



Commonwealth  
of Massachusetts

Center for Health  
Information and Analysis

Áron Boros  
Executive Director

## **Mandated Benefit Review of House Bill 941:**

**An Act Relative to Insurance Coverage  
for Devic's Disease**

**September 2013**

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# Benefit Mandate Overview: Devic's Disease

## History of the Bill

Massachusetts General Laws, chapter 3, section 38C requires the Center for Health Information and Analysis (CHIA) to review and evaluate the potential fiscal impact of each mandated benefit bill referred to the agency by a legislative committee.

The Joint Committee on Financial Services referred House Bill (H.B.) 3641, “An act relative to health insurance coverage for Devic’s disease,” to the Division of Health Care Finance and Policy (DHCFP) on January 12, 2012 for review. When the new legislative session began on January 2, 2013, a similar bill – (H.B. 941) – was filed, and the Committee requested that CHIA–successor agency to DHCFP\* – modify the scope of the review to reflect the revised bill.

## What Does the Bill Propose?

H.B. 941 requires that health insurance plans defined in the bill provide “coverage for the cost of IVIG [intravenous immunoglobulin] treatments for persons who have been diagnosed with neuromyelitis optica, also known as Devic’s disease.”

## What is Devic's Disease?

Devic’s disease is an autoimmune disease affecting the spinal cord and optic nerves, damaging the protective outer covering of the nerves (myelin) and sometimes the nerve fibers, leaving areas of broken-down tissue. Devic’s disease is rare. The Mayo Clinic estimates that it occurs at approximately 0.32 to 2.5 cases per 100,000.†

There is no cure for Devic’s disease. Treatment with IVIG is designed to prevent the attacks through which the disease damages nerve sheathing and fibers. IVIG is a blood product administered intravenously and contains antibodies extracted from the plasma of many donors. IVIG treatment is typically ongoing; it is also expensive, easily exceeding \$100,000 per year.

## Current Coverage

Current coverage by health insurers for IVIG treatment for Devic’s disease appears to vary by carrier. Coverage for IVIG treatment is sometimes denied on the grounds that it is not evidence-based. However, the disease is so rare that staff were unable to find rigorously controlled studies to identify optimal treatments.

## Cost of Implementing the Bill

Adding this benefit to fully-insured health plans would result in a low-end estimate of zero impact, and a high-end estimate of adding an average of 25 cents (0.05%) to the typical member’s monthly health insurance premiums over five years.

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\* In November 2012, under Massachusetts General Laws, chapter 224 of the Acts of 2012, the Division of Health Care Finance and Policy was re-named the Center for Health Information and Analysis, along with shifts in certain responsibilities.

† Rice, Elizabeth. Mayo Clinic newsblog, Nov. 10, 2009, retrieved July 30, 2012 at <http://newsblog.mayoclinic.org/tag/neuromyelitis-optica>.

## Plans Affected by the Proposed Benefit Mandate

Individual and group accident and sickness insurance policies, corporate group insurance policies, and HMO policies issued pursuant to the Massachusetts General Laws, as well as the Group Insurance Commission (GIC) covering state employees and their dependents would be subject to this mandate.

The proposed benefit mandate would apply to members covered under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

## Plans Not Affected by the Proposed Benefit Mandate

Health insurance plans operated as self-insured entities (i.e., where the employer policyholder retains the risk for medical expenditures and uses the insurer to provide administrative functions) are subject to federal law and not to state-level mandates.

State health benefit mandates do not apply to Medicare and Medicare Advantage plans whose benefits are qualified by Medicare. Consequently this analysis excludes any members of commercial fully-insured plans over 64 years of age. These mandates also do not apply to federally-funded plans including TRICARE (covering military and dependents), Veterans Administration, the Federal Employees' Health Benefit Plan, and Medicaid/MassHealth.

## Implications of the Federal Affordable Care Act

While this fiscal impact review focuses on premiums in accordance with H.B. 941, Affordable Care Act (ACA) changes have since gone into effect. In accordance with §1311(d)(3)(B) of the ACA and as codified in CFR §155.170, the Commonwealth is required to offset the costs of mandated benefits not included in the state's Essential Health Benefits (EHB) benchmark plan for individuals enrolled in Qualified Health Plans (QHPs) through the Health Connector, the state's ACA-compliant Exchange, or outside of the Exchange. Specifically, the costs of these mandated benefits will need to be supported through the state's operating budget or through other state resources. This would include the costs for any mandated benefits enacted on or after January 1, 2012.

As of September 2013, state benefit mandates enacted on or after January 1, 2012 (and therefore not included in the state's EHB benchmark plan) include:

1. Cleft Palate and Cleft Lip  
(M.G.L. c. 175 § 47BB; M.G.L. c. 176A § 8EE; M.G.L. c. 176B § 4EE; and M.G.L. c. 176G § 4W)
2. Hearing Aids for Children  
(M.G.L. c. 175 § 47X(f); M.G.L. c. 176A § 8Y(f); M.G.L. c. 176B § 4EE; and M.G.L. c. 176G § 4N)
3. Oral Cancer Therapy  
(M.G.L. c. 175 § 47DD; M.G.L. c. 176A § 8FF; M.G.L. c. 176B § 4FF; and M.G.L. c. 176G § 4X)

## Medical Efficacy Assessment: Devic's Disease

Massachusetts H.B. 941 requires health insurance plans to cover the cost of intravenous immunoglobulin (IVIG) treatments for persons diagnosed with neuromyelitis optica (NMO), also known as Devic's disease.<sup>¥</sup> M.G.L. c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA), formerly the Division of Health Care Finance and Policy, with reviewing the medical efficacy of mandating each benefit. Medical efficacy reports include the potential impact that each benefit could have on the quality of patient care and health status of the population as well as research results addressing the medical efficacy of the treatment or service compared to alternative treatments.

### What is Devic's Disease?

Devic's disease is a rare, debilitating and sometimes fatal autoimmune condition in which the body's immune system attacks the spinal cord and optic nerve. Related is NMO Spectrum Disorder (NMOSD), a condition in which only the spinal cord or optic nerve is affected.

Devic's disease is often misdiagnosed initially as multiple sclerosis (MS), and is sometimes referred to as a sub-type of MS, because the illnesses have similar initial symptoms. Both illnesses are characterized by "attacks" during which symptoms of optic neuritis (blurry vision) and myelitis, such as leg and/or arm weakness, pain, tingling sensation or loss of sensation, and/or bowel and bladder dysfunction, occur. However, Devic's disease attacks are generally more severe than those occurring in MS, and Devic's disease is more likely to be fatal.<sup>1</sup>

Researchers in a 2012 study noted that the 30 percent incidence of initial MS misdiagnoses that they found in Devic's patient cases "is of critical importance," given that effective therapies for MS and Devic's disease differ and a common treatment for MS "may aggravate NMO."<sup>2</sup> Improvements in diagnostic techniques for Devic's disease have been identified within the past decade.

### Pathology

A 2006 *Archives of Neurology* article describes Devic's disease as "a severe demyelinating disease recognized principally by its propensity to selectively affect optic nerves and the spinal cord, causing recurrent attacks of blindness and paralysis."<sup>3</sup> Demyelination is characteristic of Devic's disease and multiple sclerosis. It is a degenerative condition characterized by the erosion of the myelin sheath that protects nerve fibers which helps them to conduct neurological messages for movement and feeling. The symptoms of the illness can become progressively severe if additional attacks occur beyond the first one.

Devic's disease can present as "monophasic" (single episode occurring on a single day or over a period of a few days) or "relapsing" (multiple episodes, over a period of several months or up to five years). The relapsing form is more common and more serious: "About two-thirds of patients had the relapsing course; of these, most developed severe disabilities in a stepwise manner, and one-third died because of respiratory failure, which occurred when the illness attacks the spinal cord in the neck area," wrote the authors of a 1999 study published in the journal *Neurology*, referring to 71 Devic's disease patients evaluated at Minnesota's Mayo Clinic between 1950 and 1997, whose cases were reviewed.<sup>4</sup> Other studies have reported even higher prevalence of the relapsing/recurring form.

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<sup>¥</sup> This bill was introduced into the 187th General Court (2011-2012) as H.B. 3641. The bill has been re-introduced to the 188th General Court as H.B. 941.

A 1996 Canadian study found that young children who develop Devic’s disease have “an excellent prognosis for visual and systemic recovery and no future recurrence or long-term [effects],”<sup>5</sup> but a later study found “no differences in the disease course based on the age at onset.”<sup>6</sup>

## Diagnosis and Prevalence

Between 70 and 80 percent of patients with Devic’s disease carry a certain, unique autoantibody, NMO-IgG, in their blood.<sup>7</sup> An autoantibody is one that is directed against one or more of an individual’s body proteins. NMO-IgG is an antibody to Aquaporin-4, a human protein that helps conduct water through cells and is found in astrocytes – the most common cell of the human brain. Scientists discovered its existence in 2004;<sup>8</sup> the discovery “revolutionized” the understanding of both Devic’s disease and MS.<sup>9</sup> Additionally, Devic’s patients often display normal brain MRIs when first presenting with symptoms of the illness, while MRIs of MS patients are distinctive for that illness.

Criteria for diagnosing Devic’s disease, developed in 2006, include the presence of optic neuritis, myelitis, and at least two of three additional supportive criteria: (1) MRI evidence of a contiguous spinal cord lesion three or more vertebral segments in length, (2) brain MRI nondiagnostic for MS at the onset of disease, and (3) detection of NMO-IgG in serum.<sup>10</sup>

Mayo Clinic neurologist Dean Wingerchuck estimates that Devic’s disease occurs at approximately 0.32 to 2.5 cases per 100,000.<sup>11</sup> The illness is found worldwide, and among all ethnic groups – unlike multiple sclerosis, which is predominantly found in Caucasians in temperate zones of both hemispheres. In the United States, it is estimated to occur at approximately 1 percent to 2 percent the rate of MS – leading to estimates that approximately 4,000 to 8,000 people are affected nationwide.<sup>12</sup>

Reported risk factors, according to Wingerchuk, are being female (strong predilection, similar to other autoimmune disorders), of non-Caucasian racial background (slight risk, but those of African descent are disproportionately represented in studies), and older at onset than the typical MS patient – although Devic’s disease can strike at any age. One study found that the average age at onset of Devic’s disease was 41 years,<sup>13</sup> but recent news articles and medical case studies document cases of the disease occurring in teenagers and adults in their twenties.

## Potential Causes

The causes of Devic’s disease, like those of other autoimmune diseases, are not entirely clear. The disease is more common in East Asians and other non-white populations than among Caucasians, suggesting a possible genetic link, although this link has not yet been documented.<sup>14</sup> Writing in the journal *PNAS* (Proceedings of the National Academy of Sciences of the United States) in 2012, Richard M. Ransohoff noted that while research into Devic’s disease has “lagged” in North America and Europe, Asian research has been “vigorous,” if hampered by relatively low disease occurrence. Scientists have noted that Devic’s disease is found worldwide and may as a result be more common than previously thought, Ransohoff writes.

## Treatments

As noted above, Devic's disease symptoms resemble those of MS, but the illness requires a different course of treatment for optimal results. In the more common relapsing version of the disease, a patient's long-term survival is related to the number of attacks occurring in the early period after the initial attack.<sup>15</sup>

Several treatments are available for Devic's disease, but there is no known cure. Because the disease is so rare, CHIA staff were unable to find rigorously controlled studies to identify optimal treatment.

According to the National Institute of Neurological Disorders and Stroke, therapies are available to treat an attack while it is happening, to reduce symptoms, and to prevent relapses. Initial attacks are generally treated with a combination of a corticosteroid drug (methylprednisolone) to stop the attack, and an immunosuppressive drug (azathioprine) is used to prevent subsequent attacks. Chemotherapy that destroys immune cells – including those that are attacking the spinal cord and optic nerve – continues to be the subject of experimentation, but carries risk including higher susceptibility to cancer and sterility.<sup>16</sup> Plasma exchange, or plasmapheresis, a technique that removes a person's blood, separates antibody-containing plasma from a person's bloodstream and replaces the blood with healthy donor or synthetic plasma, is used for people who are unresponsive to corticosteroid therapy.<sup>17</sup>

Symptoms of Devic's disease including pain, stiffness, muscle spasms and bladder and bowel control problems, can be managed with medications and therapies. The services of occupational therapists, physiotherapists and social services professionals may also be required.<sup>18</sup>

Another alternative therapy is IVIG, or intravenous immunoglobulin. IVIG is the injection of a sterile solution of concentrated, healthy antibodies into the vein of a person whose own antibodies are attacking them. The extra antibodies are meant to override unhealthy ones and stop their attacks. The treatment differs from plasmapheresis in that it does not involve physical removal of existing plasma from a person's blood before replacing it; also, IVIG injections are usually of donor plasma, while plasmapheresis patients receive a synthetic replacement solution after their unhealthy plasma is removed.

## Cost of Treatments

Plasmapheresis costs roughly \$6,000 per treatment.<sup>19</sup> For IVIG, treatments can cost anywhere from \$4,000 to \$12,000 per month (more recent data suggests the higher end of the scale).<sup>20</sup> While individual instances of successful treatment of Devic's disease with IVIG therapy have been reported, and IVIG is approved by the U.S. Food and Drug Administration for treatment of certain other autoimmune diseases, it is considered an experimental treatment for Devic's disease.

Current Massachusetts minimum creditable coverage standards for health insurance do not mandate coverage of treatments considered experimental or investigational, even if prescribed by a physician. However, some insurers have been known to allow coverage for experimental procedures that show particular promise on a case-by-case basis.

## Endnotes

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# Center for Health Information and Analysis

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Amy Wyeth, Senior Policy Analyst, lead author

Catherine West, Director of Health Systems Policy and Stakeholder Relations

Center for Health Information and Analysis  
Two Boylston Street  
Boston, Massachusetts 02116

Phone: (617) 988-3100  
Fax: (617) 727-7662

Website: [www.mass.gov/chia](http://www.mass.gov/chia)

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**Actuarial Assessment of House Bill 941:  
An act relative to  
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Prepared by  
Compass Health Analytics, Inc.



# Actuarial Assessment of House Bill 941: An act relative to health insurance coverage for Devic’s disease

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This report was prepared by Lars Loren, JD, Tina Shields, FSA, MAAA, Andrea Clark, MS, and Devin Anderson.

# Actuarial Assessment of House Bill 941: An act relative to health insurance coverage for Devic's disease

## Executive Summary

Massachusetts House Bill 941 requires health insurance plans to cover the cost of intravenous immunoglobulin (IVIG) treatments for persons diagnosed with neuromyelitis optica, also known as Devic's disease.<sup>1</sup> M.G.L. c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA, formerly the Division of Health Care Finance and Policy) with, among other duties, reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by employers and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health care insurance in Massachusetts.

### Background

H.B. 941 requires that health insurance plans provide "coverage for the cost of IV/IG treatments for persons who have been diagnosed with neuromyelitis optica, also known as Devic's disease."

Devic's disease is an autoimmune disease affecting the spinal cord and optic nerves, damaging the protective outer covering of the nerves (myelin) and sometimes the nerve fibers, leaving areas of broken-down tissue. Devic's disease is rare, affecting between 0.32 and 2.5 people per 100,000.

The treatment named in the proposed mandate, IVIG, refers to intravenous immunoglobulin, a blood product administered intravenously and containing antibodies extracted from the plasma of many donors, and sometimes used to treat Devic's disease. There is no cure for Devic's disease; treatment with IVIG is designed to prevent the attacks through which the disease damages nerve sheathing and fibers. IVIG treatment is therefore typically ongoing; it is also expensive, often costing more than \$100,000 per year.

Coverage by health insurers for IVIG treatment for Devic's disease appears to vary by carrier. Coverage for IVIG treatment is sometimes denied on the grounds that it is not evidence-based. And indeed the disease is so rare that rigorously-controlled studies to identify optimal treatments for it are rare or nonexistent.

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<sup>1</sup> This bill was introduced into the 187th General Court (2011-2012) as H.B. 3641. The bill has been re-introduced to the 188th General Court as House Bill 941. Our analysis will be guided by the intent as communicated to the Center by the sponsors in discussions about the bill and by the language of the re-submitted version.

## Analysis

Compass estimated the impact of H.B. 941 with the following steps:

- Estimate the populations covered by the mandate (members, age 64 and under, of commercial, fully-insured health insurance plans)
- Estimate the prevalence of Devic's disease
- Estimate the per-patient cost of IVIG treatment
- Estimate the portion of the population with Devic's disease that IVIG treatment can help
- Estimate the portion of IVIG treatment cost that Massachusetts carriers currently reimburse
- Estimate the proposed mandate's incremental effect on carrier medical expense and the impact on premiums of insurers' retention (administrative costs and profit), and project the results over the next five years

The combination of Devic's disease's rarity and the high costs of IVIG has at least the following impacts on the analysis:

- Estimates of the prevalence of the disease are imprecise
- Claims related to Devic's disease, in particular to the use of IVIG in treatment, which would be useful in estimating the cost of treatment, are rare
- Controlled studies designed to determine the best treatment for Devic's disease, useful in estimating the portion of people diagnosed with Devic's disease that would find IVIG helpful, are rare or nonexistent
- Existing coverage for IVIG treatment for Devic's disease, relevant to estimating the net impact of the proposed mandate, varies by carrier

## Summary results

Table ES-1 summarizes the effect of H.B. 941 on premium costs for fully-insured plans, averaged over five years. We estimate the bill, if enacted, would increase fully-insured premiums by as much as 0.05 percent on average over the next five years. We think the more likely increase is in the range of 0.01 percent.

The degree of precision achievable in this analysis is hampered by the lack of empirical data about a rare condition. But while the results have a substantial amount of variation, measured by the ratio between low- and high-level scenarios, even the high-level scenario represents a small increase in overall premiums.

The impact of H.B. 941 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 that level of benefits will change under the proposed mandate.

**Table ES-1  
Estimated Incremental Impact of H.B. 941 on Premium Costs**

	2014	2015	2016	2017	2018	Average	5 Yr Total
Members (000's)	2,219	2,195	2,171	2,146	2,121	2,170	
Medical Expense Low (\$000's)	\$ 52	\$ 53	\$ 54	\$ 55	\$ 56	\$ 54	\$ 269
Medical Expense Mid (\$000's)	1,134	1,166	1,200	1,234	1,268	1,200	6,001
Medical Expense High (\$000's)	5,442	5,653	5,870	6,094	6,322	5,876	29,381
Premium Low (\$000's)	\$ 58	\$ 59	\$ 60	\$ 61	\$ 62	\$ 60	\$ 300
Premium Mid (\$000's)	1,263	1,299	1,336	1,374	1,412	1,337	6,683
Premium High (\$000's)	6,060	6,295	6,537	6,786	7,040	6,544	32,718
Change in PMPM Low	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Change in PMPM Mid	0.05	0.05	0.05	0.05	0.06	0.05	0.05
Change in PMPM High	0.23	0.24	0.25	0.26	0.28	0.25	0.25
Estimated Monthly Premium	\$ 487	\$ 512	\$ 537	\$ 564	\$ 592	\$ 538	\$ 538
Premium % Change Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Change Mid	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Premium % Change High	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%

# Actuarial Assessment of House Bill 941: An act relative to health insurance coverage for Devic's disease

## 1. Introduction

Massachusetts House Bill 941 requires health insurance plans to cover the cost of intravenous immunoglobulin (IVIG) treatments for persons diagnosed with neuromyelitis optica, also known as Devic's disease.<sup>2</sup> M.G.L. c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA, formerly the Division of Health Care Finance and Policy) with, among other duties, reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by employers and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health care insurance in Massachusetts.

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

Section 2 of this analysis 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. Section 5 describes the calculation of the estimate.

## 2. Interpretation of H.B. 941

The following subsections describe the provisions of H.B. 941, as redrafted for the 188th General Court.

### 2.1. Plans affected by the proposed mandate

The bill amends the statutes that regulate insurers providing health insurance in Massachusetts. It has the following five sections, each addressing statutes dealing with a particular type of health insurance policy:

- Section 1: Insurance for persons in service of the Commonwealth (creating M.G.L. c. 32A, § 27)
- Section 2: Accident and sickness insurance policies (creating M.G.L. c. 175, § 47BB)

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<sup>2</sup> This bill was introduced into the 187th General Court (2011-2012) as H.B. 3641. The bill has been re-introduced to the 188th General Court as House Bill 941. Our analysis will be guided by the intent as communicated to the Center by the sponsors in discussions about the bill and by the language of the re-submitted version.



- Section 3: Contracts with non-profit hospital service corporations (creating M.G.L. c. 176A, § 8EE)
- Section 4: Certificates under medical service agreements (creating M.G.L. c. 176B, § 4EE)
- Section 5: Health maintenance contracts (creating M.G.L. 176G, § 4U)

All sections mandate coverage for members covered under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

Health insurance plans operated as self-insured entities (i.e., when the employer policyholder retains the risk for medical expenditures and uses the insurer to provide administrative functions) are subject to federal law, and not to state-level mandates.

Section 1 of the bill directs the commissioners of the Commonwealth's own largely self-insured employee plan (the Group Insurance Commission, or GIC) to provide coverage. While the bill reaches the GIC, CHIA has instructed Compass not to include it in this analysis.<sup>3</sup>

State health benefit mandates do not apply to Medicare, and we assume this mandate likewise does not apply to Medicare extension/supplement plans even to the extent they are regulated by state law. Such plans are typically excluded from mandate legislation.

## 2.2. Covered services

H.B. 941 requires that each of the targeted types of health insurance plans listed above provide “coverage for the cost of IV/IG treatments for persons who have been diagnosed with neuromyelitis optica, also known as Devic’s disease.”

Devic’s disease is a rare autoimmune disease affecting the spinal cord and optic nerves, damaging the protective outer covering of the nerves (myelin) and sometimes the nerve fibers, leaving areas of broken-down tissue. The disease has some similarities to, and is sometimes confused with, multiple sclerosis.<sup>4</sup>

IVIG refers to intravenous immunoglobulin, a blood product administered intravenously and containing antibodies extracted from the plasma of many donors, and sometimes used to treat Devic’s disease.<sup>5</sup> There is no cure for Devic’s disease; treatment with IVIG is designed to prevent the attacks through which the disease incrementally damages nerve sheathing and fibers. IVIG treatment is therefore typically ongoing.

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<sup>3</sup> Note that the membership of any fully-insured plans sponsored by the GIC will be included in the membership estimate for the commercial, fully-insured plans that are the primary focus of this analysis.

<sup>4</sup> National Institutes of Health, Office of Rare Diseases Research. [http://rarediseases.info.nih.gov/GARD/Condition/6267/Devic\\_disease.aspx](http://rarediseases.info.nih.gov/GARD/Condition/6267/Devic_disease.aspx).

<sup>5</sup> This actuarial analysis takes no position on the clinical efficacy of IVIG in the treatment of Devic’s disease.

### 2.3. Medical necessity

In some cases, coverage for IVIG for Devic's disease has been denied on the grounds that the treatment is not evidence-based, or perhaps is experimental, and therefore is not medically necessary.<sup>6,7</sup> Indeed, the condition is so rare that our research has not uncovered published studies of controlled trials that normally constitute evidence for the efficacy of a treatment.

H.B. 941 does not address explicitly the criteria carriers may use in evaluating the medical necessity of a treatment. However, considering the history of the bill's revisions,<sup>8</sup> a reasonable interpretation of the bill is that it requires coverage for IVIG for patients with Devic's disease regardless of whether the carrier regards the treatment as experimental or not evidence-based.

Finally, we assume the bill makes no changes to general insurance policy requirements such as cost-sharing.

### 2.4. Existing laws affecting the cost of H.B. 941

No existing federal or state mandates related to the subject matter of this bill have been identified. Massachusetts has enacted mandates related to coverage for off-label uses of prescription drugs, but those are targeted at other conditions, notably cancer and HIV/AIDS.<sup>9</sup>

Finally, in accordance with §1311(d)(3)(B) of the federal Affordable Care Act (ACA) and as codified in CFR §155.170, the Commonwealth is required to offset the costs of mandated benefits not included in the state's Essential Health Benefits (EHB) benchmark plan for individuals enrolled in Qualified Health Plans (QHPs) through the Health Connector, the state's ACA-compliant Exchange, or outside of the Exchange. These include the costs of any mandated benefits enacted on or after January 1, 2012. The costs of these mandated benefits will need to be supported through the state's operating budget or through other state resources. However, because the potential impact of H.B. 931 on state resources does not directly affect commercial premiums, CHIA has not requested an estimate of the magnitude of that impact in this analysis.

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<sup>6</sup> Interview with Marion C. Stein, MD, Staff Neurologist, Beth Israel Deaconess Medical Center and Assistant Professor, Harvard Medical School (November 19, 2012).

<sup>7</sup> See also testimony submitted to the Legislature regarding H.B. 3641/941.

<sup>8</sup> An earlier version of the bill cited guidelines for interpreting medical necessity set forth in M.G.L. c. 1760 § 16. In doing so the bill was citing guidelines already in effect for coverage for Devic's disease. The revised version of the bill eliminated this reference and discussion on October 15, 2012 with Center staff and the sponsors indicated they did not wish to be bound by it.  
<http://www.malegislature.gov/Bills/187/House/H3641>.

<sup>9</sup> See M.G.L. c. 175 §§ 47K, 47L; c. 176A § 8N; c. 176B § 4N; c. 176G § 4E.

## 3. Methodology

### 3.1. Steps in the analysis

Compass estimated the impact of H.B. 941 with the following steps:

- Estimate the populations covered by the mandate, projected for the coming five years
- Estimate the prevalence of Devic's disease
- Estimate the per-patient cost of IVIG treatment
- Estimate the portion of the population with Devic's disease that IVIG treatment can help
- Estimate the portion of IVIG treatment cost that Massachusetts carriers currently reimburse
- Calculate the proposed mandate's incremental effect on carrier medical expense
- Estimate the impact on premiums of insurers' retention (administrative costs and profit)
- Project the estimated cost over the next five years

### 3.2. Data sources

The primary data sources used in the analysis were:

- Interviews with legislative and CHIA staff regarding legislative intent
- Interviews with clinical experts
- Academic literature, including population data, cited as appropriate
- Massachusetts insurer claim data from the Division's 2009 Health Care Quality and Cost Council (HCQCC) all-payer claim database, for plans covering the overwhelming majority of the under-65 fully insured population subject to mandates
- Responses to a survey sent to Massachusetts health insurance carriers with questions about their coverage for Devic's disease and experience with the cost of IVIG

The step-by-step description of the estimation process below addresses limitations in some of these sources and the uncertainties they contribute to the cost estimate.

## 4. Factors Affecting the Analysis

Several issues arise in translating the provisions of H.B. 941 into an analysis of incremental cost.

## 4.1. Prevalence of Devic's disease

Estimates of the prevalence of the disease in the general population range from approximately 0.32 to 2.5 cases per 100,000.<sup>10,11</sup> (In comparison, cancer affects 462 per 100,000 each year.<sup>12</sup>) The rarity of Devic's disease has repercussions for almost every element of this analysis, limiting the availability of empirical data about treatment practices, costs, and coverage.

From one year's worth of Massachusetts all-payer claim data available to Compass,<sup>13</sup> we can identify some 50 members with a diagnosis of neuromyelitis optica in fully-insured plans. This corresponds to the upper end of the published range. The claim-based member count might be inflated by members who moved from one carrier to another and were counted twice, but still supports a range with a higher low-end value than that in the cited published range. To be conservative, we will use a range of 1.0 to 2.5 per 100,000, and use a mid-point of 1.75.<sup>14</sup>

Devic's disease can be a severely debilitating condition. People with the condition might be disproportionately likely to be disabled and therefore perhaps underrepresented in commercial plans, at least in employer-sponsored plans, except as dependents. And even if IVIG proved very effective in managing symptoms, we have no information (beyond an anecdote or two) about how it might affect a patient's disability status. Without additional information, we assume the prevalence of Devic's disease among the fully-insured population is the same as that in the general population.

## 4.2. Per-patient cost of IVIG treatment

IVIG is expensive. Published estimates of its cost range from \$4,000 to \$12,000 per month.<sup>15</sup> Claim data from 2009 available to Compass contain limited information on individuals with a diagnosis of Devic's disease who were reimbursed for IVIG. The treatment costs roughly \$8,000 per month. Furthermore, without evidence-based treatment protocols, the dosage level is subject to variation.<sup>16</sup>

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<sup>10</sup> Rice, Elizabeth. *Mayo Clinic Newsblog*. November 10, 2009.

<http://newsblog.mayoclinic.org/tag/neuromyelitis-optica/> (accessed July 30, 2012).

<sup>11</sup> Additional informal estimates from interviews cited elsewhere ran from 0.4 to 2 per 100,000.

<sup>12</sup> The Henry J. Kaiser Family Foundation [statehealthfacts.org](http://www.statehealthfacts.org). *Age-Adjusted Cancer Incidence Rate per 100,000 Population*. 2008. <http://www.statehealthfacts.org/comparemaptable.jsp?ind=64&cat=2> (accessed August 1, 2012).

<sup>13</sup> Massachusetts Health Care Quality and Cost Council. 2009. <http://www.mass.gov/hqcc/>.

<sup>14</sup> A casual estimate by at least one clinician was in the 1 to 2 per 100,000 range. Interview with Michael Levy, MD, PhD, Assistant Professor, Johns Hopkins University and Medical Director of General Neurology, Johns Hopkins Hospital (November 12, 2012).

<sup>15</sup> Blackhouse, Gord. "Cost-Utility of Intravenous Immunoglobulin (IVIG) compared with corticosteroids for the treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in Canada." *National Institutes of Health, National Center for Biotechnology Information*. June 17, 2012.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2903512/> (accessed August 6, 2012; "IVIG intravenous therapy a life saver for many." *ABC-7 News, San Francisco*. November 7, 2007.

<http://abclocal.go.com/kgo/story?section=news/health&id=5749369>; Seminara, Dave. "Should insurers get to decide your medication?" *Boston Globe Magazine*, April 8, 2012.

<sup>16</sup> Interview with Marion C. Stein.

Patients with Devic's disease who do not receive IVIG often receive other drugs, typically ones that suppress the immune system; the costs of most of these are much lower than the cost of IVIG.<sup>17</sup> We will not evaluate the savings due to eliminating the need for other treatments.

The cost of administering IVIG is much smaller than the cost of the blood product itself and is not a concern here. Regardless of the magnitude of such costs, they do not significantly affect the incremental cost of the mandate because most treatments other than IVIG also require some sort of controlled administration. Finally, because of the relatively high cost of IVIG, we do not expect member cost-sharing to reduce significantly the impact of the mandate.

This analysis projects the costs of the mandate five years into the future. Projecting the change in the price of a single treatment such as IVIG is difficult. The 2009 claim data for the one individual treated with IVIG for Devic's disease, as described above, showed a unit cost for one form of IVIG which appears to have changed only modestly since, based responses from carriers to questions about their current cost for IVIG.<sup>18</sup> Still, to be conservative, we will assume the cost of IVIG treatment rises at a rate approximating the upper end of general inflation.<sup>19</sup> We will assume an annual increase of four percent over the years since 2009; continuing into the future, we will assume four percent as a midpoint, with three and five as the lower and upper ends of the range.

### 4.3. Effect of the mandate on IVIG use in treating Devic's disease

Multiplying the prevalence of Devic's disease by the monthly cost of IVIG treatment would yield the cost (per member per month) of treating everyone with Devic's disease using IVIG. However, there is no evidence that IVIG will help everyone with the disease. Furthermore, there is evidence that at least some carriers already cover IVIG for the treatment of Devic's disease. Therefore, in estimating the net impact of the proposed mandate, we will need to reduce the maximum potential cost of treating all cases of Devic's disease with IVIG.

If all carriers covered IVIG for Devic's disease patients without a legal requirement to do so, the net cost to premium payers of H.B. 941 would be zero, and indeed we have evidence that some carriers in the past have covered it. However, we have also heard of cases in which coverage for IVIG for Devic's disease has been denied on the grounds that the treatment is not evidence-based, or perhaps is experimental, and therefore is not medically necessary. Some such anecdotes ended with the patient eventually receiving coverage. And because the disease and IVIG treatment are, in combination, exceedingly rare, it is unlikely we can glean anything about coverage policy from claim data.

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<sup>17</sup> Interview with Michael Levy.

<sup>18</sup> Comparing the amount allowed per unit of J1569, used in treating Devic's disease, in 2009 HCQCC claim data with the unit cost for the same item reported in response to the Center's survey to carriers in support of this analysis.

<sup>19</sup> In addition, we have anecdotal evidence from a clinician interview that the costs of treating a patient with IVIG are likely to be higher than the four-year-old monthly per-patient cost of \$8000 we measured for one patient. Interview with Michael Levy.

Therefore, looking across the full range of plans and policies for the purpose of this analysis, it appears we must regard decisions about coverage for IVIG for Devic's disease as "case-by-case." Responses to a survey of carriers about their coverage policies for this treatment show no uniformity across payers; some had no history with the treatment on which to base a response. In estimating the impact of the bill, we will have to allow for this uncertainty in existing coverage.

As noted above, Devic's disease is so rare that our research has not uncovered published studies of controlled trials that normally constitute evidence for the efficacy of a treatment. To the extent that a standard treatment for Devic's disease even exists, IVIG is probably not yet part of typical patient regimen.<sup>20</sup> Interviews with clinicians produced a wide range of the portion of patients helped by other treatments (mostly immunosuppressants): from 30 to 80 percent.<sup>21,22</sup> Yet we do not know what portion of those might do better with IVIG (which tends to be associated with fewer tolerance problems than do immunosuppressants). We could find no controlled trials dealing specifically with IVIG, though anecdotal evidence for the effectiveness of IVIG exists.<sup>23</sup>

Because IVIG is so expensive and reimbursement is in question, it is possible, even likely, that its cost has inhibited experimentation with the treatment and that use of IVIG will increase once coverage is available. In other words, we do not know with any certainty whether current use of IVIG reflects either clinical decisions about the best treatment for the patient, or the cost of the IVIG. The 2009 claim data revealed only one member receiving IVIG treatment for Devic's disease.

Given our limited information on what portion of patients with Devic's disease might be helped by IVIG treatment, we assume that portion to be the complement of the portion of patients helped by other treatments, i.e., 20 to 70 percent of patients might be helped by IVIG treatment. From that, we subtract an estimate of the patients who would receive coverage under current policies, assuming that value runs from 80 percent down to 20 percent. Therefore, of the potential IVIG treatment for the population diagnosed with Devic's disease, we assume that the incremental increase in reimbursed IVIG utilization will run from 4 percent (20 percent, less 80 percent of 20 percent) up to 56 percent (70 percent, less 20 percent of 70 percent).

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<sup>20</sup> Interview with Michael Levy.

<sup>21</sup> Interview with Marion C. Stein.

<sup>22</sup> Interview with Michael Levy.

<sup>23</sup> Interview with Marion C. Stein.

## 5. Estimate of Impact on Premiums

To estimate the impact of the proposed legislation on premiums for fully-insured plans, we executed the following calculations. We developed a best estimate “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.

### 5.1. Insured membership affected by the mandate

Table 1 shows the number of members in plans potentially affected by the mandate. This analysis does not include individuals with Medicare coverage and federally-regulated “medigap” policies; we have excluded people over age 64. Further, we have not attempted to adjust the projection for possible future effects of the federal Affordable Care Act on the number of people enrolling in fully-insured plans.

**Table 1:  
Commercial Fully-Insured under-65 Projected Population**

<u>Year</u>	<u>Projected Members</u>
2014	2,218,814
2015	2,194,845
2016	2,170,890
2017	2,146,143
2018	2,120,524

### 5.2. Prevalence of Devic’s disease

As noted above, we assumed a range of 1.0 to 2.5 per 100,000, with a mid-point of 1.75 for the prevalence (treatment prevalence) of Devic’s disease. Table 2 displays the values used in the analysis.

**Table 2:  
Prevalence of Devic’s Disease per 100,000**

Low Scenario	1.00
Mid Scenario	1.75
High Scenario	2.50

### 5.3. Per patient cost of IVIG treatment

Four-year-old data suggests the cost of IVIG treatment is in the range of \$4,000 to \$12,000 per month. As noted in Section 4.2, we assumed an annual increase of 4 percent to bring it to 2013

levels. Applying four years of that factor to the available data on treatment cost yields the range displayed in Table 3.

**Table 3:  
Estimate of 2013 Monthly Cost of IVIG Treatment per Patient**

Low Scenario	\$ 4,700
Mid Scenario	\$ 9,400
High Scenario	\$ 14,000

#### 5.4. Effect of the mandate on reimbursement for IVIG

As outlined in Section 4.3, we assume 20 to 70 percent of patients might be helped by IVIG treatment. From that we subtracted an estimate of the patients who would currently receive coverage, assuming that value runs from 80 percent down to 20 percent. Therefore, for the population diagnosed with Devic’s disease, we assumed that the incremental increase in reimbursed IVIG use will run from 4 percent (20 percent, less 80 percent of 20 percent) up to 56 percent (70 percent, less 20 percent of 70 percent). Tables 4a, 4b, and 4c display these ranges and the chosen midpoints.

**Table 4a:  
Percent of Patients with Devic’s Disease Helped by IVIG Treatment**

Low Scenario	20%
Mid Scenario	50%
High Scenario	70%

**Table 4b:  
Percent of IVIG Treatment Covered**

Low Scenario	80%
Mid Scenario	50%
High Scenario	20%

**Table 4c:  
Incremental Increase in Reimbursement for IVIG Treatment**

Low Scenario	4%
Mid Scenario	25%
High Scenario	56%

#### 5.5. Net increase in carrier medical expense

Multiplying the prevalence by the monthly cost reflected in Table 3, and applying the factors in Table 4c reflecting the net impact of the mandate, yields the medical expense (i.e., the amount paid



out for services, whether under medical or pharmacy benefits) per member per month (PMPM) displayed in Table 5.

**Table 5:  
Estimate of Increase in Carrier Medical Expense PMPM**

Low Scenario	\$ 0.00
Mid Scenario	\$ 0.04
High Scenario	\$ 0.20

## 5.6. Net increase in premium

Assuming an average retention rate of 10.2 percent, based on CHIA's analysis of insurance carrier administrative costs and profit in Massachusetts,<sup>24</sup> we adjusted the increase in medical expense upward to approximate the impact on premiums. Table 6 shows the result.

**Table 6:  
Estimate of Increase in Premium PMPM**

Low Scenario	\$ 0.00
Mid Scenario	\$ 0.05
High Scenario	\$ 0.22

Note again these values reflect estimated 2013 dollars, which we project in turn into the future in the next step.

## 5.7. Five-year estimated impact

For each year in the five-year analysis period (2014 to 2018), Table 7 displays the projected net impact of the proposed mandate on medical expense and premiums using a projection of Massachusetts fully-insured membership. We estimate H.B. 941 will increase premiums by as much as 0.05 percent on average over the next five years. We think the more likely increase is in the range of 0.01 percent.

The degree of precision achievable in this analysis is hampered by the lack of empirical data about a rare condition. But while the results have a substantial amount of variation measured by the ratio between low- and high-level scenarios, even the high-level scenario represents a small increase in overall premiums.

The impact of H.B. 941 on premiums rises steadily throughout the analysis period because of our assumptions about continuing increases in the average cost of IVIG treatment. Finally, the impact of the bill on any one individual, employer-group, or carrier may vary from the overall results

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<sup>24</sup>Massachusetts Division of Health Care Finance and Policy. "Massachusetts Health Care Cost Trends: Premiums and Expenditures." May 2012. <http://www.mass.gov/chia/docs/cost-trend-docs/cost-trends-docs-2012/premiums-and-expenditures.pdf>.

depending on the current level of benefits each receives or provides and on how that level of benefits will change under the proposed mandate.

**Table 7:  
Summary Results**

	2014	2015	2016	2017	2018	Average	5 Yr Total
Members (000's)	2,219	2,195	2,171	2,146	2,121	2,170	
Medical Expense Low (\$000's)	\$ 52	\$ 53	\$ 54	\$ 55	\$ 56	\$ 54	\$ 269
Medical Expense Mid (\$000's)	1,134	1,166	1,200	1,234	1,268	1,200	6,001
Medical Expense High (\$000's)	5,442	5,653	5,870	6,094	6,322	5,876	29,381
Premium Low (\$000's)	\$ 58	\$ 59	\$ 60	\$ 61	\$ 62	\$ 60	\$ 300
Premium Mid (\$000's)	1,263	1,299	1,336	1,374	1,412	1,337	6,683
Premium High (\$000's)	6,060	6,295	6,537	6,786	7,040	6,544	32,718
Change in PMPM Low	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Change in PMPM Mid	0.05	0.05	0.05	0.05	0.06	0.05	0.05
Change in PMPM High	0.23	0.24	0.25	0.26	0.28	0.25	0.25
Estimated Monthly Premium	\$ 487	\$ 512	\$ 537	\$ 564	\$ 592	\$ 538	\$ 538
Premium % Change Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Change Mid	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Premium % Change High	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%	0.05%