December 20, 2012

# Annual Mandate Report: Coverage for Orthotics for Diabetics

Prepared for the Maryland Health Care Commission Pursuant to Insurance Article 15-1501 Annotated Code of Maryland



John Welch Karen Bender, FCA, ASA, MAAA Randall Fitzpatrick, ASA, MAAA



## Craig P. Tanio, M.D., Chair

Chief Medical Officer
JenCare Neighborhood Medical Centers

Garrett A. Falcone, Vice Chair Executive Director Heron Point of Chestertown

Reverend Robert L. Conway Retired Principal and Teacher Calvert County Public School System

John E. Fleig, Jr. Director United Healthcare

Paul Fronstin, Ph.D. Director, Health Research & Education Program Employee Benefit Research Institute

Kenny W. Kan Senior Vice President/Chief Actuary CareFirst BlueCross BlueShield

Robert Lyles, Jr., M.D. Medical Director LifeStream Health Center Barbara Gill McLean Retired, Senior Policy Fellow University of Maryland School of Medicine

Kathryn L. Montgomery, Ph.D. Associate Dean, Strategic Partnerships & Initiatives University of Maryland School of Nursing

Marilyn Moon, Ph.D. Vice President and Director, Health Program American Institutes for Research

Darren W. Petty Vice President Maryland State and DC AFL-CIO General Motors/United Auto Workers

Glenn E. Schneider Chief Program Officer The Horizon Foundation

Adam J. Weinstein, M.D. Medical Director Nephrology and Transplant Services Shore Health System

# Mandated Coverage of Foot Orthotics for People with Diabetes

Insurance Article § 15–1501, Annotated Code of Maryland, requires that the Maryland Health Care Commission (the Commission) annually assess the medical, social, and financial impact of proposed mandated health insurance services that failed to pass during the preceding legislative session or that are submitted to the Commission by a legislator by July 1 of each year. The assessment reports are due to the General Assembly annually by December 31.

Mercer and its sibling company, Oliver Wyman Actuarial Consulting, Inc., (collectively called "Mercer" in this report) have been contracted as the Commission's consulting actuary. We have prepared an evaluation for the single proposed newly mandated benefit: coverage of foot orthotics for people with diabetes.

This report includes information from several sources to provide more than one perspective on a proposed mandate. Mercer's intent is to be unbiased. At times, as a result, the report contains conflicting information. Although we included only sources that we consider credible, we do not state that one source is more credible than another. The reader is advised to weigh the evidence.

The Affordable Care Act (ACA) describes a broad set of benefits that must be included in any essential health benefit (EHB) package. In its December 2011 bulletin, the Department of Health and Human Services (HHS) provided guidance on the types of health benefit plans each state could consider when determining a benchmark EHB for its residents. The ACA also requires states to fund the cost of any mandates that are not reflected in the state-specific EHBs for policies purchased through the Health Benefit Exchange. Determining whether this particular mandate, if adopted, would require additional funding by the State of Maryland is outside the scope of this analysis. We bring this to the attention of policymakers as background.

Senate Bill 163 of the 2012 legislative session obligates health insurance carriers that are required to cover medically appropriate and necessary diabetes equipment, supplies, outpatient self-management training, and educational services to also cover orthotics for the management of a diabetic's feet. It is important to note that the proposed bill focuses on orthotics and not prosthetics. To clarify, prosthetics are artificial devices that replace a missing body part. Orthotics correct a physical deformity or malfunction, or support a weak or deformed portion of the body. Both are used by people with amputations, musculoskeletal conditions, neurological disorders, and congenital or acquired physically disabling conditions, as well as people who have suffered a stroke. Currently, Maryland mandates the coverage of prosthetics for a variety of conditions and requires coverage for medically appropriate and necessary diabetes equipment, supplies, outpatient self-management training, and educational services. The proposed bill adds orthotics for the management of a diabetic's feet. We attempted to obtain clarification on the intent of the legislation - specifically, how it differs from existing legislation; however, no additional guidance was provided by testimony during the bill hearings, inquiries to sponsors, legislative staff, etc. This analysis has been completed assuming that only medically necessary orthotics requiring a prescription would be eligible for coverage. Over-the-counter orthotics such as compression stockings which are gradient stockings that help control edema/lymphedema and aid in venous return would not be covered by this mandate, even if prescribed by a health care professional.

1

<sup>&</sup>lt;sup>1</sup> California Health Benefits Review Program. "Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices." June 15, 2006.

There are 23 states that currently mandate coverage of prosthetics and/or orthotics.<sup>2</sup> Over half cover both prosthetics and orthotics.<sup>3</sup>

### **Medical Impact**

In this section, we answer questions regarding diabetes treatments relating to the feet.

- What risks do foot problems pose for people with diabetes?
- What are the appropriate standards of care for patients?
- How are orthotics expenses typically covered?

### The Risks

Diabetes affects 25.8 million people – over 8% of the US population.<sup>4</sup> By 2034, the number of people with diagnosed or undiagnosed diabetes is expected to increase to 44.1 million, and annual diabetic spending could rise almost threefold, to \$336 billion in constant dollars.<sup>5</sup>

If we examine only the population under age 65, we note that 14.9 million people have either diagnosed or undiagnosed diabetes, which represents about 5.5% of the under-65 population in the US.<sup>6</sup>

Of the 25.8 million people with diabetes in this country, 15% will likely develop a foot ulcer in their lifetime. (Deep ulcers often become infected and these infections can lead to amputation of limbs or digits.) Diabetic foot ulcers are extremely common; 85% of all lower-limb amputations are attributed to them. Foot ulcers affect approximately 15% of all people with diabetes. Of those, 15% to 20% will lose a limb.

Foot problems are the most common cause of hospitalization among people with diabetes. Related services cost billions of dollars every year. More than 80,000 amputations are performed annually on people with diabetes, and almost 60% of these patients have a second amputation within three to five years of the first. Estimates are that 20% to 50% of these patients die within three years of the first amputation.<sup>10</sup> These numbers have not changed

<sup>&</sup>lt;sup>2</sup> V.C. Bunce, "Health Insurance Mandates in the States 2011." Council for Affordable Health Insurance. Alexandria, VA. (Accessed October 2012.)

<sup>&</sup>lt;sup>3</sup> K. Mason, R. Cauchi, Y. Chung, and A. Thangasamy. "Providing Diabetes Health Coverage: State Laws & Programs." National Conference of State Legislatures Health Program. Denver, CO. May 2011.

<sup>&</sup>lt;sup>4</sup> US Department of Health and Human Services, National Center for Chronic Disease Prevention and Health Promotion. "National Diabetes Fact Sheet, 2011." Atlanta, GA. (Accessed September 2012.)

<sup>&</sup>lt;sup>5</sup> E.S. Huang, A. Basu, M. O'Grady, and J.C. Capretta. "Projecting the Future Diabetes Population Size and Related Costs for the U.S." Diabetes Care, Volume 32, Number 12. December 2009. Care.Diabetesjournals.org

<sup>&</sup>lt;sup>6</sup> U.S. Department of Health and Human Services, National Center for Chronic Disease Prevention and Health Promotion.

<sup>&</sup>lt;sup>7</sup> T. Dutra. "The Diabetic Foot." FootAnkleHealth.com. <u>www.footanklehealth.com/diabetics/diabetic-foot.html</u>. Last updated September 25, 2012.

<sup>&</sup>lt;sup>8</sup> A. Gordois, P. Scuffham, A. Shearer, A. Oglesby, and J.A. Tobian. "The Health Care Costs of Diabetic Peripheral Neuropathy in the U.S." Diabetes Care, Volume 26, Number 6. American Diabetes Association. June 2003.

<sup>&</sup>lt;sup>9</sup> T. Dutra.

r. Duna.

<sup>&</sup>lt;sup>10</sup> I. Kruse and S. Edelman. "Evaluation and Treatment of Diabetic Foot Ulcers." Clinical Diabetes, Volume 24, Number 2, 2006.

much in the past 30 years, despite huge advances in the medical and surgical treatment of people with diabetes.<sup>11</sup>

#### Standards of Care

The feet of a person with diabetes are at risk for trauma because of a loss of protective sensation. <sup>12</sup> Nerve damage caused by diabetes can cause a person to lose sensation in his or her feet, potentially preventing the person from feeling a foot injury or a developing wound until severe damage occurs or an infection develops. <sup>13</sup>

Untreated or poorly treated foot problems can lead to serious complications – potentially life-threatening ones. Examples include:

- Infections (diabetes hinders the body's ability to fight infections)
- Deep ulcers
- Limb or digit amputation
- Deep internal bleeding<sup>14</sup>
- Inactivity-related complications (such as peripheral vascular disease; knee or hip problems; and wrist, elbow, or shoulder problems)<sup>15</sup>

These complications often lead to substantial and lasting disabilities.<sup>16</sup> In addition, mortality rates are high within three years of amputation.<sup>17</sup>

Diabetes can cause many complications that lead to diabetic foot problems. Several risk factors increase the risk of these problems, including:

- Improper footwear
- Foot abnormalities
- Nerve damage
- Poor circulation
- Trauma to the foot
- Seemingly minor infections, such as athlete's foot, ingrown toenails, or fungal infections<sup>18</sup>

Orthotics can play an important role in managing the diabetic foot. They are designed to accomplish the following:

- Redistribute pressure
- Absorb shear forces, i.e., the internal pressure on the foot that is attributed to external contact (Note: constant pressure can lead to dying tissue)

<sup>12</sup> D.L. Bartley. "The Role of Orthotics in the Management of the Diabetic Foot." Clinical Topics, The Canadian Orthopaedic Association. 2009. (Accessed September 26, 2012.)

<sup>15</sup> T. Dall, S.E. Mann, Y. Zhang, J. Martin, Y. Chen, and P. Hogan. "Economic Costs of Diabetes in the U.S. in 2007." Diabetes Care, Volume 31, Number 3. March 2008.

<sup>11</sup> lbid.

<sup>13</sup> T. Dutra.

<sup>14</sup> Ibid.

<sup>16</sup> Ihid

<sup>&</sup>lt;sup>17</sup> I. Kruse and S. Edelman.

<sup>&</sup>lt;sup>18</sup> T. Dutra.

- Reduce internal mechanical stress
- Immobilize or control motion of the foot or ankle

The goal is to prevent trauma, foot ulcers (open sores on the feet), and associated morbidity. 19

Studies indicate that custom orthotics can reduce the recurrence rate of neuropathic foot ulcers (those leading to amputation) in people with diabetes from 83% to 26%.<sup>20</sup> (Interestingly, there is no similar evidence that custom orthotics can prevent an initial open sore from developing.)<sup>21</sup> Patient compliance with the prescribed regimen is critical to success.<sup>22</sup> Another study seemingly conflicts: A 2002 randomized controlled trial indicated no appreciable difference in the reulceration rate between users of therapeutic shoes and inserts and users of typical footwear.<sup>23</sup> This study suggests that health professionals' careful attention to foot care may be more important than therapeutic orthotics but acknowledges that special footwear could be beneficial for people with diabetes who are not monitored so closely by their health care providers.<sup>24</sup>

Normal feet withstand the pressures of normal walking, including friction, plantar pressure, and compression/shear forces. Friction may lead to blisters when the foot is subject to constant, rapid friction – or calluses or corns when subject to slow, intermittent friction. In the diabetic foot, changes in these mechanical stresses due to bony abnormalities, limited joint mobility, skin changes, and peripheral nerve damage significantly increase the risk of ulceration. When pain sensors are intact, foot pain and discomfort provide an early warning to the individual. When the pain sensors are compromised, as they are for many people with diabetes, neuropathic sores can develop during even the moderate repetitive pressure of walking. Orthotics can be considered pressure off-loading devices, and off-loading of pressure is an established treatment option for diabetic ulcers.

If a person with diabetes has pain sensors intact, orthotics are not usually needed. However, once pain sensors are compromised, prevention of the first foot ulcer is critical.<sup>27</sup> The National Hansen's Disease Center (NHDC) outlined specific foot risk categories and suggested protective footwear for each one (The NHDC in Carville, Louisiana, was closed in 1999, but its work is continued through the Louisiana State University Health Sciences Center). As the NHDC care grid shows in Table 1, orthotics play an important role in the more advanced risk categories.<sup>28</sup>

```
<sup>19</sup> D. Bartley.
```

<sup>&</sup>lt;sup>20</sup> Ibid.

<sup>21</sup> lbid.

<sup>22</sup> lbid.

<sup>&</sup>lt;sup>23</sup> G.E. Reiber, D.G. Smith, C. Wallace, K. Sullivan, S. Hayes, C. Vath, M.L. Maciejewski, O. Yu, P.J. Heagerty, and J. Lemaster. "Effect of Therapeutic Footwear on Foot Reulceration in Patients With Diabetes." Journal of the American Medical Association, Volume 287, Number 19. May 15, 2002.

<sup>24</sup> Ibid.

<sup>25</sup> D. Bartley.

<sup>26</sup> Ibid.

<sup>&</sup>lt;sup>27</sup> "Comprehensive Diabetes Lower Extremity Amputation Program: Risk and Management Categories for the Foot." National Hansen's Disease Center in Carville, LA. 1999. www.medschool.lsuhsc.edu/dfp/Categories.PDF

<sup>28</sup> lbid.

### Table 1

# LSU Health Sciences Center Diabetes Foot Program Lower Extremity Amputation Prevention Program

### Risk and Management Categories for the Foot

Risk Category Description		
0	Diabetes, but no loss of protective sensation in feet	
1	Diabetes, loss of protective sensation in feet	
2	Diabetes, loss of protective sensation in feet with <u>either</u> high pressure (callout/deformity) or poor circulation	
3	Diabetes, history of plantar ulceration or neuropathic fracture	
Note: "loss of pr	otective sensation" is assessed using a 5.07 monofilament at 10 locations on each foot	

Category	Management Category
	Education emphasizing disease control, proper shoe fit/design
0	Follow-up yearly for foot screen
	Follow as needed for skin/callus/nail care or orthoses
	Education emphasizing disease control, proper shoe fit/design, daily self-inspection,
1	skin/nail care, early reporting of foot injuries
	Proper fitting/design footwear with soft inserts/soles
	Routine follow-up 3 – 6 months for foot/shoe examination & nail care
	Education emphasizing disease control, proper shoe fit/design, self-inspection,
2	skin/nail/callus care, early reporting of foot injuries
	Depth-inlay footwear, molded/modified orthoses; modified shoes as needed
	Routine follow-up 1 – 3 months for foot/activity/footwear evaluation and callus/nail care
	Education emphasizing disease control, proper fitting footwear, self-inspection,
3	skin/nail/callus care and early reporting of foot injuries
	Depth-inlay footwear, molded/modified orthoses; modified/custom footwear, ankle-foot
	orthoses as needed
	Routine follow-up 1 – 12 weeks for foot/activity/footwear evaluation and callus/nail care

Diabetes foot clinic visit frequency may vary based on individual patient needs.

Absent the requested guidance, it remains unclear whether the proposed mandate includes both custom and non-prescription orthotics, and Maryland's health insurance carriers have assumed it covers only prescription orthotics. Care literature discounts the effectiveness of non-prescription orthotics in some cases because they "may not be satisfactory in cushioning, protecting, and redistributing high plantar pressure in the person with a neuropathic or morphologically abnormal foot." The decision is best made by the care provider. The NHDC guide suggests that custom orthotics are the rule in the more advanced risk categories. 31

\_

<sup>&</sup>lt;sup>29</sup> D.L. Bartley,

<sup>&</sup>lt;sup>30</sup> M.L. Maciejewski, G.E. Reiber, D.G. Smith, C. Wallace, S. Hayes, and E.J. Boyko. "Effectiveness of Diabetic Therapeutic Footwear in Preventing Reulceration." Diabetes Care, Volume 27, Number 7. American Diabetes Association. July 2004.

<sup>&</sup>lt;sup>31</sup> "Comprehensive Diabetes Lower Extremity Amputation Program: Risk and Management Categories for the Foot." National Hansen's Disease Center in Carville, LA. 1999. www.medschool.lsuhsc.edu/dfp/Categories.PDF

### The Coverage

Carriers cover orthotics for the treatment of a diabetic's feet in different ways, often dictated by the terms of any applicable mandates in the situs jurisdictions. (Some jurisdictions require that services be covered as any other basic health service, some mandate that coverage be offered as an option, and some have no relevant requirement at all). Fundamentally, services may be included in a package of basic benefits generally extended to all contract holders, offered as an optional benefit in at least one of the carrier's product offerings, or excluded. In the first two instances, coverage may be no less than coverage for other basic services or as determined by the carrier; i.e., there may be a mandate to offer but no minimum plan requirements.

Until recently, orthotics for the treatment of a diabetic's feet, if covered, were included in a plan's durable medical equipment (DME) provisions. These DME benefits often included separate annual and lifetime benefit maximums, specific deductible and coinsurance provisions, and frequency limitations. Benefits were only payable if prescribed by a physician or other approved health care provider and if the services met the carrier's medical necessity criteria. In some jurisdictions, the provider list might be more extensive.

More recently, annual and lifetime benefit maximums have disappeared, and copayment, coinsurance, out-of-pocket limits, et al, have followed the rules applicable to other services. However, carriers often continue to impose frequency limitations and, in addition, subject these services to medical necessity rules.

## **Social Impact**

In this section, we address the following questions:

- To what extent will the proposed mandate generally be used by a significant portion of the population?
- To what extent is the insurance coverage already available?
- To what extent does the lack of coverage result in individuals' avoiding necessary health care treatments?
- To what extent does lack of coverage result in unreasonable financial hardship?
- What is the level of public demand for these services?
- To what extent is the mandated health insurance service covered by self-funded employers in the State with at least 500 employees?

According to the CDC, there are 302,000 people in Maryland with diabetes, including 185,000 under age 65.<sup>32</sup> Based on a 2011 US Census estimate of the number of people under age 65 covered by private health benefit plans,<sup>33</sup> we estimate that there are 160,000 insured Marylanders under age 65 with diabetes. Approximately 15% (24,000) of those people will develop foot ulcers, and 15% to 20% of those (3,600 to 4,800) will lose a limb at some point in their life.

\_

<sup>&</sup>lt;sup>32</sup> K. Mason et al.

<sup>&</sup>lt;sup>33</sup> C. DeNavas-Walt, B.D. Proctor, and J.C. Smith. U.S. Census Bureau, Current Population Reports, P60-243. "Income, Poverty, and Health Insurance Coverage in the United States: 2011." U.S. Government Printing Office, Washington, DC. 2012.

Approximately 720 to 2,400 will die within three years of the first amputation.<sup>34</sup> Data suggest that recurring neuropathic foot ulcers, which can lead to amputation, could be reduced by two-thirds through the proper use of orthotics.<sup>35</sup>

Medicare currently covers therapeutic shoes or inserts for people with diabetes who have severe diabetic foot disease. Eligibility requirements are as follows: (1) the need must be certified by a doctor, (2) a podiatrist or other qualified doctor must prescribe the shoes or inserts, and (3) a doctor or other qualified individual – such as a pedorthist, orthotist, or prosthetist – must fit and provide the shoes. Medicare will cover one pair of therapeutic shoes and inserts per calendar year, and shoe modifications may be substituted for inserts.<sup>36</sup>

In a survey of Maryland's health insurance carriers conducted as part of this study, all but one carrier that responded to this question reported that they cover prescribed medically necessary orthotics for the treatment of a diabetic's feet for substantially all of their customers. Eligible expenses are covered without any annual dollar limits or frequency limits.

Table 2 summarizes the carrier's responses to the survey.

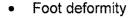
<u>Table 2</u>

Coverage of Orthotics for Diabetic Feet

Health Plan	Percentage of Medically Necessary Orthotics Covered by Carriers Responding to this Survey	
Carrier 1	Did not respond	
Carrier 2	Just under 100%	
Carrier 3	100% for customers with impaired peripheral sensation and/or altered peripheral circulation	
Carrier 4	100% with prior authorization	
Carrier 5	94%	
Carrier 6	100%	
Carrier 7	0%	

While there appeared to be some anecdotal indication that health benefit plans have cut back on the coverage of certain services for the treatment of a diabetic's feet in the last several years, none of the carriers surveyed indicated any change in medical policy for these items during the last five years. Some plans indicated they had eliminated any annual or lifetime maximums to comply with ACA – which results in an expansion of coverage as opposed to a cutback.

All of the carriers indicated that they apply "medical necessity" when determining whether orthotics are eligible for payments. Although there is no standard definition of "medical necessity" in Maryland that carriers must use to determine eligibility of orthotics for members with diabetes, the following criteria are a good representation:



<sup>&</sup>lt;sup>34</sup> I. Kruse and S. Edelman.

<sup>35</sup> Ibid.

<sup>26</sup> 

<sup>&</sup>lt;sup>36</sup> "Medical Coverage of Durable Medical Equipment and Other Devices." Centers for Medicare & Medicaid Services. Department of Health & Human Services. (Accessed October 19, 2012.)

- History of pre-ulcerative calluses
- History of previous ulceration
- Peripheral neuropathy with evidence of callus formation
- Poor circulation
- Previous amputation of the foot or part of the foot

Most employer plans, especially those sponsored by large employers, would have minimal or no compliance costs, as services are currently covered.

None of the surveyed health benefit plans in Maryland reported dollar or other limits on medically necessary orthotics for the treatment of a diabetic's feet. Maryland insurance carriers reported that generally all of the large self-insured plans that they administer treat these expenses the same as insured plans.

The Maryland surveyed health benefit plans also estimated the out-of-pocket expenses for each member with diabetes. The reported numbers shown in Table 3 ranged widely, suggesting potential reporting inconsistency.

<u>Table 3</u>
Estimated Out-of-Pocket Expenses for Members with Diabetes

Health Plan	Out-of-Pocket Expenses per Diabetic Member
Carrier 1	Did not report
Carrier 2	2010: \$0 - \$36,865 (\$660 median)
	2011: \$0 - \$43,310 (\$661 median)
Carrier 3	2010: \$102 median
	2011: \$81 median
Carrier 4	Did not report
Carrier 5	2010: \$0 - \$4,650 (\$44 median)
	2011: \$0 - \$7,000 (\$63 median)
Carrier 6	0 – 50%*
Carrier 7	2010: \$0 - \$194.05
	2011: \$0 - \$243.66

<sup>\*</sup>From this carrier's response, it appears that the 50% reflects the maximum coinsurance required for orthotics.

We also surveyed several of Maryland's labor plans and received responses from four. Each indicated that its plan covered the services specified in the proposed mandate. As a result, there was no reported impact on costs if the mandate were adopted.

Table 4 indicates any circumstances in which coverage might be denied and any contractual limitations regarding coverage.

<u>Table 4</u>
Labor Plans' Exclusions and Limitations for Orthotics

Labor Plan	Coverage Exclusions	Contractual Limitations
Plan A Plan B	Orthotic must be prescribed by a physician and patient must receive preauthorization  Therapeutic shoes (depth or	Orthotic must be the least expensive product available to meet the patient's needs as determined by the health plan.  One of the following per year if
FIGILE	custom-molded) along with inserts must be medically necessary for the treatment of diabetes mellitus and any of the following complications involving the foot:  Foot deformity, or History of pre-ulcerative calluses, or History of previous ulceration, or Peripheral neuropathy with evidence of callus formation, or Poor circulation, or Previous amputation of the foot or part of the foot	medically necessary:  No more than one pair of custom-molded shoes (including inserts provided with the shoes) and two additional pairs of inserts, or  No more than one pair of depth shoes and three pairs of inserts (not including the non-customized removable inserts provided with such shoes)
Plan C	None	\$200/calendar year
Plan D	None	None

Based on the results of our review, coverage for physician-prescribed foot orthotics for diabetic patients is almost universal for insured health benefit plans in Maryland. The median out-of-pocket cost for insureds with diabetes ranges from \$44 to \$661 for health benefit plans with group coverage. One carrier reported higher costs, but that is probably more reflective of the fact that they operate exclusively in the individual market, where cost sharing generally is much greater than in the group market. If the mandate were extended to include over-the-counter orthotics, the results could be different.

# Financial Impact

In this section, we estimate the cost of enacting the proposed mandated benefit and compare the results of our analysis with those of publicly available sources. Our discussion of the financial impact assumes that only orthotics prescribed by an authorized physician would be required to be covered thereby excluding costs associated with over-the-counter orthotics.

Mercer surveyed seven major carriers in Maryland to obtain information on current practices regarding coverage of orthotics for the management of a diabetic's feet. All seven carriers provide coverage for orthotics at levels close to the proposed mandate, with six of the seven carriers stating that the financial impact of the proposed mandate would be 0.1% or less. One carrier did state that the financial impact could be 0.5%. However, the same carrier stated that 100% of its members have coverage for orthotics at levels that are consistent with the proposed

mandate. These appear to be contradictory statements. In Table 5, we have summarized the estimated premium impact of the proposed mandate as reported by the carriers.

<u>Table 5</u>

Proposed Mandate's Estimated Impact on Premium

	Predicted Rate Impact	
Carrier 1	0.04 - 0.05%	
Carrier 2	0%	
Carrier 3	0.5%	
Carrier 4	0%	
Carrier 5	Less than 0.1%	
Carrier 6	0%	
Carrier 7 0.05%		

Mercer also surveyed several labor plans to obtain information on current practices regarding coverage of orthotics for the management of a diabetic's feet and the financial impact of the proposed mandate. All surveyed plans currently cover orthotics at a level that is consistent with the proposed mandate. Consequently, the marginal financial impact of this mandate for these plans would be zero. Note, the labor plans did state there are contract limitations on orthotic devices, which were discussed in a prior section of this report. If orthotics are considered to be part of an EHB, then annual dollar limits would no longer be allowed under the ACA (although it appears that limitations on the number of orthotics covered within a given year may be allowed). If orthotics are not considered to be part of an EHB, then annual dollar limits could continue.

Using an internal database that contains 2010 medical and prescription drug claims for over 45 million members (including 384,000 residing in Maryland), we estimated the annual claims costs to cover lower-limb orthotics. We pulled these data separately for members diagnosed with diabetes in 2010 and for members without a diabetes diagnosis anytime in 2010.<sup>37</sup> The majority of the costs associated with foot orthotics are for members who have not been diagnosed with diabetes in the same year. In 2010 dollars, the average annual cost for a lower-limb orthotic device was roughly \$150 and the PMPM cost was \$0.25. Only 12% of the cost (or \$0.03 PMPM) was associated with people diagnosed with diabetes. In today's market, diagnostic coding on claims data is **not always required** for a claim to be paid.<sup>38</sup> Consequently, the \$0.03 PMPM estimate may be understated. The total cost for foot orthotics, \$0.25 PMPM, is consistent with the carriers' estimations. For this analysis, it was assumed that 100% of the cost of the foot orthotics provided would be covered under the proposed mandate.

The estimates provided include only the cost to cover foot orthotics. There can be significant costs associated with treating foot ulcers. It is unclear whether orthotics limit the risk of foot ulcers for people with diabetes. However, the cost to treat foot ulcers can range from \$8,000 to \$17,000 (if infected).<sup>39</sup> This imposes a much more significant cost to the health benefit plan relative to offering orthotics for roughly \$150.

10

<sup>&</sup>lt;sup>37</sup> Diabetes diagnoses were identified as members with a diagnostic code of 249 or 250 at any point in 2010.

<sup>&</sup>lt;sup>38</sup> Unlike Medicare Advantage and Medicare Part D, which impose financial consequences for incomplete coding of fields not critical to the payment of claims, commercial carriers' focus has been timely payment of claims to avoid penalties from the U.S. Department of Labor.

<sup>&</sup>lt;sup>39</sup> http://care.diabetesjournals.org/content/26/6/1790.full.pdf

It is estimated that roughly 15% of people with diabetes develop a foot ulcer at some time in their life.<sup>40</sup> Assuming this represents the diabetic population that would medically necessitate lower-limb orthotics, it is estimated that just over 1% (15% x 8%<sup>41</sup>) of the population would be eligible for foot orthotics. With an average cost of \$150, if each eligible person purchased one lower-limb orthotic in a year, the PMPM cost would be \$0.15. This is reasonably close to the estimate developed using the internal claims data.

Mercer's estimate for the full cost of the proposed mandate is between \$0.15 and \$0.25 PMPM. We define the marginal cost of a proposed mandate as the additional cost carriers will incur as a result of being required to provide coverage for a proposed mandate that they would not have provided without the mandate. Table 6 summarizes the full and marginal cost of the proposed mandate.

<u>Table 6</u>
Full and Marginal Cost Estimates for Mandated Coverage of Orthotics

	Full Cost	Marginal Cost
Estimated cost as a % of average cost per group policy	0.03% to 0.06%	0.00%
Estimated cost as a % of average wage	0.00% to 0.01%	0.00%

These cost estimates are consistent with the estimates provided by the carriers that were surveyed for this analysis.

<sup>40</sup> Ibid.

<sup>1</sup> 

### References

Bartley, D.L. "The Role of Orthotics in the Management of the Diabetic Foot." Clinical Topics, The Canadian Orthopaedic Association. 2009. (Accessed September 26, 2012.)

Bunce, V.C. "Health Insurance Mandates in the States 2011." Council for Affordable Health Insurance. Alexandria, VA. (Accessed October 2012.)

California Health Benefits Review Program. "Analysis of Assembly Bill 2012 – Amended: Orthotic and Prosthetic Devices." June 15, 2006.

CareFirst Medical Policy Reference Manual, Orthotic Devices https://provider.carefirst.com/wps/portal/!ut/p/c5/04\_SB8K8xLLM9MSSzPy8xBz9CP0os3hLbzN\_Q09LYwMDM0NLA09fd0cT97BglwNHI\_1wkA68KgqysxUBJo4OWA!!/?WT.z\_navItem=Medical Policies&WT.z\_from=providerLeftNav (Accessed October 18, 2012.)

Centers for Medicare & Medicaid Services. "Medical Coverage of Durable Medical Equipment and Other Devices." Department of Health & Human Services. (Accessed October 19, 2012.)

Dall, T., S.E. Mann, Y. Zhang, J. Martin, Y. Chen, and P. Hogan. "Economic Costs of Diabetes in the U.S. in 2007." Diabetes Care, Volume 31, Number 3. March 2008.

DeNavas-Walt, C., B.D. Proctor, and J.C. Smith. U.S. Census Bureau, Current Population Reports, p60–243. "Income, Poverty, and Health Insurance Coverage in the United States: 2011." U.S. Government Printing Office. Washington, DC. 2012.

Dutra, T. "The Diabetic Foot." FootAnkleHealth.com. www.footanklehealth.com/diabetics/diabetic-foot.html. (Last updated September 25, 2012.)

Gordois, A., P. Scuffham, A. Shearer, A. Oglesby, and J.A. Tobian. "The Health Care Costs of Diabetic Peripheral Neuropathy in the U.S." Diabetes Care, Volume 26, Number 6. American Diabetes Association. June 2003.

Huang, E.S., A. Basu, M. O'Grady, and J.C. Capretta. "Projecting the Future Diabetes Population Size and Related Costs for the U.S." Diabetes Care, Volume 32, Number 12. December 2009. Care.Diabetesjournals.org

Kruse, I., and S. Edelman. "Evaluation and Treatment of Diabetic Foot Ulcers." Clinical Diabetes, Volume 24, Number 2. 2006.

Maciejewski, M.L., G.E. Reiber, D.G. Smith, C. Wallace, S. Hayes, and E.J. Boyko. "Effectiveness of Diabetic Therapeutic Footwear in Preventing Reulceration." Diabetes Care, Volume 27, Number 7. American Diabetes Association. July 2004.

Mason, K., R. Cauchi, Y. Chung, and A. Thangasamy. "Providing Diabetes Health Coverage: State Laws & Programs." National Conference of State Legislatures Health Program. Denver, CO. May 2011.

National Hansen's Disease Center in Carville, LA. "Comprehensive Diabetes Lower Extremity Amputation Program: Risk and Management Categories for the Foot." 1999. www.medschool.lsuhsc.edu/dfp/Categories.PDF

Reiber, G.E., D.G. Smith, C. Wallace, K. Sullivan, S. Hayes, C. Vath, M.L. Maciejewski, O. Yu, P.J. Heagerty, and J. Lemaster. "Effect of Therapeutic Footwear on Foot Reulceration in Patients With Diabetes." Journal of the American Medical Association. Volume 287, Number 19. May 15, 2002.

U.S. Department of Health and Human Services, National Center for Chronic Disease Prevention and Health Promotion. "National Diabetes Fact Sheet, 2011." Atlanta, GA. (Accessed September, 2012.)