



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Analysis of Assembly Bill 213 Health Care Coverage for Lymphedema

A Report to the 2005-2006 California Legislature
April 7, 2005

CHBRP 05-03



Established in 2002 to implement the provisions of Assembly Bill 1996 (*California Health and Safety Code*, Section 127660, et seq.), the California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates. The statute defines a health insurance benefit mandate as a requirement that a health insurer and/or managed care health plan (1) permit covered individuals to receive health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

A small analytic staff in the University of California's Office of the President supports a task force of faculty from several campuses of the University of California, as well as Loma Linda University, the University of Southern California, and Stanford University, to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate bill. A certified, independent actuary helps estimate the financial impacts, and a strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, made up of experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes sound scientific evidence relevant to the proposed mandate but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment of health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at CHBRP's Web site, www.chbrp.org.

A Report to the 2005-2006 California State Legislature

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 213, a bill to mandate coverage for the diagnosis and treatment of lymphedema. In response to a request from the California Assembly Committee on Health on February 8, 2005, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Assembly Bill 1996 (2002) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

Wade Aubry, MD, Patricia Franks, BA, Harold S. Luft, PhD, Karen Rappaport, MD, PhD, and Edward Yelin, PhD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Susan Frohreich, Registered Physical Therapist, of the St. Mary's Comprehensive Lymphedema Program, provided technical assistance with the literature review and clinical expertise for the medical effectiveness analysis. Helen Halpin, PhD, Sara McMenamin, PhD, and Nicole Bellows, MHSA, all of the University of California, Berkeley, prepared the public health impact analysis. Gerald Kominski, PhD, Miriam Laugesen, PhD, and Nadereh Pourat, PhD, all of the University of California, Los Angeles, prepared the analysis of the cost impacts. Robert Cosway, FSA, MAAA, and Christopher Girod, FSA, MAAA, both of Milliman, provided actuarial analysis. Susan Philip, MPP, and Sachin Kumar, BA, of CHBRP staff prepared the background section and contributed to preparing the individual sections into a single report. Other contributors include Bob O'Reilly, BA, and Cynthia Robinson, MPP, of CHBRP Staff. Cherie Wilkerson provided editing services. In addition, a subcommittee of CHBRP's National Advisory Council (see final pages of this report) reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

Jay Ripps, FSA, MAAA, of Milliman recused himself from contributing to this and all CHBRP analyses, beginning March 1, 2005. His recusal is valid through his duration as acting chief actuary at Blue Shield of California.

CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to CHBRP:

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 213

The California Legislature has asked the California Health Benefits Review Program to conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill 213: Health Care Coverage for Lymphedema.

In California and in the United States, most cases of lymphedema, which is usually a progressive condition involving an accumulation of lymphatic fluid in a body part, are found in patients who have been treated for breast cancer with axillary lymph node dissection and radiation therapy.

AB 213 would mandate coverage of the diagnosis and treatment of lymphedema based on specific standards of care. The mandate would apply to health care services plans licensed by Knox-Keene¹ and to health insurance policies regulated under the California Insurance Code².

The bill specifies who may diagnose lymphedema, develop a course of therapy for the condition, and provide certain types of treatment, as well as the qualifications of these providers. AB 213 also specifies that treatment may include but is not limited to, a course of manual lymph drainage (MLD) and must be performed by a therapist certified by a recognized training program with a minimum of 135 hours. AB 213 identifies organizations with current standards of care for lymphedema (National Lymphedema Network [NLN], International Society of Lymphology [ISL], and the American Cancer Society). The bill also describes a number of specific treatments for lymphedema.

I. Medical Effectiveness

Summary of the review of the medical literature:

- There is a lack of consensus on the clinical definition of lymphedema, as well as on the standards of care for its treatment, even among the organizations identified in the mandate as defining a current standard of care.
- Many different terms are used to describe treatment of lymphedema, both in the United States and in Europe.
- Treatment for lymphedema includes several different, but interrelated, components.
 - The mainstay of treatment for lymphedema consists of a multi-component therapy described in the mandate as Complex Decongestive Therapy (CDT). CDT is referred to in the literature by other, similar terms.

¹ Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

² Specialized health care service plans such as vision- or dental-only plans would be exempt from this legislation.

- CDT is a physical therapy-based program involving manual lymphatic drainage (MLD), compression therapy (CT), skin and nail care, exercise, and patient education.
- A review of the evidence of the effectiveness of treatments for lymphedema, primarily from randomized controlled trials (RCTs) reported in the literature from January 1998 through January 2005, shows that:
 - The outcomes of lymphedema treatments fall into three categories: physical outcomes (size of the affected limb), management of symptoms, and medical complications.
 - Most of the RCT studies use a physical outcome, that is, reduction in the size of the affected limb, as measured by reduction in the volume of lymphatic fluid, as the principal outcome measure to assess the effectiveness of treatments. The relationship of reduction in limb size (reduction in volume of lymphedema) and better health outcomes, such as improved limb function or reduced pain and discomfort, is not addressed in most studies.
- No studies were found that contrasted the effectiveness of delivery of lymphedema treatment by trained lymphedema specialists with delivery by licensed physical therapists not specifically trained in lymphedema management.

Summary of Outcomes

- Physical outcome: limb size (volume of lymphedema)
 - MLD reduces lymphedema by rerouting lymph flow around blocked areas. Patients receiving MLD exhibit volume reduction over time, but the evidence on whether MLD results in greater volume reduction than compression therapy alone is mixed.
 - CT uses various types of compression bandages and compression garments, including multi-layer bandaging and fitted elastic sleeves, to reduce the volume of edema. Studies showed significant effects of compression therapy in reducing the volume of edema in extremities in the initial stages of edema as well as in maintaining the effect of therapy. These effects were significant across all studies for all types of bandages tested.
 - Exercise did not significantly decrease limb volume in the one RCT of exercise that was found in the published literature. The type of exercise involved was a progressive upper body exercise program with resistance and aerobic components.
- Management of symptoms
 - A few studies provide evidence of reduced pain and discomfort levels, sensations of heaviness, and tension in the affected limb in patients after MLD and compression bandaging.
- Medical complications
 - Several studies report significant reductions in infections over time with treatment. One study used selenium and another, physiotherapy, to reduce

infections. Another found that adding MLD to the treatment regimen did not reduce infections. A fourth study compared two drug therapies (an antifilarial drug and a broad-spectrum antiparasitic drug) with foot and skin care combined with antibiotics and antifungal agents in the treatment of adenolymphangitis (infections in the affected limbs) in patients in India who had lymphedema caused by a parasitic disease. In this study, the combined drug therapies did not prevent any more cases of infection than did good foot care, antibiotics, and antifungal agents.

- Education in skin and nail care to reduce susceptibility to infection has not been studied through RCTs. In the studies reviewed, education in skin and nail care was considered basic therapy offered to control groups in randomized trials of CDT.

Caveats for medical effectiveness analysis

- Most studies in the literature, even the randomized controlled trials, have small sample sizes. Furthermore, it is impossible to blind the patient to the treatment, in order to discern whether treatments have an effect and which specific aspects of the treatments have an effect.
- Most studies available in the literature use a physical outcome (reduction in limb size, usually measured in reduction in volume of lymphedema) as an intermediate outcome measure, rather than health outcome measures, such as improved limb function, reduced discomfort or pain, increased patient satisfaction, or a reduction in number of infections or other consequences of lymphedema.
- The studies include different packages of treatments, and the components of the package, or the program of therapy, are not described in many studies.
- The studies often did not mention assessment of known complications of therapy for lymphedema, such as those associated with the use of pneumatic compression pumps or pharmacologic agents.
- The services required by the proposed mandate do not align perfectly with those analyzed in the studies in the literature, for example, by listing specific qualifications for the therapists used in treatment, making it difficult to ascertain the effectiveness of the mandated services definitively. In addition, there were few studies other than those concerning lymphedema secondary to such conditions as breast cancer.

II. Utilization, Cost, and Coverage Impacts

Baseline

- 100% of the 20,368,000 insured Californians that would be affected by this mandate have coverage for lymphedema treatment. Currently, under Knox-Keene³ and the Insurance Code⁴, health plans and insurers are required to cover the treatment of lymphedema following a mastectomy. The only limits noted were limits on the number of compression

³ Health and Safety Code § 1367.635

⁴ Insurance Code § 10123.86

garments covered by insurers; otherwise coverage was complete, subject to medical necessity.

- Based on an analysis of national claims data, an estimated 0.07% of the 0-64 insured population has a diagnosis of lymphedema. Assuming the same proportion in California, that translates to approximately 14,000 insured or 0.07% of 20,368,000 insured individuals affected by this mandate.
- Among patients with lymphedema, the average utilization is 8.08 services per patient per year. As used in this report, health care services include all services used for the treatment of lymphedema, not just those related to physical therapy or manual lymph drainage.
- These services include inpatient care, prescription drugs, physical and occupational therapy, equipment and compression garments, physician and other professional services.
- It costs approximately \$963 per year to treat each patient with lymphedema. This cost estimate includes only those services where lymphedema was identified as a diagnosis.

Postmandate

- The average utilization per patient diagnosed with lymphedema is expected to increase by 0.12 services to 8.20 services. This is an increase of 1.48%. This utilization increase includes a small increase in the utilization of compression garments due to the removal of any limits currently in place and a 2% increase in utilization of services for durable medical equipment, compression garments, manual lymph drainage, and physical therapy due to increased awareness of coverage.
- The increase in utilization is expected to increase the average cost of treatment per year by approximately \$12—from \$963 to \$975 per patient.
- Total annual health care costs for the 20,368,000 insured individuals affected by this mandate are expected to increase by \$201,855 per year, which is an increase of 0.0003% or \$0.01 per person, per year.
- Out-of-pocket expenditure is estimated to increase by a total of \$12,075 per year, or \$0.0006 per person per year, when spread across the entire insured population affected by this bill.

Caveats Applying to the Cost Analysis

- Claims data used for this analysis include 7 million insured persons. We assume comparable rates of utilization among our claims data and utilization across the 20,368,000 people in California.
- Costs maybe easier to identify than the long-term benefits of this legislation, and so the absence of information regarding benefits in this section should not be an indication of the benefits of this legislation.
- Cost estimates should be weighed against estimates of clinical and public health benefit that may or may not be easily quantifiable.

Table 1. Summary of Coverage, Utilization, and Cost Effects of AB 213

Total Insured Population = 20,368,000	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
<u>Coverage</u>				
Percentage of insured individuals with coverage for mandated benefit	100%	100%	0	0%
Number of insured individuals in California with coverage for the benefit	20,368,000	20,368,000	0	0%
Number of insured individuals in California without coverage for the benefit	0	0	0	0%
<u>Per person costs</u>				
Total treatment costs, per year	\$963.31	\$975.46	\$12.15	1.26%
<u>Utilization (Services per Lymphedema Patient)</u>				
Durable medical equipment	0.91	0.93	0.02	2.00%
Compression garments	0.52	0.55	0.03	5.95%
Physician, physical therapy, and other services	5.94	6.01	0.07	1.19%
Prescription drugs	0.16	0.16	0.00	0.00%
Inpatient services	0.54	0.54	0	0.00%
Total utilization	8.08	8.20	0.12	1.48%
<u>Annual Expenditures</u>				
Premium expenditures by private employers for group insurance	\$35,360,054,895	\$35,360,157,052	\$102,157	0.0003%
Premium expenditures by individuals with group insurance, CalPERS, or Healthy Families	\$10,261,105,248	\$10,261,135,874	\$30,626	0.0003%
Premium expenditures for individually purchased insurance	\$3,818,726,236	\$3,818,745,254	\$19,018	0.0005%
CalPERS employer expenditures	\$2,212,881,156	\$2,212,887,569	\$6,413	0.0003%
Medi-Cal state expenditures	\$3,939,662,640	\$3,939,692,276	\$29,636	0.0008%
Healthy Families state expenditures	\$347,858,333	\$347,860,263	\$1,930	0.0006%
Out-of-pocket expenditures and other expenditures for noncovered services	\$4,074,892,839	\$4,074,904,914	\$12,075	0.0003%
Total annual expenditures	\$60,015,181,348	\$60,015,383,203	\$201,855	0.0003%

Source: California Health Benefits Review Program, 2005.

Notes:

The population includes individuals and dependents in California who have private insurance (group and individual), or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families.

All population figures include enrollees aged 0-64, except the Medi-Cal population, which includes dually eligible Medicare/Medi-Cal recipients of all ages enrolled in managed care plans.

Employees and their dependents that receive their coverage from self-insured firms are excluded because these plans are not subject to mandates.

III. Public Health Impacts

- While incidence and prevalence of total lymphedema cases are unknown, it is estimated that the incidence of lymphedema after breast cancer treatment is 26%. This would translate into close to 6,000 cases annually in California. Estimates based on utilization data indicate that the total number of annual cases of lymphedema in California from all causes is 14,000.
- Based on the studies found in the medical effectiveness literature review, the available evidence suggests that the mandate would have a favorable impact on the health of the community as measured by the reduction in limb size to the extent that utilization increases for compression therapy. Due to the lack of consensus within the literature on the clinical definition of lymphedema and the standards of care for its treatment, however, it is not possible to quantify the overall impact of this mandate on the health of the community.
- Likely due to its relationship with the treatment of breast cancer, women are more likely to be diagnosed with lymphedema compared to men. No research was found to examine gender or racial disparities in the treatment or outcomes of lymphedema.
- There is less than one death per year due to lymphedema in California. In addition, there is no literature indicating that people with lymphedema have a reduced life expectancy. Therefore, we conclude that lymphedema does not lead to premature death.
- While some anecdotal data suggests that there may be indirect economic costs associated with lymphedema such as loss of employment, no research was found to estimate the indirect costs of lymphedema at the state or national level.

INTRODUCTION

Assembly Bill (AB) 213: Health Care Coverage for Lymphedema would mandate coverage of the diagnosis and treatment of lymphedema based on specific standards of care. AB 213 would apply to health care services plans licensed by Knox-Keene⁵ and to health insurance policies regulated under the California Insurance Code⁶.

Lymphedema is an accumulation of lymphatic fluid in a body part. The accumulation of fluid may be caused by reduced return of fluid due to obstruction of the lymphatic system or by increased production of fluid. Primary lymphedema occurs at birth or later in life as a congenital condition. Secondary lymphedema can be caused by cancer and its treatments, such as lymph node dissection and radiation therapy. The condition may also be caused by trauma, burns, and parasitic infections. In California and in the United States, most cases of lymphedema are found in women who have been treated for breast cancer with axillary node dissection and radiation therapy and who develop lymphedema in their upper limbs (Zuther, 2005).

Lymphedema is usually a progressive disease. “Although the swelling may recede slightly during the night in some early-stage cases, lymphedema is a progressive condition. Regardless of genesis, lymphedema, in most cases, will gradually progress through its stages, if left untreated” (Zuther, 2005). There are three stages of lymphedema: Stage I: Early accumulation of fluid with the limb or affected area normal or almost normal size on waking. Stage II: Fibrosing of the tissue (hardening of the tissue) marks the beginning of hardening of the limb and increasing limb size. Stage III. Signs and symptoms of infection (i.e., lymphangitis) with the limb very large in size and the tissue fibrotic.

AB 213 specifies who may diagnose lymphedema, develop a course of therapy for the condition, and provide certain types of treatment, as well as the qualifications of these providers

AB 213 would mandate coverage for:

- Differential diagnosis of lymphedema by a qualified physician knowledgeable of the condition.
- Determination of a course of therapy by a qualified, competent physician knowledgeable in the diagnosis and current treatment standards of lymphedema, as defined by the National Lymphedema Network (NLN), International Society of Lymphology (ISL), or the American Cancer Society.
- Development of a treatment plan defining the goal of the therapy, the schedule, and the measurements to be made to validate the efficacy of treatment and patient compliance.
- Treatment based on the current standard of care for primary lymphedema and secondary lymphedema.
- Treatment “may include but is not limited to, a course of manual lymph drainage (MLD)” and must be performed by a therapist certified by a recognized training program with a minimum of 135 hours. Coverage for manual lymphatic drainage would not be subject to

⁵ Health maintenance organizations in California are licensed under the Knox-Keene Health Care Services Plan Act, which is part of the California Health and Safety Code.

⁶ Specialized health care service plans such as vision or dental only plans would be exempt from this legislation.

coverage guidelines governing rehabilitative therapy, and instead be provided on the length, duration, and frequency as determined on the basis of medical necessity.

- A supply of medically required compression garments, compression pads, bandages, bandage liners and pads, orthotic devices, and special footwear and their necessary fittings and replacements.
- Patient education for: 1) training of the patient to perform self-treatment in a home setting; 2) appropriate bandaging, wearing, and caring for compression garments, manually adjusting orthotic devices, donning aids and other required ancillary equipment, techniques for self-measurement; skin care, recognition of early infection, and steps to be taken if infection occurs.

AB 213 also states that no one other than a licensed physician and surgeon competent to evaluate the specific clinical issues involved in the request care may deny requests for authorization of health care services.

Currently 17 states, including California, have enacted laws requiring insurers to provide coverage for lymphedema treatment, primarily in relation to breast cancer.⁷ The Health and Safety Code and Insurance Code both require health plans and insurers to “cover all complications from a mastectomy, including lymphedema.”⁸

I. MEDICAL EFFECTIVENESS

The therapeutic interventions in AB 213 include a number of interrelated treatments described in the mandate as complex decongestive therapy (CDT) and in studies reviewed in this analysis by other terms.⁹ CDT commonly includes manual lymphatic drainage (MLD), compression therapy (CT), specifically, compression garments, compression pads, bandages, bandage liners and pads, orthotic devices, and special footwear. Other treatments for lymphedema listed in AB 213 and described in the literature include skin and nail care, exercise, and patient education on home self-care. While not specifically mentioned in the mandate, the effectiveness of pharmacologic agents and compression pumps also has been reviewed in this analysis.

Standards of care for lymphedema treatment are a key aspect of AB 213 and were investigated as part of the literature search.

The outcomes of lymphedema treatments fall into three categories: reduction in limb size (reduction in volume of lymph fluid), management of symptoms, and medical complications. The outcome most often measured in lymphedema is a physical outcome (reduction in the size of

⁷ Communication with the National Conference of State Legislatures, March 16, 2005. The other states are: AR, DE, DC, IL, KS, KY, LA, NE, NV, OR, PA, RI, TX, UT, VA, and WV.

⁸ Health and Safety Code § 1367.635, Insurance Code § 10123.86

⁹ Complex decongestive therapy is also referred to as complete decongestive therapy, complex decongestive physiotherapy, combined physiotherapy, non-invasive complex lymphedema therapy, early conservative lymphedema management, complicated physi-therapeutics multi-modal lymphedema therapy, palliative lymphedema therapy, and decongestive lymphatic therapy.

the affected limb), rather than a health outcome, such as improvement in limb function, reduction in pain or discomfort, or prevention of infection.

- Physical outcomes
 - Size of the affected limb (e.g., usually measured by reduction in volume of lymph fluid)
- Management of symptoms
 - Pain and discomfort control (e.g., sensation of heaviness or tension in limb)
 - Ability to take part in usual activities and activities of daily living (no articles were found)
 - Quality of life (e.g., worry, irritability)
- Medical complications
 - Infection rate (e.g., lymphangitis, cellulitis, and sepsis)
 - Skin ulcers (primarily on affected legs) or non-healing wounds
 - Severe functional impairment (no articles were found)
 - Deep venous thrombosis (no articles were found)
 - Limb amputation (no articles were found)

The literature search was conducted through PubMed and the Cochrane Library to include articles published from January 1998 through January 2005.

A description of methods used to conduct the medical effectiveness review, as well as the process used to “grade” the evidence of effectiveness for each outcome measure can be found in Appendix A: Literature Review Methods. Summary tables with detailed findings and evidence from the literature can be found in Appendix B: Summary of Findings on Medical Effectiveness..

Standards of Care for Lymphedema Treatment

A key issue in the analysis of AB 213 is current treatment standards for lymphadema. The three organizations identified in the bill (National Lymphedema Network [NLN], International Society of Lymphology [ISL], and the American Cancer Society [ACS]) each have guidelines. The table below (Table 2) summarizes the guidelines of these organizations:

Table 2: Treatment Guidelines for Lymphedema

	National Lymphedema Network (NLN) (1)	International Society of Lymphology (ISL)(2)	American Cancer Society (ACS)(3)
Skin care	Prophylactic methods should be followed at all times.	Meticulous skin hygiene and care is essential.	Most of the ACS website on lymphedema is devoted to information about preventing and controlling lymphedema by avoiding infections, burns, and injuries of all kinds. ACS information instructs patients on hazards in daily life, such as needle and pin pricks, phlebotomy, hot bath water, etc.
Combined physical therapy (CPT), another term for complex decongestive therapy (CDT)	The approach to treatment should be based on CPT.	Therapy should be provided by clinicians who are highly trained and educated in CPT.	Treatment should be administered by a physical therapist or other health care professional who has gone through special training. CPT includes skin care, massage, special bandaging, exercise, and fitting for a compression sleeve. The consensus statement published by the ACS states that the various interrelated modalities that comprise CDT are most efficacious when used in an interdependent manner.
Massage alone (Not to be confused with manual lymphatic drainage [MLD]), which is part of CPT or CDT		The consensus document notes that massage performed as an isolated technique (i.e., classical massage or effleurage) usually has limited benefits. If performed overly vigorously, this type of massage may damage lymphatic vessels.	
Intermittent pneumatic compression (pneumomassage)		The consensus document describes this therapy as a two-phase program involving external compression therapy (preferably through a sequential gradient “pump”) and then form-fitting, low-stretch elastic stockings or sleeves to maintain edema reduction.	The consensus document states that this therapy is most efficacious when used as an adjunct to MLD.

	National Lymphedema Network (NLN) (1)	International Society of Lymphology (ISL) (2)	American Cancer Society (ACS) (3)
“Wringing out” or “tuyautage” performed with bandages or rubber tubes		The consensus document notes that it is probably injurious to lymph vessels and should seldom if ever be performed.	
Thermal therapy		The consensus document notes that the role of thermotherapy in treatment of edema remains unclear.	
Elevation		Works for early stage. If swelling can be reduced in this manner, the effect should be maintained using low-stretch elastic stocking or sleeve.	To be undertaken when the affected limb aches.
Drug therapy		The consensus document notes that diuretics are occasionally useful in initial stages. The role of benzopyrones (many of which are not FDA-approved in the U.S.) has not been definitively determined, including as treatment for filariasis. Antimicrobials should be administered for acute inflammation (i.e., cellulitis, lymphangitis, or erysipelas)	The consensus document states that long-term use of antibiotics is recommended. The routine use of diuretics specifically for the treatment of lymphedema is not warranted.
Mesotherapy		Mesotherapy, the injection of hyaluronidase to loosen the extracellular matrix, is not recommended	
Diet	Proper diet (not specified) should be followed at all times	No special diet	
Psycho-social rehabilitation		Integral component of many lymphedema programs	
Operative treatment (i.e., resection, microsurgical procedures)		Not yet accepted worldwide.	
Treatment assessment		An assessment of limb volume should be made before and after treatment.	

Notes: (1) From: <http://www.lymphnet.org/whatis.html>, accessed March 14, 2005. (2) From following two consensus documents: International Society of Lymphology (ISL). (2003). The diagnosis and treatment of peripheral lymphedema, and the consensus document of the International Society of Lymphology. *Lymphology*. 36(2):84-91 (3) The information in this column is derived from two Web pages, http://www.cancer.org/docroot/MIT/content/MIT_7_2x_Understanding_Lymphedema.asp (ACS, 2005a) and http://www.cancer.org/docroot/MIT/content/MIT_7_2x_Lymphedema_and_Breast_Cancer.asp (ACS, 2005b), and the report from the American Cancer Society’s Lymphedema Workshop (Rockson et al., 1998)

Treatment Interventions and Outcomes

Physical Outcomes (Limb Size and Lymphedema Volume)

Manual lymphatic drainage (MLD)

Manual lymphatic drainage is described as a gentle manual technique involving various strokes (Zuther, 2005). It is performed to reroute lymph flow around blocked areas. Several studies show a benefit from MLD. Johansson et al. (1999) looked at differences between patients treated with compression bandaging alone versus patients treated with both compression bandaging and MLD and found that patients in both groups benefited significantly in terms of volume reduction in comparison with baseline values. The group that received both compression bandaging and MLD experienced greater lymphedema volume reductions, but the difference in volume reduction between the two groups at the end of the study was not statistically significant. Williams et al. (2002) found a significant benefit from MLD as well as a benefit (not significant) from simple lymphatic massage (SLM), a modified version of MLD that patients can do themselves at home.

Andersen et al. (2000) compared two groups of patients: One group underwent MLD eight times in two weeks and received instructions on how to perform self-massage (22 patients); the control group (20 patients) did not receive these interventions. All patients in both the intervention and control groups received compression bandages. The authors' conclusion was that the benefit in terms of reduced limb volume that they observed (48% in the MLD group and 60% reduction in the control group) was due to the compression therapy and not MLD. McNeely et al. (2004) reached similar conclusions, finding that most patients who received MLD in addition to compression bandaging did not experience significantly greater reductions in lymphedema volume than those patients who received only compression bandaging ($p = 0.812$). The only exceptions were patients with mild lymphedema, who appeared to benefit from a combination of both MLD and compression bandaging.

In conclusion, the evidence is mixed for MLD. Several studies suggest that MLD reduces the volume of lymphedema, but others show that MLD did not have an effect or that the effect was not always statistically significant.

Compression therapy (CT)

Compression therapy uses various types of compression bandages and compression garments, including multi-layer bandaging and fitted elastic sleeves, to prevent re-accumulation of fluid. Compression therapy has a significant effect, both on reducing the volume of edematous extremities during the initial stages of treatment as well as on maintaining the effect of therapy. In several studies, all patients were given compression sleeves, while another intervention, such as MLD, was tested, and significant improvement from baseline was observed in the compression sleeve-only group (Johansson et al., 1999). Other studies showed the effectiveness of compression sleeves alone (Hornsby, 1995). There is a wide variety of compression bandages, with various studies reporting on different types of bandages. No studies comparing different types of bandages were found. However, significant benefits of compression therapy were noted across all studies for all types of bandages tested.

In conclusion, the evidence was favorable with respect to compression therapy in the studies reviewed.

Pneumatic compression pumps

Pneumatic compression pumps have occasionally been used to alleviate lymphedema. Szuba et al. (2002) and Dini et al. (1998) both found that patients receiving pneumatic compression pump therapy for breast cancer associated lymphedema had better results than did their counterparts not receiving the therapy, but the differences were not significant. There have also been reports of problems with compression therapy. Boris et al. (1998) found that 23 of 53 patients developed a genital edema after using a pump for lower limb edema, in contrast to two of 75 patients who did not use a pump ($p < 0.0001$) for this condition. The authors called the high incidence of genital edema among patients undergoing pneumatic compression therapy for lower limb edema unacceptable.

Exercise

In the article by McKenzie and Kalda (2003), no benefit from exercise, as measured by decreased limb volume, was detected from a progressive upper body exercise program with resistance and aerobic components.

Skin and nail care

No RCTs on skin and nail care were found in the literature review. In the studies reviewed, education in skin and nail care was considered a “basic therapy” offered to control groups in randomized trials of CDT.

Pharmacologic agents

The literature contains reports of the use of pharmacologic agents, primarily benzopyrones. Most of the drugs in this class are not approved by the Federal Drug Administration (FDA). Because these are not approved by the FDA, the effectiveness of the benzopyrones will not be addressed in this analysis. Other pharmacologic agents have been suggested for the treatment of lymphedema, but few studies of these agents exist. Gothard et al. (2004) showed a non-significant benefit from vitamin E in terms of reducing arm volume

Management of Symptoms

Pain and discomfort control

Johansson et al. (1999) found significantly reduced pain and discomfort levels, including sensations of heaviness and tension as measured on a 100 mm visual analog scale, following treatment with compression bandaging and MLD.

Quality of life

Using results from the European Organisation for the Treatment of Cancer self-reported questionnaire EORTC QLC¹⁰, Williams et al. (2002) reported significantly improved emotional function after treatment with MLD. However, it is difficult to undertake a “double-blind” study of MLD to assess whether it is the specific therapy that makes a difference in such outcomes, or simply the added attention of a set of visits.

In conclusion, some treatments improved management of pain and discomfort and quality of life, but it is difficult to interpret the effects of specific treatments. One study showed significant reduction in these symptoms using compression bandaging and MLD. In another study patients self-reported significantly improved emotional function after having received MLD. None of these studies tested for the relative effectiveness of these treatments in comparison to less extensive interventions.

Medical Complications

Infection rate

Few investigators have studied the number of infections (i.e., lymphangitis, cellulitis, and sepsis) averted due to therapies for lymphedema. In Badger et al. (2000) the addition of MLD to the therapeutic regimen did not reduce the incidence of infections. Kasseroller et al. (1998), showed that patients receiving selenium are significantly less likely than those receiving placebo to contract erysipilis (a skin infection), but the studies have not been replicated. Foldi (1996) noted that physiotherapy (the specific program was not described) significantly reduced the risk of dermatolymphoangioadenitis (DLA) in patients with histories of at least three episodes of the condition. The data suggest that decongestive lymphatic therapy (DLT) reduces the incidence of infection in lymphedema patients, but the evidence is limited. Shenoy et al. (1998, 1999) analyzed methods of preventing adenolymphangitis (infections in the affected limbs) of patients in India suffering from lymphedema caused by brugian filariasis, a parasitic disease. These investigators found that the use of diethylcarbamazine, an antiparasitic drug, and ivermectin, a broad-spectrum antiparasitic drug, did not prevent any more cases of adenolymphangitis than good foot and skin care combined with antibiotics and antifungal agents.

Limitations of the Analysis

There are several caveats in the interpretation of the data from the studies reviewed. Most of the studies in the literature, even the randomized controlled trials, have small sample sizes. In addition, most of the studies do not adequately describe the randomization process, making it difficult to determine if the patients were truly randomized. Furthermore, it is impossible to blind

¹⁰ The authors report that there are no condition-specific quality of life tools available for lymphedema. The EORTC QLQ C30 is, according to the authors, an instrument consisting of 30 functional, symptom, and individual items designed to address a range of quality of life issues relevant to cancer patients and is designed for patients to complete on their own. The instrument is apparently called by its abbreviation, and the authors do not provide information on the complete, unabbreviated name. However, a search on the internet reveals that the initials *EORTC* stand for the “European Organization for Research and Treatment of Cancer”. The *QLQ* most likely stands for *quality of life questionnaire*.

the patient to the treatment, and thus discern whether treatments truly have an effect beyond that of a placebo. There are no studies of which specific aspects of the treatments have an effect. Most of the studies available in the literature use reduction in limb size—usually measured as a reduction in volume of lymphedema. This is an intermediate physical outcome measure, rather than a health outcome measure, such as improved limb function, reduced discomfort or pain, increased patient satisfaction, or a reduction in number of infections or other consequences of lymphedema. The studies each include different packages of treatments, and in some studies, the components of the package, or the program of therapy, are not described. The RCT of pneumatic compression therapy did not mention any assessment of known complications of therapy (Boris et al., 1998). Although it is well known that it takes as long as six months for the lymph fluid to be reabsorbed into the body, few of the studies observed patients for three months, let alone six months.

Conclusions

In conclusion, the evidence suggests that patients realize significant reductions in limb size from compression therapy. Some investigators have shown significant improvements for MLD relative to baseline in terms of reduced limb size and improved patient emotional health (Johansson et al., 1999; Williams et al., 2002). The evidence is much less clear in terms of benefits for MLD relative to other treatments or specific components of MLD.

II. UTILIZATION, COST, AND COVERAGE IMPACTS

The California Health Benefits Review Program (CHBRP) assesses the utilization, cost, and coverage impacts of a proposed health benefit(s) mandate based on criteria specified under Assembly Bill 1996 (2002) (AB 1996), *California Health and Safety Code (Section 127660, et seq.)* This section is organized by and addresses each criterion specified in the statute.

As previously discussed, AB 213 would require health plans regulated under the Health and Safety Code and health insurance policies that cover hospital, medical, or surgery expenses to cover the diagnosis and treatment of lymphedema as specified in the bill.

This mandate affects insured individuals younger than 65 years who have private insurance (group and individual), or are enrolled in public plans subject to the Health and Safety Code, including CalPERS Health Maintenance Organization (HMO) plans, Medi-Cal managed care, or Healthy Families. It also affects people who are older than 65 and enrolled in Medi-Cal managed care plans, excluding county-organized health systems. Thus, the total population in California affected by this mandate is 20,368,000 people.^{11, 12}

¹¹ For an overview of the cost impact process, data sources, and methods, please see the [Cost Impact Analysis Summary](http://www.chbrp.org/costimpactsun.html) (<http://www.chbrp.org/costimpactsun.html>).

¹² This total of 20,368,000 insured individuals excludes individuals who work for firms that self-insure, because those firms would be considered exempt from state-level health insurance mandates.

Present Baseline Cost and Coverage

Current coverage of the mandated benefit (3(i))

- 100% of the 20,368,000 insured Californians that would be affected by this mandate have coverage for lymphedema treatment. Currently, under Knox-Keene¹³ and the Insurance Code¹⁴, health plans and insurers are required to cover the treatment of lymphedema following a mastectomy.
- Only a small percentage of the population has lymphedema.
- Of the seven health plans and insurers surveyed by CHBRP, four responded by the date of this report. All stated that they cover physical therapy, including manual lymphatic drainage (MLD) as medically necessary. All stated that they cover compression garments, compression pads, and pads as medically necessary. The only limits noted were limits on the number of compression garments covered by insurers; otherwise coverage was complete, subject to medical necessity. One health plan, with one of the smaller proportion of California membership, also stated that most bandages were usually considered excluded items.
- Orthotic devices were either covered under a separate rider for purchase by a group or covered as medically necessary. Specialized footwear was covered as a separate rider for purchase by a group or generally not covered because it was not considered medically necessary for the treatment of lymphedema. Some responded that certain items, such as specialized hose, would be considered over-the-counter treatment and therefore not covered under the plan benefit.

Current utilization levels and costs of the mandated benefit (Section 3(h))

Claims data from large private insurers nationwide was used to estimate baseline utilization. The claims database included 7 million people under age 65. The data was analyzed to establish the utilization rates and cost of treatment for lymphedema. The analysis focused on people with diagnoses of lymphedema and their utilization of services mandated in AB 213 for treatment of lymphedema.

National claims data suggests that 0.07% of the insured population has lymphedema. Among the insured population that would be affected by AB 213 in California (20,368,000 persons), the number of people expected to need treatment for lymphedema is about 14,000 (0.07% of 20,368,000). This estimate depends on the assumption that the utilization and diagnoses of lymphedema in the national claims data reflects the utilization and diagnoses of lymphedema among the 20,368,000 insured people whose plans or insurers will have to comply with AB 213 if enacted. Utilization at baseline is reported in Table 3.

Patients with lymphedema use a wide range of services. Overall utilization among lymphedema patients is low, with treatment considerably underutilized. Claims data show, for example, that around 12% of lymphedema patients utilize physical or occupational therapy, around 20% use compression garments, and fewer than 10% use manual lymphatic drainage.

¹³ Health and Safety Code § 1367.635

¹⁴ Insurance Code § 10123.86

Table 3 shows the utilization among the population of people diagnosed with lymphedema. Overall utilization is 8.08 services per lymphedema patients per year, at a cost of \$963.31 per patient per year. Eleven services were identified within the claims data used by the cost impact team. This is comprised of the following services:

- Equipment:
- Durable medical equipment: An average of 0.91 items of equipment per patient are furnished, at a cost of \$139.61 per patient per year.
- Compression garments: An average of 0.52 garments are received per patient, at a cost of \$50.64 per year.
- Pharmaceuticals: The average number of prescriptions filled is 0.16 prescriptions per lymphedema patient, at a cost of \$23.78 per year.
- Physical and occupational therapy is provided by therapists in private practice, and through outpatient facilities within hospitals. The average number of physical and occupational therapy visits from therapists is 1.06 visits per lymphedema patient, at a cost of \$57.40 per year. The average number of physical and occupational therapy visits at outpatient facilities is 1.63 services per lymphedema patient, at a cost of \$172.20 per year.
- Physical and occupational therapists with special training also provide MLD. The average number of visits for this treatment is 0.86 per lymphedema patient, at a cost of \$87.60 per year.
- Inpatient hospitalization: The average utilization is 0.54 services per lymphedema patient at a cost of \$136.31 per year.
- Physician visits: On average, there is one-half of a visit (0.54) per lymphedema patient, with an average cost of \$47.31 per patient per year.
- Other services provided to lymphedema patients include:
 - An average of 0.40 other unspecified facility visits per lymphedema patient, at a cost of \$70.91 per patient per year.
 - An average of 0.91 visits per lymphedema patient per year, to other professionals (not specified), at a cost of \$62.93.
 - An average of 0.55 unspecified services per patient year, with an average cost of \$114.61.

The extent to which costs resulting from lack of coverage are shifted to other payers, including both public and private entities. (Section 3(f))

There is no data available to measure how many individuals seek care from public programs or other private sources of care because of the lack of mandated coverage for lymphedema treatment. In the absence of this data, it is not possible to make estimates of cost shifting. However, because insurers already cover services for lymphedema, it is unlikely that any cost shifting to other programs is occurring.

Public demand for coverage (Section 3(j))

Based on information submitted to CHBRP by interested parties, there appears to be some public interest in favor and against passage of AB 213 (see Appendix D). Based on criteria specified under AB 1996 (2002), CHBRP is to report on the extent to which collective bargaining negotiate for and the extent to which self-insured plans currently have coverage for the benefits specified under the proposed mandate. Based on conversations with the largest collective bargaining agents in California, there is no evidence that unions currently include such detailed provisions during the negotiations of their health insurance policies. In order to determine whether any local unions engage in negotiations at such detail, they would need to be surveyed individually.¹⁵ Currently, the largest public self-insured plans, California Public Employees' Retirement System (CalPERS) preferred provider organization (PPO) plans, cover treatment for lymphedema through their physical therapy, durable medical equipment, and prosthetic and orthotic provisions (for the devices and supplies associated with lymphedema management).

Impacts of Mandated Coverage

How will changes in coverage related to the mandate affect the benefit of the newly covered service and the per-unit cost? (Section 3(a))

The only explicit utilization increase assumed due to the mandate was a small increase in the utilization of compression garments due to the removal of any limits currently in place. CHBRP also assumed that an increased awareness of coverage as a result of the mandate will result in a 2% increase in utilization of services for DME, compression garments, manual lymph drainage, and physical therapy.

The impact of the mandate is expected to increase overall average utilization from 8.08 services per lymphedema patient to 8.20 services per lymphedema patient per year. The increases in services are expected to be mainly concentrated among occupational and physical therapy services, durable medical equipment, and compression garments.

Per patient cost of treatment could increase by \$12.15 per year because of the increase in utilization to 8.20 services per lymphedema patient per year. The entire increase in per-unit cost is attributed to increased utilization, rather than to an increase in price.

AB 1996 requires estimates of any supply restrictions as a result of increased utilization or demand; as well as any price increases that result. The increase in demand of 1.48% from 8.08 services to 8.20 services per patient per year should not adversely impact the supply of services.

One impact of the legislation may be to encourage more physical and occupational therapists to seek certification in lymphedema treatment. According to a content expert consulted for this project, training for this certification takes 135 hours, although being certified for lymphedema treatment does not require a physical or occupational therapy license. Therefore, there are no significant barriers to entry for providers who wish to gain treatment certification specific to lymphedema.

¹⁵ Conversations with SEIU and California Labor Federation on February 8, 2005

The supply of services postmandate typically determines whether any change could occur in the price of services. Because supply constraints are thought to be very limited, consequently, prices for the services mandated by AB 213 are not expected to increase.

There is no data available to indicate a change, either positive or negative, in the clinical benefit of the services mandated, if utilization increases.

How will utilization change as a result of the mandate? (Section 3(b))

Average utilization is expected to increase from 8.08 services per lymphedema patient to 8.20 services per lymphedema patient per year.

Table 3 shows the changes in utilization by type of service. Of the 11 services listed in the table, five types of services are expected to have increased utilization: durable medical equipment, compression garments, visits to therapists for MLD, and physical and occupational therapy in outpatient facilities and private practice offices:

- Average utilization of durable medical equipment may increase from 0.91 services per patient to 0.93 services per patient per year.
- Utilization of compression garments may increase from an average of 0.52 garments to 0.55 garments per patient per year.
- Physical and occupational therapy provided in outpatient hospital facilities may increase from an average of 1.63 visits to 1.66 per patient per year.
- Physical and occupational therapy provided by office-based therapists may increase from an average of 1.06 visits to 1.08 per patient per year.
- MLD visits may increase from an average of 0.86 visits to 0.88 visits per patient per year.

The estimates of how much utilization of each of these services could increase was based on expert judgment of how mandates affect patient demand for treatment and on assumptions used by actuaries and health economists about supply and demand for services.

Some utilization changes are expected to result from increased awareness among providers and patients of the services mandated by AB 213.

Mandated coverage may also induce supplier demand; in other words, mandated coverage of services may encourage providers to recommend more visits or services. However, the impact of supplier or patient demand for treatment is not expected to be large, given that coverage is apparently already high. Therefore, the changes that do occur are expected to be minimal.

Certain assumptions were made regarding how mandated coverage may increase utilization. An assumption was made regarding insurers' ability to manage utilization. We assume that insurance companies manage utilization of these services at the present time, and that coverage of durable medical equipment, compression garments, MLD, and physical and occupational therapy is managed more aggressively than other services. If enacted, AB 213 will loosen these

restrictions, but insurers are likely to continue to manage utilization. Therefore, a small increase in utilization as a result of the mandate is predicted.

Second, claims data shows that utilization overall among lymphedema patients is low. For example, as stated earlier, around 12% of lymphedema patients utilize physical or occupational therapy, around 20% use compression garments, and less than 10% use manual lymphatic drainage. This pattern of utilization was also noted by actuaries estimating the impact of a similar mandate proposed in Massachusetts. Actuaries said in their report that utilization of the covered benefits is “dramatically less than the benefit levels in place.” (Commonwealth of Massachusetts Mandated Benefit Review 2004. Review and Evaluation of Proposed Legislation Entitled “An Act Providing Coverage for Lymphedema Treatments” Provided for the Joint Committee on Insurance, Division of Health Care Finance and Policy, July 26). This suggests that even when benefits are covered, there tends to be underutilization of services rather the existence of large unmet demand for coverage.

Likewise, Figure 1 shows that the patients who do seek treatment do not utilize a large quantity of services. Twenty-five percent of patients only have one physical therapy visit per year, 35.6% have between two and five visits, and 15.6% have between six and ten visits per year. As the number of visits increases, the number of patients receiving treatment declines after ten visits. Around 85% of patients have 15 or fewer physical therapy visits.

Many lymphedema patients do not utilize any services. Patients who do utilize any of the treatments tend to not see providers frequently. This suggests that mandated benefits for lymphedema treatment are unlikely to create a situation where patients with previously unmet needs demand a significantly increased quantity of services.

The utilization of many other services is unlikely to change after implementation of AB 213.

- Physician office visits are not expected to change because people are already covered for physician services, and physicians’ have a more limited role in treating lymphedema, indicated by the baseline utilization data. Office visits to primary care physician practices are less subject to utilization review.
- Treatment by other professionals at other kinds of facilities was difficult to estimate, because of the range of services within these categories and the lack of information about the kinds of visits these claims represent. Utilization of prescription drug coverage, and inpatient treatment is expected to be unaffected by the mandate.

No alternative services, substitutes, or complementary services could be identified beyond the services already identified and mandated in AB 213. As a result, no change could be identified in the utilization of these services.

To what extent does the mandate affect administrative and other expenses? (Section 3I)

CHBRP assumes that administrative costs are the same across all plans and insurers, regardless of firm size or insurance type, except in the individual market. These costs are included in the baseline and premium estimates in Table 4. There is no evidence to suggest that AB 213 would alter the distribution or amount of administrative costs, other than plans and insurers needing to notify enrollees and policy-holders in annual notifications of benefit changes or terms.

However, health plans stated that they would face administrative burdens associated with (1) training and credentialing requirements for physical therapy to meet the 135 hour requirement proposed under the mandate; (2) documentation associated with the “treatment plan” for patients that is required under this mandate (3) educating employees and delegated providers and physicians.

Table 5 shows how cost sharing is expected to increase as a result of the mandate by a total of \$12,075. The increase in cost sharing is a result of increased utilization.

Impact of the mandate on total health care costs (Section 3(d))

As discussed above AB 213 is not expected to have an impact on personal out of pocket costs. Total expenditure, as shown in Table 1, including private sector expenditures and public expenditures, are expected to increase by \$201,855 per year or 0.0003%.

Costs or savings for each category of insurer resulting from the benefit mandate (Section 3(e))

The following cost impacts are expected across major categories of purchasers of health care benefits

- All private sector employers offering plans affected by this mandate could expect to pay a total of \$102,157 per year in additional employee insurance costs, or an extra 0.0073 cents per employee per year.
- All employees combined could expect to pay an additional \$30,626 in premiums per year, or 0.0017 cents per person per year.
- Individually purchased health plan or insurance coverage could expect to increase by a total of \$19,018 per year (spread across all individual purchasers), or 0.0097 cents per person per year.
- The California Public Employees’ Retirement System (CalPERS) could expect to pay an additional total \$6,413 per year in premiums, or an additional 0.0081 cents per person per year.
- Medi-Cal could expect to pay an additional total \$29,636 per year or 0.0030 cents per person per year.
- Healthy Families could expect to pay an additional \$1,930 or 0.0039 cents per person per year.

Substitution effects are not expected to be important because the proposed mandate does not have a substantial impact on premiums or public program cost, as discussed above.

Because of the 0.0003% overall increase in premiums for private employers, the premium increases are unlikely to have an impact on the following:

- The availability of the benefit, including the types of providers offering the service postmandate;
- The willingness of employers to offer higher-cost insurance (i.e., offer rate);
- The willingness of employers to pay higher premiums on behalf of their employees (i.e., employer contribution rate);
- The willingness of employees to purchase insurance if premiums and/or copayments increase (i.e., take-up rate);
- The willingness of individuals with privately purchased coverage to purchase insurance if premiums and/or copayments increase.

Impact on access and health service availability (Section 3(g))

Utilization is expected to increase by 1.48%, and total costs are expected to increase by \$201,855 or 0.0003%. Therefore, no impact on access and availability of health services is expected.

III. PUBLIC HEALTH IMPACTS

Present Baseline Health Outcomes

The incidence and prevalence of primary and secondary lymphedema at the state or national level are unknown. This information is not contained in any of the California population-based datasets customarily used in our analysis such as the California Health Interview Survey (CHIS) or the California Behavioral Risk Factor Survey (BRFS). Estimates at the national level are also not available through the National Health Interview Survey (NHIS) or the national BRFS. In addition, the Centers for Disease Control and Prevention the National Institutes of Health, the National Center for Health Statistics, and the National Cancer Institute were all searched for data on prevalence and incidence of lymphedema. This search resulted in two pieces of data. First, the National Institutes of Health estimate that the incidence of primary lymphedema is somewhere between one in 6,000 to one in 300 live births (NIH, 2001). This would translate into an annual incidence in California of somewhere between 100 and 1,800 cases.¹⁶ Second, estimates of the incidence of secondary lymphedema have been made primarily for breast cancer patients. Although estimates of the rate of development of lymphedema among those treated for breast cancer vary greatly, the National Cancer Institute cites the annual incidence of upper arm edema after breast cancer treatment as 26% (Erickson et al., 2001). This would translate into close to 6,000 cases annually in California.¹⁷ The incidence rates of lymphedema due to other causes (i.e., other types of cancer, trauma, or infection) are unknown. As reported in the previous

¹⁶ This is based on 529,357 number of births in California in 2002 as reported in Martin et al., 2003

¹⁷ This is based on 22,145 new cases of breast cancer in California in 2003 as reported in Kwong and Wright, 2003.

section, the Milliman claims database estimates that 0.07% of the insured population in California have lymphedema (from all causes), which is approximately 14,000 persons.

There are three types of outcomes identified in the review of the medical effectiveness literature with sufficient evidence to examine the impact of mandated coverage for the treatment of lymphedema. These outcomes are reduction in limb size, management of symptoms, and medical complications. There are no baseline data available on the rates of these outcomes in the population of patients undergoing treatment for lymphedema in California.

Impact of the Proposed Mandate on Public Health

Impact on Community Health (Section 1A)

Based on the studies found in the medical effectiveness literature review, the available evidence implies that the mandate would have a favorable impact on the health of the community as measured by the reduction in limb size, to the extent that utilization increases for compression therapy. Due to the lack of consensus within the literature on the clinical definition of lymphedema, the stages of the condition as it progresses, and the standards of care for its treatment, it is not possible to quantify the overall impact of this mandate on the health of the community.

Impact on Community Health where Gender and Racial Disparities Exist (Section 1B)

A literature review was conducted to examine whether gender and racial disparities exist with regards to lymphedema. A majority of the studies reviewed in this report examine lymphedema in breast cancer patients (Andersen et al, 2000; Dini et al, 1998; Gothard et al, 2004; Johansson et al, 1998, 1999; Kasseroller, 1998; McKenzie and Kalda, 2003; Szuba et al 2002; Williams et al, 2002). Likely due to the relationship of lymphedema with the treatment of breast cancer, women are more likely to be diagnosed with lymphedema compared with men. Milliman utilization data show that almost 75% of the lymphedema cases in California are in women. No research was found that examines gender or racial disparities in the treatment or outcomes of lymphedema.

Reduction of Premature Death and the Economic Loss Associated with Disease (Section 1C)

The specific health outcomes examined in this report include: reduction in limb size, management of symptoms, and medical complications. The studies on these outcome measures do not include evidence related to the impact of treatment for lymphedema on premature death. Furthermore, there is no literature indicating that people with lymphedema have a reduced life expectancy. In addition, mortality data collected by the Centers for Disease Control and Prevention's WONDER (Wide-ranging OnLine Data for Epidemiologic Research) database indicate that there were eight lymphedema-related deaths in California from 1989-1998 (a 10-year period). Therefore, we conclude that lymphedema does not lead to premature death.

The economic costs associated with lymphedema include the direct costs as reported in Section II and the indirect costs of lost productivity. Although some anecdotal data suggests that there may be indirect economic costs associated with lymphedema, such as loss of employment (Thiadens, 1998), no research was found to estimate the indirect costs of lymphedema at the state or national level.

TABLES AND FIGURES

Table 3. Utilization at Baseline and Postmandate

Service Type	Baseline (Per Patient Per Year)		Postmandate (Per Patient Per Year)	
	Services	Allowed Cost (2005)	Services	Allowed Cost (2005)
Equipment				
Durable medical equipment	0.91	139.61	0.93	\$142.41
Compression garments	0.52	\$50.64	0.55	\$53.65
Pharmaceuticals	0.16	\$23.78	0.16	\$23.78
Occupational/physical therapy				
Therapist in private practice	1.06	\$57.40	1.08	\$58.55
Therapist in outpatient facility	1.63	\$172.20	1.66	\$175.65
Therapist with specialized training for MLD	0.86	\$87.60	0.88	\$89.35
Inpatient hospitalization	0.54	\$136.31	0.54	\$136.31
Physician visits	0.54	\$47.31	0.54	\$47.31
Visits to other professionals	0.91	\$62.93	0.91	\$62.93
Unspecified facility visits	0.40	\$70.91	0.40	\$70.91
Other (1)	0.55	\$114.61	0.55	\$114.61
Total	8.08	\$963.31	8.20	\$975.46

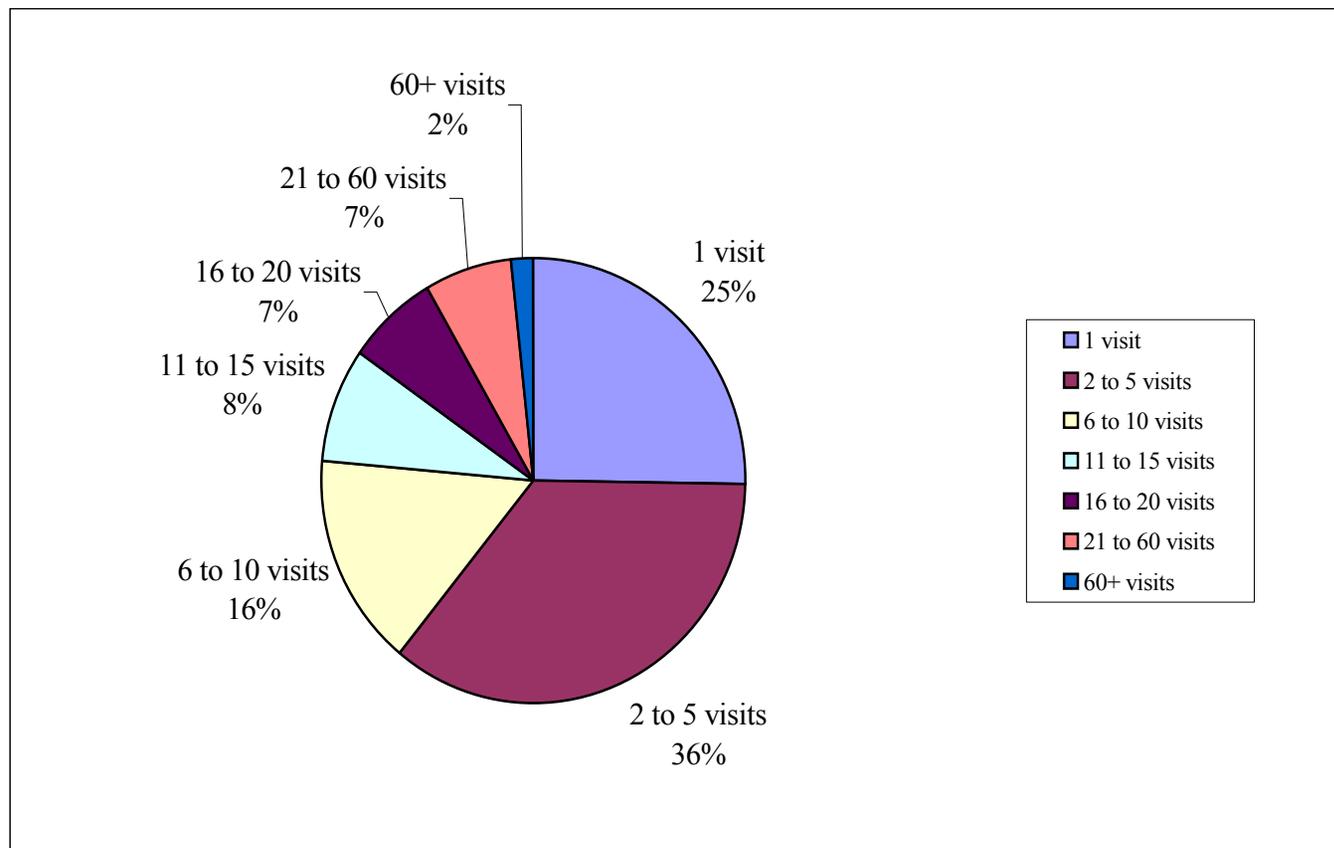
Source: California Health Benefits Review Program, 2005.

Utilization of services during the year with a primary or secondary diagnosis of 457.0, 457.1, or 457.2.

Note: (1) 'Other' includes services for which the coding used made it impossible to determine the provider type or service.

Key: MLD = manual lymphatic drainage

Figure 1. Physical Therapy Visits by Lymphedema Patients: Proportion of Patients



Source: California Health Benefits Review Program, 2005.

Table 4. Baseline (Premandate) Per Member Per Month Premium and Expenditures, California, Calendar Year 2005

	Large Group				Small Group				Individual		Public				Total Annual Expenditures
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	HMO	PPO	CalPERS HMO	Medi-Cal HMO Over 65	Medi-Cal HMO Other	Healthy Families HMO	Total (Members)
Population currently covered	7,400,000	3,220,000	457,000	19,000	1,498,000	875,000	454,000	4,000	887,000	1,065,000	795,000	354,000	2,846,000	494,000	20,368,000
Average premium paid by employer	\$187.97	\$283.90	\$234.95	\$240.59	\$161.28	\$234.40	\$180.93	\$181.88	\$0.00	\$0.00	\$231.96	\$235.05	\$86.12	\$58.68	\$41,860,457,024
Average premium paid by employee	\$50.45	\$57.87	\$51.96	\$63.25	\$83.36	\$73.27	\$94.91	\$37.09	\$214.23	\$120.38	\$44.18	\$0.00	\$0.00	\$6.32	\$14,079,831,484
Total premium	\$238.42	\$341.77	\$286.90	\$303.83	\$244.64	\$307.67	\$275.84	\$218.97	\$214.23	\$120.38	\$276.14	\$235.05	\$86.12	\$65.00	\$55,940,288,508
Deductibles, copayments paid by members	\$8.44	\$46.18	\$18.14	\$67.04	\$12.49	\$45.71	\$21.55	\$51.02	\$13.04	\$28.09	\$9.78	\$0.00	\$0.00	\$1.77	\$4,074,892,839
Benefits not covered*	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	
Total expenditures	\$246.87	\$387.95	\$305.04	\$370.87	\$257.13	\$353.38	\$297.39	\$269.98	\$227.27	\$148.47	\$285.92	\$235.05	\$86.12	\$66.77	\$60,015,181,348

Source: California Health Benefits Review Program, 2005.

Note: *Includes cost of mandated benefits only. Note: The population includes individuals in California, younger than 65 years who have private insurance (group and individual), or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families. It also affects people who are over 65 who are enrolled in Medi-Cal managed care plans, excluding county-organized health systems. This figure excludes individuals who work for firms that self-insure.

Key: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization. CalPERS: = California Public Employees' Retirement System.

Table 5. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, calendar year 2005

	Large Group				Small Group				Individual		Public				Total Annual Expenditures
	HMO	PPO	POS	FFS	HMO	PPO	POS	FFS	HMO	PPO	CalPERS HMO	Medi-Cal HMO Over 65	Medi-Cal HMO Other	Healthy Families HMO	Total (Members)
Population currently covered	7,400,000	3,220,000	457,000	19,000	1,498,000	875,000	454,000	4,000	887,000	1,065,000	795,000	354,000	2,846,000	494,000	20,368,000
Average Portion of Premium Paid by Employer	\$0.0006	\$0.0006	\$0.0006	\$0.0005	\$0.0005	\$0.0006	\$0.0005	\$0.0006	\$0.0000	\$0.0000	\$0.0007	\$0.0019	\$0.0006	\$0.0003	\$140,136
Average Portion of Premium Paid by Employee	\$0.0002	\$0.0001	\$0.0001	\$0.0001	\$0.0003	\$0.0002	\$0.0003	\$0.0001	\$0.0009	\$0.0007	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$49,644
Total Premium	\$0.0008	\$0.0007	\$0.0008	\$0.0007	\$0.0008	\$0.0008	\$0.0008	\$0.0007	\$0.0009	\$0.0007	\$0.0008	\$0.0019	\$0.0006	\$0.0004	\$189,781
Covered Benefits Paid by Member (Deductibles, copays, etc)	\$0.0000	\$0.0001	\$0.0000	\$0.0001	\$0.0000	\$0.0001	\$0.0001	\$0.0002	\$0.0001	\$0.0002	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$12,075
Total Expenditures*	\$0.0008	\$0.0008	\$0.0008	\$0.0008	\$0.0009	\$0.0009	\$0.0009	\$0.0009	\$0.0010	\$0.0009	\$0.0008	\$0.0019	\$0.0006	\$0.0004	\$201,855
Percentage Impact of Mandate:															
Insured Premiums	0.0003%	0.0002%	0.0003%	0.0002%	0.0003%	0.0002%	0.0003%	0.0003%	0.0004%	0.0006%	0.0003%	0.0008%	0.0007%	0.0006%	0.0003%
Total Expenditures	0.0003%	0.0002%	0.0003%	0.0002%	0.0003%	0.0002%	0.0003%	0.0003%	0.0004%	0.0006%	0.0003%	0.0008%	0.0007%	0.0006%	0.0003%

Source: California Health Benefits Review Program, 2005.

Note: The population includes individuals in California, younger than 65 years who have private insurance (group and individual), or are enrolled in public plans subject to the Health and Safety Code, including CalPERS, Medi-Cal, or Healthy Families. It also affects people who are over 65 who are enrolled in Medi-Cal managed care plans, excluding county-organized health systems. This table excludes individuals who work for firms that self-insure. Total annual expenditures are not per member per month. *Some totals do not add up due to rounding.

Key: FFS = fee for service; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization. CalPERS: California Public Employees' Retirement System.

APPENDIX A Literature Review Methods

AB 213 is an act relating to health care coverage to add Section 1367.666 to the California Health and Safety Code, and to add Section 10123.175 to the Insurance Code. AB 213 would require health care service plans and health insurers to provide coverage for the medical diagnosis and treatment of lymphedema in accordance with the current standard of care. The interventions specifically mentioned in the mandate include *medically required compression garments, compression pads, bandages, bandage liners and pads, orthotic devices, and special footwear deemed by the patient's qualified caregiver to be medically necessary, with replacements provided when required to maintain the compressive function or to accommodate changes in the patient's dimensions*. The bill notes the components of complex decongestive therapy (CDT) and states that *treatment may include, but is not limited to, a course of manual lymphatic drainage (MLD) with the length, duration, and frequency determined on the basis of medical necessity*. It specifies that *MLD shall be performed by a therapist who is trained and certified in the specialized treatment of lymphedema from a recognized training program with a minimum of 135 hours*.

Appendix A describes the literature search for studies on the medical effectiveness of lymphedema treatment, including the effectiveness of the different components of CDT (i.e., MLD, compression therapies, exercise, and education about skin care) and drug therapies. This appendix also discusses the outcomes used in analysis of the mandate.

To “grade” the evidence for all outcome measures, the CHBRP effectiveness team uses a system¹⁸ with the following categories:

1. Favorable (statistically significant effect): Findings are uniformly favorable, and many or all are statistically significant.
2. Pattern¹⁹ toward favorable (but not statistically significant): Findings are generally favorable, but there may be none that are statistically significant.
3. Ambiguous/mixed evidence: Some findings are significantly favorable, and some findings with sufficient statistical power show no effect.
4. Pattern toward no effect/weak evidence: Studies generally find no effect, but this may be due to a lack of statistical power.
5. No effect: There is statistical evidence of no clinical effect in the literature with sufficient statistical power to make this assessment.
6. Unfavorable: No findings show a statistically significant benefit, and some show significant harms.
7. Insufficient evidence to make a “call”: There are very few relevant findings, so that it is difficult to discern a pattern.

¹⁸The foregoing system was adapted from the system used by the U.S. Preventive Services Task Force, available at <http://www.ahcpr.gov/clinic/3rduspstf/ratings.htm>. The medical effectiveness team also considered guidelines from the Centers for Medicare & Medicaid Services, (available at <http://www.cms.hhs.gov/mcac/8b1-i9.asp>) and guidelines from the Blue Cross and Blue Shield Association (available at <http://www.bcbs.com/tec/teccriteria.html>).

¹⁹ In this instance, the word “trend” may be used synonymously with “pattern.”

The literature search was conducted through PubMed and Cochrane Library databases for the period through January 1998 through January 2005.

The lymphedema treatment interventions searched for in the literature included:

1. Physical therapy

Complex or complete decongestive therapy (CDT) or
Complex or complete decongestive physiotherapy (CDP),
including manual lymphatic drainage, compression garments,
compression bandage, compression pumps, self-care,
exercise therapy, skin care, patient education

Intermittent pneumatic compression

Massage

Thermal therapy

2. Drug therapy

benzopyrones

diuretics

selenium

3. Surgery

liposuction

microsurgery

The *Medical Subject Headings* (MeSH) terms used by the librarian in the PubMed search were:

lymphedema

Lymphedema with subheadings: complications, drug therapy, etiology,
prevention and control, rehabilitation, therapy, surgery

Massage

Massage with subheading: methods

Bandages

Bandages with subheading: methods

Drainage

Drainage with subheading: methods

Pressure

Physical Therapy Techniques

Physical Therapy Techniques with subheading: methods

Exercise

Exercise Therapy

Incidence

Prevalence

Mastectomy with subheading: adverse effects

Breast Neoplasms with subheadings: drug therapy, surgery

Lymph Node Excision with subheading: adverse effects
Arm with subheadings: pathology, physiopathology
Leg with subheadings: pathology, physiopathology
Sepsis
Lymphangitis
Cellulitis
Infection with subheading: epidemiology
inflammation
Venous Thrombosis
Skin Ulcer
Wounds and Injuries
Pain
Pain Measurement
Quality of Life
Activities of Daily Living
Patient Satisfaction
Benzopyrones with subheading: therapeutic use
Coumarins with subheading: therapeutic use
Selenium with subheading: therapeutic use
Elephantiasis with subheading: drug therapy
Treatment Outcome
Patient Education
Clinical Trials
Randomized Controlled Trials
Practice Guidelines

Below is a list of keywords used in PubMed search to retrieve newly published articles that haven't been indexed with MeSH terms.

effect*
efficacy
incidence
prevalence
lymphedema
lymphedema management
lymphoedema management
mastectomy adverse effects
breast neoplasms drug therapy, surgery
lymph node excision
complex decongestive therapy
decongestive lymphatic therapy
lymphedema compression therapy
compression therapy
compression garment*
compression pump*
manual lymph drainage

massage
physical therapy techniques
exercise
exercise therapy
patient education
skin care
benzopyrone
coumarins
selenium
lymphedema complication*
infection rate
lymphangitis
cellulitis
sepsis
elephantiasis
pain
deep venous thrombosis
limb amputation
skin ulcer
non healing wounds
functional impairment
cosmetic embarrassment
patient satisfaction
quality of life
activities of daily living
treatment outcome
clinical trials
randomized controlled trials
practice guidelines

(The asterisk * means that the word has been truncated, meaning that the search retrieves all variations with the same root. For example, effect* would retrieve effect, effects, effectiveness, effective, etc.)

The publication types included in the search are:

Randomized Controlled Trial
Clinical Trial
Review
Journal Articles
Case Reports
Practice Guidelines

Randomized controlled trials (RCT) and three meta-analyses were found:

1. Badger C, Preston N, Seers K, Mortimer P. (2004). Benzo-pyrones for reducing and controlling lymphoedema of the limbs. *Cochrane Database of Systematic Reviews*. (2):CD003140.
2. Badger C, Preston N, Seers K, Mortimer P. (2004). Physical therapies for reducing and controlling lymphoedema of the limbs. *Cochrane Database of Systematic Reviews*. (4):CD003141.
3. Badger C, Seers K, Preston N, Mortimer P. (2004). Antibiotics / anti-inflammatories for reducing acute inflammatory episodes in lymphoedema of the limbs. *Cochrane Database of Systematic Review*. (2):CD003143.

At the time of the literature search in February, 2005, no RCTs relevant to the mandate had yet been published in 2005. One additional, relevant RCT published in 2004, the year of publication of the meta-analyses, was found during the literature search:

McNeely ML, Magee DJ, Lees AW, Bagnall KM, Haykowsky M, Hanson J. (2004). The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial. *Breast Cancer Research and Treatment*. 86(2):95-106.

The search was limited to articles that appeared in English. Most of the articles focused on women with lymphedema following treatment for breast cancer. A majority of the studies were European, and only a small number of American studies were included.

The Cochrane Review article concerning physical therapies for reducing lymphedema by Badger et al. (2004b) lists 10 randomized controlled study articles, seven of which did not meet the standards imposed by the reviewers. Articles were rejected if the trials on which they were based did not meet the authors' criteria of at least six months of follow-up. Articles were also rejected if the method used to assess limb size was based on circumference measurements and not on the volume of the lymphedematous fluid. One of the rejected articles was only in abstract form, and the authors of the review were awaiting clarification about the design of the trial on another. This left only three articles on the use of physical therapy techniques in the treatment of lymphedema. One of these articles has proven to be difficult to obtain via inter-library loan.

Because Complex Decongestive Therapy (CDT) or one of its components is the mainstay of treatment for lymphedema in the United States, a decision was made to look at the studies rejected by the Cochrane Review. Four of the studies, which had originally been rejected from the Cochrane Review either because of insufficient follow-up time or because limb sizes were based on circumference, are included in the Appendix B in the charts B1 and B2. The lack of acceptance in the Cochrane Review is noted. The remaining two studies on physical therapies that were reviewed and rejected by the Cochrane Review were also rejected for this review. Both evaluated the use of electrically stimulated lymphatic drainage and were beyond the scope of the mandate:

1. Bergan JJ, Sparks S, Angle N. (1998). A comparison of compression pumps in the treatment of lymphedema. *Vascular Surgery*. 32(5):455-462.
2. Bertelli G, Venturini M, Forno G Macchiavello F, Dini D. (1991). Conservative Treatment of postmastectomy lymphedema: a controlled randomized trial. *Annals of Oncology*. 2:575-578.

The article by Foldi (1996) concerning an observational study about the use of CDT to prevent infections was included in the analysis because of the lack of RCTs that address this outcome. Another article that was an observational study of the dangers associated with pneumatic compression pumps was also discussed in the report, because the RCT about compression pumps did not discuss potential side effects.

The scope of the literature search included effects of treatments for lymphedema on:

- 1) Limb diameter
- 2) Health related quality of life
 - a) Ability to perform/take part in usual activities
 - b) Comfort level
 - c) Ability to wear usual clothes
- 3) Patient satisfaction
- 4) Infection rate
 - a) Lymphangitis
 - b) Cellulitis
 - c) Sepsis
- 5) Deep venous thrombosis
- 6) Severe functional impairment
- 7) Cosmetic embarrassment
- 8) Limb amputation
- 9) Leg ulcers/ nonhealing wounds

Search results included 111 English language articles. At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion.

Full-text articles were obtained and reviewers reapplied the initial eligibility criteria. At least two reviewers read each article retrieved.

Articles chosen for inclusion are summarized in Appendix B, Table B-1. Results from each study are organized into a table specific to each outcome in Table B-2. The tables were organized as follows:

Physical Outcome

- Reduction in Limb Size (Reduction in Volume of Lymphedema)
- Physical Therapy Interventions
- Pharmacologic Agents
- Management of Symptoms
- Pain and Discomfort Level
- Quality of Life

Medical Complications

- Infection Rate

Several major difficulties were encountered in the analysis of AB 213. Although the National Lymphedema Network (NLN), the International Society of Lymphology (ISL) and the American Cancer Society (ACS) have issued guidelines for the treatment of lymphedema involving combined physical therapy (CPT), there remains a lack of consensus on a standard of care for the treatment of lymphedema in the United States.

Each of the studies reflects different programs or practices at the authors' institutions. These programs and practices often are described by different terms and include different components. A recent book by Joachim Zuther (2005) on the management of lymphedema describes a variety of bandage types and compression levels for use in the initial phase of treatment as well as during the maintenance phase of treatment. However, the RCTs do not always provide sufficient information to compare compression bandaging techniques across studies.

Most of the articles available in the literature use reduction in the size of the affected limb, usually measured as reduction in lymphedema volume, rather than improved limb function, patient satisfaction, or the number of infections or other consequences of lymphedema prevented.

The sample sizes in the studies are small, and very few of the studies have been replicated.

APPENDIX B
Summary of Findings on Effectiveness
Related to Treatment of Lymphedema

Table B-1. Summary of Published Studies on Effects of Treatment of Lymphedema

Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Gothard et al., 2004	RCT (Double-blind simple intervention: vitamin E vs. placebo)	Group 1 (Intervention): 6-mo trial of alpha-tocopherol (vitamin E) and pentoxifylline (35 patients) vs. Group 2 (Control): placebo (33 patients)	68 patients with chronic arm lymphedema and fibrosis after treatment for breast cancer causing \geq 20% increase in arm volume	England
McKenzie and Kalda, 2003	RCT	Group 1 (Intervention): Exercise vs. Group 2 (Control): No exercise	14 breast cancer survivors (unilateral lymphedema >2 cm and l<8 cm on at least one measurement point)	British Columbia, Canada
McNeely et al., 2004	RCT	Group 1: MLD + CB (25 patients) vs. Group 2: CB alone	50 female breast cancer survivors with diagnosis of lymphedema made by physician and unilateral edema with at least a 150-ml excess volume in comparison with unaffected arm Patients had to be free of therapy for lymphedema for at least 4 mo prior to study	Canada



Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Szuba et al., 2002	RCT (2 studies investigating IPC: the first study as initial therapy and the second as maintenance therapy with cross-over design)	<u>Study 1 (Initial therapy):</u> Group 1 (Intervention): DLT, including MLD and CB + IPC)vs. Group 2 (Control): DLT (including MLD and CB) alone (10-day randomized study with 30-day follow-up) <u>Study 2 (Maintenance):</u> Group 1: DLT alone Vs. Group 2: DLT + IPC (randomized, cross-over, 2-mo design with 6-mo follow-up)	<u>Study 1:</u> 23 patients with breast carcinoma-associated lymphedema <u>Study 2:</u> 27 patients with breast carcinoma-associated lymphedema	United States
Williams et al., 2002	RCT (Trial with cross-over for all patients at 6 wk)	12-wk study Group 1: MLD for 3 wk, followed by 6 wk of nontreatment, ↓ and then SLD)for 3 wk vs. Group 2: SLD for 3 wk, followed by 6 wk of nontreatment, and then MLD for 3 wk	31 women with breast cancer-related lymphedema All patients had two consistent limb volume measurements >10% excess volume	England

Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Andersen et al., 2000 ²⁰	<p>RCT</p> <p>(Single intervention—MLD—vs. standard therapy with cross-over at 3 mo from control group to intervention group allowed)</p>	<p>Group 1 (Intervention): Standard therapy (custom-made sleeve-and-glove compression garment, compression sleeve, education, and instruction in exercises) + MLD (23 patients)</p> <p>vs.</p> <p>Group 2 (Control): Standard therapy (21 patients)</p> <p>Intervention group received 1-hr sessions for MLD administered 8× in 2 wk with instruction in self-administered massage</p> <p>Cross-over from control group allowed after 3 mo (10 patients opted)</p>	<p>44 breast cancer patients attending lymphedema clinic</p> <p>Patients had a difference in volume between the two arms of at least 200 ml</p>	Denmark
Badger et al., 2000	<p>RCT</p> <p>(Simple trial: intervention MLB + hosiery vs. hosiery alone)</p>	<p>Group 1 (Intervention): MLB with standard treatment of hosiery (MLB+hosiery)</p> <p>vs.</p> <p>Group 2 (Control): Hosiery alone</p>	<p>90 patients (mostly women) with unilateral lymphedema of the upper or lower limbs</p> <p>The volume of affected arm was at least 20% greater than normal arm.</p>	London, England

²⁰ Included in Badger et al. (2005b).

Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Johansson et al., 1999	RCT (Trial with consecutive allocation. 2 wk one intervention (CB) then CB alone or CB + MLD)	Part I: CB for 2 wk for all patients, followed by (Part II): Group 1 (Intervention): CB+MLD (1 wk) vs. Group 2 (Control): CB alone (1 wk).	38 female patients with arm lymphedema after breast cancer surgery Patients had difference in volume >10% between normal and abnormal arm	Sweden
Shenoy et al., 1999	RCT	Each patient was randomly allocated to one of five daily regimens for 1 y and followed an additional year: 800-mg oral penicillin or 1 mg diethylcarbamazine (DEC)/kg (an antifilarial drug) or 800-mg oral penicillin plus 1-mg DEC/kg or Local antibiotics or Placebo	150 patients with lymphedema caused by brugian filariasis, each of whom recalled two or more attacks of ADL) Each patient was enrolled in a comprehensive footcare program	India
Boris et al., 1998	Observational study	Group 1 (Intervention): 53 patients using compression pumps vs. Group 2 (Control): 75 patients not using a compression pump	128 patients with lower limb lymphedema	United States

Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Dini et al., 1998 ²¹	RCT	Group 1 (Intervention): two cycles of five 2-hr sessions of IPC, separated by a 5-wk interval (40 patients) vs. Group 2 (Control): no treatment (40 patients)	80 patients with unilateral post-mastectomy lymphedema The differences in circumference measurements between limbs at each point were added together and the result was designated “delta.” Only patients with a baseline delta _{bas}) value 10 cm were considered to have clinically significant lymphedema.	Italy
Johansson et al., 1998	RCT	2 wk of compression sleeve for all patients, then randomization: Group 1: MLD (2 wk) vs. SPC (2 wk)	28 female breast cancer survivors Lymphedema was defined as >10% difference in volume between normal and affected limbs.	Sweden
Kasseroller, 1998 ²²	RCT (Simple trial of intervention—selenium versus placebo)	Group 1 (Intervention): Selenium (sodium selenite-penta-hydrate) (29 patients) vs. Group 2 (Control): placebo (28 patients). Both groups underwent 3 wk of physical therapy	Breast cancer patients in upper limb lymphedema clinic with history of >3 episodes of skin infection (erysipelas) in 2 yr	Austria

²¹ Excluded from review (did not meet criteria of 6 mo of follow-up or accepted measurement of lymphedema): Badger et al. (2005b).

²² Included in Badger, Seers, et al (2004).

Citation	Type of Study	Intervention vs. Comparison Group	Population Studied	Location
Shenoy et al 1998	RCT	In addition to local care of the affected limbs, the patients were randomly allocated to receive 12, monthly treatments of Ivermectin (400 micrograms/kg) DEC (10 mg/kg) or Placebo Patients were followed up for an additional year	120 patients who had each had at least two ADL attacks in the previous year were each admitted to the study at the time of an ongoing episode of ADL	India
Foldi, 1996	Observational study	Patients followed up for at least 2 yr after “Phase 1” of combined physiotherapy ²³ (the intensive treatment period). No comparison group	150 patients with arm lymphedema after treatment for breast cancer. Patients also had at least 3 episodes of DLA	Germany
Hornsby, 1995	RCT	Compression sleeves worn day and night (14 patients) vs. No sleeve (11 patients)	Patients with lymphedema attending a follow-up breast clinic	England

Key: ADL = adenolymphangitis; CB = compression bandaging; DLA = dermatolymphangiadenitis; DLT = decongestive lymphatic drainage; IPC = intermittent pneumatic compression; MLB = multi-layered bandaging; MLD = manual lymphatic drainage; RCT = randomized controlled trials; SLD = simple lymphatic drainage

²³ The term “combined physiotherapy” is a synonym for complex decongestive therapy.

Table B-2. Summary of Evidence of Effectiveness by Outcome for Technologies to Treat Lymphedema

Physical Outcome

Reduction in Limb Size (Reduction in Volume of Lymphedema²⁴)

Physical Therapy Interventions, favorable for most interventions
Multi-layer Bandaging (MLB), favorable
Compression Bandaging (CB), favorable
Manual Lymphatic Drainage (MLD), ambiguous, mixed evidence, but favorable for patients with mild lymphedema
Simple Lymphatic Drainage (SLD), pattern toward favorable
Intermittent Pneumatic compression therapy (IPC), favorable
Exercise, Pattern toward no effect/ weak evidence
Decongestive Lymphatic Therapy (DLT: MLD + CB), pattern toward favorable

Citation	Results	Categorization of Results (Significance, Direction)
McNeely et al., 2004	<p>A significant % reduction in lymphedema volume from baseline was found over 4-wk period of study for both MLD/CB and CB groups (p < 0.001 for both groups):</p> <p>MLD/CB group: 46.1% ± 22.6</p> <p>CB group: 38.6% ± 16.1</p> <p>The difference between the groups in milliliter reduction in volume was NS (p = 0.812).</p> <p>When patients were divided into groups (mild, moderate, and severe) based on the lymphedema volume, it was found that patients with mild lymphedema in the MLD/CB group experienced sig larger volume reductions. The box-plot provided in the paper shows that “MLD + CB” patients with mild lymphedema experienced ~70% volume reduction compared to those in the CB only group, who experienced ~35% volume reduction. (p value not provided)</p>	<p>Sig Favorable for both CB and CB + MLD groups in comparison with baseline.</p> <p>Difference between CB and CB + MLD groups: NS Favorable for CB + MLD group</p> <p>Sig Favorable for CB + MLD group for patients with mild lymphedema</p>

²⁴ For most of the studies, the measurement of lymphedema reduction that is used is “volume reduction”, i.e., the number of ml of fluid the intervention removes. Dini et al. (1998) used a measure of limb circumference instead of volume to assess lymphedema.

Citation	Results	Categorization of Results (Significance, Direction)
McKenzie and Kalda, 2003	<p>Subjects were tested every 2 weeks for 8 weeks (five tests, including baseline).</p> <p>Exercise group: Mean volume of affected arm as percentage of volume of unaffected arm ranged from ~123% to ~126%.</p> <p>Control group: Mean volume of affected arm as percentage of volume of unaffected arm ranged from ~132% at test 2 to 135% at test 5.</p>	<p>NS</p> <p>Pattern toward no effect/ weak evidence</p>
Szuba et al., 2002	<p>Study 1: After 2 weekswk, mean % reduction in volume of affected arm was 45.3% for 12 patients in group I (DLT + IPC) and 26% for group II (DLT alone) ($p < 0.05$).</p> <p>Study 2: Random, 2-month cross-over design with 6-month follow-up (25 patients completed study).</p> <p>DLT + IPC: mean reduction in volume of 89.5± 195.5 ml ($p < 0.05$)</p> <p>DLT group alone: During month of study increase in volume of treated limb of 32.7± 115.2 ml.</p>	<p>Sig</p> <p>Favorable for intervention (IPC)</p> <p>NS</p> <p>Unfavorable for DLT alone (sig level not provided)</p>
Williams et al., 2002 ²⁵	<p>All 29 subjects (2 subjects failed to complete the study) given advice on skin care and new elastic sleeves.</p> <p>Although this was a study with a cross-over design, the authors did not separate the results according to whether the patients underwent MLD or SLD first.</p> <p>MLD (45 minutes 5× per wk- Mon-Fri for 3 wks) produced a statistically sig ↓ in excess limb volume (mean difference, $d = 71$ ml, 95% CI = 16 to 126, $p = 0.013$).</p> <p>After SLD (taught by researcher and therapist and performed 20 min daily), there was a NS mean ↓ in excess limb volume (mean difference, $d = 30$ ml, 95% CI = -4 to 63, $p = 0.08$)</p>	<p>Sig</p> <p>Favorable for intervention (MLD)</p> <p>NS</p> <p>Favorable for SLD</p>

²⁵ Williams et al. (2002) also used before and after MLD and SLD caliper creep readings to obtain measurements of trunk swelling on affected side for 21 patients: MLD reduced readings on affected side ($d = 0.23$ mm, 95% CI = -0.01 to 0.47, $p = 0.06$). SLD was associated with a NS increase in caliper creep ($d = -0.07$ mm, 95% CI = -0.22 to 0.09, $p = 0.38$)

Williams et al. (2002) also measured skin thickness: MLD but not SLD significantly reduced dermal thickness on upper arm ($d = 0.15$, 95% CI = 0.12-0.29, $p = 0.03$). Neither MLD nor SLD significantly reduced dermal thickness at other sites along the arm (forearm, posterior axilla, or flank).

Citation	Results	Categorization of Results (Significance, Direction)
Andersen et al., 2000	<p>At 3 mo, 22 patients in intervention group and 20 patients in control group were evaluable. Intervention consisted of MLD 8× in 2 wk with training in self-massage to be done daily for remainder of 12 mo</p> <p>% reduction in excess limb volume in intervention (MLD) group: 48% Control (standard therapy) group: 60% (p = 0.66) Addition of MLD at cross-over did not further improve edema reduction (p=0.86).</p> <p>Authors concluded that improvements seen in both groups were attributable to use of compression sleeves and that MLD did not provide extra benefit</p>	<p>NS Unfavorable No benefit for intervention (MLD group)</p>
Badger et al., 2000	<p>MLB + hosiery group (comprised of 32 patients at week 24), either admitted to rehabilitation ward or seen as outpatients for 18 days of daily bandaging. Outpatients had bandages left in place over weekend</p> <p>Treatment followed by hosiery: 31% lymphedema volume reduction averaged over observation periods</p> <p>Hosiery group comprised of 47 patients: 15.8% lymphedema volume reduction averaged over observation periods- about half of MLB + hosiery group (p = 0.001)</p> <p>All patients followed for 24 wk. Arm sleeves replaced every 3-4 mo, stockings every 6 mo</p>	<p>Sig Favorable for MLB</p>

Citation	Results	Categorization of Results (Significance, Direction)
<p>Johansson et al., 1999</p>	<p>18 patients in the CB only group and 20 in the CB + MLD group. Bandage changed every 2nd day. MLD for 3rd wk only (45 min for 5 days).</p> <p>Part I: Mean lymphedema volume reduction for total group after CB was 188 ml ± 155 ml (p < 0.001), a mean reduction of 26 ± 15%.</p> <p>Part II: Volume reduction in CB group was 20±46 ml (p = 0.8). Volume reduction in CB + MLD group was 47±42 ml (p < 0.001)</p> <p>There was no sig difference between the 2 groups (p < 0.07)</p> <p>A further % reduction in Part II of 4 ± 10% (NS) in the CB group and 11 ± 9% (p < 0.001) in the CB + MLD group was obtained, revealing a sig difference between the two groups.</p>	<p>Sig Favorable for intervention (CB) relative to baseline</p> <p>Sig Favorable for intervention (CB+MLD) in comparison with baseline</p> <p>NS (A sig difference was not observed between those patients who received only CB and those who received CB + MLD.)</p> <p>Sig Favorable for CB + MLD compared to CB alone.</p>

Citation	Results	Categorization of Results (Significance, Direction)
<p>Dini et al., 1998 (<i>Note: Trial is a 9-wk trial that does not follow-up patients long enough to meet the standard of the Cochrane Review. In addition, the authors used the “Delta method,” not a volume method, as required by Cochrane</i>)</p>	<p>At the end of the study, 35 patients in the control group and 32 patients in the pneumatic compression (PC) group were evaluative evaluated in terms of absolute delta values²⁶. Mean baseline delta values were 14.6 ± 4.4, and 16.1 ± 5.4 in the control and PC groups, respectively, and mean end delta values were 14.1 ± 5.6 cm and 14.2 ± 6.0 cm in control and PC groups, respectively. Within-group comparison showed that the PC group had obtained a sig mean decrease in delta values, but the control group did not.</p>	<p>Sig Favorable for intervention (IPC)</p>
<p>Johansson et al., 1998</p>	<p>After Part I involving compression sleeve for both groups in the study: lymphedema reduced by 49 ml (7% reduction) ($p = 0.01$)</p> <p>After Part II (patients continued to wear compression sleeves), MLD group (45 min/day) decreased by 75 ml (15% reduction) ($p < 0.001$)</p> <p>SPC group: lymphedema reduced by 28 ml (7% reduction) ($p = 0.03$)</p> <p>NS difference between MLD and SPC in terms of reducing lymphedema volume.</p>	<p>Sig Favorable for intervention (compression sleeve) for outcomes of lymphedema volume and symptoms</p> <p>Sig Favorable for intervention (MLD)</p> <p>Sig Favorable for intervention (SPC)</p>

²⁶ The differences in circumference measurements between limbs at designated points were added together and result designated as “delta.”

Citation	Results	Categorization of Results (Significance, Direction)
Hornsby, 1995	<p>Fitted elastic compression sleeves + standard care group (exercise, skin care, and self-administered massage)</p> <p style="text-align: center;">versus</p> <p>Standard care</p> <p>8 of the 14 experimental group patients remained in the study for at least 16 wk, during which time they showed a ↓ in swelling ranging from 21% reduction to 70%. The patient with ↑ swelling showed a 66% ↑ in swelling at the end of 16 wk. However, swelling diminished so that at the end of the trial (32 wk), her arm was the same size as it had been at entry. Only 3 patients in the experimental group remained in the trial for the full 32 wk.</p> <p>4 of 11 patients in the control group showed reductions (ranging from 12% to 38%) in volume after 4 wk in the study. All but one dropped out by the end of 16 wk.</p> <p>High study drop-out rate was not explained.</p>	Sig Favorable for intervention group

Physical Outcome

Reduction of Limb Size (Reduction of Lymphedema Volume)

Pharmacologic Agents

Alpha-tocopherol (vitamin E) and pentoxifylline, no benefit for decreasing lymphedema

Citation	Results	Categorization of Results (Significance, Direction)
Gothard et al., 2004	% change in arm volume at 12 mo: 2.5% (95% CI -0.40 to 5.3) in treatment group versus 1.2% (95% CI -2.8 to 5.1) in placebo group Difference not clinically sig (p = 0.6) Quality of life: no sig changes in self-assessed function (data not provided)	NS No benefit from intervention (vitamin E) NS (information to determine direction not provided for quality of life data)

Management of Symptoms

Pain and Discomfort Level

Quality of Life

Manual Lymphatic Drainage (MLD)

Reduced worry, irritability, and depression, favorable for intervention

Reduced sleep disturbance, favorable for intervention

Reduced heaviness, favorable for intervention

Reduced tension, favorable for intervention

Compression Bandaging (CB)

Reduced pain, favorable for intervention

Reduced heaviness, favorable for intervention

Reduced tension, favorable for intervention

Compression Bandaging plus Manual Lymphatic Drainage (CB +MLD)

Reduced pain, favorable for intervention

Reduced heaviness, favorable for intervention

Reduced tension, favorable for intervention

Reduced pain, favorable for intervention

Citation	Results	Categorization of Results (Significance, Direction)
Williams et al., 2002	<p>Results from a EORTC QLC²⁷ self-reported questionnaire showed MLD improved emotional function:</p> <p>Reduced worry, irritability, tension, and depression ($d = 7.2$, 95% CI = 2.3 to 12.1, $p = 0.006$).</p> <p>Reduced sleep disturbance ($d = -9.2$, 95% CI = -17.4 to -1.0, $p = 0.03$).</p> <p>SLD- NS changes to any quality of life parameters</p>	<p>Sig Favorable for MLD</p> <p>Sig Favorable for MLD</p> <p>NS No effect</p>
Johansson et al., 1999	<p>Subjective assessment of pain, heaviness, and tension as measured on a 100-mm visual analogue scale:</p> <p>CB + MLD group: decreased pain ($p = 0.03$), heaviness and tension ($p < 0.001$)</p> <p>CB group: heaviness ($p = 0.006$) and tension ($p < 0.001$) were decreased (but not pain)</p>	<p>Sig Favorable for both CB and CB + MLD</p> <p>(but only CB + MLD sig ↓ pain)</p>

²⁷ The authors report that there are no condition-specific quality of life tools available for lymphedema. The EORTC QLC C30 is, according to the authors, an instrument consisting of 30 functional, symptom and individual items designed to address a range of quality of life issues relevant to cancer patients for patients to complete on their own. The instrument is apparently called by its abbreviation, and the authors do not provide information on the complete, unabbreviated name. However, a search on the internet reveals that the initials *EORTC* stand for the “European Organization for Research and Treatment of Cancer”.

Citation	Results	Categorization of Results (Significance, Direction)
Johansson et al., 1998	<p>Subjective assessment of pain, heaviness, and tension as measured on a 100-mm visual analog scale:</p> <p>Part 1 of study: (Compression sleeve) Decrease in tension ($p = 0.004$) and heaviness ($p = 0.01$)</p> <p>Part 2 of study: Only MLD group (not PC group) experienced further decrease of tension ($p = 0.01$) and heaviness ($p = 0.008$)</p>	<p>Sig Favorable for CB</p> <p>Sig Favorable for MLD</p>

Medical Complications
Infection rate

Multi-layer Bandaging, insufficient evidence
Decongestive lymphatic therapy (entire program), insufficient evidence
Hosiery, insufficient evidence
Selenium, favorable for reducing infections
Footcare combined with local antibiotics and antifungals, favorable
Penicillin, favorable
Diethylcarbamazine (DEC), insufficient evidence
Local antibiotics, favorable

Citation	Results	Categorization of Results (Significance, Direction)
Badger et al., 2000	Cellulitis during trial: MLB + hosiery group: 5 of 34 patients Hosiery-alone group: 3 of 49 patients	NS (statistical information not provided)
Shenoy et al., 1999	For each regimen group (including the placebo group), the number of ADL attacks in the treatment year was significantly less than that in the year prior to treatment ($p < 0.001$). There were: 127 episodes of ADL for all groups (150 patients) during treatment year 684 episodes reported for same participants during pretreatment year. 228 ADL episodes reported during follow-up year Mean number of inflammatory episodes: Penicillin group: 4.6 episodes (30 patients at start) 0.5 (26 patients after treatment) 1.9 (26 patients at end of follow-up) DEC group: 4.0 episodes (30 patients at start) 0.75 (28 patients after treatment)	Sig Favorable for footcare combined with local antibiotics and antifungal agents Diethylcarbamazine (DEC)

Citation	Results	Categorization of Results (Significance, Direction)
Shenoy et al., 1999 (continued)	<p>1.3 (29 patients at end of follow-up)</p> <p>DEC + penicillin group: 5.8 (30 patients at the start) 0.25 (29 patients after treatment) 2.1 (29 patients at end of follow-up)</p> <p>Local antibiotic group: 4.2 (30 patients at the start) 1.1 (29 patients after treatment) 1.8 (29 patients at end of follow-up)</p> <p>Placebo group: 4.7 (30 patients at start of treatment) 1.8 (28 patients after treatment) 1.0 (28 patients for at end of follow-up)</p> <p>In all but the placebo group, there was a slight increase in the number of episodes in the follow-up year compared with the treatment year, but the increase was only significant in the two groups given penicillin:</p> <p>Footcare seems to play the most important role in the prevention of ADL attacks. Additional benefit may accrue from local or systemic antibiotic use in those with high grades of edema, but antifilarials have no place in the prevention of ADL attacks in an individual patient</p> <p>For each regimen group (including the placebo group), the number of ADL attacks in the treatment year was significantly less than that in the year prior to treatment ($p < 0.001$).</p>	
Kasseroller, 1998	<p>0 of 29 cases of infection in intervention group (during initial 3-wk period and after 3-mo)</p> <p>1 of 28 cases of erysipelas (a particular type of skin infection that usually extends into cutaneous lymphatics) in placebo group during initial 3-wk period (50% exhibited erysipelas at 3 mo)</p>	<p>Sig at 3 mo Favorable for intervention group</p>

Citation	Results	Categorization of Results (Significance, Direction)
Shenoy et al., 1998	<p>Significant reduction in the frequency of ADL attacks in each of the three groups:</p> <p>Ivermectin (400 µg/kg), DEC (10 mg/kg), or placebo (in addition to local care of the affected limbs) during the 2-yr study period; $p < 0.001$ for each comparison</p> <p>There were no significant differences in frequency of attacks between the three groups, either at the end of the treatment phase or at the end of the post-treatment phase ($p > 0.15$ for each comparison)</p> <p>Conclusion: footcare combined with appropriate use of local antibiotics or antifungals is adequate to reduce the number of ADL attacks</p>	<p>Sig</p> <p>Favorable for footcare combined with local antibiotics and antifungals</p>
Foldi, 1996	<p>Of 150 women with a history of at least 3 episodes of dermatolymphangioadenitis (DLA) between 1990 and 1994, following DLT:</p> <p>95 (63.3%): no further DLA episodes 38 (25.3%): one recurrent DLA episodes 17 (11.3%) 3 or more recurrent DLA episodes</p> <p>59 (39.3%) of these women had DLA risk factors such as fungal infections, psoriasis, etc. Of these, 46 patients (77.9%) had episodes of DLA despite DLT. Long term antibiotic therapy might be warranted in this subgroup of patients</p>	<p>No comparison group</p>

Key: ADL = adenolymphangitis; CB = compression bandaging; DLA = dermatolymphangioadenitis; DLT = decongestive lymphatic drainage; IPC = intermittent pneumatic compression; MLB = multi-layered bandaging; MLD = manual lymphatic drainage; NS = nonsignificant; sig = significant; SLD = simple lymphatic drainage; SPC = sequential pneumatic compression

APPENDIX C

Cost Impact Analysis: General Caveats and Assumptions

This appendix describes general caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site, <http://www.chbrp.org/costimpact.html>.

The cost analysis in this report was prepared by Milliman and University of California, Los Angeles, with the assistance of CHBRP staff. Per the provisions of AB 1996 (California Health and Safety Code, Section 127660, et seq.), the analysis includes input and data from an independent actuarial firm, Milliman. In preparing cost estimates, Milliman and UCLA relied on a variety of external data sources. The *Milliman Health Cost Guidelines* (HCG) were used to augment the specific data gathered for this mandate. The HCGs are updated annually and are widely used in the health insurance industry to estimate the impact of plan changes on health care costs. Although this data was reviewed for reasonableness, it was used without independent audit.

The expected costs in this report are not predictions of future costs. Instead, they are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs could differ from these estimates for a wide variety of reasons, including:

- If the prevalence of mandated benefits before and after the mandate is different from our assumptions.
- If utilization of mandated services before and after the mandate is different from our assumptions.
- Random fluctuations in the utilization and cost of health care services.

Additional assumptions that underlie the cost estimates presented here are:

- Cost impacts are only shown for people with insurance.
- The projections do not include people covered under self-insurance employer plans because those employee benefit plans are not subject to state-mandated minimum benefit requirements.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.

There are other variables that may affect costs, but which Milliman did not consider in the cost projections presented in this report. Such variables include, but are not limited to:

- Population shifts by type of health insurance coverage. If a mandate increases health insurance costs, then some employer groups or individuals may elect to drop their coverage. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans. To help offset the premium increase resulting from a mandate, members or insured may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and the insured person, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). Milliman did not include the effects of such potential benefit changes in its analysis.

- Adverse Selection. Theoretically, individuals or employer groups who had previously foregone insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their medical management of the mandated benefit. This would tend to dampen our cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., FFS and PPO plans).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan types we modeled (HMO, PPO, POS, and FFS), there are variations in utilization and costs within California. One source of difference is geographic. Utilization differs within California due to differences in the health status of the local commercial population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between health plans and providers.

Both the baseline costs prior to the mandate and the estimated cost impact of the mandate could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, we have estimated the impact on a statewide level.

APPENDIX D
Information Submitted by Outside Parties for Consideration for CHBRP Analysis

In accordance with its policy to analyze evidence submitted by outside parties during the first two weeks of each 60-day review of a proposed benefit mandate, CHBRP received the following submissions:

Robert Weiss, MA, Lymphedema Treatment Activist, National Lymphedema Network
Health Care Coverage for Lymphedema—Short Fact Sheet
AB 1996 Responses
Cost-Efficacy of Lymphedema Treatment—Preliminary Model
Cost-Efficacy of Lymphedema Treatment—A Collection of Case Studies
Submission dated February 22, 2005

Kaiser Foundation Health Plan, Inc.,
Information about the clinical rationale and standards of care for the treatment of lymphedema.
Letter dated February 22, 2005

The following was submitted after the two week window:

Carolyn Chastain, B.S.
Letter in support of AB 213 and information regarding personal experience on being denied treatment for lymphedema care.
Letter dated April 1, 2005

CHBRP analyzes all evidence received during the public submission period according to its relevance to the proposed legislation and the program's usual methodological criteria. For more information about CHBRP's methods, to learn how to submit evidence relevant to an on-going mandate review, or to request email notification of new requests CHBRP receives from the California Legislature, please visit: <http://www.chbrp.org>.

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California Health Benefits Review Program Committees and Staff

A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis. The CHBRP **staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature. The level of involvement of members of CHBRP's Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others.

As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, Milliman, to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP's methods for assessing that impact.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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