progression at two years (mostly in RRMS)	Infusion site tissue necrosis; myelotoxicity; infections; cardiotoxicity; acute leukemia
Peginterferon beta 1a 125 mcg subcutaneously every two weeks	36% reduction of ARR over one year	Same as above
Natalizumab 300 mg intravenously every four weeks	68% reduction of ARR over two years 42% reduction of progression of disability at two years	Infusion associated reactions; anaphylaxis; infections; hepatotoxicity; progressive multifocal leukoencephalopathy
Teriflunomide 14 mg orally every day	31%-36% reduction of ARR over one year or more 26%-32% reduction of progression of disability at one year or more	Myelotoxicity; hepatotoxicity; infections; peripheral neuropathy; pancreatic fibrosis; teratogenicity (requires accelerated elimination procedure)

<sup>iv</sup> CDMS: Clinically Definite MS; CIS: Clinically isolated syndrome; RRMS: Relapsing-remitting MS; ARR: Annualized relapse rate.

## ENDNOTES

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**Actuarial Assessment of  
House Bill 800  
Submitted to the 189<sup>th</sup> General Court:  
“An Act promoting continuity of care for  
multiple sclerosis treatment”**

Prepared for  
Commonwealth of Massachusetts  
Center for Health Information and Analysis

October 2016

Prepared by  
Compass Health Analytics, Inc.



**Actuarial Assessment of House Bill 800:  
“An Act promoting continuity of care for multiple sclerosis treatment”**

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# Actuarial Assessment of House Bill 800: “An Act promoting continuity of care for multiple sclerosis treatment”

## Executive Summary

Massachusetts House Bill (H.B.) 800, as submitted in the 189<sup>th</sup> General Court, requires health insurance carriers to provide continued coverage of a “disease-modifying prescription drug to treat multiple sclerosis (MS) that the individual has already been prescribed and has already been taking.” This coverage “shall not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other disease-modifying prescription drug for multiple sclerosis provided by the insurer.”<sup>1</sup>

Massachusetts General Laws (M.G.L.) c.3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. (Compass) to provide an actuarial estimate of the effect enactment of the bill would have on the cost of insured health plans in Massachusetts.

### Background

H.B. 800 requires health insurance carriers to provide continued coverage of a disease-modifying treatment (DMT) drug to treat MS that the individual has already been prescribed and has already been taking, and that increasing cost sharing for such coverage is not allowed. There are thirteen<sup>2</sup> DMT drugs for MS currently on the market. The treatments are distinct and not all are safe or effective for every patient.<sup>3</sup> Appendix A lists these drugs, their routes of administration, clinical effectiveness, common side effects, and safety issues.

Considerable evidence supports the importance of early initiation of a DMT in the course of MS.<sup>4,5</sup> Once a patient is being managed effectively on a DMT, the literature supports continuing that specific DMT drug indefinitely unless there are contraindications such as sub-optimal treatment response or intolerable side effects.<sup>6</sup>

### Current Coverage

All carriers responding to a Compass survey regarding H.B. 800<sup>i</sup> covered most available DMT drugs for MS throughout the retrospective analysis period of calendar year 2014.<sup>ii</sup> The main exception is Extavia®, which is not covered by a set of carriers comprising the majority of fully-insured commercial membership. However, Betaseron®, which is covered by all surveyed carriers, has the same active compound, dosage, and route of administration as Extavia®.

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<sup>i</sup> Eleven major Massachusetts commercial carriers, with a combined membership comprising approximately 90% of the Massachusetts commercial fully-insured population, responded to the survey.

<sup>ii</sup> Plegridy® received FDA approval in August 2014, Lemtrada® in November 2014, and Glatopa® in April 2015.

All responding carriers use a tiered system to manage pharmacy benefits. Most use a closed three-tier formulary (where Tier 1, the tier with the lowest patient cost sharing, includes generic drugs, Tier 2 includes the carrier's "preferred" brands, and Tier 3, the tier with the highest patient cost sharing, includes the carrier's "non-preferred" brands) system. All carriers require "step therapy" before they will cover a non-preferred drug. In step therapy, a member must try other medications first and have documented therapeutic failure or severe side effects before a similar higher-tier drug will be covered.

Carriers stated in their step therapy policies that these programs may allow members with a chronic condition such as MS to waive step therapy and continue on a non-preferred medication if the prescribing provider requests it as medically necessary.

In a closed-formulary system, drugs not on the formulary are not covered. All carriers reporting a closed-formulary system reported that they would consider covering non-formulary DMT drugs for MS on a case-by-case basis if the member's healthcare provider requested an exception for medical necessity. When such exceptions are granted, the member pays the highest-tier cost sharing.

### Expanded Coverage

If H.B. 800 were enacted, carriers would immediately cover any DMT drug for MS a new member had already been taking, regardless of the drug's status with respect to its formulary. This provision is the only portion of the law that would have a material cost impact. In the case where a carrier removes a DMT drug for MS from its formulary, a current member already taking that drug would have continued coverage, a provision which data reviewed for this study suggests would not have a material cost impact. In both cases, the drug would be covered with member cost sharing no greater than the highest cost sharing of a DMT drug for MS on the carrier's formulary. Based on data collected for this study, this cost-sharing provision would also not have a significant cost impact.

In addition, the text of the bill might be read to suggest that, if a drug were moved to a tier higher than that of any other DMT drug for MS on the carrier's formulary (e.g., a carrier moved a DMT drug to Tier 3, when prior to the move all covered DMT drugs had been on lower tiers), those members already taking the drug would be covered under the terms of the highest tier for a DMT drug prior to the change. In the example above, the drug moved to Tier 3 would have to be covered as a Tier 2 drug for current members who had already been taking it at the time of the change. Current carrier coverage indicates this interpretation would not have a material cost impact.

### Analysis

Estimating H.B. 800's impact on premiums requires estimating the number of commercial fully-insured Massachusetts residents using DMT drugs for MS who may be affected by the bill, and the average annual cost per affected user of continuous coverage for DMT drugs for MS when members switch carriers.

Compass then multiplied these estimates together and projected them forward over the next five years (2017 to 2021) for individuals under age 65 with Massachusetts-regulated, fully-insured

commercial coverage, forecasting prescription drug inflation and adding carrier retention (administrative cost and profit) to arrive at an estimate of the bill's effect on premiums.

This analysis relies on estimates of the number of fully-insured Massachusetts residents taking DMT drugs who would be affected by the proposed mandate, the annual cost to carriers of continuing the coverage, and the rate of inflation of prescription drug prices. The uncertainties inherent in such estimates are addressed by modeling a range of assumptions within reasonable judgment-based limits, and producing a range of incremental impact estimates based on varying these parameters.

### Summary results

Table ES-1 summarizes the estimated effect of H.B. 800 on premiums for fully-insured plans over five years. This analysis estimates that the proposed mandate, if enacted as drafted, would increase fully-insured premiums by as much as 0.021 percent on average over the next five years; a more likely increase is in the range of 0.008 percent, equivalent to an average annual expenditure of \$879 thousand over the period 2017 to 2021.

The impact of the bill on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides and on how those benefits would change under the proposed mandate.

**Table ES1:  
Summary Results**

	2017	2018	2019	2020	2021	Weighted Average	5 Yr Total
Members (000s)	2,020	2,018	2,015	2,011	2,007		
Medical Expense	\$245	\$365	\$387	\$411	\$436	\$391	\$1,843
Medical Expense	\$490	\$729	\$774	\$821	\$871	\$782	\$3,685
Medical Expense	\$1,198	\$1,909	\$2,167	\$2,460	\$2,791	\$2,234	\$10,525
Premium Low	\$275	\$410	\$435	\$461	\$489	\$439	\$2,070
Premium Mid	\$550	\$819	\$870	\$923	\$979	\$879	\$4,140
Premium High	\$1,346	\$2,144	\$2,435	\$2,763	\$3,136	\$2,509	\$11,824
PMPM Low	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02
PMPM Mid	\$0.03	\$0.03	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04
PMPM High	\$0.08	\$0.09	\$0.10	\$0.11	\$0.13	\$0.10	\$0.10
Estimated	\$463	\$473	\$483	\$493	\$503	\$483	\$483
Premium % Rise	0.003%	0.004%	0.004%	0.004%	0.004%	0.004%	0.004%
Premium % Rise	0.007%	0.007%	0.007%	0.008%	0.008%	0.008%	0.008%
Premium % Rise	0.017%	0.019%	0.021%	0.023%	0.026%	0.021%	0.021%

# Actuarial Assessment of House Bill 800: “An Act promoting continuity of care for multiple sclerosis treatment”

## 1. Introduction

Massachusetts House Bill (H.B.) 800, as submitted in the 189<sup>th</sup> General Court, requires health insurance carriers to provide continued coverage of a “disease-modifying prescription drug to treat multiple sclerosis (MS) that the individual has already been prescribed and has already been taking.” This coverage “shall not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other disease-modifying prescription drug for multiple sclerosis provided by the insurer.”<sup>7</sup>

Massachusetts General Laws (M.G.L.) c.3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged Compass Health Analytics, Inc. (Compass) to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health insurance in Massachusetts.

Assessing the impact of the proposed mandate on premiums entails analyzing its incremental effect on spending by insurance plans. This in turn requires comparing spending under the provisions of the bill to spending under current statutes and current benefit plans for the relevant services.

Section 2 of this report outlines the provisions of the bill. Section 3 summarizes the methodology used for the estimate. Section 4 discusses important considerations in translating the bill’s language into estimates of its incremental impact on health care costs and steps through the calculations. Section 5 summarizes the results.

## 2. Interpretation of H.B. 800

H.B. 800 requires carriers to provide continued coverage of a disease-modifying therapy (DMT) drug to treat MS that the patient has already been prescribed and has already been taking. This coverage shall not be subject to any cost-sharing terms or out-of-pocket limits greater than those for any other disease-modifying prescription drug for multiple sclerosis provided by the carrier.

### 2.1. Plans affected by the proposed mandate

The bill amends statutes that regulate health insurance carriers in Massachusetts. It includes five sections, each of which addresses statutes dealing with a particular type of health insurance policy:

- Section 1: Group Insurance Commission (GIC) (amending M.G.L. c. 32A by adding §28 )
- Section 2: Accident and sickness insurance policies (amending M.G.L. c. 175 by inserting §47EE after §47DD)

- Section 3: Contracts with non-profit hospital service corporations (amending M.G.L. c. 176A by inserting §8GG after §8FF)
- Section 4: Certificates under medical service agreements (amending M.G.L. c. 176B by inserting §4GG after §4FF)
- Section 5: Health maintenance contracts (amending M.G.L. 176G by inserting §4Y after §4X)

This bill requires coverage for Massachusetts residents insured under the license types listed above, with the exception of individuals insured under GIC, who are covered regardless of state of residence. Self-insured plans, except for those managed by the GIC, are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare or Medicare Advantage plans, the benefits of which are qualified by Medicare; this analysis excludes members of fully-insured commercial plans over 64 years of age and does not address any potential effect on Medicare supplement plans even to the extent they are regulated by state law. This analysis does not apply to Medicaid/MassHealth.

## 2.2. Covered services

H.B. 800 requires health insurance carriers to provide continued coverage of a DMT drug to treat MS that the patient has already been prescribed and has already been taking. Considerable evidence supports the importance of early initiation of a DMT in the course of MS.<sup>8,9</sup>

Once a patient is managed effectively on a DMT, the literature supports continuing that specific DMT drug indefinitely unless contraindications such as sub-optimal treatment response or intolerable side effects appear.<sup>10</sup> Thirteen<sup>iii</sup> DMT drugs for MS are currently on the market. The treatments are distinct and not all are safe or effective for every patient.<sup>11</sup> Appendix A lists these drugs, their routes of administration, clinical effectiveness, common side effects, and safety issues.

## 2.3. Current coverage

All carriers responding to a Compass survey regarding H.B. 800<sup>iv</sup> covered most available DMT drugs for MS throughout the retrospective analysis period of calendar year 2014.<sup>v</sup> The main exception is Extavia®, which is not covered by a set of carriers comprising the majority of fully-insured commercial membership. However, Betaseron®, which is covered by all surveyed carriers, has the same active compound, dosage, and route of administration as Extavia®.

All responding carriers use a tiered formulary system to manage pharmacy benefits. Most use a closed three-tier formulary system (where Tier 1, the tier with the lowest patient cost sharing, includes generic drugs, Tier 2 includes the carrier’s “preferred” brands, and Tier 3, the tier with the highest patient cost sharing, includes the carrier’s “non-preferred” brands). Only one DMT drug for

<sup>iii</sup> This analysis treats Copaxone® 20mg and Copaxone® 40mg as distinct drugs.

<sup>iv</sup> Eleven major Massachusetts commercial carriers, with a combined membership comprising approximately 90% of the Massachusetts commercial fully-insured population, responded to the survey.

<sup>v</sup> Plegridy® received FDA approval in August 2014, Lemtrada® in November 2014, and Glatopa® in April 2015.

MS, Glatopa®, is generic. All other covered DMT drugs for MS fall in the preferred or non-preferred brand tiers.<sup>vi</sup>

All carriers require “step therapy” before they will cover a non-preferred drug. In step therapy, a member must try and have documented therapeutic failure or side effects so severe as to preclude use of similar lower-tier drugs (e.g., the generic and the preferred brand), if alternatives exist. Carriers stated that their step therapy policies allow members with a chronic condition such as MS to waive step therapy and continue on a non-preferred medication if the prescribing provider requests it as medically necessary.

In a closed-formulary system, drugs not on the formulary are not covered. All carriers reporting a closed-formulary system reported that they would consider covering non-formulary DMT drugs for MS on a case-by-case basis if the member’s healthcare provider requested an exception with adequate documentation of step therapy and/or that the member’s condition was stable on the non-formulary drug and that discontinuing the non-formulary drug would threaten that stability. When such exceptions are granted, the member pays the highest-tier cost sharing.

## 2.4. Expanded coverage

H.B. 800 contains two main provisions related to DMTs for multiple sclerosis:

1. *Continuity of Coverage.* Carriers would be required to provide continued coverage of a “disease-modifying prescription drug to treat multiple sclerosis (MS) that the individual has already been prescribed and has already been taking.”<sup>12</sup> This provision requires that:
  - a. A carrier must immediately cover any DMT drug for MS that a new member had already been taking, regardless of the drug’s status in the carrier’s formulary.
  - b. If a carrier removed a DMT drug for MS from its formulary, the carrier would continue to cover that drug for current members already taking it.
2. *Comparable cost sharing.* This coverage “shall not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other disease-modifying prescription drug for multiple sclerosis provided by the insurer.”<sup>13</sup>

Under the first continuity of coverage requirement, carriers would immediately cover any DMT drug for MS that a new member had already been taking, whether or not the drug is included in the member’s new pharmacy benefit plan and regardless of the new plan’s step therapy requirements. This provision drives the cost of the proposed mandate, as it removes carriers’ discretion to require new members who have already been taking a particular DMT drug to change to an alternative that is less expensive to the carrier.

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<sup>vi</sup> Some carriers offer a four-tier formulary in some plans. Typically, the highest cost-sharing fourth tier will consist of expensive “specialty drugs.” DMT drugs for MS are likely to be placed in this specialty tier on such formularies.

In the second continuity of coverage requirement, under which a carrier removes a DMT drug for MS from its formulary, a current member who has already been taking that particular drug would have continued coverage. Formulary changes are infrequent, and likely to occur only in the case of therapeutic equivalence between two drugs, the removal of a drug from the market, or significant adverse reactions. One major carrier noted that the last time a DMT drug for MS was removed from their formulary was in 2011; the non-covered drug is one of two that are therapeutically equivalent. Also, as noted above, all carriers have exception processes in place allowing coverage of non-formulary drugs as medically necessary. Given these facts, the cost of this requirement of the mandate, if any, is likely to be immaterial.

The provision of the bill requiring comparable cost sharing might be read to suggest that, if a drug were moved to a tier higher than that of any other DMT drug for MS on the carrier's formulary (e.g., a carrier moved a DMT drug to Tier 3, when prior to the move all covered DMT drugs had been on lower tiers), those members already taking the drug would be covered under the terms of the highest tier for a DMT drug prior to that change. In the example above, the drug moved to Tier 3 would have to be covered as a Tier 2 drug for current members already taking it at the time of the change. Given that all carriers responding to the Compass survey already cover at least one DMT drug for MS at the highest tier, this analysis estimates the cost of this provision to be zero.

## 3. Methodology

### 3.1. Overview

Based on the interpretation of H.B. 800's provisions in Section 2, the analysis focused on the effect of the continuity of coverage provision on members moving from one carrier to another. Estimating the bill's impact on premiums requires estimating the number of commercial fully-insured Massachusetts residents affected by the bill, and the average annual cost per affected user of continuous coverage for DMT drugs for MS. Combining these components, and accounting for carrier retention, results in a baseline estimate of the proposed mandate's incremental effect on premiums, which is then projected over the five years following the assumed January 1, 2017 implementation date of the law.

### 3.2. Data sources

The primary data sources used in the analysis were:

- Information, including descriptions of current coverage, from responses to a survey of commercial health insurance carriers in Massachusetts
- Academic literature, published reports, and population data, cited as appropriate
- An interview with a panel of experts on MS including the author of the bill text and a neurologist who treats MS patients



- Massachusetts carrier claim data from CHIA’s Massachusetts All Payer Claim Database (MA-APCD) for calendar year 2014, for plans covering the majority of the under-65 fully-insured population subject to the mandate

### 3.3. Steps in the analysis

The analysis was executed in the following steps.

#### *Estimate the number of members affected by the bill*

- Estimate the number of commercial fully-insured Massachusetts residents taking a DMT drug for MS.
- Identify all commercial DMT drug claims during the study period in the MA-APCD.
- Calculate the percent of fully-insured DMT drug users during the study period who skipped doses at the time of the carrier switch, defined as a gap of greater than one month’s supply, but who later had claims for the drug under the new carrier.
- Calculate the average number of doses missed per user who skipped doses but later had DMT claims under the new carrier.
- Calculate the percent of fully-insured DMT drug users who discontinued use of a DMT for the remainder of the study period at the time of the carrier switch.
- Multiply the estimated number of commercial fully-insured Massachusetts residents taking DMT drugs for MS by the rates of coverage discontinuities to estimate the number of members affected by the mandate in each group.

#### *Estimate the annual medical expense of continued DMT coverage*

- Using the MA-APCD, calculate the average paid cost per user per month for all DMT drugs.
- Estimate the average cost per user per year for members with missed doses as the average cost per month of DMT drugs multiplied by the average number of doses skipped and then by the estimated number of affected fully-insured individuals.
- Estimate the average cost per user per year for members dropping DMT utilization when switching carriers as the average cost per month of DMT drugs multiplied by twelve and then by the estimated number of affected fully-insured individuals.
- Sum the cost estimates for the two types of affected individuals.

#### *Calculate insurance premium impact of continued DMT coverage over the next five years*

- Divide the annual incremental cost by the corresponding membership to calculate a baseline per-member per-month (PMPM) cost.
- Estimate the impact of carrier retention (administrative costs and profit) on premiums.

- Calculate the annualized rate of price inflation of DMT drugs for MS for commercial fully-insured users in the MA-APCD over the period 2011 to 2014.
- Project the PMPM cost forward over the five-year analysis period using annualized rates of pharmaceutical price inflation from published studies.
- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2017 to 2021).
- Multiply the PMPM costs by the corresponding membership to calculate annual incremental cost.

Section 4 describes these steps in more detail.

### 3.4. Limitations

Challenges and limitations in estimating the cost of this mandate include:

- *Data limitations:* Compass reviewed MA-APCD claim records for DMT drugs for members who switched carriers during the period November 15, 2013 to November 14, 2014 to identify members possibly affected by the mandate. These gaps may have indicated a break in treatment while seeking an exception for coverage with the new carrier, failure to obtain coverage under a new carrier, or a voluntary break in adherence. It is impossible to discern from claim data if a member discontinued a drug for coverage reasons or because the member voluntarily discontinued the drug coincidentally with a coverage change.
- *Lack of information on carrier pharmacy rebates:* Many carriers receive rebates from the makers of certain pharmaceutical products, likely including some DMT drugs for MS. These rebates can materially change the carriers' costs for the rebated products. However, rebate data are proprietary to the carriers and are not submitted to the MA-APCD, nor are there any secondary public sources available for this information.

These uncertainties are addressed by modeling a range of assumptions within reasonable judgment-based limits, and producing a range of estimates of incremental cost by varying the modeled parameters. The more detailed step-by-step description of the estimation process outlined in the next sections addresses these uncertainties further.

## 4. Analysis

This section describes the calculations outlined in the previous section in more detail. The analysis includes development of a “middle-cost” scenario, as well as a low-cost scenario using assumptions that produced a lower estimate, and a high-cost scenario using more conservative assumptions that produced a higher estimated impact.

Sections 4.1 and 4.2 below describe the steps used to calculate the number of fully-insured commercial members affected by the mandate and the associated cost per user per year. Sections

4.3 to 4.8 discuss the incremental cost calculation and the projection over the 2017 to 2021 reporting period.

#### 4.1. Estimate members affected by the mandate

Estimating the cost of the mandate requires first estimating the number of commercial fully-insured Massachusetts residents affected by the mandate in one year.

Continuous use of DMT for MS is extremely important to the treatment's efficacy; even short lapses in adherence can allow relapses resulting in permanent neurological consequences to the patient. However, studies of DMT drug adherence in MS patients have found adherence rates ranging from 61 to 87 percent.<sup>14</sup> Compass's review of MA-APCD claim data and anecdotal evidence from a neurologist specializing in MS interviewed by Compass staff are consistent with these results.

Compass reviewed all MA-APCD claim records for members with consistent DMT drug utilization who switched carriers during the period November 15, 2013 to November 14, 2014 to identify members experiencing coverage discontinuities. These missed doses may have indicated a break in treatment while seeking an exception for coverage with the new carrier, failure to obtain coverage under a new carrier, or a voluntary break in adherence. It is impossible to discern from claim data if a member discontinued a drug for coverage reasons or because the member voluntarily discontinued the drug coincidentally with a coverage change. To account for this uncertainty, Compass estimated a range of estimates of incremental cost for the proposed mandate in the following steps.

##### Estimate the number of commercial fully-insured Massachusetts residents taking DMT for MS

The Greater New England Chapter of the National MS Society states that "more than 12,000" Massachusetts residents have MS.<sup>15</sup> Approximately 85 percent of people with MS have a relapsing form of the disease, for whom the literature supports initiating DMT as soon as possible following diagnosis,<sup>16,17</sup> with treatment to continue indefinitely unless contraindicated.<sup>18</sup> Approximately 15 percent of individuals with MS have Primary Progressive MS (PPMS), for which there are no FDA-approved treatments.<sup>19</sup> Assuming total MS incidence of 12,000 in the population, Compass estimated approximately 3,000 fully-insured commercial members using DMT drugs for MS resided in the Commonwealth in 2014, using the following calculation and rounding the result to the nearest hundred:

	12,000	Massachusetts residents with MS
X	85.0%	MS patients with a relapsing form of MS
X	84.9%	Proportion of Massachusetts residents aged 0-64 <sup>20</sup>
X	34.2%	Massachusetts residents with fully insured commercial insurance <sup>21</sup>
	2,963	Commercial fully-insured Massachusetts residents using DMT in 2014

### Calculate an estimate of DMT drug users missing doses due to coverage gaps

Between November 15, 2013 and November 15, 2014,<sup>vii</sup> approximately 1.7 percent of commercial fully-insured DMT drug users that showed consistent monthly prescription fills for MS reported in the MA-APCD showed a gap of at least one month in DMT drug claims after switching carriers.

Applying this rate to the estimated 3,000 fully-insured commercial Massachusetts residents using DMT drugs for MS yields an estimate of 51 affected users:

$$\begin{array}{r} 3,000 \text{ Massachusetts-resident FI users of DMT Drugs for MS} \\ \times \quad 1.7\% \text{ of FI MA-APCD DMT users with gaps in coverage} \\ \hline 51 \text{ FI Massachusetts residents potentially affected by the mandate} \end{array}$$

The average gap in coverage (based on prescription fill dates or service dates) was approximately 6.5 weeks (1.52 months). Assuming that members switching carriers would continue to experience short administrative delays in obtaining coverage in the presence of the proposed mandate (time would still be required for documentation of the ongoing prescription to be provided to the new carrier, and for the authorization to be processed in order to begin coverage), Compass assumed a half-month coverage gap would remain under the proposed mandate due to administrative delays, yielding a reduction in average length of coverage gaps per user of approximately one month (1.52 months less 0.5 months) to calculate the incremental cost to carriers of H.B. 800, resulting in an estimated 52 incremental months of coverage for these members:

$$\begin{array}{r} 51 \text{ Massachusetts-resident FI users with gaps in coverage} \\ \times \quad 1.02 \text{ Average incremental increase in coverage (in months)} \\ \hline 52 \text{ Incremental months of coverage under H.B. 800} \end{array}$$

### Calculate an estimate of DMT drug users discontinuing use

Between November 15, 2013 and November 15, 2014, approximately 0.4 percent of commercial fully-insured DMT drug users reported in the MA-APCD discontinued use of their DMT drug after switching carriers. Applying this discontinuation rate to the estimated 3,000 fully-insured commercial Massachusetts residents using DMT drugs for MS yields an upper bound estimate of eleven affected users:

$$\begin{array}{r} 3,000 \text{ Massachusetts-resident FI users of DMT Drugs for MS} \\ \times \quad 0.4\% \text{ of MA-APCD DMT users discontinuing at the time of carrier switch} \\ \hline 12 \text{ Incremental users} \end{array}$$

## **4.2. Monthly cost per user of continued DMT drug treatment for MS**

Compass calculated an upper bound average annual cost per user of continued DMT for MS of \$68,000, representing a \$5,667 cost per month. This monthly amount is the 2014 weighted average commercial carrier paid cost per user per month before rebates for DMT drugs for MS.

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<sup>vii</sup> This time span was chosen in order to observe January 1<sup>st</sup> coverage changes.

### 4.3. Annual incremental medical expense of continued DMT drugs for MS

Compass calculated the high-cost scenario incremental cost for the additional months of coverage for members with missed doses by multiplying the estimated 52 months of additional coverage by \$5,667.

The high-cost scenario incremental cost for the eleven users who discontinued use upon switching carriers was calculated by multiplying the eleven incremental users by \$68,000, the average monthly drug cost multiplied by twelve. This estimate reflects two conservative assumptions: (i) that affected members are discontinuing use of DMT drugs for MS due to a change in carriers at the beginning of the year with no administrative gap in coverage and (ii) that affected members would have 100 percent treatment adherence throughout the year in the presence of the proposed mandate.

Both high-cost scenario estimates reflect the conservative assumption that all observed discontinuities in DMT drug claims were the result of carrier coverage issues, not medical decisions or voluntary gaps in adherence.

Using assumptions more conservative than can be directly supported by data reflects the uncertainty introduced by the lack of carrier pharmaceutical rebate data. The resulting upper bound cost estimate, although larger than observable evidence supports, reflects the fact that carriers may experience costs in the presence of the proposed mandate (due to lost rebates) that are not measurable within the scope of this study.

The mid-level cost scenario is assumed to be half of the high scenario cost (e.g. a slightly longer administrative gap and an average mid-year carrier change). In the absence of evidence on which to base the low-cost cost scenario, the low-level cost is assumed to be half of the mid-level cost. Table 1 displays these results.

**Table 1:  
Estimated 2014 Annual Marginal Cost of Continuous Coverage of DMT Drugs for MS**

	Incremental Cost of Missed Doses	Incremental Cost of Discontinuing Users	Total Incremental Cost of H.B. 800
Low Scenario	\$74,000	\$204,000	\$278,000
Mid Scenario	\$147,000	\$408,000	\$555,000
High Scenario	\$295,000	\$816,000	\$1,111,000

H.B. 800 may be interpreted to require each carrier to cover all DMT drugs for MS on the same cost-sharing terms as the *lowest*-tier DMT drug for MS on its formulary. This interpretation, while not used in this cost analysis, would likely have a minimal incremental impact on the estimated cost of the mandate given the low number of claims impacted.<sup>viii</sup>

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<sup>viii</sup> While this amount is not material from the carrier or market-wide perspective, such a co-pay differential may be a material benefit to the individual members, especially considering MS patients often take multiple expensive drugs to manage symptoms in addition to DMT.

#### 4.4. Incremental PMPM medical expense

The annual cost is then divided by estimated commercial fully-insured 2014 member months for Massachusetts residents to derive the estimated baseline PMPM incremental medical expense attributable to the proposed mandate. Table 2 shows these results.

**Table 2:  
Estimate of Increase in Carrier 2014 Claim Cost**

	Total Incremental Cost of H.B. 800
Low Scenario	\$0.01
Mid Scenario	\$0.02
High Scenario	\$0.05

#### 4.5. Carrier retention and increase in premium

Assuming an average annual retention rate of 11.0 percent based on CHIA's analysis of health insurance carrier administrative costs and profit in Massachusetts,<sup>22</sup> the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 3 shows the result.

**Table 3:  
Estimate of Increase in Carrier 2014 Premium Expense**

Low Scenario	\$0.01
Mid Scenario	\$0.03
High Scenario	\$0.05

#### 4.6. Projected fully-insured population in Massachusetts

Table 4 shows the fully-insured population in Massachusetts age 0 to 64 projected for the next five years. Appendix B describes the sources of these values.

**Table 4:  
Projected Fully-Insured Population in Massachusetts, Age 0-64**

<u>Year</u>	<u>Total (0-64)</u>
2017	2,019,690
2018	2,017,526
2019	2,014,919
2020	2,011,109
2021	2,007,384

## 4.7. Projection of total marginal medical expense

The low and middle scenario incremental medical expenses calculated in section 4.4 were projected for the period January 1, 2017 to December 31, 2021 using a 6.3 percent per year estimate of inflation for all prescription drugs for the period 2014 to 2024.<sup>23</sup> The high scenario incremental medical expense was projected forward using a 13.7 percent per year estimate of inflation for MS drugs for the period 2010 to 2014.<sup>24</sup> The trended incremental PMPM medical expenses were multiplied by the member months displayed in Table 4 and rounded to the nearest thousand dollars to calculate the total projected incremental medical expenses shown in Table 5.

This analysis assumes the bill, if enacted, would be effective January 1, 2017.<sup>25</sup>

**Table 5:  
Projected Marginal Medical Expense  
of Continuous Coverage of DMT Drugs to treat MS, 2017 to 2021**

	2017	2018	2019	2020	2021
Low Scenario	\$245,000	\$365,000	\$387,000	\$411,000	\$436,000
Mid Scenario	\$490,000	\$729,000	\$774,000	\$821,000	\$871,000
High Scenario	\$1,198,000	\$1,909,000	\$2,167,000	\$2,460,000	\$2,791,000

## 4.8. Carrier retention and increase in premium

Adjusting the projected incremental medical expense shown in Table 5 by an 11 percent retention factor<sup>26</sup> and rounding to the nearest thousand dollars results in the estimated incremental increase in premiums related to H.B. 800 as shown in Table 6.

**Table 6:  
Projected Increase in Premium  
of Continuous Coverage of DMT Drugs to treat MS, 2017 to 2021**

	2017	2018	2019	2020	2021
Low Scenario	\$275,000	\$410,000	\$435,000	\$461,000	\$489,000
Mid Scenario	\$550,000	\$819,000	\$870,000	\$923,000	\$979,000
High Scenario	\$1,346,000	\$2,144,000	\$2,435,000	\$2,763,000	\$3,136,000

## 5. Results

The estimated impact of the proposed mandate on medical expense and premiums appears below. The analysis includes development of a “mid-level” scenario, as well as a low-level scenario using assumptions that produced a lower estimate, and a high-level scenario using more conservative assumptions that produced a higher estimated impact.

The impact on premiums is based primarily on estimates of the number of commercial fully-insured Massachusetts residents using DMT drugs for MS who may be affected by the bill, and the average annual cost per affected user of continuous coverage for DMT drugs for MS.

Starting in 2020, the federal Affordable Care Act will impose an excise tax, commonly known as the “Cadillac Tax”, on expenditures on health insurance premiums and other relevant items (health savings account contributions, etc.) that exceed specified thresholds. To the extent relevant expenditures exceed those thresholds (in 2020), H.B. 800, by increasing premiums, has the potential of creating liability for additional amounts under the tax. Estimating the amount of potential tax liability requires information on the extent to which premiums, notwithstanding the effect of H.B. 800, will exceed or approach the thresholds and is beyond the scope of this analysis.

## 5.1. Five-year estimated impact

For each year in the five-year analysis period, Table 7 displays the projected net impact of the mandate on medical expense and premiums using a projection of Massachusetts-resident fully-insured membership. Note that the relevant provisions of H.B. 800 are assumed effective January 1, 2017.<sup>27</sup>

The high scenario assumes plans covered by the mandate will cover 196 additional monthly supplies of DMT drugs for MS at an average price of \$5,666.67 in the base year and that MS drugs will experience annual inflation more than twice as high as that of prescription drugs overall throughout the projection period. These assumptions result in an average cost of \$2.5 million per year. The middle scenario halves the base-year upper bound estimate and assumes MS drug inflation will be the same as that of prescription drugs overall, resulting in an average annual cost of \$879 thousand, or an average of 0.008 percent of premium.

Finally, the impact of the proposed law on any one individual, employer-group, or carrier may vary from the overall results depending on the current level of benefits each receives or provides, and on how the benefits will change under the mandate.

**Table 7:  
Summary Results**

	2017	2018	2019	2020	2021	Weighted Average	5 Yr Total
Members (000s)	2,020	2,018	2,015	2,011	2,007		
Medical Expense	\$245	\$365	\$387	\$411	\$436	\$391	\$1,843
Medical Expense	\$490	\$729	\$774	\$821	\$871	\$782	\$3,685
Medical Expense	\$1,198	\$1,909	\$2,167	\$2,460	\$2,791	\$2,234	\$10,525
Premium Low	\$275	\$410	\$435	\$461	\$489	\$439	\$2,070
Premium Mid	\$550	\$819	\$870	\$923	\$979	\$879	\$4,140
Premium High	\$1,346	\$2,144	\$2,435	\$2,763	\$3,136	\$2,509	\$11,824
PMPM Low	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02	\$0.02
PMPM Mid	\$0.03	\$0.03	\$0.04	\$0.04	\$0.04	\$0.04	\$0.04
PMPM High	\$0.08	\$0.09	\$0.10	\$0.11	\$0.13	\$0.10	\$0.10
Estimated	\$463	\$473	\$483	\$493	\$503	\$483	\$483
Premium % Rise	0.003%	0.004%	0.004%	0.004%	0.004%	0.004%	0.004%
Premium % Rise	0.007%	0.007%	0.007%	0.008%	0.008%	0.008%	0.008%
Premium % Rise	0.017%	0.019%	0.021%	0.023%	0.026%	0.021%	0.021%



## 5.2. Impact on the GIC

The proposed mandate is assumed to apply to both fully-insured and self-insured plans operated for state and local employees by the GIC, with an effective date for all GIC policies on July 1, 2017.

Because the benefit offerings of GIC plans are similar to those of most other commercial plans in Massachusetts, the estimated PMPM effect of the proposed mandate on GIC medical expense is not expected to differ from that calculated for the other fully-insured plans in Massachusetts. This is consistent with carrier survey responses which, in general, did not indicate differences in coverage for the GIC.

To estimate the medical expense separately for the GIC, the PMPM medical expense for the general fully-insured population was applied to the GIC membership starting in July of 2017.

Table 8 breaks out the GIC-only fully-insured membership and the GIC self-insured membership, and the corresponding incremental medical expense and premium. Note that the total medical expense and premium values for the general fully-insured membership displayed in Table 7 also include the GIC fully-insured membership. Finally, the proposed mandate is assumed to require the GIC to implement the provisions on July 1, 2017; therefore, the results in 2017 are approximately one-half of an annual value.

**Table 8:  
GIC Summary Results**

	2017	2018	2019	2020	2021	Weighted Average	5 Yr Total
<b>GIC Fully-Insured</b>							
Members (000s)	54	54	54	54	54		
Medical Expense Low (\$000s)	\$5	\$10	\$10	\$11	\$12	\$11	\$47
Medical Expense Mid (\$000s)	\$9	\$19	\$21	\$22	\$23	\$21	\$95
Medical Expense High (\$000s)	\$22	\$51	\$58	\$66	\$75	\$60	\$272
Premium Expense Low (\$000s)	\$5	\$11	\$12	\$12	\$13	\$12	\$53
Premium Expense Mid (\$000s)	\$10	\$22	\$23	\$25	\$26	\$24	\$106
Premium Expense High (\$000s)	\$25	\$57	\$65	\$74	\$84	\$68	\$305
<b>GIC Self-Insured</b>							
Members (000s)	270	270	269	268	268		
Medical Expense Low (\$000s)	\$23	\$49	\$52	\$55	\$58	\$53	\$236
Medical Expense Mid (\$000s)	\$46	\$97	\$103	\$110	\$116	\$105	\$472
Medical Expense High (\$000s)	\$112	\$255	\$289	\$328	\$372	\$302	\$1,357

## Appendix A: Disease-Modifying Therapy Drugs for Multiple Sclerosis<sup>28,29,30</sup>

DMT Drug	Treatment	Clinical efficacy in placebo-controlled Phase III trials	Most Common Side Effects	Other Safety Issues	Current Coverage per Survey
<b>Alemtuzumab</b>					
Lemtrada®	12 mg/d intravenously for five days followed by 12 mg/d intravenously for three days one year after the first course	49%-55% reduction of ARR over two years compared to subcutaneous interferon beta 1a 42% reduction of progression of disability at two years compared to subcutaneous interferon beta 1a	Rash, headache, fever, nasal congestion, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infections, hives, itching, thyroid gland disorders, fungal infection, pain in joints, extremities and back, diarrhea, vomiting, flushing. Infusion reactions (including nausea, hives, itching, insomnia, chills, flushing, fatigue, shortness of breath, changes in the sense of taste, indigestion, dizziness, pain) also common while the medication is being administered and for 24 hours after infusion.	Infusion associated reactions; cytokine release syndrome; lymphopenia; infections; autoimmune thyroiditis; thrombocytopenic purpura; glomerulonephritis	Approved by the FDA for treatment of relapsing MS in November 2014.
<b>Dimethyl Fumarate</b>					
Tecfidera®	240 mg orally twice a day	44%-53% reduction of ARR over two years 38% reduction of progression of disability at two years	Flushing (sensation of heat or itching and a blush on the skin), gastrointestinal issues (nausea, diarrhea, abdominal pain).	Lymphopenia; progressive multifocal leukoencephalopathy	Covered by all responding carriers; Tier 2 for most, Tier 3 for others.
<b>Fingolimod</b>					
Gilenya®	0.5 mg orally every day	48%-54% reduction of ARR over two years 30% reduction of progression of disability at two years	Headache, flu, diarrhea, back pain, liver enzyme elevations, sinusitis, abdominal pain, pain in extremities and cough.	Bradycardias after first dose; lymphopenia; viral infections (VZV); macular edema; hepatotoxicity; hypertension	Covered by all responding carriers, about half Tier 2 and half Tier 3.

DMT Drug	Treatment	Clinical efficacy in placebo-controlled Phase III trials	Most Common Side Effects	Other Safety Issues	Current Coverage per Survey
<b>Glatiramer acetate</b>					
Copaxone 20®	20 mg subcutaneously every day	29% reduction of ARR over two years (RRMS) 45% risk reduction of conversion to CDMS at three years (CIS) No statistically significant effect on disability progression	Injection site reactions (redness, pain, swelling), flushing, shortness of breath, rash, chest pain.	Cutaneous necrosis; anaphylaxis (rare)	Covered by all responding carriers, generally on Tier 2.
Copaxone 40®	40 mg subcutaneously three times a week	33% reduction in ARR over 12 months (RRMS), significant reduction in cumulative number of gadolinium-enhancing T1 (44.8) and new or newly enlarging T2 lesions (34.7%) at months 6 and 12. <sup>31</sup>	Injection site reactions (redness, pain, swelling), flushing, shortness of breath, rash, chest pain.	Cutaneous necrosis; anaphylaxis (rare)	Covered by all responding carriers, generally on Tier 2.
Glatopa®	20 mg subcutaneously every day	29% reduction of ARR over two years (RRMS) 45% risk reduction of conversion to CDMS at three years (CIS) No statistically significant effect on disability progression	Injection site reactions (redness, pain, swelling).	Cutaneous necrosis; anaphylaxis (rare)	Generic; did not launch until 2015.
<b>Interferon beta 1a</b>					
Avonex®	30 mcg Intramuscularly (into a large muscle) once a week intramuscularly	18% reduction of ARR over two years (RRMS) 44% risk reduction of conversion to CD MS at two years (CIS) No statistically significant effect on disability progression	Headache, flu-like symptoms (chills, fever, muscle pain, fatigue, weakness), injection site pain and inflammation.	Hepatotoxicity; myelotoxicity; autoimmune thyroiditis; microangiopathy; epileptic seizures (rare)	Covered by all responding carriers, usually on Tier 2.

<b>DMT Drug</b>	<b>Treatment</b>	<b>Clinical efficacy in placebo-controlled Phase III trials</b>	<b>Most Common Side Effects</b>	<b>Other Safety Issues</b>	<b>Current Coverage per Survey</b>
Rebif®	44 mcg subcutaneously three times a week	32% reduction of ARR over two years (RRMS) 45% risk reduction of conversion to CD MS at two years (CIS) 30% reduction of progression of disability at two years (RRMS)	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness, headache), injection site reactions (redness, pain, swelling).	Hepatotoxicity; myelotoxicity; autoimmune thyroiditis; microangiopathy; epileptic seizures (rare)	Covered by all responding carriers, usually on Tier 2.
<b>Interferon beta 1b</b>					
Betaseron®	250 mcg subcutaneously every other day	34% reduction of annualized relapse rate (ARR) over two years (RRMS) 50% risk reduction of conversion to CD MS at two years (CIS) No statistically significant effect on disability progression	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness) following injection, headache, injection site reactions (swelling, redness, pain), injection site skin breakdown, low white blood count.	Hepatotoxicity; myelotoxicity; autoimmune thyroiditis; microangiopathy; epileptic seizures (rare)	Covered by all responding carriers, generally on Tier 3.
Extavia®	250 mcg subcutaneously every other day	34% reduction of annualized relapse rate (ARR) over two years (RRMS) 50% risk reduction of conversion to CD MS at two years (CIS) No statistically significant effect on disability progression	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness) following injection, headache.	Hepatotoxicity; myelotoxicity; autoimmune thyroiditis; microangiopathy; epileptic seizures (rare)	Not covered by several carriers, all of whom cover Betaseron®. If covered, covered on Tier 3.
<b>Mitoxantrone</b>					
Novantrone®	12 mg/m <sup>2</sup> intravenously every three months or 8 mg/m <sup>2</sup> intravenously every month	65% reduction of relapse risk over two years (mostly in RRMS) 66% reduction of risk of disability progression at two years (mostly in RRMS)	Nausea, hair loss, menstrual change, upper respiratory infection, urinary tract infection, mouth sores, irregular heartbeat, diarrhea, constipation, back pain, sinusitis, headache, blue-green urine.	Infusion site tissue necrosis; myelotoxicity; infections; cardiotoxicity; acute leukemia	Covered as a medical benefit.

<b>DMT Drug</b>	<b>Treatment</b>	<b>Clinical efficacy in placebo-controlled Phase III trials</b>	<b>Most Common Side Effects</b>	<b>Other Safety Issues</b>	<b>Current Coverage per Survey</b>
<b><i>Natalizumab</i></b>					
Tysabri®	300 mg intravenously every four weeks	68% reduction of ARR over two years 42% reduction of progression of disability at two years	Headache, fatigue, joint pain, chest discomfort, urinary tract infection, lower respiratory tract infection, gastroenteritis, vaginitis, depression, pain in extremity, abdominal discomfort, diarrhea, rash.	Infusion associated reactions; anaphylaxis; infections; hepatotoxicity; progressive multifocal leukoencephalopathy	Covered as a medical benefit.
<b><i>Peginterferon beta 1a</i></b>					
Plegridy®	125 mcg subcutaneously every two weeks	36% reduction of ARR over one year	Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness, headache, itching). Injection site reactions (swelling, redness, pain).	Hepatotoxicity; myelotoxicity; autoimmune thyroiditis; microangiopathy; epileptic seizures (rare)	Launched in August 2014.
<b><i>Teriflunomide</i></b>					
Aubagio®	14 mg orally every day	31%-36% reduction of ARR over one year or more 26%-32% reduction of progression of disability at one year or more	Headache, hair thinning, diarrhea, nausea, abnormal liver tests.	Myelotoxicity; hepatotoxicity; infections; peripheral neuropathy; pancreatic fibrosis; teratogenicity (requires accelerated elimination procedure)	Covered by all responding carriers, about half Tier 2 and half Tier 3.

## Appendix B: Membership Affected by the Proposed Mandate

This appendix describes the calculations used to estimate the number of members whose coverage is potentially affected by a proposed mandate. It addresses several different aggregations of members and analysis of the impact of a given proposed mandate may draw on some or all of these aggregations. Sources used to develop these population estimates and projections are provided below.

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance issued by a Massachusetts-licensed company (including through the GIC), non-residents with fully-insured employer-sponsored insurance issued in Massachusetts, Massachusetts residents with individual (direct) health insurance coverage, and, in some cases, lives covered by GIC self-insured coverage. Membership projections for 2017 to 2021 are derived from the following sources.

Total Massachusetts population estimates for 2013, 2014, and 2015 from U. S. Census Bureau data<sup>32</sup> form the base for the projections. Distributions by gender and age, also from the Census Bureau,<sup>33</sup> were applied to these totals. Projected growth rates for each gender/age category were estimated from Census Bureau population projections to 2030.<sup>34</sup> The resulting growth rates were then applied to the base amounts to project the total Massachusetts population for 2017 to 2021.

The number of Massachusetts residents with employer-sponsored or individual (direct) health insurance coverage was estimated using Census Bureau data on health insurance coverage status and type of coverage<sup>35</sup> applied to the population projections.

To estimate the number of Massachusetts residents with fully-insured employer-sponsored coverage, projected estimates of the percentage of employer-based coverage that is fully-insured were developed using historical data from the Medical Expenditure Panel Survey Insurance Component Tables.<sup>36</sup>

To estimate the number of non-residents covered by a Massachusetts policy – typically cases in which a non-resident works for a Massachusetts employer offering employer-sponsored coverage – the number of lives with fully-insured employer-sponsored coverage was increased by the ratio of the total number of individual tax returns filed in Massachusetts by residents<sup>37</sup> and non-residents<sup>38</sup> to the total number of individual tax returns filed in Massachusetts by residents.

Projections for the GIC self-insured lives were developed using GIC base data for 2013,<sup>39</sup> 2014,<sup>40</sup> and 2015,<sup>41</sup> and the same projected growth rates from the Census Bureau that were used for the Massachusetts population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

## Endnotes

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<sup>1</sup> The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill, “An Act promoting continuity of care for multiple sclerosis treatment.” Accessed 24 May 2016: <https://malegislature.gov/Bills/189/House/H800>.

<sup>2</sup> This analysis treats Copaxone® 20mg and Copaxone® 40mg as distinct drugs.

<sup>3</sup> Gajofatto A, Benedetti M. Treatment strategies for multiple sclerosis: When to start, when to change, when to stop? *World J Clin Cases*. 2015 Jul 16; 3(7): 545–555. Accessed 25 May 2016: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4517331/>.

<sup>4</sup> Marcus J, Waubant E. Updates on Clinically Isolated Syndrome and Diagnostic Criteria for Multiple Sclerosis. *Neurohospitalist*. 2013 Apr; 3(2): 65–80. Accessed 26 May 2016: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3726117/>.

<sup>5</sup> Noyes K, Weinstock-Guttman B. Impact of diagnosis and early treatment on the course of multiple sclerosis. *Am J Manag Care*. 2013 Nov;19(17 Suppl):s321-31. Accessed 22 June 2016: <https://www.ncbi.nlm.nih.gov/pubmed/24494633>.

<sup>6</sup> *Op. cit.* Gajofatto A, Benedetti M, Treatment strategies for multiple sclerosis: When to start, when to change, when to stop?

<sup>7</sup> The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill, “An Act promoting continuity of care for multiple sclerosis treatment.” Accessed 24 May 2016: <https://malegislature.gov/Bills/189/House/H800>.

<sup>8</sup> *Op. cit.* Marcus J, Waubant E, Updates on Clinically Isolated Syndrome and Diagnostic Criteria for Multiple Sclerosis.

<sup>9</sup> *Op. cit.* Noyes K, Weinstock-Guttman B, Impact of diagnosis and early treatment on the course of multiple sclerosis.

<sup>10</sup> *Op. cit.* Gajofatto A, Benedetti M, Treatment strategies for multiple sclerosis: When to start, when to change, when to stop?

<sup>11</sup> *Op. cit.* Gajofatto A, Benedetti M, Treatment strategies for multiple sclerosis: When to start, when to change, when to stop?

<sup>12</sup> The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill, “An Act promoting continuity of care for multiple sclerosis treatment.” Accessed 24 May 2016: <https://malegislature.gov/Bills/189/House/H800>.

<sup>13</sup> *Op. cit.* The 189<sup>th</sup> General Court of the Commonwealth of Massachusetts, House Bill, “An Act promoting continuity of care for multiple sclerosis treatment.”

<sup>14</sup> Remington G, Rodriguez Y, Logan D, et. al. Facilitating Medication Adherence in Patients with Multiple Sclerosis. *International Journal of MS Care*. 2013 Spring; 15(1): 36–45. Accessed 20 June 2016: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3883032/>.

<sup>15</sup> Dickson, Michelle. Testimony submitted on October 20<sup>th</sup>, 2015 to the Joint Committee on Financial Services in support of *HB 800 An Act promoting continuity of care for multiple sclerosis treatment*. 20 October 2015.

<sup>16</sup> *Op. cit.* Noyes K, Weinstock-Guttman B, Impact of diagnosis and early treatment on the course of multiple sclerosis.

<sup>17</sup> *Op. cit.* Marcus J, Waubant E, Updates on Clinically Isolated Syndrome and Diagnostic Criteria for Multiple Sclerosis.

<sup>18</sup> *Op. cit.* Gajofatto A, Benedetti M. Treatment strategies for multiple sclerosis: When to start, when to change, when to stop?

<sup>19</sup> National Multiple Sclerosis Society. Primary Progressive Multiple Sclerosis (PPMS). Accessed 8 June 2016: <http://www.nationalmssociety.org/What-is-MS/Types-of-MS/Primary-progressive-MS>.

<sup>20</sup> U.S. Census Bureau. PEPSYASEX-Geography-Massachusetts: Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States, States, and Puerto Rico Commonwealth: April 1, 2010 to July 1,

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2014 Accessed 28 April 2016:

<http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk>.

<sup>21</sup> U.S. Census Bureau. Health Insurance Coverage in the United States: 2014. Report. Accessed 8 June 2016: [http://www.census.gov/hhes/www/hlthins/hlthins.html.hi05\\_acs.xls](http://www.census.gov/hhes/www/hlthins/hlthins.html.hi05_acs.xls).

<sup>22</sup> *Op. cit.* U.S. Census Bureau, Health Insurance Coverage in the United States: 2014.

<sup>23</sup> Centers for Medicare and Medicaid Services (CMS), Office of the Actuary. National Health Expenditure Data, NHE Projections 2014-2024 - Forecast Summary. Accessed 8 June 2016: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>.

<sup>24</sup> Optum. Multiple Sclerosis Cost Drivers. Posted September 9<sup>th</sup>, 2014. Accessed 11 June 2016: <https://www.optum.com/resources/library/ms-spending-cost-drivers.html>.

<sup>25</sup> The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2017. The impact of the mandate on cost in 2017 was estimated at 71.3 percent of the annual cost, using an assumed renewal distribution by month, by market segment, and by the Massachusetts market segment composition.

<sup>26</sup> Massachusetts Center for Health Information and Analysis. Performance of the Massachusetts Health Care System, Annual Report September 2015. Accessed 19 January 2016: <http://www.chiamass.gov/assets/2015-annual-report/2015-Annual-Report.pdf>.

<sup>27</sup> The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2017. The impact of the mandate on cost in 2017 was estimated at 71.3 percent of the annual cost, using an assumed renewal distribution by month, by market segment, and by the Massachusetts market segment composition.

<sup>28</sup> National Multiple Sclerosis Society. Medications. Accessed 27 May 2016: <http://www.nationalmssociety.org/Treating-MS/Medications>.

<sup>29</sup> National Multiple Sclerosis Society. Disease-Modifying Therapies for MS. Updated February 2016. Accessed 27 May 2016: <http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Brochure-The-MS-Disease-Modifying-Medications.pdf>.

<sup>30</sup> Adapted from *Op. cit.* Gajofatto A, Benedetti M, Treatment strategies for multiple sclerosis: When to start, when to change, when to stop?

<sup>31</sup> Khan O, Rieckmann P, Boyko A, et. al. Three times weekly glatiramer acetate in relapsing-remitting multiple sclerosis. *Ann Neurol*. 2013 June;73(6):705-13. Accessed 8 June 2016: <http://www.ncbi.nlm.nih.gov/pubmed/23686821>.

<sup>32</sup> U.S. Census Bureau. Annual Estimates of the Resident Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2015. Accessed 28 April 2016: <http://www.census.gov/popest/data/state/totals/2015/index.html>.

<sup>33</sup> U.S. Census Bureau. PEPYASEX-Geography-Massachusetts: Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States, States, and Puerto Rico Commonwealth: April 1, 2010 to July 1, 2014. Accessed 28 April 2016: <http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk>.

<sup>34</sup> U.S. Census Bureau. File 4. Interim State Projections of Population by Single Year of Age and Sex: July 1, 2004 to 2030. U.S. Census Bureau, Population Division, Interim State Population Projections, 2005. Accessed 28 April 2016: <http://www.census.gov/population/projections/data/state/projectionsagesex.html>.

<sup>35</sup> U.S. Census Bureau. Table HIB-4. Health Insurance Coverage Status and Type of Coverage by State All Persons: 1999 to 2012. Accessed 28 April 2016: <https://www.census.gov/data/tables/time-series/demo/health-insurance/historical-series/hib.html>. Where source i and iv are slightly different projections, we use iv because the sampling is more current. Sampling methods and margin for error described at the link: [http://www2.census.gov/programs-surveys/acs/tech\\_docs/accuracy/ACS\\_Accuracy\\_of\\_Data\\_2014.pdf](http://www2.census.gov/programs-surveys/acs/tech_docs/accuracy/ACS_Accuracy_of_Data_2014.pdf).



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<sup>36</sup> Agency for Healthcare Research and Quality. Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and State (Table II.B.2.b.1), years 1996-2012: 1996 (Revised March 2000), 1997 (March 2000), 1998 (August 2000), 1999 (August 2001), 2000 (August 2002), 2001 (August 2003), 2002 (July 2004), 2003 (July 2005), 2004 (July 2006), 2005 (July 2007), 2006 (July 2008), 2008 (July 2009), 2009 (July 2010), 2010 (July 2011), 2011 (July 2012), 2012 (July 2013), 2013 (July 2014), 2014 (July 2015). Medical Expenditure Panel Survey Insurance Component Tables. Generated using MEPSnet/IC. Accessed 25 January 2016:

[https://meps.ahrq.gov/mepsweb/data\\_stats/quick\\_tables\\_results.jsp?component=2&prfricon=yes&searchText=insured&subcomponent=2&tableSeries=2&year=-1](https://meps.ahrq.gov/mepsweb/data_stats/quick_tables_results.jsp?component=2&prfricon=yes&searchText=insured&subcomponent=2&tableSeries=2&year=-1).

<sup>37</sup> IRS. Historical Table 2. Individual Income and Tax Data, by State and Size of Adjusted Gross Income, Tax Year 2010. Accessed 6 March 2014: <https://www.irs.gov/uac/SOI-Tax-Stats-Historic-Table-2>.

<sup>38</sup> Massachusetts Department of Revenue. Massachusetts Nonresident Personal Income Tax after Credit by State for Tax Year 2010. Accessed 23 January 2014: <http://www.mass.gov/dor/tax-professionals/news-and-reports/statistical-reports/>.

<sup>39</sup> Group Insurance Commission. GIC Health Plan Membership by Insured Status FY2013. Accessed 28 March 2016: <http://www.mass.gov/anf/docs/gic/annual-report/annualreportfy2013.pdf>.

<sup>40</sup> Group Insurance Commission. GIC Health Plan Membership by Insured Status FY2014. Accessed 28 March 2016: <http://www.mass.gov/anf/docs/gic/annual-report/fy2014annual-report.pdf>.

<sup>41</sup> Group Insurance Commission, Group Insurance Commission Fiscal Year 2015 Annual Report. Accessed 25 January 2016: <http://www.mass.gov/anf/docs/gic/annual-report/gic-annual-reportfy15.pdf>.