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MANDATED BENEFIT REVIEW OF H.B. 989: AN ACT RELATIVE TO LYME DISEASE TREATMENT COVERAGE

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TABLE OF CONTENTS

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Benefit Mandate Overview: H.B. 989: Chronic Lyme Disease

HISTORY OF THE BILL

The Joint Committee on Financial Services referred House Bill (H.B.) 989, "An Act relative to Lyme disease treatment coverage," sponsored by Rep. Speliotis of Danvers, to the Center for Health Information and Analysis (CHIA) for review. Massachusetts General Laws, chapter 3, section 38C requires CHIA to review and evaluate the potential fiscal impact of each mandated benefit bill referred to the agency by a legislative committee.

WHAT DOES THE BILL PROPOSE?

H.B. 989 requires that health insurance plans defined in the bill "provide coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment."

MEDICAL EFFICACY OF CHRONIC LYME DISEASE TREATMENT

Lyme disease is the most common vector-borne illness[i] in the United States and Europe,[ii,iii] and is transmitted to humans through tick bites.[iv] While the majority of Lyme disease patients are successfully treated with a single or double course of antibiotics, an estimated 10 to 20 percent of patients have symptoms that last months or years after antibiotic treatment, including fatigue and sleep disturbances, muscle and joint pain, and cognitive deficits.[v]

The proposed mandate refers to chronic Lyme disease (CLD) and is intended to provide insurance coverage for long-term antibiotic treatment for this subset of patients. A consensus definition of CLD currently does not exist, and the means of detecting the presence of the disease in an atypical case, in which symptoms last months or years after a single or double course of antibiotics, is not clearly defined. Symptoms vary in type and severity.

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i Vector-borne disease: "[B]acteria, viruses, or parasites transmitted to people by mosquitoes, ticks, and fleas." Vectorborne Diseases: The Centers for Disease Control and Prevention (CDC) joins the World Health Organization (WHO) and other public health partners in recognizing World Health Day, which this year spotlights vectorborne diseases; accessed 22 April 2014: http://www.infectioncontroltoday.com/galleries/2014/04/vectorborne-diseases.aspx?pg=3#gallery.

ii U.S. Centers for Disease Control (CDC): Lyme Disease Diagnosis and Testing. Updated 10 January 2013; accessed 30 January 2014: http://www.cdc.gov/lyme/diagnosistesting/.

iii Wormser GP, Dattwyler RJ, Shapiro ED, et. al. The clinical assessment, treatment, and prevention of lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America (IDSA Lyme Guidelines). Clin Infect Dis. 2006 Nov 1;43(9):1089-134. Epub 2 Oct 2006; accessed 3 February 2014: http://cid.oxfordjournals.org/content/43/9/1089.full.

iv *Ibid*. Species *Ixodes scapularis* and *Ixodes pacificus*.

v U.S. CDC: Post-Treatment Lyme Disease Syndrome. Updated 24 February 2014; accessed 21 February 2014: http://www.cdc.gov/lyme/postLDS/index.html.

These challenges result in treatment regimens in which length of treatment is often based on a patient's symptoms rather than on a concretely pre-determined time period. While this approach is recommended by the International Lyme and Associated Diseases Society (ILADS)[vi], the U.S. Centers for Disease Control and Prevention (CDC), the National Institute for Allergy and Infectious Disease (NIAID), and the Infectious Disease Society of America (IDSA) have stated that the use of long-term antibiotic treatment for Lyme disease or CLD, specifically beyond one or two 10- to 28-day treatment regimens, is not effective and may result in serious complications; these agencies hold that reported cases in which CLD has been successfully treated are more likely the result of the "placebo effect" rather than of the antibiotic treatment itself.[vii,viii,ix]

CURRENT COVERAGE

In a recent survey of eight of the largest insurance carriers in Massachusetts, all carriers note that at least one round of intravenous antibiotic therapy, lasting between two and four weeks, is covered by their policies, as are oral antibiotics. Some plans allow an additional course, following the guidelines of the Infectious Disease Society of America (IDSA).[x] Carriers are more likely to restrict the length of treatment with intravenous than with oral antibiotics.

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 insurance premiums of between a negligible amount (0.00%) and $0.13 (0.02%) per year.

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 Massachusetts General Laws, as well as the Group Insurance Commission (GIC) covering public employees and their dependents, would be subject to this proposed 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.

vi International Lyme and Associated Diseases Society (ILADS): Evidence-based guidelines for the management of Lyme disease. Released 2004; accessed 27 February 2014: http://www.ilads.org/files/ILADS_Guidelines.pdf.

vii CDC: Post-Treatment Lyme Disease Syndrome. Updated 7 February 2014; accessed 21 February 2014: http://www.cdc.gov/lyme/postLDS/index.html.

viii NIAID: "Chronic Lyme Disease". Updated 27 September 2013; accessed 21 February 2014: http://www.niaid.nih.gov/topics/lymeDisease/understanding/Pages/chronic.aspx.

ix *Op. cit.* Wormser GP, Dattwyler RJ, Shapiro ED, et. al.

x *Ibid*.

PLANS NOT AFFECTED BY THE PROPOSED BENEFIT MANDATE

Self-insured plans (i.e., where the employer policyholder retains the risk for medical expenses and uses an insurer to provide administrative functions) are subject to federal law and not to state-level health insurance benefit 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 personnel and dependents), Veterans Administration, and the Federal Employee's Health Benefit Plan. Finally, this bill does not apply to Medicaid/MassHealth.

PRELIMINARY ESTIMATE OF POTENTIAL MASSACHUSETTS LIABILITY UNDER THE ACA

Analysis of the cost associated with proposed state benefit mandates is important in light of new requirements introduced by the Affordable Care Act (ACA). In accordance with the ACA, all states must set an Essential Health Benefits (EHB) benchmark that all qualified health plans (QHPs), and those plans sold in the individual and small-group markets, must cover, at a minimum. Section 1311(d)(3)(B) of the ACA, as codified in 45 C.F.R. § 155.170, explicitly permits a state to require QHPs to offer benefits in addition to EHB, provided that the state is liable to defray the cost of additional mandated benefits by making payments to or on behalf of individuals enrolled in QHPs. The state is not financially responsible for the costs of state-required benefits that are considered part of the EHB benchmark plan. State-required benefits enacted on or before December 31, 2011 (even if effective after that date) are not considered "in addition" to EHB and therefore will not be the financial obligation of the state. The policy regarding state-required benefits is effective as of January 1, 2014 and is intended to apply for at least plan years 2014 and 2015.

To provide additional information about the potential state liability under the ACA associated with mandating this benefit, CHIA generated a preliminary estimate of the incremental annual premium costs to QHPs associated with this benefit mandate; incremental premium costs exclude the cost of services already provided absent the mandate or already required by other federal or state laws. CHIA's review of the proposed health benefit mandate is not intended to determine whether or not this mandate is subject to state liability under the ACA. CHIA generated this estimate to provide neutral, reliable information to stakeholders who make decisions that impact health care access and costs in the Commonwealth.

CHIA applied the mid-range PMPM (per-member per-month) actuarial projection for 2015 cost ($0.03) to an estimated 800,000 potential QHP members.[xi] This results in an estimated potential incremental premium increase to QHPs of approximately $21,000 per month or $255,000 per year. If fewer (or more) enrollees join QHPs in the merged market than expected, the potential incremental premium cost may be less (or more) than this estimate. A final determination of the Commonwealth's liability will require a detailed analysis by the appropriate state agencies.

xi Estimated QHP membership provided by the Massachusetts Division of Insurance.

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H.B. 989 Medical Efficacy Assessment: Chronic Lyme Disease

Massachusetts House Bill (H.B.) 989 requires health insurance plans to cover the costs of "diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment."[1] The bill further states that treatment shall not be denied because it may be characterized as unproven, experimental, or investigational in nature.[2] 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.[3] Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service, often compared to alternative treatments, and describe the potential impact of a mandated benefit on the quality of patient care and the health status of the population.

A recent report from a National Institute of Medicine workshop on Lyme disease noted that "a significant impasse has developed in the world of Lyme disease. There are conflicts within and among the science; policy; politics; medicine; and professional, public, and patient views pertaining to the subject…."[4] Reflecting this controversy in Massachusetts, a law was enacted in 2010 explicitly permitting physicians to "prescribe, administer or dispense long-term antibiotic therapy for a therapeutic purpose to eliminate infection or to control a patient's symptoms upon making a clinical diagnosis that the patient has Lyme disease or displays symptoms consistent with a clinical diagnosis of Lyme disease, if such clinical diagnosis and treatment are documented in the patient's medical record by the prescribing licensed physician," which would, in effect, protect physicians from medical board discipline for prescribing or dispensing long-term antibiotic treatment for Lyme disease.[5]

This review will attempt to summarize current widely-supported positions, including those reflected in guidelines of the U.S. Centers for Disease Control and Prevention (CDC), the National Institute for Allergy and Infectious Disease (NIAID), and the Infectious Disease Society of America (IDSA). It also describes some of the arguments supporting different disease definitions and treatment guidelines, especially pertaining to chronic Lyme disease (CLD), including those made by the International Lyme and Associated Diseases Society (ILADS).

LYME DISEASE

Lyme disease is the most common vector-borne illness[6] in the United States and Europe,[7,8] and is transmitted to humans through bites of ticks[9] infected with spirochete bacteria,[10] specifically *Borrelia burgdorferi* in North America.[11] The incidence of CDC-confirmed cases of Lyme disease in Massachusetts has been somewhat erratic over time, with the most recent estimates of 51.1 cases per 100,000 residents in the state in 2012.[12] However, this number is based on 3,396 confirmed cases in the state; the CDC reports another 1,742 probable cases of Lyme disease in Massachusetts in 2012.[13] Including these probable cases would raise the incidence rate of Lyme disease to 77.3 per 100,000 residents in the most recent year measured. This number also may be understated, as additional cases may not be reported to the CDC and not included in its statistics. In 2012, Massachusetts had the fifth highest confirmed-case incidence rate of Lyme disease in the U.S.[14]

Common early symptoms of Lyme disease, which can mimic the flu, are fatigue, headache, fever, and joint aches.[15] When undiagnosed or untreated, the disease can affect the circulatory, muscular, nervous, and skeletal systems in the body,[16] sometimes causing arthritis, meningitis, cardiac problems, eye inflammation, Bell's palsy, and hepatitis, among other illnesses.[17]

Often indicative of Lyme disease is a "bull's-eye" skin rash – appearing most often as a red center surrounded by a clear area and outlined by a red ring – clinically called erythema migrans (EM), and unique to Lyme disease.[18,19] When a patient presents with an EM rash, a diagnosis of Lyme disease is fairly straightforward, and may be more easily correctly identified and treated in earlier stages of the disease.[20] However, estimates of the portion of patients who develop the EM rash vary from less than fifty percent[21] to seventy to eighty percent.[22]

In the absence of an EM rash, a diagnosis of Lyme disease is sometimes difficult to make, given that the disease's symptoms are often similar to those of other diseases.[23] The NIAID states that diagnosis should be made based on clinical judgment of the signs and symptoms of the disease, specifically on a patient's detailed medical history and symptoms, the patient's exposure in an area where Lyme disease exists, and the time of year.[24] Later-stage diagnosis of the disease is often made based on the presence of Lyme arthritis, or neurologic symptoms such as Bell's palsy.[25] Laboratory testing may be supportive of the diagnosis, but has been found to be problematic in its sensitivity for identifying the disease in its early stages.[26,27] Moreover, while these tests are more likely to accurately identify Lyme disease in its second or third phases, treatment is generally more effective when prescribed in an earlier disease stage[28], resulting in the paradox that early treatment makes laboratory testing less accurate in later Lyme disease stages. And while often used by clinicians in community settings, the CDC's diagnostic criteria was developed for use in defining cases for surveillance purposes in reporting Lyme disease nationally; the agency explicitly states that their definition "is not intended to be used in clinical diagnosis."[29]

The challenges in making a correct Lyme disease diagnosis can be further complicated by infections by other tick-transmitted organisms; these co-infections may cause additional symptoms or co-morbidities and prevent the successful treatment of Lyme disease.[30] Likewise, the presence in the patient of autoimmune disorders or previously undiagnosed diseases also makes diagnosis and treatment of Lyme disease difficult.[31] These difficulties in making a clear diagnosis, and the heterogeneity of symptom presentation, can make early successful treatment difficult, and may in part explain the progress of the disease to a post-treatment or chronic phase.

CHRONIC LYME DISEASE

While the majority of Lyme disease patients are successfully treated with a single or double course of antibiotics, especially if treatment begins in the early disease stage, an estimated 10 to 20 percent of patients have symptoms that last months or years after antibiotic treatment, including fatigue and sleep disturbances, muscle and joint pain, and cognitive deficits.[32] The NIAID reports that studies have "reinforced the evidence that patients reporting [post-treatment Lyme disease syndrome] symptoms have a severe impairment in overall physical health and quality of life."[33]

A variety of terms have been used to group these cases, including "post-treatment Lyme disease syndrome,"[34] "post-Lyme disease syndrome,"[35] and "chronic Lyme disease" (CLD). This report uses "CLD" following the language in the proposed mandate, H.B. 989. ILADS further classifies CLD into persistent, recurrent, and refractory Lyme disease.[36]

Views on the definition and very existence of CLD vary significantly. In addition to continuing symptoms, some patients may have another tick-borne infection[37] which may complicate treatment of Lyme disease. For other patients, Lyme disease may have coincided with autoimmune diseases or chronic syndromes, including fibromyalgia, Gulf War syndrome, and chronic fatigue, or Lyme disease may exacerbate the symptoms of these conditions. Still others may continue to experience symptoms after treatment and during recovery of the disease, given that healing of the neurological or cardiac system or joints, for example, often occurs after elimination of the bacteria from the body. According to IDSA, "[t]here is no well-accepted definition… This has contributed to confusion and controversy and to a lack of firm data on its incidence, prevalence, and pathogenesis."[38]

While there is widespread agreement on the existence of cases with post-treatment symptoms (10 to 20 percent, as noted previously), a consensus definition of these cases does not currently exist, and the means of detecting the presence of the disease in an atypical case, in which symptoms last months or years after a single or double course of antibiotics, is not clearly defined. Some patients with persistent symptoms have been documented as having previously tested positive for Lyme disease using a commercially-approved blood test and have followed the recommended antibiotic course without symptom abatement.[39] Others cannot or did not confirm Lyme disease with a blood test, but had a diagnosis based on medical history and symptoms.

The exact cause of continuing symptoms is a point of disagreement, and according to the CDC, unknown.[40] The CDC states that the cause of ongoing symptoms is not due to continuing infection with the Lyme disease bacteria, and mentions a possible autoimmune response by the patient.[41] The IDSA states in its proposed definition for post-Lyme disease syndrome that "having once had objective evidence of *B. burgdorferi* infection must be a condition sine qua non."[42]

Another perspective suggests that CLD could be residual symptoms of an episode of active Lyme disease, or that it could be a persistent form of the disease not recognizable by current testing.[43,44] Proponents of the latter position hold that because no approved commercially-available test detects the presence of the bacteria, but only typical antibody response, and because those tests that measure antibody response have limitations, the absence of the Lyme disease bacteria in people with ongoing symptoms cannot be unequivocally proven.[45]

Results from some basic science (non-clinical) studies appear to provide information that may contradict clinical research.[46] The NIAID has sponsored research that concluded that *B. burgdorferi* persisted in animals (including mice and non-human primates) after antibiotic treatment, and has indicated that additional research is needed to understand the potential implication of these findings on human disease.[47] Moreover, there are published peer-reviewed studies that show that CLD may be caused by persistent infection with *B. burgdorferi,*[48] may not trigger the expected immune response in some patients,[49] or that certain types or courses of antibiotics may not be sufficient to eradicate the disease.[50]

TREATMENT FOR CHRONIC LYME DISEASE

Accompanying the divergence of opinion on the existence or definition of CLD is significant disagreement on how to treat these patients, including the length of treatment and types of antibiotics. Based on the results of several published double-blind, placebo-controlled studies, the CDC, NIAID, and IDSA have stated that the use of long-term antibiotic treatment for Lyme disease or CLD, specifically beyond one or two 10- to 28-day treatment regimens, is not effective; these agencies hold that reported cases in which CLD has been successfully treated are more likely the result of the "placebo effect" rather than of the antibiotic treatment itself.[51,52,53] These agencies underscore rare but serious complications from long-term antibiotic treatment, most often associated with intravenous treatment, as well as an increased risk for infection with other harmful bacteria *(c. difficile)* from increased antibiotic use.[54]

On the other hand, ILADS guidelines state that "[t]he management of chronic Lyme disease must be individualized, since patients will vary according to severity of presentation and response to previous treatment," and that, "the patient's clinical response should guide duration of [antibiotic] therapy."[55] For CLD specifically, ILADS also considers the use of intramuscular antibiotics when oral or intravenous treatments fail. The group cautions against routinely combining oral and intravenous treatments as it "raises the risk of adverse reactions," but does consider sequential treatment of CLD, first with intravenous treatment followed by an oral therapy, as a possible alternative.[56]

Finally, in the absence of a consensus "standard" CLD treatment regimen, other treatments have been proposed, including alternative antibiotics, indefinite and possibly lifelong antibiotic treatment, and hyperbaric oxygen therapy. This review has uncovered no widely-recognized sources of support for routine use of these treatments.[57]

Again, widespread agreement exists that the symptoms of a certain portion of patients with Lyme disease are not ameliorated through short-course treatments of antibiotic. The disagreement on whether this population continues to be ill due to some form of Lyme disease, or whether their symptoms result from other causes, produces further differences on recommended treatments. The dilemma for clinicians is avoiding inappropriate or over-treatment while effectively managing their patients' ailments. The NIAID itself states that "[t]o help combat these problems, researchers are trying to find out how long a person should take antibiotics for the various symptoms that may follow a bout with Lyme disease."[58]

Endnotes

1 The 188th General Court of the Commonwealth of Massachusetts. Bill H. 989: An Act relative to Lyme Disease treatment coverage. Accessed 26 February 2014: https://malegislature.gov/Bills/188/House/H989.

2 *Ibid.*

3 M.G.L. c. 3, § 38C: Health insurance coverage; mandated health benefit bills; review and evaluation; report. Accessed 14 May 2014: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleI/Chapter3/Section38C.

4 Institute of Medicine (US) Committee on Lyme Disease and Other Tick-Borne Diseases: The State of the Science. Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme and Other Tick-Borne Diseases: The Short-Term and Long-Term Outcomes: Workshop Report. Washington (DC): National Academies Press (US); 2011. Accessed 21 February 2014: http://www.ncbi.nlm.nih.gov/books/NBK57020/.

5 Massachusetts Session Laws 2010 c.131 §67 "A licensed physician may prescribe, administer or dispense long-term antibiotic therapy for a therapeutic purpose to eliminate infection or to control a patient's symptoms upon making a clinical diagnosis that the patient has Lyme disease or displays symptoms consistent with a clinical diagnosis of Lyme disease, if such clinical diagnosis and treatment are documented in the patient's medical record by the prescribing licensed physician." Accessed 27 February 2014: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12DD.

6 Vector-borne disease: "[B]acteria, viruses, or parasites transmitted to people by mosquitoes, ticks, and fleas." Vectorborne Diseases: The Centers for Disease Control and Prevention (CDC) joins the World Health Organization (WHO) and other public health partners in recognizing World Health Day, which this year spotlights vectorborne diseases; accessed 22 April 2014: http://www.infectioncontroltoday.com/galleries/2014/04/vectorborne-diseases.aspx?pg=3#gallery.

7 U.S. Centers for Disease Control (CDC): Lyme Disease Diagnosis and Testing. Updated 10 January 2013; accessed 30 January 2014: http://www.cdc.gov/lyme/diagnosistesting/.

8 Wormser GP, Dattwyler RJ, Shapiro ED, et. al. The clinical assessment, treatment, and prevention of lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America (IDSA Lyme Guidelines). Clin Infect Dis. 2006 Nov 1;43(9):1089-134. Epub 2 Oct 2006; accessed 3 February 2014: http://cid.oxfordjournals.org/content/43/9/1089.full.

9 *Ibid*. Species *Ixodes scapularis* and *Ixodes pacificus*.

10 Spirochete: A type of double-membrane bacteria which is long, slender and tightly-coiled, and moves by rotating in place. Wikipedia: Spirochaete. Accessed 30 January 2014: http://en.wikipedia.org/wiki/Spirochaete.

11 Hu L, Steere AC, Mitty J. Up To Date: Clinical Manifestations of Lyme disease in adults. Updated 5 February 2013; accessed 30 January 2014: http://www.uptodate.com/contents/clinical-manifestations-of-lyme-disease-in-adults. Additional strains of *Borrelia afzelii* and *Borrelia garinii* are found in cases originating in Europe or Asia. This distinction is important as there are patients with Lyme disease in the United States caused by bites from ticks carrying other strains of the bacteria that occurred during travel overseas.

12 CDC: Lyme Disease Incidence Rates by State, 2003-2012. Updated 16 September 2013; accessed 21 February 2014: http://www.cdc.gov/lyme/stats/chartstables/incidencebystate.html.

13 CDC: Reported cases of Lyme disease by state or locality, 2003-2012. Updated 16 September 2013; accessed 21 February 2014: http://www.cdc.gov/lyme/stats/chartstables/reportedcases_statelocality.html.

14 *Ibid.*

15 CDC: Lyme disease. Updated 15 November 2013; accessed 30 January 2014: http://www.cdc.gov/lyme/.

16 *Ibid*.

17 National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID): A History of Lyme Disease, Symptoms, Diagnosis, Treatment, and Prevention. Updated 9 October 2012; accessed 30 January 2014: http://www.niaid.nih.gov/topics/lymedisease/understanding/Pages/intro.aspx.

18 *Ibid.*

19 Meyerhoff JO, Cunha BA, Brent LH, et. al. Medscape: Lyme disease. Updated 19 November 2013; accessed 30 January 2014: http://emedicine.medscape.com/article/330178-overview#showall.

20 *Op cit.* NIAID: A History of Lyme Disease.

21 International Lyme and Associated Diseases Society (ILADS): Basic Information About Lyme Disease. Updated 15 April 2006; accessed 30 January 2014: http://www.ilads.org/lyme_disease/about_lyme.html.

22 *Op cit.* CDC: Signs and Symptoms of Lyme Disease.

23 *Op cit.* NIAID: A History of Lyme Disease.

24 *Ibid*.

25 Interview with Samuel Donta, MD, infectious disease specialist, Falmouth Hospital, 10 February 2014.

26 Brown SL, Hansen SL, Langone JJ. Role of serology in the diagnosis of Lyme disease. JAMA. 1999 Jul 7;282(1):62-6. Abstract accessed 21 February 2014: http://www.ncbi.nlm.nih.gov/pubmed/10404913.

27 Laboratory testing for Lyme disease in its early stages with serum (blood) diagnostics is not effective, as the test measures a typical patient's antibody response to exposure to the bacteria, and not the presence of the bacteria itself. In the early stage, antibodies in a patient's blood may not have accumulated to a level sufficient for detection; however, the laboratory tests can be an important diagnostic tool for confirming the disease in its second or third stages. HHS (CDC, NIH, FDA) Federal Research Update on Lyme Disease Diagnostics Webinar. Broadcast 24 September 2012; accessed 21 February 2014: http://www.cdc.gov/lyme/diagnosistesting/index.html. TRANSCRIPT: HHS Federal Research Update on Lyme Disease Diagnostics Activities September 24, 2012. Accessed 21 February 2014: http://www.cdc.gov/lyme/resources/webinar/09242012_DiagnosticsWebinarTranscript.pdf.

28 *Op cit.* NIAID: A History of Lyme Disease.

29 CDC: National Notifiable Diseases Surveillance System, Lyme disease (Borrelia burgdorferi), 2011 Case Definition, CSTE Position Statement(s), 10-ID-06. Updated 8 May 2014; accessed 14 May 2014: http://wwwn.cdc.gov/NNDSS/script/casedef.aspx?CondYrID=752&DatePub=1/1/2011%2012:00:00%20AM.

30 *Op cit.* ILADS: Basic Information About Lyme Disease.

31 *Op cit.* IDSA Lyme Guidelines.

32 CDC: Post-Treatment Lyme Disease Syndrome. Updated 7 February 2014; accessed 21 February 2014: http://www.cdc.gov/lyme/postLDS/index.html.

33 NIAID: "Chronic Lyme Disease". Updated 27 September 2013; accessed 21 February 2014: http://www.niaid.nih.gov/topics/lymeDisease/understanding/Pages/chronic.aspx.

34 *Ibid.*

35 *Op cit.* IDSA Lyme Guidelines.

36 ILADS: Evidence-based guidelines for the management of Lyme disease. Released 2004; accessed 27 February 2014: http://www.ilads.org/files/ILADS_Guidelines.pdf.

37 According to the CDC, these may include anaplasmosis, babesiosis, ehrlichiosis, Rocky Mountain Spotted Fever (RMSF), and Southern Tick-Associated Rash Illness (STARI), among others in the United States. CDC: Tickborne Diseases of the U.S. Updated 3 February 2014; accessed 6 March 2014: http://www.cdc.gov/ticks/diseases/.

38 *Op cit.* IDSA Lyme Guidelines.

39 *Op cit.* NIAID: "Chronic Lyme Disease".

40 CDC: Signs and Symptoms of Lyme Disease. Updated 11 January 2013; accessed 30 January 2014: http://www.cdc.gov/lyme/signs_symptoms/index.html.

41 *Op cit.* CDC: Post-Treatment Lyme Disease Syndrome.

42 *Op cit.* IDSA Lyme Guidelines.

43 *Op cit.* Interview with Samuel Donta, MD, infectious disease specialist, Falmouth Hospital, 10 February 2014.

44 ILADS: Summary of ILADS Guidelines for Lyme Disease. Accessed 28 April 2014: http://www.ilads.org/lyme_disease/treatment_guidelines_clearing_ilads.html.

45 *bid.*

46 Phillips SE, Harris NS, Horowitz R, et. al. Lyme disease: scratching the surface. Lancet. 2005 Nov 19;366(9499):1771. Accessed 27 February 2014: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)67721-5/fulltext.

47 *Op cit.* NIAID: "Chronic Lyme Disease".

48 Oksi J, Marjamäki M, Nikoskelainen J, et al. Borrelia burgdorferi detected by culture and PCR in clinical relapse of disseminated Lyme borreliosis. Ann Med. 1999 Jun;31(3):225-32. Accessed 27 February 2014: http://www.ncbi.nlm.nih.gov/pubmed/10442678.

49 Kalish RS, Wood JA, Golde W, et. al. Human T lymphocyte response to Borrelia burgdorferi infection: no correlation between human leukocyte function antigen type 1 peptide response and clinical status. J Infect Dis. 2003 Jan 1;187(1):102-8. Epub 2002 Dec 13; Accessed 27 February 2014: http://www.ncbi.nlm.nih.gov/pubmed/12508152.

50 Fallon BA, Keilp JG, Corbera KM, et al. A randomized, placebo-controlled trial of repeated IV antibiotic therapy for Lyme encephalopathy. Neurology. 2008 Mar 25;70(13):992-1003. Epub 10 Oct 2007; Accessed 27 February 2014: http://www.neurology.org/content/70/13/992.

51 *Op cit.* CDC: Post-Treatment Lyme Disease Syndrome.

52 *Op cit.* NIAID: "Chronic Lyme Disease".

53 *Op cit.* IDSA Lyme Guidelines.

54 CDC: Healthcare Associated Infections: *Clostridium difficile* infection. Updated 1 March 2013; accessed 27 February 2014: http://www.cdc.gov/hai/organisms/cdiff/cdiff_infect.html.

55 *Op cit.* ILADS: Evidence-based guidelines for the management of Lyme disease.

56 *Ibid.*

57 *Op cit.* ILADS: Summary of ILADS Guidelines for Lyme Disease.

58 National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID): A History of Lyme Disease, Symptoms, Diagnosis, Treatment, and Prevention. Updated 9 October 2012; accessed 30 January 2014: http://www.niaid.nih.gov/topics/lymedisease/understanding/Pages/intro.aspx.

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APPENDIX

Actuarial Assessment of House Bill 989:
"An Act relative to Lyme disease treatment coverage"

Prepared for
Commonwealth of Massachusetts
Center for Health Information and Analysis

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Prepared by
Compass Health Analytics, Inc.

Actuarial Assessment of House Bill 989:
"An Act relative to Lyme disease treatment coverage"

Table of Contents

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Actuarial Assessment of House Bill 989:
"An Act relative to Lyme disease treatment coverage"

Executive Summary

Massachusetts House Bill 989 (H.B. 989) requires health insurance plans to "provide coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease (CLD) when determined to be medically necessary and ordered by a physician after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment."[1] Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with, among other duties, 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. to provide an actuarial estimate of the effect enactment of the bill would have on the cost of health insurance in Massachusetts.

Background

H.B. 989 states that insurers "shall provide coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment. Treatment otherwise eligible for benefits pursuant to this section shall not be denied solely because such treatment may be characterized as unproven, experimental, or investigational in nature."

Lyme disease is the most common vector-borne disease[i] in the United States and Europe,[2,3] and is transmitted to humans through tick bites.[4] In 2012, the CDC confirmed 51.1 cases of Lyme disease per 100,000 people in Massachusetts, or almost 3,400 cases; another 1,700 probable cases were also reported to the CDC.[5,6]

When a patient presents with the erythema migrans ("EM") or "bull's-eye" rash that is unique to Lyme disease, a diagnosis is fairly straightforward.[7] In its absence, a diagnosis is made based on a clinician's interpretation of a patient's detailed medical history and symptoms, including the patient's exposure in an area where Lyme disease exists and the time of year.[8] Depending on the stage of the disease and timing of diagnosis, a laboratory test may sometimes be used for aid in diagnosis, although use of these tests is somewhat complex and problematic. Further, the diagnosis

[i] Vector-borne disease: "[B]acteria, viruses, or parasites transmitted to people by mosquitoes, ticks, and fleas." Vectorborne Diseases: The Centers for Disease Control and Prevention (CDC) joins the World Health Organization (WHO) and other public health partners in recognizing World Health Day, which this year spotlights vectorborne diseases; accessed 22 April 2014: http://www.infectioncontroltoday.com/galleries/2014/04/vectorborne-diseases.aspx?pg=3#gallery.

of Lyme disease is sometimes difficult to make, as the symptoms are often similar to those of other diseases.[9]

While the majority of Lyme disease patients are successfully treated with a single or double course of antibiotics, especially if treatment begins in the early disease stage, an estimated 10 to 20 percent of patients have symptoms that last months or years after antibiotic treatment, including fatigue and sleep disturbances, muscle and joint pain, and cognitive deficits.[10]

The proposed mandate refers to chronic Lyme disease (CLD) and is intended to provide insurance coverage for long-term antibiotic treatment for this subset of patients who experience continuing symptoms after a single or double course of antibiotic treatment. A consensus definition of these cases does not currently exist, and the means of detecting the presence of the disease in these atypical cases is not clearly defined. Moreover, symptoms vary in type and severity. This results in treatment regimens where length of treatment is often defined based on a patient's symptoms rather than on a pre-determined time period.

In a recent survey of eight of the largest insurance carriers in Massachusetts, all note that oral antibiotic therapy, including multiple courses, and at least one round of intravenous antibiotic therapy, lasting between two and four weeks, are covered by their policies. Two plans may allow an additional course of intravenous antibiotics per the guidelines of the Infectious Disease Society of America (IDSA).[11] Carriers are more likely to restrict the length of treatment with intravenous rather than oral antibiotics, although their responses indicate that these policies may change as some of their contracted pharmacy benefits management (PBM) companies are currently developing their own limits to the long-term use of oral antibiotics.

Analysis

Compass estimated the impact of H.B. 989 by performing the following steps:

- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2015 to 2019)
- Estimate the number of cases of Lyme disease for the study period
- Estimate the number of cases of chronic Lyme disease
- Estimate the average length of treatment for chronic Lyme disease
- Estimate the average per-patient cost of diagnostic testing and long-term antibiotic treatment for chronic Lyme disease
- Estimate the portion of these costs that Massachusetts carriers currently reimburse
- Calculate the proposed mandate's incremental effect on carrier medical expenses
- Estimate the impact of insurer's retention (administrative costs and profit) on premiums
- Project the estimated cost over the next five years

Factors affecting the analysis include:

- Estimates of the prevalence of the disease are imprecise
- Estimates of the length of treatment can vary widely and are based on patient response to treatment versus a predetermined regimen duration
- Estimates of the costs of treatment depend on the mode of delivery (oral, intravenous or combination)
- Estimates of the costs of diagnostic testing also vary widely and are not currently completely captured by claim data
- Studies designed to determine the diagnosis of, and best treatment for, chronic Lyme disease, useful in estimating the portion of people diagnosed with Lyme disease who will develop the chronic condition as well as the costs for their treatment, are not uniformly accepted in the medical community
- Existing coverage for diagnostic testing for Lyme disease, as well as for long-term antibiotic treatment, relevant to estimating the net impact of the proposed mandate, varies

Despite these sources of uncertainty, the relatively small number of people affected by chronic Lyme disease, even at the high end of estimated cases, produces cost estimates that are relatively modest.

Summary results

Table ES-1 summarizes the effect of H.B. 989 on premium costs for fully-insured plans, averaged over five years. This analysis estimates that the mandate, if enacted, would increase fully-insured premiums by as much as 0.02% on average over the next five years; a more likely increase is in the range of 0.01%. Note that the total cost in the second year of study decreases slightly over the previous year; this is due to fewer projected cases of overall Lyme disease in the population in that year, which reflects fluctuating case incidence described in the report body.

The degree of precision achievable in this analysis is hindered by the issues outlined in section 4; to account for the uncertainty in the number of individuals who have chronic Lyme disease, the length of their treatment, and the type of treatment received, the high scenarios allow for a combination of more-expensive assumptions. This results in a disproportionately costly high scenario, though still not a significant percentage of overall annual premium.

Finally, 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 the benefits will change under the proposed mandate.

Table ES-1:
Summary Results

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	2,144	2,121	2,096	2,071	2,045		
Medical Expense Low ($000s)	$13	$13	$13	$14	$15	$14	$68
Medical Expense Mid ($000s)	$606	$601	$618	$654	$681	$632	$3,159
Medical Expense High ($000s)	$2,336	$2,318	$2,368	$2,504	$2,615	$2,428	$12,141
Premium Low ($000s)	$15	$15	$15	$16	$17	$15	$77
Premium Mid ($000s)	$685	$679	$698	$739	$769	$714	$3,570
Premium High ($000s)	$2,639	$2,620	$2,675	$2,830	$2,955	$2,744	$13,719
PMPM Low	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
PMPM Mid	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03
PMPM High	$0.10	$0.10	$0.11	$0.11	$0.12	$0.11	$0.11
Estimated Monthly Premium	$512	$537	$564	$592	$622	$566	$566
Premium % Rise Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Rise Mid	0.01%	0.00%	0.00%	0.01%	0.01%	0.01%	0.01%
Premium % Rise High	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%

Actuarial Assessment of House Bill 989:
"An Act relative to Lyme disease treatment coverage"

1. Introduction

Massachusetts House Bill 989 requires health insurance plans to "provide coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment."[12] Massachusetts General Laws (M.G.L.) c. 3 § 38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with, among other duties, 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. 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. Finally, Section 5 describes the calculation of the estimate.

2. Interpretation of H.B. 989

The following subsections describe the provisions of H.B. 989, as drafted 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. The following five sections of the bill, each addressing statutes dealing with a particular type of health insurance policy, were interpreted as relevant to this analysis:[13]

- Section 1: Insurance for persons in service of the Commonwealth (creating M.G.L. c. 32A, § 23)
- Section 2: Accident and sickness insurance policies (creating M.G.L. c. 175, § 47AA)
- 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. c. 176G, § 4W)

The bill requires coverage for members under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

Self-insured plans are subject to federal law and not to state-level health insurance benefit mandates. State mandates do not apply to Medicare, and this analysis assumes this proposed mandate does not affect Medicare extension/supplement plans even to the extent they are regulated by state law.

2.2. Covered services

H.B. 989 states that insurers "shall provide coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment. Treatment otherwise eligible for benefits pursuant to this section shall not be denied solely because such treatment may be characterized as unproven, experimental, or investigational in nature."

Lyme disease is the most common vectorborne disease[ii] in the United States and Europe,[14,15] and is transmitted to humans through tick bites.[16] In 2012, the CDC confirmed 51.1 cases of Lyme disease per 100,000 people in Massachusetts, or almost 3,400 cases; another 1,700 probable cases were also reported to the CDC.[17,18]

When a patient presents with the erythema migrans (EM) or "bulls-eye" rash that is unique to Lyme disease, a diagnosis is fairly straightforward.[19] However, not all patients develop or even notice the rash. In its absence, a diagnosis is made based on a clinician's interpretation of a patient's detailed medical history and symptoms, including the patient's exposure in an area where Lyme disease exists, and the time of year.[20] Depending on the stage of the disease and timing of diagnosis, a laboratory test may sometimes be used for aid in diagnosis, although use of these tests is somewhat complex and problematic. Further, the diagnosis of Lyme disease is sometimes difficult to make, as the symptoms, such as fever, headache, stiff neck, body aches and fatigue,[21] are often similar to those of other diseases, including the flu.[22] Likewise, a patient may be infected with other tick-borne illnesses, or may also have an autoimmune disorder or other previously undiagnosed condition, further complicating a clear diagnosis.[23] Later-stage diagnosis of Lyme disease is often made based on the presence of Lyme arthritis or neurologic symptoms such as Bell's palsy.[24]

[ii] Vectorborne disease: "[B]acteria, viruses, or parasites transmitted to people by mosquitoes, ticks, and fleas." Vectorborne Diseases: The Centers for Disease Control and Prevention (CDC) join the World Health Organization (WHO) and other public health partners in recognizing World Health Day, which this year spotlights vectorborne diseases; accessed 22 April 2014: http://www.infectioncontroltoday.com/galleries/2014/04/vectorborne-diseases.aspx?pg=3#gallery.

While the majority of Lyme disease patients are successfully treated with a single or double course of antibiotics, especially if treatment begins in the early disease stage, an estimated 10 to 20 percent of patients have symptoms that last months or years after antibiotic treatment, including fatigue and sleep disturbances, muscle and joint pain, and cognitive deficits.[25]

The proposed mandate refers to chronic Lyme disease (CLD) and is intended to provide insurance coverage for long-term antibiotic treatment for this subset of patients who have continuing symptoms after a single or double course of antibiotics. While there is widespread agreement on the existence of atypical cases (10 to 20 percent according to the CDC[26]) that do not respond to the IDSA-recommended antibiotic treatment regimen of two to four weeks, a consensus definition of these cases does not currently exist and the means of detecting the presence of the disease in such atypical cases is not clearly defined. Moreover, the cases themselves are heterogeneous, with patients presenting with symptoms that vary in type and severity. This results in treatment regimens where length of treatment is often defined based on a patient's symptoms rather than on a pre-determined time period.

In a recent survey of eight of the largest insurance carriers in Massachusetts, all note that at least one round of intravenous antibiotic therapy, lasting between two and four weeks, is covered by their policies, as are oral antibiotics. Some plans allow an additional course per the guidelines of the Infectious Disease Society of America (IDSA).[27] Carriers are more likely to restrict the length of treatment with intravenous rather than oral antibiotics, although their responses indicate that these policies may change as some of their contracted pharmacy benefits management (PBM) companies are currently developing their own policies on the long-term use of oral antibiotics.

2.3. Existing laws affecting the cost of H.B. 989

Massachusetts currently has a law in place that, in effect, protects physicians from medical board discipline for prescribing, administering, or dispensing long-term antibiotic treatment for Lyme disease;[28] however, no mandates are currently in place in Massachusetts regarding insurance coverage for such treatments. Moreover, no existing federal mandates related to the specific subject matter of this bill have been identified.

3. Methodology

3.1. Steps in the analysis

Compass estimated the impact of H.B. 989 by performing the following steps:

- Estimate the fully-insured Massachusetts population under age 65, projected for the next five years (2015 to 2019)
- Estimate the number of cases of Lyme disease for the study period
- Estimate the number of cases of chronic Lyme disease
- Estimate the length of treatment for chronic Lyme disease

- Estimate the average per-patient cost of diagnostic testing and long-term antibiotic treatment for chronic Lyme disease
- Estimate the portion of the antibiotic treatment that Massachusetts carriers currently reimburse
- Calculate the proposed mandate's incremental effect on carrier medical expenses
- Estimate the impact of insurer's retention (administrative costs and profit) on premiums
- 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 staff regarding legislative intent
- Information from clinical providers and billing staff
- Information from a survey of private health insurance carriers in Massachusetts
- Academic literature, including population data
- Massachusetts insurer claim data from CHIA's Massachusetts All-Payer Claim Database (APCD) for calendar years 2010 to 2012, for plans covering the overwhelming majority of the under-65 fully insured population subject to the proposed mandate[29]

Below, the step-by-step description of the estimation process 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. 989 into an analysis of incremental cost.

4.1. Cases of Lyme disease

Cases of Lyme disease are reported nationally to the Centers for Disease Control from information collected throughout the state by the Massachusetts Department of Public Health Infectious Diseases Epidemiology Program.[30,31] The first CDC surveillance definition for a case of Lyme disease was released in 1990,[32] and outlined a definition used for "confirmed" cases of Lyme disease. In a revised definition released in 2008 and updated most recently in 2011, the classification system expanded to include cases of Lyme disease in three separate categories:[33,34]

1. Confirmed: A case of erythema migrans (EM or "bull's-eye" rash) with a known exposure or a case of EM without a known exposure with laboratory evidence of infection or a case with at least one late manifestation that has laboratory evidence of infection

2. Probable: Any other case of physician-diagnosed Lyme disease that has laboratory evidence of infection

3. Suspected (unclassified): A case of EM where there is no known exposure and no laboratory evidence of infection

Beyond the change in definition categories, the number of cases published by the CDC is often further updated by the Massachusetts Department of Public Health when they release their own reports of cases in subsequent years. For example, the number of confirmed cases of Lyme disease in Massachusetts published by the CDC for 2011 totaled 1,801;[35] when the Massachusetts Department of Health released its report on Lyme disease for 2012, the 2011 number was revised to 2,651,[36] representing an increase of over 47%. The exact count of previous cases of Lyme disease, therefore, is somewhat unstable.

Additionally, Lyme disease incidence differs from other diseases in that the number of cases can fluctuate widely from year to year, making estimations of future incidence more complex. While the number of annual cases has been increasing overall, there are pronounced spikes in certain years, presumably due to changes in the distribution and feeding habits of the vector ticks.[37]

4.2. Cases of chronic Lyme disease

As described in the medical efficacy review of CHIA's report on H.989, there is disagreement about the existence of chronic Lyme disease, and about a specific definition for the condition. This makes estimating the number of CLD cases challenging. However, as there is widespread agreement that between 10 to 20 percent of patients present atypical symptoms (including fatigue and sleep disturbances, muscle and joint pain, and cognitive defects) that last months or years after the conclusion of antibiotic treatment,[38] this figure will be used as a basis for estimating the number of CLD cases.

4.3. Length of treatment for chronic Lyme disease

Per the IDSA, treatment for typical Lyme disease includes antibiotic treatment lasting between two to four weeks, with an additional round recommended if necessary for certain cases.[39] For those with CLD, treatment depends on a patient's symptoms and response rather than on a set time period.[40] This analysis assumes low, mid, and high scenarios in which the length of successful treatment is counted in three-month increments, up to a total of eighteen months of antibiotic treatment. While there is anecdotal and claim evidence of patients receiving treatment for even longer periods of time, the number of these cases is very small and does not significantly impact the overall medical expense premium.

4.4. Cost of testing and treatment for chronic Lyme disease

Current antibiotic treatment for Lyme disease is administered orally, intravenously, or through some combination of the two in succession. According to a survey of carriers in the state, the costs of oral treatment are not currently limited. Most carriers limit coverage for intravenous antibiotic

treatment to either 14 or 28 days of treatment, with some extensions allowed by certain carriers in limited circumstances.

To allow for these exceptions, the average treatment costs for antibiotic treatment were estimated using claim data on a quarterly basis. Costs of intravenous treatment include the costs of the antibiotic itself, as well as infusion charges.

Projecting the costs of diagnostic testing for Lyme disease is more difficult. Currently, carriers are inconsistent regarding coverage for diagnostic testing for Lyme disease. Some specifically cover only the two-stage ELISA/Western blot testing currently approved by the FDA, while others routinely also cover other laboratory tests such as indirect immunofluorescence assay (IFA) and/or polymerase chain reaction (PCR) on appropriate specimens. Still others cover IFA or PCR tests on a per-patient basis, determining the medical necessity of each test individually.

To estimate the marginal cost of diagnostic testing if this proposed mandate becomes law, the cost of diagnostic testing was estimated based on the average length of treatment for each patient. That is, the total cost of diagnostic test per patient increased in proportion to the length of their treatment, such that those in treatment for the shortest period of time (three months in this model) received a proportionally less expensive set of tests, while those in treatment for the longest period of time (18 months in this model) received the most expensive set of diagnostic tests.

5. Analysis

To estimate the overall impact of the proposed legislation, the following calculations were executed. The analysis includes development of 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. Projected fully-insured population in Massachusetts, ages 0 to 64

Table 1 shows the fully-insured population in Massachusetts ages 0 to 64 projected for the next five years. Appendix A describes the sources of these values.

Table 1:
Projected fully-insured population in Massachusetts, Ages 0-64

Year	Total (0-64)
2015	2,144,066
2016	2,120,558
2017	2,096,250
2018	2,071,138
2019	2,045,433

The five-year projection required in this analysis uses the estimates of utilization and cost in the following subsections. These are measured/estimated for the specified baseline period and are then adjusted appropriately when incorporated into the final forward-looking projections.

5.2. Projected incidence of Lyme disease

Table 2 shows the incidence of Lyme disease cases per 100,000 Massachusetts residents projected for the next five years, under three scenarios. The low scenario is projected based on the incidence rate of confirmed cases of Lyme disease as reported to the CDC and updated by the Massachusetts Department of Public Health (MDPH). The mid scenario is projected based on these confirmed cases plus probable cases as reported to the CDC. The high scenario is projected with the additional suspected/unclassified cases of Lyme disease as published by the MDPH.

Table 2:
Projected incidence of Lyme disease in Massachusetts[41]

Year	Low	Mid	High
2015	49.1	73.8	88.5
2016	47.1	70.7	84.9
2017	48.1	72.4	86.8
2018	49.5	74.4	89.2
2019	49.2	73.9	88.7

5.3. Estimated cases of chronic Lyme disease

As noted previously, this model assumes the number of cases of chronic Lyme disease as a percentage of overall Lyme disease, based on an estimate of atypical cases that do not respond to the IDSA-recommended treatment regimen. Table 3 displays the values used in this analysis.

Table 3:
Estimated Percent of chronic Lyme disease cases

Low Scenario	10.0%
Mid Scenario	15.0%
High Scenario	20.0%

5.4. Length of treatment

The average length of treatment for chronic Lyme disease is not well-defined, and is often based on patient symptoms and response to treatment. This analysis assumes treatment length increased in three month intervals above initial treatment, and varies assumptions about the percent of the population that would be successfully treated within these increments under three scenarios. The low scenario assumes that 75.2% of patients would be successfully treated for CLD with three additional months of antibiotic therapy beyond the one- to two-month treatment recommended by

the IDSA and currently covered by most insurance carriers. The middle scenario assumes that only 50.4% of patients would be successfully treated in three months, while the high scenario further reduces this assumption to 25.6%. Each progressive scenario, therefore, increases the overall average length of treatment for chronic Lyme disease; these assumptions are displayed in Table 4.

Table 4:
Length of treatment of chronic Lyme disease

Months	Low	Mid	High
3	75.2%	50.4%	25.6%
6	12.8%	25.6%	38.4%
9	6.4%	12.8%	19.2%
12	3.2%	6.4%	9.6%
15	1.6%	3.2%	4.8%
18	0.8%	1.6%	2.4%

5.5. Average cost of treatment

The average cost of treatment will vary by whether antibiotics are delivered via oral medications, intravenous infusion or both. Claim data for 2012 were used as a baseline to calculate the average cost of these treatments per quarter.

The low scenario represents the use of oral antibiotics only plus the cost of quarterly diagnostic testing. The high scenario represents the use of intravenous antibiotics only plus the cost of quarterly diagnostic testing. The mid scenario represents the average of the two, or the use of combination therapy plus quarterly diagnostic testing. Table 5 displays the 2012 baseline values.

Table 5:
Average Total Quarterly Treatment
& Diagnostic Testing Cost,
Baseline Year 2012

Low Scenario	$138
Mid Scenario	$1,176
High Scenario	$2,215

5.6. Effect of the mandate on reimbursement for Lyme disease

Currently, carriers do not limit the use of oral antibiotic treatments, although one carrier indicated its intention to develop such a policy. As the costs of oral antibiotics are currently covered, these costs are not part of the marginal cost of treatment resulting from this mandate. Therefore, the two scenarios in which oral antibiotics are used were reduced by the costs of the oral treatments, leaving only the cost of quarterly diagnostic testing in the low scenario, and testing plus intravenous therapy costs in the mid scenario representing combination therapy. As the high scenario represents the use of intravenous therapy plus quarterly diagnostic testing only, the

estimated cost is unchanged from Table 5. Table 6 displays the new marginal values; these figures were then projected for the study period 2015 to 2019 using an annual medical inflation rate of 4.5%.

Table 6:
Average Marginal Quarterly Treatment & Diagnostic Testing Cost, Baseline Year 2012

Low Scenario	$73
Mid Scenario	$1,144
High Scenario	$2,215

5.7. Net increase in carrier medical expense

For each scenario, multiplying the estimated incidence of chronic Lyme disease first by the assumed treatment length and then by the average marginal quarterly treatment and diagnostic testing cost, and dividing by the projected fully insured membership yields the medical expense per member per month (PMPM) displayed in Table 7.

Table 7:
Estimate of Increase in Carrier Medical Expense PMPM

Low Scenario	$0.00
Mid Scenario	$0.03
High Scenario	$0.10

5.8. Net increase in premium

Assuming an average retention rate of 11.5 percent, based on CHIA's analysis of administrative costs and profit in Massachusetts,[42] the increase in medical expense was adjusted upward to approximate the total impact on premiums. Table 8 shows the result.

Table 8:
Estimate of Increase in Premium PMPM

Low Scenario	$0.00
Mid Scenario	$0.03
High Scenario	$0.11

5.9. Five-year estimated impact

For each year in the five-year analysis period, Table 9 displays the projected net impact of the proposed mandate on medical expense and premiums using a projection of Massachusetts fully-insured membership. This analysis estimates that the mandate, if enacted, would increase fully-

insured premiums by as much as 0.02% on average over the next five years; a more likely increase is in the range of 0.01%. Note that the total cost in the second year of the study decreases slightly over the previous year; this is due to fewer projected cases of overall Lyme disease in the population in that year, which reflects fluctuating case incidence as described in section 4.1.

The degree of precision achievable in this analysis is hindered by the issues outlined in section 4; to account for the uncertainty in the number of individuals who have chronic Lyme disease, the length of their treatment, and the type of the treatment received, the high scenarios allow for a combination of more-expensive assumptions. This results in a disproportionately costly high scenario result.

Finally, 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 the benefits will change under the proposed mandate.

Table 9:
Summary Results

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	2,144	2,121	2,096	2,071	2,045		
Medical Expense Low ($000s)	$13	$13	$13	$14	$15	$14	$68
Medical Expense Mid ($000s)	$606	$601	$618	$654	$681	$632	$3,159
Medical Expense High ($000s)	$2,336	$2,318	$2,368	$2,504	$2,615	$2,428	$12,141
Premium Low ($000s)	$15	$15	$15	$16	$17	$15	$77
Premium Mid ($000s)	$685	$679	$698	$739	$769	$714	$3,570
Premium High ($000s)	$2,639	$2,620	$2,675	$2,830	$2,955	$2,744	$13,719
PMPM Low	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
PMPM Mid	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03
PMPM High	$0.10	$0.10	$0.11	$0.11	$0.12	$0.11	$0.11
Estimated Monthly Premium	$512	$537	$564	$592	$622	$566	$566
Premium % Rise Low	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Premium % Rise Mid	0.01%	0.00%	0.00%	0.01%	0.01%	0.01%	0.01%
Premium % Rise High	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%

5.10. Impact on the GIC

Because the benefit offerings of GIC plans are similar to most other commercial plans in Massachusetts, and cover the treatments proposed in the mandate for chronic Lyme disease similarly to other carriers, the estimated effect of the proposed mandate on GIC coverage is not expected to differ from that calculated for the other fully-insured plans in Massachusetts. Note that the total medical expense and premium numbers displayed in Table 9 include the GIC fully-insured membership. To calculate the medical expense separately for the self-insured portion of the GIC, the medical expense per member per month was applied to the GIC self-insured membership; the results are displayed in Table 10.

Table 10:
GIC Self-Insured Summary Results

	2015	2016	2017	2018	2019	Average	5 Yr Total
Members (000s)	259	259	259	258	258		
Medical Expense Low ($000s)	$0	$0	$0	$0	$0	$0	$1
Medical Expense Mid ($000s)	$6	$6	$6	$7	$7	$7	$33
Medical Expense High ($000s)	$24	$24	$24	$26	$27	$25	$125

Appendix A: Membership Affected by the Proposed Mandate

Membership potentially affected by a proposed mandate may include Massachusetts residents with fully-insured employer-sponsored health insurance (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 2015 – 2019 are derived from the following sources.

Total Massachusetts population estimates for 2012 and 2013 from U. S. Census Bureau data[43] form the base for the projections. Distributions by gender and age, also from the Census Bureau,[44] were applied to these totals. Projected growth rates for each gender/age category were calculated from Census Bureau population projections to 2030.[45] The resulting growth rates were then applied to the base amounts to project the total Massachusetts population for 2015 to 2019.

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[46] 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.[47]

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[48] and non-residents[49] to the total number of individual tax returns filed in Massachusetts by residents.

The number of residents with individual (direct) coverage was adjusted further to remove the estimated number of people currently covered by Commonwealth Care who will shift into MassHealth due to expanded Medicaid eligibility under the Affordable Care Act beginning in 2014.[50]

Projections for the GIC self-insured lives were developed using GIC base data for 2012[51] and 2013[52] 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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