

WORCESTER POLYTECHNIC INSTITUTE

Robotic Prosthetic Availability Analysis

An Interactive Qualifying Project Report:

Submitted to the Faculty of the

WORCESTER POLYTECHNIC INSTITUTE

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Date Submitted:

May 31, 2012

Table of Contents

Table of Figures	iv
Table of Tables	v
Abstract	1
Acknowledgements.....	2
Executive Summary	3
Background.....	5
Amputation Statistics	5
Why Microprocessor Controlled Prosthetics?.....	7
HCPCS Level II Codes (L-Codes).....	9
Prosthetist Company Insurance Contracts.....	11
Health Insurance Coverage of Prosthetic Devices	12
An Explanation of Level II Modifiers (K-Levels)	15
Parity Laws.....	16
Donation	17
Methodology.....	18
Results.....	19
Prosthetist Survey Data	19
Prosthetist Interview Questions and Answers	20
Amputee Survey Data	26
Interview with Hugh Herr ²⁴	28
Interview with Bob Dzuranda ¹²	30
Conclusions.....	31
Prosthetist Survey Conclusions.....	31
Amputee Survey Conclusions	32
Discussion.....	33
Prosthetist Survey Discussion	33
The Issues with Insurance Contracts and L Codes.....	34
The Prosthetic Designer’s Dilemma	35
The Issues with Level II Modifiers (K-Levels).....	36
Need for Parity Laws.....	38

Future Work	39
Surveys and Studies	39
Free Market	39
Prosthetist Hospital Integration	40
Appendix.....	41
HCPCS Code Addition/ Revision Application Form.....	41
HCPCS Revision/Addition Flow Chart	45
Definitions and Clarifications of HCPCS Flow Chart.....	46
Some Health Insurance Quotes	47
A Description of each K Level and the Amputee Mobility Predictor Tool	51
Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices	54
Prosthetic Designers/Manufacturers Interview Questions	56
Robotic Prosthetic User Survey	58
Amputee Survey Flyer	61
Works Cited	62

Table of Figures

Figure 1: Amputation by Location ¹⁶	5
Figure 2: Amputation by Cause ¹⁶	6
Figure 3: An Excerpt from Maryland’s SB 98 (2008), Prosthetic Parity Act (amputecoalition.org) ¹⁷	16
Figure 4: HCPCS Revision/Addition Flow Chart (cms.gov).....	45

Table of Tables

Table 1: C-Leg vs. Non-Microprocessor Knees ⁸	8
Table 2: Examples of Out-Of-Pocket Expenses with a Family Plan ¹³	13
Table 3: Examples of Out-of-Pocket Expenses with an Individual Plan ¹³	14
Table 4: Amputee Survey Questions and Responses.....	26
Table 5: Aetna Health Insurance Quotes ¹⁵	47
Table 6: Assurant Health Insurance Quotes ²⁸	48
Table 7: Anthem Blue Cross Blue Shield Health Insurance Quotes ¹³	49
Table 8: Medicare Coverage ¹⁴	50
Table 9: Description of K Levels ²⁹	51
Table 10: The Amputee Mobility Predictor Tool ²⁹	53

Abstract

Microprocessor controlled lower-limb prosthetics provide many advantages over mechanical prosthetics such as, increased walking speed, decreased self-reported falls and stumbles, and boosted self-image. However, these devices remain out of the financial reach of the average prosthetic user. Interviews were performed with Hugh Herr, Bob Dzuranda, and prosthetists in the New England area in order to investigate a means to increase robotic prosthetic availability. It was determined that the prosthetics industry suffers from a slow billing code application process, Medicare-imposed fitness restrictions (on amputees that are likely to suffer from diabetes or obesity), insurance contracts that hurt prosthetist office profits, and private health insurance plans that restrict patients' options.

Acknowledgements

We would like to extend a very special thanks to our advisor Marko Popovic, whose experience in designing electronic prosthetics provided us guidance and insight. His previous work experience with Hugh Herr was also incredibly helpful in establishing contact and arranging an interview with Hugh.

We would also like to thank Hugh Herr and Bob Dzuranda for taking time out of their busy schedules to speak with us. The experiences they shared helped illuminate details about the prosthetics industry that this report would have otherwise lacked.

Lastly, we would like to thank the prosthetists and amputees who participated in this study.

Executive Summary

In recent years, news and media outlets have applauded the advancements in robotic prosthetics, with special attention being paid to Dean Kamen's DEKA arm and Hugh Herr's PowerFoot BiOM.^{1,2} Robotic prosthetics have been getting extra attention in the past decade due to the large number of amputees returning from Iraq and Afghanistan. According to the Congressional Research Service, the number of returning soldiers with full limb and/or partial amputation has climbed to over 1,600 as of 2010.³ This is only a small fraction of the U.S. population of amputees, however, which includes approximately 1.9 million individuals.⁴ Despite the growing need for prosthetics that suit the active user's lifestyle, these devices still remain out of the financial reach of the average user.

Many never look at the fine print of their private health insurance to see how much of the price of a prosthetic will be covered in case of an accident. Private insurers typically cover anywhere from 50-80% of the cost of a prosthetic, but some health insurance plans limit the insured member with payment caps that barely cover the cost or only allow the insured 1 prosthetic for a lifetime. The price of these prosthetics is also variable, depending on what the insurance contract between the insurer and the prosthetist office stipulates. After interviewing prosthetists we found that microprocessor knees can cost anywhere from \$33,000-\$80,000 and robotic upper limb prosthetics can cost anywhere from \$20,000-\$120,000.⁶ As a result of these high prices and poor insurance coverage, stories where amputees are denied robotic prosthetics are all too common. For example, Robert Riiber, a bilateral transfemoral amputee (both legs amputated above the knee) was unable to purchase two C-Legs with the insurance he had. He reported falling a total of 25 times with his traditional prosthetics, once while he was crossing the street.² He was forced to quit his job so he could become eligible for Medicare, since Medicare covers 80% of the cost of the device.

To further add insult to injury, Medicare and other insurers require that the patient meet physical fitness requirements before receiving a lower limb robotic prosthetic. The patient is asked to perform a series of tasks, as shown in Table 10 of the Appendix, and is diagnosed a functional level, or "K Level." Only the highest two K Levels, K3 and K4, are eligible to receive a robotic lower limb prosthetic, which excludes a large portion of elderly or diabetic patients, who make up the majority of lower limb amputations. These physical restrictions keep K2 Level patients from receiving microprocessor knees, despite the fact that a report from the Veteran's Affairs showed that K2 Level amputees were capable of increasing their activity level to K3 with the use of a robotic prosthetic. The interview results from the prosthetist interviews supported this claim, since 4/5 prosthetists answered that some of their patients who don't use a robotic prosthetic would benefit from one. Of the four that said their patients would benefit from a robotic prosthetic, two said that K2 Levels should be granted access to robotic prosthetics.

Hugh Herr was interviewed in order to gain an insight from a prosthetic designer's point of view. Herr, who wears two powered ankle prosthetics himself, acknowledged that health

insurance companies are reluctant to pay for devices that they deem not “medically necessary.” Herr claimed that health insurance companies would be more willing to pay for robotic prosthetics if they understood that they would actually be saving money because microprocessor controlled prosthetics prevent the patient from suffering from repeated falls and long-term related injuries. For example, the development of knee or hip problems from walking incorrectly could cost \$80,000-\$150,000 to fix with surgery (Analysis of Assembly Bill in the Appendix). However, since robotic prosthetics are still relatively new, there are no long term studies available to assert this claim to health insurance companies.

After interviewing Bob Dzuranda, president of the prosthetic-fitting company Biometrics, it was discovered that most private insurers do not reimburse prosthetist offices as much for prosthetics as Medicare does, and that these reimbursement rates are decreasing. Private insurers also typically set their reimbursement rates as percentages of what Medicare pays. This makes it difficult for prosthetists to sell expensive microprocessor controlled prosthetics and in some cases prosthetist offices cannot accept a patient’s health insurance if the insurance company’s reimbursement rates are too low. Proposed prosthetic parity laws could fix this, however, by ensuring that private insurers reimburse prosthetist offices the same amount that Medicare does.

In addition to fitness restrictions and low reimbursement rates, the prosthetics industry suffers from a lack of competition. Ottobock and Ossur are the manufacturers of the two most popular microprocessor controlled knees, the C-Leg and the Rheo Knee. Since these companies have very little competition, it is possible for them to sell the devices at higher prices without worrying about losing their customer base.

Finally, the system that is in place to create new billing codes for prosthetics is slow. This discourages prosthetists from selling newer prosthetics, since offices that use the improper billing code are subject to Medicare audits. One of the major flaws in the billing process, is that new devices must complete three months of marketing before they can receive a new billing code. A need for a new billing code must also be recognized by Medicare, Medicaid, or a national private insurance company. If a device does not receive a billing code of its own, it is usually billed using a combination of older codes. In Medicare Region A, prosthetists must use the same billing codes for a C-Leg Genium as a C-Leg, even though a Genium is twice the cost of a C-Leg. Since the billing codes are the same, the prosthetist office gets reimbursed the same amount of money by the patient’s insurance, which discourages prosthetists from offering the newer device.

Reduced physical restrictions for lower limb amputees, parity laws, and billing code application reform have the potential to increase the number of robotic prosthetic users and grant amputees a healthier, more active lifestyle.

Background

The purpose of this section is to familiarize the readers of this report with the complexities of the amputee population and the prosthetic Industry. Our conclusions and discussion topics are partly based on the information that can be found in this section, so it may be important to understand the information in this section to understand the discussion topics later in the report.

Amputation Statistics

According to the People with Amputation Speak Out study, which was conducted in 2006 in a collaborated effort between the Limb Loss Research and Statistics Program and the Amputee Coalition of America there are nearly 1.9 Million individuals living with limb loss in the United States of America.⁷ Approximately 185,000 Americans undergo the amputation of a limb each year.⁷ Figure 1, below, is an analysis of amputations in the United States by location of amputation. Figure 2, on the next page, is an analysis of amputations by the primary cause for the necessity of an amputation.

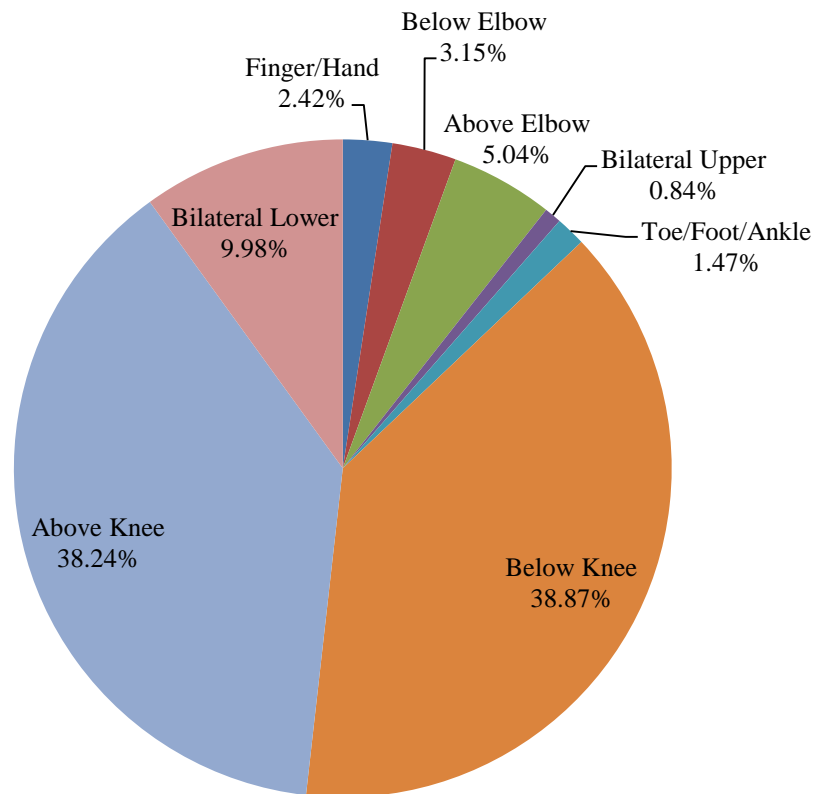


Figure 1: Amputation by Location¹⁶

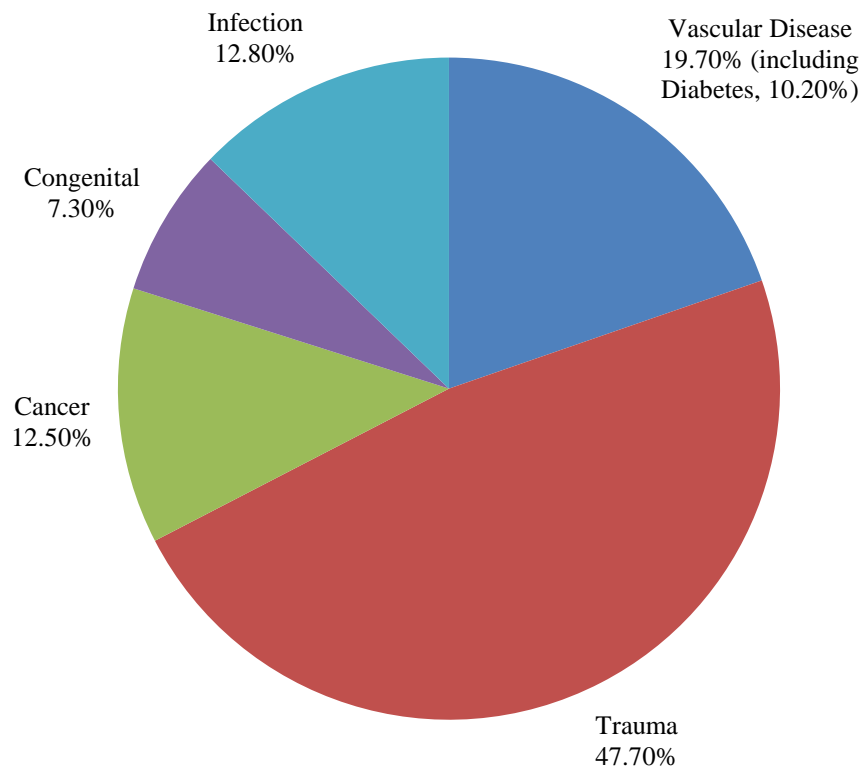


Figure 2: Amputation by Cause¹⁶

According to the People with Amputation Speak Out study, the number of trauma related amputees per year has been steadily decreasing due to advancements in treatment.⁷ According to Robert Swift, PhD, MD, associate chief of staff for research at the Providence Veterans Center, “People are surviving injuries that formerly were fatal [because of advances in battlefield medicine and armor].”⁸ Additionally, there has been an increase in the number of vascular disease, especially diabetes, related amputations per year⁷, and up to 55% of diabetic amputees require the amputation of the second leg within three years of the first amputation.⁴

Also interesting to note, African Americans are 1.5 to 3.5 times more likely to undergo amputation, and Hispanic Americans are 3.6 times more likely to undergo amputation than white Americans. These differences may be due to the large number of Hispanic and African Americans living with diabetes and other vascular diseases.⁷

Why Microprocessor Controlled Prosthetics?

Microprocessor controlled prosthetics perform significantly differently than mechanical prosthetics. Unlike traditional knee prosthetics, microprocessor controlled knee prosthetics can “sense” when to apply resistance, which gives the user much greater stability. A typical variable friction knee may apply resistance during the stance phase (when the leg in question touches the ground), but during swing phase (when the leg is off the ground) the prosthetic joint straightens at a constant rate. As a result, the user is forced to adjust his/her gait to the device. In addition, since traditional prosthetics does not actively sense when to apply resistance, the device is not suited for preventing falls or for making quick changes in walking speed. This especially applies to single axis mechanical prosthetics, which may apply constant friction or have a locking mechanism, but otherwise they provide no resistance during stance phase.⁹

The two most popular microprocessor controlled prosthetics on the market are Ottobock’s C-Leg and Ossur’s Rheo Knee. These prosthetics utilize microprocessors and sensors to determine when to provide resistance and when the knee should swing forward. The Rheo Knee uses a magnetorheological fluid between metal plates to provide resistance. When the heel strikes the ground, the sensors instruct the microprocessor to send a current through the magnetorheological fluid, which causes the knee to resist bending. The benefit of this system is that the knee freely swings forward when the leg is in the swing phase, which reduces the user’s energy expenditure. The downside is that the leg does not provide any resistance until the prosthetic detects that the heel has struck the ground. The C-Leg is a hydraulic microprocessor knee. When there is no current running through it, it functions like a normal hydraulic prosthetic, which gives the user added stability in case the battery dies unexpectedly. The onboard microprocessor controls tiny valves, which open and close to affect the resistance in the knee joint. It’s important to note that these are not powered prosthetics, like the PowerFoot BiOM is. This means that the C-Leg and Rheo Knee do not provide any extra force to help propel the user. The battery onboard each prosthetic merely controls an electronic braking system that gives the patient more stability. The downside to this is that someone using a C-Leg or Rheo Knee expends more energy walking than the average able-bodied individual.

"Comparison of Non-microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire," a study conducted by the Department of Veteran's Affairs published in November 2008, compared the performance of non-microprocessor knee mechanisms (NMKM) to the performance of the Ottobock C-Leg. Nineteen above knee amputees wore a mechanical prosthetic for 90 days and then wore a C-Leg for 90 days. The subjects then reported the total number of times they thought they were going to fall or actually fell. These responses were used to determine the number of patient “stumbles” or “falls” as shown in Table 1. The subjects were also given the Prosthesis Evaluation Questionnaire (PEQ) to evaluate the prosthesis function and the subject’s prosthesis-related quality of life.⁸

The prosthetic function was also evaluated based on the walking speeds of the subjects. Each subject was instructed to walk at either a self-selected walking speed (SSWS) or his/her fastest possible walking speed (FPWS) and the time it took them to cross specific distances was recorded.

Results of *t*-tests (mean \pm standard deviation) and percent change on performance evaluative measures for C-Leg vs nonmicroprocessor knee mechanism (NMKM) (*N* = 19).

Measure	NMKM	C-Leg	<i>p</i> -Value	% Change
PEQ	942.3 \pm 269.3	1,184.1 \pm 243.1	0.007*	20
Stumbles (No.)	7 \pm 6	3 \pm 4	0.006*	59
Falls (No.)	3 \pm 3	1 \pm 2	0.03 [†]	64
SSWS 75 m (s)	101.3 \pm 47.8	86.4 \pm 32.8	0.03 [†]	15
FPWS 75 m (s)	81.4 \pm 33.6	71.2 \pm 26.1	0.005*	12
FPWS 38 m Uneven Terrain (s)	55.9 \pm 22.0	44.2 \pm 16.4	<0.001*	21
FPWS 6 m (s)	6.5 \pm 2.6	5.4 \pm 2.2	0.001*	17

*Significant at $p \leq 0.01$.

[†]Significant at $p \leq 0.05$.

PEQ = Prosthesis Evaluation Questionnaire, SSWS = self-selected walking speed, FPWS = fastest possible walking speed.

Table 1: C-Leg vs. Non-Microprocessor Knees⁸

As Table 1 shows, there was a statistically significant improvement in all categories when the subject switched to the C-Leg. Self-reported stumbles decreased by 59% and self-reported falls decreased by 64%. There was also a 21% decrease in the amount of time it took the subjects to traverse 38m of uneven terrain. Microprocessor knees outperform standard above knee prosthetics walking speeds and provide the user with greater stability, resulting in fewer injuries.

After the study was completed, the subjects were given the option to keep the C-Leg or return to their previous NMKM. Fourteen out of the nineteen (74%) subjects preferred the C-Leg and five subjects said they would rather return to their NMKM. Some of the reasons why the subjects refused to accept the C-Leg were that it was too expensive (even though it would have been free) and that it didn't have the same cosmetic options as other prosthetics.

Microprocessor knees provide the user with a greater sense of stability and they help prevent future injuries that could stem from the use of a poor prosthetic. For example, the development of knee or hip problems from walking incorrectly could cost \$80,000-\$150,000 to fix with surgery. Amputees may also suffer from wrist, elbow, and shoulder problems from crutch overuse, which can cost \$7,500-\$25,000 to correct, according to the Analysis of Assembly Bill in the Appendix. The C-Leg and other microprocessor knees are superior to traditional prosthetics in that they provide users with increased stability, increased walking speed, and an increased desire to ambulate. Microprocessor knees provide users with a healthier lifestyle and have the potential to prevent future medical bills.

HCPCS Level II Codes (L-Codes)

In order to facilitate the billing process, Medicare assigns billing codes for medical procedures, diagnoses, durable medical equipment, etc. The Healthcare Common Procedure Coding System (HCPCS) was established for this purpose. The HCPCS is divided into two categories: HCPCS Level I and HCPCS Level II. HCPCS Level I codes are used to identify medical services and procedures furnished by physicians and other health care professionals. Since HCPCS Level I codes are not used for the billing of prosthetic devices, they will not be discussed further in this report, but more information on them can be found at (http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS_Coding_Questions.html).

Level II of the HCPCS is a standardized coding system that is used to identify products and services not included in HCPCS Level I. These products and services include, but are not limited to, ambulatory services, durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The Level II HCPCS codes were established in order for Medicare and other insurers to submit claims for services, supplies, and equipment that may be provided to a patient outside of a physician's office (in order to cover prosthetist's fees, for example.) Prosthetic procedures are listed in the HCPCS Level II codes from code L5000-L9999 and are commonly referred to by prosthetists (or others in the prosthetics industry) as "L-Codes."

In order to establish these codes, Medicare contracts an outside company to assign billing codes to new devices. Noridian Systems has been the Pricing, Data Analysis and Coding Contractor (PDAC) for Medicare since it took over the coding duties from Palmetto GBA in 2008.) As the coding contractor for Medicare, Noridian Systems reviews billing code applications and revisions.¹⁰

If a new prosthetic device is invented, and it functions differently than any other categorized device, then a new billing code is required before Medicare or other insurers will cover the device. Anyone can send an HCPCS Level II code application in order to revise an existing L Code or to create a new one. The HCPCS Code Addition/ Revision Application Form can be found in the appendix. Anyone can send in an application, but if the applicant is not the manufacturer of the device, he must get the manufacturer to authorize the submission. The application process itself can be quite lengthy, especially if the medical device requires FDA approval, but thankfully for manufacturers, prosthetic devices are FDA Class II Exempt and do not require pre-market approval.

Once the application is accepted, it must be approved. The application approval process is fairly arduous in order to prevent unnecessary billing code additions or revisions. Figure 4 in the Appendix shows the steps that must be taken before a proposed addition or revision is accepted. A closer look at the HCPCS Decision Tree reveals that *National Programmatic Need* is required in order for a code to proceed to Tier II Categorization. National Programmatic Need is also necessary in order to create a new code, use a miscellaneous code, or use an existing code as

a substitute. The HCPCS defines National Programmic Need as “At least one insurance sector, public (Medicare or Medicaid) or private (commercial insurers) identified a program operating need to separately identify the item and that need is common across the sector, (i.e., nationally, as opposed to one or a handful of individual insurers or states). Does not apply if item identification is statutorily required.” Essentially, an HCPCS Level II Code cannot be assigned to a new device unless Medicare, Medicaid, or a national private insurance company deems a new code necessary.

Another requirement for the code revision/addition to get approved is that the device needs to meet volume and marketing criteria. The HCPCS defines volume and marketing criteria as there being “sufficient claims activity or volume in 3% of the affected population, as evidenced by 3 months of marketing activity.” This is necessary to demonstrate that a new or revised HCPCS Level II code is worth the administrative costs involved to change the existing code set. The marketing performed prior to code revision/addition is advantageous for the HCPCS administration, but not for prosthetic manufacturers.

Because the billing code categorization process is so lengthy, it is not uncommon for older billing codes to be used for newer devices. For example, Ottobock recommends that prosthetist offices use a combination of previously adopted C-Leg billing codes to bill the new C-Leg Genium. However, this can have undesired consequences for the prosthetist office if Medicare or a private insurer deems the billing code as inappropriate. However, this does not prevent all prosthetists from selling newer devices without L-codes as we discovered. The PowerFoot BiOM does not have an L Code, as reported by Hugh Herr, but this does not stop prosthetist offices that are PowerFoot certified from selling the device.

Prosthetist Company Insurance Contracts

The amount that Medicare or a private insurance company reimburses a prosthetist office is known as a fee schedule. Medicare utilizes the HCPCS Level II codes to determine how much it will reimburse the prosthetist's office for the goods and services it renders to Medicare recipients. For example, Medicare will reimburse the prosthetist's office \$31,267 for a C-Leg with the Pyramid Top (the HCPCS Level II codes for which are, L5828 + L5845 + L5848 + L5856 + L5930) sold in Connecticut in 2012. This means that the patient would then be charged \$31,267, 80% of which would be covered by Medicare, leaving the patient with a bill for \$6,253. The amount that Medicare reimburses the prosthetist's office varies from state-to-state in order to compensate for differences in cost of living (the national average reimbursement amount for a C-Leg with Pyramid Top is \$30,864.56).¹¹

When a prosthetic-fitting company or office wishes to sell a prosthetic or orthotic to a patient, that company or office first makes an arrangement with the patient's health insurance. The private insurance company makes a contract with the prosthetist company to determine the amount of money that the private insurer will reimburse the prosthetist company for each piece of durable medical equipment that the company offers its patients. The private insurer usually uses the L-Codes established by Medicare in order to facilitate the billing process. The insurance company and prosthetist company negotiate to determine how much money the private insurer should pay for each L-Code. For example, a private insurer may agree to reimburse the prosthetist company a large amount of money for orthotic shoes, as long as the private insurer can make discounted reimbursements for prosthetics.

When the insurance contract is made, the private insurer usually decides to set its reimbursement rate in relation to Medicare's. For example, a private insurer may agree to set its reimbursement amount as 10% less than what Medicare would reimburse for the same L-Code. This kind of negotiation may be beneficial to some insured members, since the overall price of the device is lower, but usually it just makes the device more difficult for the prosthetist's office to sell. For example, United HealthCare wished to reimburse Biometrics, a prosthetic-fitting company, 45% less than what Medicare reimburses for prosthetics. United HealthCare would then only reimburse Biometrics \$17,197 for a C-Leg that Medicare would reimburse \$31,267 for. According to Bob Dzuranda, the president of Biometrics, this was simply not enough money to compensate for the price that his company pays to buy the device from Ottobock. He was uncomfortable specifying how much money his company pays Ottobock for each C-Leg, however. Since United HealthCare reimbursements are so low, Biometrics is unable to provide in-network service to United HealthCare members.¹²

Health Insurance Coverage of Prosthetic Devices

Several example medical insurance plan quotes from a small selection of insurers, including Medicare, can be found in the appendix. This section of the report will explain these quotes and how they affect the out-of-pocket expense of a range of insured amputees.

The coverage of robotic prosthetics by private and government insurers alike falls into the category of Durable Medical Equipment (D.M.E). For this category of medical coverage the coinsurance, the coinsurance maximum, the out-of-pocket maximum (stop loss), and any specific maximums on D.M.E can all affect how much the user of a robotic prosthetic must pay out of pocket to receive their device. The aforementioned expenses vary depending on the monthly premium and deductible that are selected by the insured policy holder in the policy acquisition process. Using the medical insurance quotes found in the appendix, several examples are given below to show the relationship between the above costs and the amount a patient must pay out of pocket.

For the sake of ease, say patient X is a thirty-year-old non-tobacco-using male, is assessed to be K-level 4 (An explanation of K-levels can be found in the next section of this report), and his prosthetist recommends the robotic prosthetic “Y” which conveniently costs exactly \$100,000.

If patient X is able to afford a low deductible, high monthly premium variant of Anthem Blue Cross Blue Shield’s “Premier” plan (found in the appendix), his out of pocket expense towards his robotic prosthetic can be relatively low. After first paying the deductible of \$500, he is then responsible for the coinsurance of 20% of the remaining cost. This coinsurance is limited by the coinsurance maximum which in this case is \$3000. Since 20% of \$99,500 (\$19,900) is greater than the coinsurance maximum, patient X is responsible for only an additional \$3000. This means that patient X will end up paying only **\$3,500**, which is the out-of-pocket maximum (as seen in Table 7 in the appendix). The downside is that patient X is quoted to be responsible for a \$3,752 premium expense per calendar year (\$312.56 per month), which most people find unnecessary or unaffordable.¹³

If patient X chose, instead, a low premium, high deductible variant of the same “Premier” plan offered by Anthem Blue Cross Blue Shield, his out of pocket expense is much different. First, as before, he must pay the deductible of \$10,000 in this case. The coinsurance for this plan is 0% and the coinsurance maximum is \$0, so patient X’s out-of-pocket expense is the out-of-pocket maximum of **\$10,000**. The premium for this plan is quoted much less at \$1448.88 per calendar year (\$120.74 per month).¹³

If patient X decided the more affordable high premium, low deductible variant of the “SmartSense” plan offered by Anthem Blue Cross Blue Shield was right for him, his out-of-pocket expense will be different still. After paying the deductible of \$750, he would be responsible for the coinsurance of 30% of the remaining cost up to the coinsurance maximum of \$4000. His total out-of-pocket expense will equal the out-of-pocket maximum of **\$4,750**. His premium is quoted at \$2976.96 (\$248.08 per month).¹³

With the low premium, high deductible variant of the “SmartSense” plan offered by Anthem Blue Cross Blue Shield. Patient X, like before, will first be responsible for the deductible of \$12,000 in this case. The coinsurance for this plan is 0%, so patient X’s out-of-pocket expense will be the out-of-pocket maximum of **\$12,000**. The premium for this plan is quoted at \$1025.76 per calendar year (\$85.48 per month).¹³

If patient X was insured under Medicare Part B, like before, he would first be responsible for the deductible of \$140. He would then be responsible for the 20% coinsurance for the remaining \$99,860. Since Medicare does not have a coinsurance maximum, patient X must pay an additional \$19,972 bringing the total out-of-pocket expense to **\$20,112**.¹⁴

Many Insurance companies have a cap per calendar year specific to the D.M.E category of medical coverage that is befitting to such equipment as blood testing strips for diabetics, but that far undershoots the cost of modern robotic prosthetics. For instance, the three example plans from Aetna (Table 5 in the Appendix) all have a cap of \$2000 per calendar year for durable medical equipment. This means that if patient X is insured by one of these plans, he is responsible for **\$98,000** towards the \$100,000 prosthetic. Furthermore, if patient X is a diabetes sufferer, he will have already used part of his \$2000 cap on his testing and other diabetes related supplies.¹⁵

The out-of-pocket maximums for a family insurance plan can be more than double those of an individual plan. If patient X is a member of a family that is insured collectively with a family plan, the total out-of-pocket expense can be higher than in the previous examples.

Family Plan Variants		
Medical Insurance Plan:	High Premium, Low Deductible	Low Premium, High Deductible
Premier Plan	\$7000	\$20,000
SmartSense Plan	\$9,500	\$24,000

Table 2: Examples of Out-Of-Pocket Expenses with a Family Plan¹³

Individual Plan Variants		
Medical Insurance Plan:	High Premium, Low Deductible	Low Premium, High Deductible
Premier Plan	\$3,500	\$10,000
SmartSense Plan	\$4,750	\$12,000

Table 3: Examples of Out-of-Pocket Expenses with an Individual Plan¹³

The prices Tables 2 and 3 are the estimated out-of-pocket expenses for a 30 year-old non-tobacco-using male for a hypothetical \$100,000 robotic prosthetic called the “Y”. They can be used to easily see the relationship between the family and individual plan expenses. Although these example family plans all estimate the out-of-pocket expense to be twice the out-of-pocket expense for the corresponding individual plans, this is not always the case. Many family plans offered by other insurers can vary independently from their individual plan counterparts.

The numbers used in this section are meant only as an example to show how the out of pocket expense for a robotic prosthetic vary based on the above defined terms. Actual out of pocket expenses can be higher. For instance, as seen in the Amputee Survey Results section of this report, one amputee reported to have paid \$30,000-\$35,000 out of pocket on his C-Leg. He also reported that the price of the device would have been greater than \$80,000 without insurance and that the insurance covered 60-70% of the cost of the device.

There is another limitation in many existing insurance policies that has yet to be discussed. For some policies there is a limit on the number of prosthetic or prosthetic related devices that can be purchased per calendar year. This limitation has serious repercussions. For instance, Robert Riiber, a bilateral transfemoral amputee was unable to purchase two C-Legs with his insurance plan as mentioned in the Executive Summary section of this report. Patients who suffer the loss of multiple limbs in a single year can run into problems with their insurance coverage. As seen in the Health Insurance Appeals section of the Prosthetist Survey Results, prosthetists sometimes have to fight denial after denial with several appeals before an insurance company finally accepts a claim. Even patients who lose only a single limb have trouble with prosthetic caps imposed by insurance companies. Often times a temporary prosthetic is used for the first several months after an amputation to allow the swelling in the residual limb to subside before switching to the permanent prosthetic as seen in the Difference in Approach subsection of the Prosthetist Interview Questions and Answers section of this report.. If the temporary prosthetic is bought with an insurance plan that only covers a single device per calendar year, the amputee may have to wait a full year before receiving their permanent device. Additionally, if a single part on the prosthetic were to break, this policy may inhibit an amputee from receiving replacement parts in a timely manner. Some insurance companies even limit the insured member to one prosthetic per lifetime, which is unreasonable with the amount of damage a prosthetic endures from everyday use.

An Explanation of Level II Modifiers (K-Levels)

The demographic of amputees ranges from young, fit soldiers coming back from overseas to elderly and overweight diabetes sufferers. Naturally, some of these patients seek the newest and best technology prosthetics in order to return their bodies to the most functional state possible, but this is not the case for every amputee. In many cases, a traditional device is preferable over a robotic or myoelectric device due to simplicity, ease of use, and/or cost effectiveness.

The Level II or “K-modifiers” system is a well-tested and validated tool that was developed by Medicare as a means of classifying amputees by their level of activity. As a guide to determine what type of prosthetic would be best for their patients, prosthetists use the “Amputee Mobility Predictor Assessment Tool” (found in the appendix) for assessing a patient’s activity level or “K” level. For lower extremity prosthetic users there are five K levels ranging from K0, the least physically active patients, to K4, the most physically active patients. A description of each K level can be found in Table 9 of the Appendix along with the assessment tool.

Many private insurance companies use the Level II Modifiers to determine which devices they will cover for each of their clients. The K level of a patient determines the subgroup of L-codes and therefore the selection of prosthetic devices that their insurance company will cover. For instance, the insurance of an elderly patient whom has been assessed as a K1 will likely cover only the most basic mechanical or aesthetic prosthetics. Respectively, the insurance of a young soldier whom has been assessed as a K4 will likely provide coverage for the most up to date technology available. Amputees of K levels K0 through K2 whom desire a robotic device do not receive coverage for such a device and must pay full price out of pocket. Even some pneumatic mechanical prosthetics are covered exclusively for K3 and K4 patients.

In theory, the system works to provide the best and most cost effective treatment for patients by providing them with devices that neither exceed nor fail to meet their specific needs. As the system currently stands, patients whom have been assessed as K levels 2 and below cannot receive insurance coverage for robotic and myoelectric prosthetic devices. However, as seen in the Results section of this report, prosthetists from Next Step in Newton, Massachusetts and from NEOPS in New London, Connecticut expressed that robotic prosthetic coverage should be extended to patients deemed to have a “K Level” of 2. These patients have the potential to greatly benefit from the use of better technology prosthetics.

Parity Laws

Coverage of Prosthetic Devices

As presented, SB 98 (2008), the Prosthetic Parity Act, would revise the requirements that a health insurer, a nonprofit health service plan, or an HMO (further referred to as “carriers”) would need to meet in providing coverage for prosthetic devices and orthopedic braces. The proposed changes are as follows:

- Section 15–820, Insurance Article, Annotated Code of Maryland, would be revised to mandate nonprofit health service plans that provide hospital benefits to provide benefits for orthopedic braces only. (Currently, Section 15–820 mandates nonprofit health service plans to provide benefits for both prosthetic devices and orthopedic braces).
- Section 15–843, Insurance Article, Annotated Code of Maryland, would be added as a new mandate. This would require carriers to provide the following:
 - For prosthetic devices, coverage and payment at least equal to that provided under federal laws and regulations for the aged and disabled
 - Coverage for the prosthetic device determined to be the most appropriate model that adequately meets the insured’s medical needs
 - Coverage for repair or replacement of a prosthetic device because of a change in the insured’s physical condition.

While SB 98 does address benefits for orthopedic braces, the mandated benefit that needs to be offered by nonprofit health service plans is not changing. This report will focus on the impact of mandating prosthetic devices by carriers.

Following is a discussion of the medical, social, and financial impacts of this proposal.

Figure 3: An Excerpt from Maryland’s SB 98 (2008), Prosthetic Parity Act (amputeecoalition.org)¹⁷

The above figure is an excerpt from SB 98 (2008), the Prosthetic Parity Act. The rest of the act can be found on the amputee coalition site and focuses mainly on defining the reasoning and necessity for the act. More on that topic can be found in the “Need for Parity Laws” section of this report. As seen above the act will require all private insurance providers to provide a level of coverage that is at least on par with the coverage provided by government programs for the aged and disabled. This mandate will have a noticeable effect on the prosthetic industry.

The Amputee Coalition of America performed an analysis for the Virginia Special Commission on Mandated Health Benefits in order to better predict some of these effects. This analysis can be found in the Appendix under “Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices” and is discussed in the “Need for Parity Laws” section of this report.

Parity laws will directly affect the way prosthetic companies make contracts with insurers. Currently prosthetic company insurance contracts work as they are described in the same-named section of this report. The parity laws will force insurance companies like United HealthCare to recognize the full Medicare approved value of prosthetic devices and reimburse prosthetic offices accordingly. This will allow more amputees to have access to robotic prosthetic devices as their prosthetist will be able to accept their insurance.

Donation

It is possible to donate one's old or unused prosthetic to someone else in need. This can be done one of two ways. The prosthetic can be donated to a foundation like Limbs for Life where the prosthetic, or its components, will be given to someone in financial need or shipped overseas.¹⁸ If the individual knows who he would like to donate the prosthetic to, then he can contact the health insurance of the person receiving the device.¹⁹ The problem, however, is that the warranties on robotic prosthetics typically only cover the device for 3 years, and the devices usually break within a year or two after this. Since the devices expire quickly, are expensive, and are only given to highly active users, the prosthetic usually breaks before it can be donated.

Methodology

With our goal of increasing the availability of robotic prosthetics in mind, our project team decided the best course of action for acquiring data would be to create a set of interview/survey questions. We first broke down our intended sources into four main categories. These categories include amputees, prosthetists, prosthetic designers/manufacturers, and insurance companies since these were the sources from which we believed we would be able to acquire the most pertinent data. We developed four corresponding lists of questions, one for each subcategory. These questions and their resulting answers can be found in the Appendix and in the Results section of this report.

At the same time, we also began researching for the Background section of our report. We utilized the Amputee Coalition of America and the Department of Veterans affairs to find the studies, statistics, and data presented in this report. Interviews with prosthetists and with Bob Dzuranda, the president of Biometrics, helped to further expand our understanding of the prosthetic industry. In order to understand the role of health insurance in the prosthetic industry, we first started by calling several insurance companies and asking them basic questions about their policies and coverage of durable medical equipment. We then acquired health insurance quotes using the online tools provided by Aetna, Assurant, Anthem Blue Cross Blue Shield, and Medicare.

Before leaving each prosthetist's office, we first asked if it would be okay if we posted a flyer (found in the Appendix) that asks for robotic prosthetic users to complete the Amputee Survey (also found in the appendix). This method of acquiring data was not effective, however. After several weeks with no responses to the survey, we took more drastic measures. We posted the survey on the Amputee Coalition's Facebook page where amputees frequently visit to post about personal milestones, troubles, and to support fellow amputees. We contacted the VA outpatient center in Worcester, but they were unable to help due to confidentiality concerns. We contacted the prosthetics division of the VA center in West Roxbury as well, but they did not return our calls. We also got the survey posted to dav.org by contacting the DAV. These additional measures were also insufficient at acquiring robotic prosthetic user data. In the end, we were only able to acquire two responses to our Amputee Survey. These responses can be found in the Amputee Survey Results section of this report.

Since the interviews were performed face-to-face the prosthetists were able to answer questions freely and clarify terminology with which we were unfamiliar. However, arranging face-to-face interviews was difficult and time-consuming. It was difficult to arrange interviews during normal business hours, since this conflicted with the group members' course schedule and of the prosthetists offices that were called, only a few actually returned our phone calls or arranged interviews.

Results

In this section we will state the findings of our project including the results from our interviews and surveys.

Prosthetist Survey Data

Interviews were arranged with prosthetists over the phone and then held in person at the prosthetist's office, with the exception of the prosthetist from Hanger Orthopedic Group, who was interviewed over the phone. Prosthetists from Next Step, New England Orthotic and Prosthetic Systems (NEOPS), and Hanger Orthopedic Group were interviewed. The purpose of the interviews was to gather information about the cost of prosthetic devices, patient satisfaction, and opinions and anecdotes from the prosthetists themselves. It should be noted that prosthetists that fit a large portion of their patients with electronically-controlled prosthetics were more familiar with the prices of robotic prostheses.

Abbreviations:

A few abbreviations will have to be understood in order to interpret some of the answers:

BK-Below Knee

AK-Above Knee

UE-Upper Extremity

Prosthetist Interview Questions and Answers

The responses from the prosthetists were recorded by taking notes during the interviews. The following answers are accurate, but the prosthetist's actual answers have been abbreviated.

Experience and Customer Base:

1. How long have you been working as a prosthetist?

Worcester, MA- NEOPS: 22 years²⁰

Branford, CT-NEOPS: 13 years²¹

Newton, MA-Next Step: 26 years²²

Worcester, MA-Hanger Orthopedic Group: 2 years¹⁷

New London, CT-NEOPS: 17 years⁶

2. Approximately what percentage of your limb-loss patients use robotic prosthetics?

Worcester-NEOPS:

4%-5%

Branford-NEOPS:

20% of above knee

<5% of Below Knee amputees

5% of Upper Extremity amputees

Total: 15%

Newton-Next Step:

Reported that they treated a lot of K3 and K4 patients

Above Knee: 50%

Total: Unsure

Worcester-Hanger:

Reported that not many of the patients are above knee amputees

5%

New London-NEOPS:

5%

Average (Newton Excluded):

7.50%

Average (Newton Included):

16.00%

3. Approximately what percent of your patients choose robotic prosthetics?

Worcester-NEOPS: Mostly young patients will choose robotic prosthetics. Older patients prefer something comfortable for low activity.

Branford-NEOPS: 100% of AK amputees try to receive one, but only about 20% of AK amputees actually receive one.

Newton-Next Step: Tries to get a microprocessor controlled knee for all AK amputees.

Worcester-Hanger: 5%

New London-NEOPS: 5%

Patient Satisfaction

4. Do your patients prefer a traditional [non-electronic] prosthetic over a robotic prosthetic? Why?

Worcester-NEOPS: Most patients receive traditional. Younger patients want robotic.

Branford-NEOPS: Unsure.

Newton-Next Step: Patients prefer robotic.

Worcester-Hanger: No one prefers traditional.

New London-NEOPS: Yes. Patients prefer an electronic or microprocessor controlled prosthetic.

5. What percentage of patients who switch from traditional prosthetics to robotic prosthetics are more satisfied with the robotic device?

Worcester-NEOPS: Rarely do patients switch from traditional prosthetics to robotic ones, unless they're switching from a temporary prosthetic to a robotic one.

Branford-NEOPS: Depends on individual. Some reject the robotic prosthetic. More are amazed by what they are now capable of. Treated a patient who used a hip-down traditional prosthetic for 60 years and converted him to a robotic prosthetic in 4 months.

Newton-Next Step: 100% are more satisfied with a robotic device. The only reason to keep a traditional device handy is in the case of going to the water or the beach or another equally hazardous location for electronics.

Worcester-Hanger: 99.90%

New London-NEOPS: Patients are more satisfied with robotic prosthetics. If you were to allow a patient to adjust to a C-Leg and then gave him a traditional hydraulic leg, he would fall right on his butt.

6. Do you think some of your patients who do not use a robotic prosthetic would benefit from one?

Worcester-NEOPS: Probably. Most patients treated are diagnosed as low K Levels and are not offered robotic prosthetics

Branford-NEOPS: Yes.

Newton-Next Step: Yes. K2 levels should be able to get robotic prosthetics.

Worcester-Hanger: Yes. Usually low K levels don't get offered robotic prosthetics, but if the patient requests one, the prosthetists' office will try to get the patient's health insurance to comply with the request.

New London-NEOPS: Yes. K2s should get approved for robotic prosthetics. About 50% of the patients could be wearing a better prosthetic. Most of the time patients are not offered microprocessor controlled knees because they are not a K3 or K4 or because they do not have the funds to pay for a robotic prosthetic.

7. Overall, would you say that your patients are pleased with the functionality of their prosthetic? (traditional or robotic)

Worcester-NEOPS: Patients whom are new to the world of prosthetics tend to be pleased with the functionality of their prosthetic, but longer term patients tend to have higher standards.

Branford-NEOPS: Yes, if not they come back for a refitting.

Newton-Next Step: I've received no complaints for robotic prosthetics. Traditional prosthetic users have stability issues.

Worcester-Hanger: Yes, although patients with microprocessor controlled prosthetics are more pleased.

New London-NEOPS: Yes

8. For the patients whom are displeased with the functionality of their prosthetic, do you believe there is a prosthetic with which they would be more pleased?

Worcester-NEOPS: Displeased patients usually aren't satisfied because it's not their real limb.

Branford-NEOPS: Probably, most of the time it's a comfort issue or an attitude issue

Newton-Next Step: Most issues are with socket fit.

Worcester-Hanger: Yes.

New London-NEOPS: Most of the time it's a comfort or attitude issue.

9. Do robotic prosthetics have issues that the more traditional prosthetics do not suffer from? If so, what are they?

Worcester-NEOPS: More parts, more problems. Certain robotic prosthetics have warranty clauses that require the devices to be shipped to the manufacturer for repairs. Patient uses a temporary (less functional and less comfortable) prosthetic in the meantime. Some prosthetic companies send out loaner units.

Branford-NEOPS: Robotic prosthetics require more initial maintenance than a traditional prosthetic, since they require initial programming to match the patient's gait. Don't see them in for repair much. Robotic prosthetics are heavier which creates more discomfort. Usually lasts 2 years. Requires initial programming and maintenance.

Newton-Next Step: Water resistance and high humidity are issues. Robotic prosthetics require an outlet to charge, but robotic prosthetics are pretty reliable on the most part.

Worcester-Hanger: Yes, all need typical maintenance. Robotic prosthetics require prosthetists to receive more training.

New London-NEOPS: You need to charge a robotic prosthetic. They don't break more than traditional prosthetics.

Cost to the Patient

10. Do any of your patients have to settle for a less functional device due to cost?

Worcester-NEOPS: Yes

Branford-NEOPS: Yes. Very few.

Newton-Next Step: Absolutely. Cost is always the final deciding factor.

Worcester-Hanger: Yes.

New London-NEOPS: All the time. It depends on the patient's insurance. Recommends patients get supplementary insurance to pay for the device.

11. If so, approximately what percent?

Worcester-NEOPS: A slim percent.

Branford-NEOPS: Patients seldom have to pick a less functional device. It mostly occurs with the uninsured.

Newton-Next Step: 25%

Worcester-Hanger: Unsure.

New London-NEOPS: Unsure. A majority of the patients treated could be wearing a better prosthetic.

12. What are some prices of the devices you sell?

Worcester-NEOPS: Limb Logic VS: \$1,600 (electronic vacuum suspension system)

Branford-NEOPS: BK prosthetics: \$6,000-\$15,000 (Propriofoot); microprocessor knees: \$38,000-\$52,000; Myoelectric \$35,000; UE passive: \$3,000-\$5,000; cable driven: \$6,000-\$12,000

Newton-Next Step: Powerfoot BiOM: \$75,000; i-Limb Pulse \$45,000; C-Leg: \$45,000

Worcester-Hanger: Unsure. Prices range from \$20,000 to 90,000 for the C-Leg Genium

New London-NEOPS: BK: \$10,000-\$30,000; AK: \$33,000-\$80,000; AK powered: \$120,000; UE: \$20,000-\$120,000;

13. What are the some of the price ranges for the different types of prosthetic devices that you sell?

Worcester-NEOPS: Preparatory BK prosthetic: \$5,000 Vacuum pump suspension: \$10,000

Branford-NEOPS: See Response to Question 12

Newton-Next Step: See Response to Question 12

Worcester-Hanger: See Response to Question 12

New London-NEOPS: See Response to Question 12

14. In your opinion, are these prices reasonable or unreasonable?

Worcester-NEOPS: Reasonable with the amount of money that is spent on research and development.

Branford-NEOPS: Reasonable.

Newton-Next Step: Return on research and development is difficult. Funding is a large problem.

Worcester-Hanger: Reasonable. The devices are expensive, but they're worth it.

New London-NEOPS: Unsure. Insurance contracts are horrendous. Insurance companies are price fixing, essentially. Private insurance companies usually cover less of the price for a prosthetic than Medicare. This causes otherwise able-bodied and healthy people to quit work and go on disability in order to receive Medicare.

Prospects for the Future

15. With the decreasing price of technology in mind, do you think that robotic prosthetics will become available to the average user?

Worcester-NEOPS: With the influx of service injuries there will be more amputees and therefore more demand for high quality devices (since service men are of the highest K level) and therefore prices will come down.

Branford-NEOPS: More people will be able to get a robotic prosthetic, but the price will remain the same.

Newton-Next Step: Prices will stay the same. The C-leg costs roughly the same as it did 14 years ago.

Worcester-Hanger: Yes

New London-NEOPS: Unsure with all the money that is spent on research and development. The government is gradually paying less for prosthetics. It's difficult for advancements to be made because engineers are forced to design a device that matches an existing billing code, or alternatively, design a device that is more functional, but more expensive.

Differences in Approach

Worcester-NEOPS: Lower limb amputees usually start with a temporary prosthetic for the first six months after amputation. This allows the swelling to go down and for a proper socket fit to be made for the permanent prosthetic. If a patient's robotic prosthetic breaks, then the prosthetic is sent back to the manufacturer and the patient uses a temporary traditional prosthetic if the manufacturer doesn't send out a "loaner".

Branford-NEOPS: Lower limb amputees are given a microprocessor knee as soon as possible, if eligible. The office keeps older, donated robotic prosthetics so that patients can walk with a robotic prosthetic while they await their permanent robotic prosthetic to be delivered. These "loaner" robotic prosthetics are also used if the patient's prosthetic ever needs to be sent back to the manufacturer for repair. Spends extra time with the patients to get them accustomed to the device, even though it is not required.

Newton-Next Step: Keeps "loaner" robotic prosthetics for patients to use in case theirs breaks.

Worcester-Hanger: -

New London-NEOPS: Recommends patients get supplementary insurance to pay for their prosthetic.

Health Insurance Appeals

Worcester-NEOPS: It's not really common to have health insurance deny claims. However, there was one instance where a patient with diabetes was denied a passive ankle prosthetic. The gentleman had already had his left foot amputated earlier that year and he just had his right leg amputated above the knee. The prosthetist wanted to attach the same ankle prosthetic on the patient's temporary AK prosthetic as the one he already had on his left leg. His health insurance did not think the ankle was "medically necessary" for a temporary leg. The prosthetist wrote the patient's health insurance a letter explaining that the patient needed the two ankles to be identical for proper balance and health reasons. The health insurance approved the claim and covered the patient's second ankle prosthetic.

Branford-NEOPS: Usually sees 1-2 appeals per patient. Feels that it's the health insurance companies' job to deny claims and save money.

Newton-Next Step: 80-90% of the requests for prosthetic payment go through the health insurance without having to send the insurance company an appeal. Before the payment request is made to the health insurance company a large document entailing the patient's health history and need to ambulate is sent. This usually prevents companies from denying claims.

Worcester-Hanger: -

New London-NEOPS:-

Amputee Survey Data

Table 4: Amputee Survey Questions and Responses

Please specify your level of amputation.	
Above Knee	Above Knee
What is the name of the robotic prosthetic you use/have used?	
C-Leg	c-leg
Would you rather use a traditional prosthetic or a robotic one?	
Robotic	Robotic
Why?	
It's hard enough wearing and walking with a Prosthetic leg, so why use a manual knee. The only reason I could see would be because of cost. the microprocessors in the knee are what gives relief to my good leg and allows me to have quality of life that I use to have.	
Are you pleased with the function of your robotic prosthetic?	
Yes	Yes
Why?	
It assists me in walking. It's much better in terms of control and stability. I can do almost all of the things that I use to do, but just in different ways. Plus it allows for my good leg to get a rest.	
Do you feel there is a prosthetic that would better suit your needs?	
No	Yes
If so, please give a description or the name of the prosthetic.	
Genium by Otto Bock	
Was price a major factor when choosing your robotic prosthetic?	
No	No
If so, how did it affect your decision?	
Most people it is, but I am lucky enough to have the financial needs to cover what insurance doesn't.	
What was the total cost of your robotic prosthetic?	
\$55,000-\$59,999	>\$80,000
What was the total out-of-pocket expense for your prosthetic?	
\$10,000-\$14,999	\$30,000-\$34,999
What health insurance provider did you have when you purchased your prosthetic?	
Medicare	Blue Cross
Approximately what percent of the cost did your health insurance cover?	
70-80%	60-70%

If you received any other financial aid, who provided it?	
If you received any other financial aid, how much of the cost did it cover?	
Received no other forms of financial aid	
On a scale of 1-5, was the price of your robotic prosthetic reasonable or unreasonable?	
	4
	4
What was the total out-of-pocket expense for your physical therapy?	
>\$2,000	
>\$2,000	
If you required physical therapy, what was the total cost?	
>\$2,000	
>\$2,000	
Approximately what percent of the cost did your health insurance cover?	
80-90%	
60-70%	
If you received any other financial aid, how much of the cost of physical therapy did it cover?	
Received no other forms of financial aid	
Received no other forms of financial aid	
How long is the warranty for your robotic prosthetic?	
3 Years	
3 Years	
What's the average amount of time you use a robotic prosthetic for before it needs to be replaced or repaired?	
Still using the first robotic prosthetic	
1 Year	
With the decreasing price of technology in mind, do you think that robotic prosthetics will become available to the average user?	
<p>No, if the insurance companies continue to play games with us they way they are, then forget it! Do they actually think we enjoy missing a leg? We have to jump through hoops to get things approved. I'm a K4 amputee and Medicare declines nearly every claim that is submitted for me. It's a shame!</p> <p>I personally do not. If they do it will be in a time where I am no longer alive. Insurance has always made amputees jump through hoops in order to get proper care. Many insurance carriers do not even like to cover O&P expenses. Some only offer 1 limb in a lifetime which is just impossible.</p>	

Interview with Hugh Herr²⁴

Hugh Herr heads the Biomechatronics group at the MIT Media Lab and he is the founder and chief scientific officer of the prosthetics company iWalk. Hugh lost both of his legs below the knee in a hiking accident when he was 17 and has since devoted himself to rehabilitation engineering. We first met with Hugh Herr at the 2012 WPI Neuroprosthetics Symposium after his presentation on powered prosthetics, which he finished by bounding from one side of the stage to the other, showing off the amazing capabilities of his two powered ankle prosthetics.

Hugh reported that research and development for the PowerFoot BiOM, the latest robotic prosthetic from iWalk, cost approximately \$25 million dollars, though it is likely that much of this bill was used for developing his company. During our discussion, Hugh emphasized his opinion that the issue with the high cost of robotic prosthetics cannot be solved by cutting costs at the developer's end. Instead, designers should be striving for the designs that perfectly emulate natural human limbs. Hugh Herr refers to these emulating devices as "bionics." If perfect human limb emulation were achieved, many of the expensive medical problems associated with long term limb loss and prosthetic use could be avoided, thus saving insurance companies money in the long run while enabling amputees to return to healthy and productive lifestyles. The "Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices" (which can be found in the appendix) addresses some of the potential long term complications that prosthetic users face. If studies were conducted that highlighted the correlation between so-called "bionics" and a lower lifetime medical expense, insurance companies would be more than willing to fund their clients in the interest of saving themselves money in the long term. The "Comparison of Non-Microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire" conducted by the Department of Veterans Affairs is one such study. More extensive data focusing on the long term benefits of robotic prosthetics is needed, however. A summary of this study can be found in the "Why Microprocessor-Controlled Prosthetics?" section of the Background of this report.

Hugh was also concerned with the method and means of today's socket construction by prosthetists. He suggested that socket construction could be done with the high resolution MRI machines in hospitals, effectively removing the "craft" from socket construction and turning the process into more of a science. The MRI machines can be used to create a 3D-model of the residual limb. This model can be used to create a perfect socket-fit thus maximizing patient comfort and motivation. Hugh, himself, has been doing it this way for years. Many of the prosthetists we interviewed still use the traditional method of making plaster molds until one feels right to the patient. This process takes time and usually many repeated attempts due to imperfections and deformities before an amputee is satisfied with the fit of his socket. And even then the socket may still be imperfect.

In addition to this, Hugh offered that incorporating prosthetist offices into existing hospitals could be a much more cost effective approach. Including prosthetists as a department in

existing hospitals could greatly reduce the overhead associated with a private office and consequently reduce the markup of robotic prosthetic devices.²⁴

Interview with Bob Dzuranda¹²

Bob Dzuranda has been the president of Biometrics for 14 years. Biometrics is a prosthetic-fitting company that employs prosthetists and manages prosthetist offices. Dzuranda's input was invaluable for the construction of the Insurance Contract section in the Background Information. The over-the-phone interview that was conducted with him provided this project with a perspective on the financial aspects of the prosthetics industry that this project would have otherwise severely lacked.

According to Bob Dzuranda, Medicare and Medicaid paid the lowest amount among insurers for prosthetic fee schedules, 15 years ago. Now, however, Medicare usually reimburses the prosthetist office more than private insurers will. Because of this, private insurers set contracted fee schedules as percentages of the amount that Medicare would have reimbursed the company. Unfortunately for the prosthetist offices, it has become a trend for private insurers to discount their reimbursement amounts. While reducing the fee schedule reduces overall cost of the device, it may not reduce the out of pocket expense from the user because private insurers usually do not pay for as large a percent of the fee schedule as Medicare (80%). This trend for competitive discounting also hurts the prosthetist office because if the fee schedule is set too low, the office will not see enough return. For example, United HealthCare wished to reimburse Biometrics 45% less than what Medicare reimburses for prosthetics. United HealthCare would then only pay Biometrics \$17,197 for a C-Leg that Medicare would pay \$31,267 for. It's difficult for a prosthetist company to afford fee schedule cuts, especially when it is hiring more administrative staff. Dzuranda reported that he currently employs an approximately equal number of clinicians (prosthetists) as front office staff. This is in part because Medicare will not hesitate to audit prosthetist offices if it suspects that the prosthetist office has filed a claim incorrectly, so it's crucial for prosthetic companies to have good record keeping.

Dzuranda recounted a time that his company was audited because a written prescription's authenticity was questioned. Biometrics was not found guilty of anything, but the company did have to absorb the cost of all the attorney fees. Another issue is that patients may come in at any time or for as many visits after they purchase their prosthetic for no extra cost.

In response to Hugh Herr's interest in improving socket fit procedures, Dzuranda was asked if he believed Computer Aided Design software and 3D scans would be used more in the future. Dzuranda expressed that CAD software will be used to produce sockets more in the future and that there may be a negative side to this. 3D scans and CAD software may become more popular because they are cost effective, but currently the process is too general and does not produce a socket with the most intimate fit. While this is suitable for the majority of amputees, those with atypical or traumatic amputations may not get a proper fitting socket.

Conclusions

This section will draw conclusions from the results of our surveys and interviews. We will also use this section to highlight some of the main issues addressed in the Discussion section of this report.

Prosthetist Survey Conclusions

One thing that was apparent after conducting the interviews with prosthetists was that each had a different approach to treating their patients. Newton-Next Step and Branford-NEOPS treated the highest amount of robotic prosthetic users (approximately 50% and 20% of above knee amputees, respectively.) Since these prosthetist offices saw a lot robotic prosthetic users, they were well prepared to give their patients a temporary robotic prosthetic in case their permanent prosthetic broke. These offices were also located in predominantly wealthy areas, whereas the prosthetist offices in Worcester and New London did not treat as many robotic prosthetic users (about 5% of total amputees used robotic prosthetics). This correlation may simply be coincidental, however, because every prosthetist office reported that they had patients at one point who had to settle for less functional prosthetics due to cost (Cost to the Patient: Question 10.) However, the prosthetists were mostly unsure of the percentage of people who had to settle for a different device (Question 11).

Their uncertainty was most likely due to the manner in which a prosthetist chooses a proper prosthetic for his/her patient. If the patient has already been diagnosed as a K2 or below, the prosthetist is not going to offer the patient a \$45,000 C-Leg because the prosthetist knows that the patient's health insurance will not pay for any fraction of the cost. Since patients are dealing with the emotional stress of losing a limb, it would be cruel to offer them a prosthetic that their insurance will not cover or that is outside of their budget. This was evident in the prosthetists answers to Question 6, where prosthetists from Worcester-NEOPS, Hanger, and New London-NEOPS mentioned that low K Level patients are usually not offered or informed about robotic prosthetics, since it would just cause the patient more financial stress and grief. In response to the same question, 4/5 prosthetists answered that some of their patients who don't use a robotic prosthetic would benefit from one and 1 said his/her patients would probably benefit from one. One thing that was very intriguing was that, without prompting them, Newton-Next Step and New London-NEOPS both stated that K2 Level patients should get access to robotic prosthetics. The responses to Question 5 also showed that 4/5 of the prosthetists thought that their patients were overall more pleased with robotic prosthetics.

Four out of the five prosthetists believed that the current prices for prosthetics are reasonable; two of them cited research and development as a contributing factor to the high prices (Question 14). This agrees with Hugh Herr who reported that \$25 million was spent in development for the PowerFoot BiOM. The New London-NEOPS prosthetist was unsure of how

to answer the question. The prosthetist stated that insurance contracts do not help the patient fund their device and that since Medicare covers the largest percent of the cost, patients are sometimes forced to quit work and go on disability. When asked if they thought robotic prosthetics will become available to the average user, two prosthetists said that prices will decrease (one citing the increase in athletic amputees from Iraq and Afghanistan), two thought that prices will remain about the same, and the prosthetist from New London was unsure and believed that technological advancement is difficult, since billing codes limit designers' options.

Amputee Survey Conclusions

Because of the extremely small sample size of our Amputee Survey, it is impossible to draw any meaningful conclusions; however, it can be seen in the Amputee Survey Results section of this report that both amputees had similar responses. They both prefer robotic prosthetics over tradition prosthetics, they both thought the price of their prosthetic was highly unreasonable (having paid thousands of dollars out-of-pocket for their devices), and they both have little hope that the cost of robotic prosthetics will be reduced in the future. If the sample size of the survey were increased, it's likely that many amputees would respond similarly.

Overall, the responses from our amputee survey support the claim that robotic prosthetics are out of the financial reach of the average user. The responses to the final question, "With the decreasing price of technology in mind, do you think that robotic prosthetics will become available to the average user?" were the most revealing. Both responses point at insurance companies as the primary cause for the financial troubles that amputees face. As expressed by Hugh Herr, these insurance companies would be more willing to payout for robotic prosthetics if there was clinical data available that proves that bionics reduce lifetime medical costs.¹⁶ More on this topic can be found in the Interview with Hugh Herr and the Future Work sections of this report.

Discussion

In this section, we will discuss many of the major flaws with the financial and other aspects of the prosthetic industry. Anecdotes along with information from the background and results sections of the report will be integrated to discover exactly what the next step for the prosthetic industry should be.

Prosthetist Survey Discussion

After completing the interviews with the prosthetists, it was clear that the prices of the devices were not as large an issue as initially thought. The prices of the devices are high, but if the prosthetists aren't reimbursed properly, they cannot afford to supply the prosthetics in the first place. It seems that the issue lies with getting the proper funding for the device from health care providers. Private insurers usually cover less of a percent of the cost than Medicare and they usually reimburse the prosthetist office less as well. This can have drastic outcomes for the patient, especially if he/she is able-bodied and part of the workforce. Private insurance usually will not provide enough money to supply someone with a C-Leg or microprocessor controlled prosthetic. For someone who needs to be on their feet at their job, this may mean that they will either have to suffer through wearing a less functional prosthetic or quit their job in order to get Medicare to cover the device.

The second main issue is that patients are not offered robotic prosthetics if they do not meet the physical requirement as established by Medicare. Since most other insurers require patients to be a K3 or K4 functional level as well, it is difficult for patients who suffer from obesity, vascular disease, or old age to get a better prosthetic. This issue is discussed further in the part of the Discussion entitled "The Issue with Level II Modifiers."

The Issues with Insurance Contracts and L Codes

Bob Dzuranda and the prosthetist from New London-NEOPS were both very vocal about the problems that insurance contracts cause. According to them, it has become a recent trend for private insurers to try and reimburse prosthetist offices less and less. Since Medicare is currently the highest payer, most insurance companies set their reimbursement rates as percentages of what Medicare pays. Since Medicare is the highest payer though, it's in their best interest to decrease their reimbursement rates, because to the consumer it appears as though Medicare charges the most (when in reality they cover a larger percent of the cost than most private insurers.) According to the prosthetist from New London, the government is reducing reimbursement amounts as well, which causes private insurers reimbursement rates to drop as well. While this does decrease the overall total cost, it does not necessarily decrease the out-of-pocket expense for the patient, and decreased reimbursement rates give prosthetist offices decreased incentive to sell robotic prosthetics, since they could make higher profits selling less expensive devices. Excessive discounting is the reason why Biometrics cannot serve United Healthcare members, since United Healthcare will only reimburse prosthetists 55% of what Medicare pays. Since health insurance companies are constantly competing with each other to lower their reimbursement rates, the prosthetist companies see less return on investment as time passes. In the future, this may lead to denied service to patients that use certain private insurers or prosthetist offices will be less inclined to provide expensive electronic prosthetics, since they will not profit by offering them.

There are also problems with the L-Code application process. Since the process is so slow, and hesitant to create new codes for new devices, many times older L Codes are reused for newer devices. In some cases, the prosthetist may not be sure what L Code to use. Ottobock recommends that a combination of miscellaneous codes and L Codes be used to pay for the C-Leg Genium, however, the Durable Medical Equipment Medicare Administrative Contractor for Region A (the Northeastern United States) prohibits the use of miscellaneous codes for billing the C-Leg Genium and recommends that clinicians use the same exact L-Codes to bill the C-Leg Genium, as those that are used for the C-Leg. This means that a prosthetist office would only be reimbursed \$31,267 by Medicare (in CT) for the C-Leg and the C-Leg Genium, even though the Genium outperforms the C-Leg and costs nearly twice as much.^{6 25}

The Prosthetic Designer's Dilemma

One major hurdle in the prosthetic billing process is the billing categorization process. As it stands now, the billing code verification process is time consuming and prevents newer devices from entering the market quickly. This process can be seen in the Appendix under HCPCS Addition/ Revision Flow Chart. The billing categorization process has the effect of slowing down the market for robotic prosthetics. This effect reduces competition and creates a monopoly type situation, allowing companies to sell devices at highly marked-up prices for the lack of competition.

The slow pace of the billing categorization process makes it sometimes necessary for prosthetists to use existing codes on devices that have yet to be officially categorized. Many times these substitute codes do not accurately predict the appropriate costs of the equipment and patients or prosthetists are left to make up the difference. Insurance companies also reserve the right to audit prosthetist offices for using substitute codes on devices that do not yet have official coding. In the audits, the insurance companies may attempt to classify the yet-to-be categorized device under the “miscellaneous” category. The insurance payout for miscellaneous devices is much lower. Audits can leave prosthetist offices with large legal fees like the ones Biometrics had to face when the authenticity of a prescription came under question.¹² These legal fees and audits further increase the mark-up of the prosthetics sold by prosthetists, which further decreases the availability of robotic prosthetics. These issues make it next to impossible for designers to introduce their products into the prosthetic market before official L-codes are established. Paradoxically, the HCPCS application has volume and marketing requirements that must be met before L-codes can be established and a need for a new code must be recognized by Medicare, Medicaid, or a national private insurance company.²⁶

Furthermore, the process stifles development in that it is easier for engineers to produce and market prosthetics that operate and function similarly to devices that have already been assigned L codes than it is for them to produce new, better, and potentially “bionic” technology. Financial trouble can arise if a product that was intended by the developer to receive a new L-code (and with it a new fee schedule) is instead lumped into an existing L-code. The price of the device will be equal to the other devices under the same L code and it may be difficult to receive a viable return on the investment that was made to produce the device, since, as can be seen in The Issues with Insurance Contracts and L Codes section, it may be impossible for prosthetists to offer a device to their patients if the fee schedule is too low.

The Issues with Level II Modifiers (K-Levels)

The current Level II Modifiers (K-Levels) system is effective at its goal of predicting the appropriate type of equipment for each unique amputee; however, the way that the K level system is used by insurance companies to deny the use of robotic prosthetics to amputees whom could potentially benefit greatly from the use of them is seriously flawed and morally wrong. Data collected as part of our background research and as part of our prosthetist interviews supports this claim.

The best treatment for diabetes is an active life style and a well controlled diet. When these things fail, lower extremity amputation can sometimes be unavoidable. Allowing diabetic amputees access to robotic prosthetic technology can be key to motivating them to improve their lifestyle and become more active; however, diabetic amputees often get placed into k level 2 and below as a result of their condition, effectively banning them from robotic prosthetic use. According to People with Amputation Speak Out, up to 55% of diabetic amputees require the amputation of the second leg within 2-3 years of the first amputation.⁷ It is likely that many of these repeat amputations could be avoided if the patients are given the technology that would allow them and potentially motivate them to become more active and therefore healthier.

Additionally, the K level system how it currently stands restricts the market for many expensive robotic prosthetics. Allowing select K2 patients the use of robotic prosthetics would effectively expand the customer base and increase demand. This increased demand could lead to price drops for future amputees. In the study, “Comparison of Non-microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire”, 4 out of the 9 K2 Level subjects were able to increase their activity level to a K3 through the use of a microprocessor knee.⁸

Aside from diabetic patients, two of the prosthetists we interviewed agreed that many of their other K level 2 patients would benefit from the use of a robotic prosthetic as seen in the answers to question 6 “Do you think some of your patients who do not use a robotic prosthetic would benefit from one?” which can be found in the Prosthetist Survey Data section of this report.

“Comparison of Non-microprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire” is a study performed by the Department of Veteran’s affairs. The study had some interesting findings about the K level system as seen in the following excerpt,

“Using only the strict MFCL performance ratings typical in the clinical setting, the clinician in this study initially rated 9 of the 19 subjects as MFCL K2; these subjects would not have been considered MKM candidates. Of these nine subjects, four (47%) increased their MFCL from K2 to K3; thus, amputees who according to MFCL guidelines would not have been candidates for the C-Leg actually improved their functional performance when using the C-Leg. Specifically, we found that not only are limited community G1 (MFCL K2) candidates for MKM technology, they are also able to advance to the MFCL K3 level when prescribed an MKM. In summary, our findings support that costly high-tech components may be under-prescribed [46]. This finding is exemplary of why amputees should be provided the opportunity to use the most advanced technology that could potentially increase their function.”⁸

The Amputee Mobility Predictor Tool is designed to be performed with or without the use of a prosthetic.³⁴ The excerpt above explains that four of the subjects in the study were able to increase their assessed K-level from K2 using their non-robotic prosthetic to K3 by using the C-Leg provided by the clinicians. The data strongly suggests that many K2 amputees are unfairly restricted and would greatly benefit from the use of robotic prosthetics.

The K-level system should be used only as a predictor of the appropriate equipment an amputee should receive, not as a final judgment. The final say should be up to the patient and the prosthetist and should depend on the patient’s willingness and ability to operate robotic prosthetic devices. In this way, treatment of amputees can be both fair and effective.

Need for Parity Laws

Both Maryland's SB 98 (2008), Prosthetic Parity Act, and the amputee Coalition of America's "Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices" underline many of the reasons why medical insurance parity laws are necessary and how they could potentially affect the prosthetic industry.

The medical insurance parity laws directly affect prosthetist company insurance contracts as stated in the Parity Laws section of the Background. The overall effect of parity laws will be to increase the number of individuals with access to robotic prosthetics. The "Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices" conducted by the Amputee Coalition of America, which can be found in the appendix, outlines the reasons why increasing the availability of prosthetics is beneficial. The report highlights financial, social, and medical benefits of prosthetic devices.

Forcing private insurers to use the same fee schedule as Medicare does not mean that those private insurers will reimburse prosthetists the same amount of money as Medicare does. Medicare has a coinsurance of 20%. This means that Medicare covers 80% of the fee schedule cost and the user must cover the remaining 20%. Private insurers can have varying coinsurance rates as well as coinsurance and out-of-pocket maximums and therefore the actual payout by the insurance company can still vary. However, under the prosthetic parity laws, if the same device was purchased in the same year by two different amputees from the same billing region, amputee X with Medicare, and amputee Y with a private insurer, then the amount that amputee X must pay plus the amount that Medicare must pay will equal the amount that amputee Y must pay plus the amount that his private insurance must pay. As a result, the prosthetist office will be reimbursed an equal amount for the two same prosthetics regardless of the insurer. This will allow prosthetists to offer robotic prosthetics to more of their patients, thus potentially increasing the demand for these devices and decreasing the price while increasing the overall availability. Designers of robotic prosthetics will also benefit since their products can be offered to a larger population.

A significant argument in favor of parity laws is the fact that requiring private insurance to use the same fee schedules as Medicare will increase premiums by only \$0.12-\$0.35 per month (\$1.44 - \$4.20 per year) per policy holder according to research presented in "Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices."²⁷ Since this is the case, the benefits of parity acts far outweigh the costs, since more privately insured individuals would have better access to prosthetics.

Future Work

This section will discuss the future work that we believe should be done in order to increase the availability of robotic prosthetics.

Surveys and Studies

“Amputee Patient Comfort and Compliance” and “People with Amputation Speak Out” are two extensive surveys that were conducted in part by the Amputee Coalition of America in order to better understand the physical, social, and psychological strains that amputees face. The survey results have one major downfall; they do not distinguish between the users of robotic prosthetics and the users of traditional prosthetics. Similar if not identical studies should be conducted that do make the distinction. Included in these surveys should be questions aimed specifically at K2 and below amputees whom do not use robotic prosthetics. The questions should ask whether or not the amputees feel that they would benefit from the use of robotic prosthetics.

Additional studies should be conducted on the diabetic population. Specifically, the studies should answer whether or not diabetic amputees given robotic prosthetics are more or less likely to require the amputation of the second limb over diabetic amputees given traditional prosthetics. It should also answer whether or not the life expectancy of diabetic amputees is affected by the use of robotic prosthetics. Overall, the study should answer whether or not diabetic amputees given robotic prosthetics live healthier (and less medically costly) lives as compared with diabetic amputees given traditional prosthetics.

Free Market

For most electronic devices available, it is possible to purchase recertified or refurbished devices at a significant cost reduction. Why should prosthetics be any different? Old robotic prosthetics that have reached the end of their warranty could be bought back by the designing company (or used toward credit on the newer model) and then refurbished. These recertified devices could be sold at a lower rate (but still for a profit) to those whom cannot afford the most updated technology.

Websites such as newegg.com are known for their accurate specifications and extensive user reviews and ratings of the merchandise they sell. This idea can be brought to the robotic prosthetic industry. It would be possible for Medicare or a third party to run a website based on the Medicare fee schedules. Robotic prosthetics and other prosthetic components would be searchable by category, name, or L-code. Each Device would have a list of standardized specifications and a section for user reviews and ratings of the equipment. The site may also include searchable databases for medical insurance providers and Prosthetists. Users would be encouraged to rate and/or review their insurance provider and prosthetist as well as their prosthetic.

Prosthetist Hospital Integration

Integrating prosthetist offices into existing hospitals would have several benefits. Firstly, prosthetists would gain access to MRI imaging technology for producing computer 3D-modeled sockets for their patients.²⁴ A better fitting socket can lead to an increased level of comfort, motivation, activity and consequently better overall health. Secondly, the integration of prosthetist offices into existing hospitals would allow the prosthetists to sell robotic and traditional prosthetics at a lower markup due to decreased overhead and administrative costs, thus making the devices more accessible to lower income patients.

Appendix

HCPCS Code Addition/ Revision Application Form

Healthcare Common Procedure Coding System (HCPCS)

Alpha-Numeric Coding Recommendation Format for the 2014 Update

Instructions:

1. Please **sign and date** each recommendation. Be certain to provide the name, complete address and direct telephone number of the person to be contacted regarding this recommendation. We use this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications. Please be sure that your system can receive emails from cms.hhs.gov.
2. Please provide documentation of the item's current classification by the Food and Drug Administration (FDA). Include a copy of the cover page from the initial FDA application and **a copy of the FDA's determination, notification/approval letter**. If the

Drug/biological/product/service has been subject to an assessment by any other agency or recognized medical body, provide a copy of the results of that assessment. Note: Documentation of FDA approval of a drug or biological may be submitted after the coding application but no later than March 31, ^{provided} all other requested information is complete and submitted by the deadline.

3. Please note: **All requested information must be supplied before your recommendation for modifications to the HCPCS coding system can be considered.**

The following questions may be transferred to a word processor/computer to allow space to respond fully and completely. All questions must be answered. "N/A" is not an acceptable response. If the question does not appear to apply, provide a detailed explanation as to why it doesn't apply. Incomplete submittals will not be accepted.

4. Submit Coding Recommendations to:

Felicia Eggleston, CMS HCPCS Workgroup Coordinator Centers for Medicare and Medicaid Services C5-08-27
7500 Security Blvd Baltimore, Maryland 21244-1850

Alpha-Numeric HCPCS Coding Recommendation Format INFORMATION SUPPORTING CODING MODIFICATION RECOMMENDATION

1. For the purpose of publication on our request list and public meeting agenda on the HCPCS website, please provide a brief summary of your request (not to exceed **300 words**). In this summary, please specify your request to modify the HCPCS code set:

(e.g. number of new codes requested, recommended language; revise a code (provide old language and recommended language), discontinue a code). Include the name of the product, description, function, and the reason why existing codes do not adequately describe your product. For drugs, include the indications for use, action, dosage and route of administration, and how supplied. Text that exceeds the 300-word limit may be truncated and not appear on our published summary, therefore, it is important to provide a concise summary within the 300-word limit. CMS may edit your summary prior to publication.

2. Identify the Item (product or drug/biological) for which a Level II HCPCS Code is being requested. A) Trade or Brand Name: B) General Product Name or Generic Drug Name (active ingredient): C) FDA classification:

3. Please check one HCPCS category from the following list, which most accurately describes the item identified in question #1:

A) Medical/Surgical Supplies B) Dialysis Supplies and Equipment C) Ostomy/Urological Supplies D) Surgical Dressing E) Prosthetic F) Orthotic G) Enteral/Parenteral Nutrition H) Durable Medical Equipment I) Blood/Blood Products J) Drug/Biological K) Radiopharmaceutical L) Vision M) Hearing N) Other (please indicate/provide category)_____

4a.) Is the item durable, if so, explain how it can withstand repeated use?

Specify whether the entire item or only certain components of the item can withstand repeated use:

4b.) If the entire item can withstand repeated use, then please specify the length of the

time that the item can withstand repeated use. 4c.) If only certain components of the device can withstand repeated use, then please identify the individual components and the length of the time that the individual components can withstand repeated use. 4d.) Please provide detailed information on the warranty of the device such as the parts included under the warranty, the length of the warranty and the parts excluded from the warranty. In addition, please specify if the device includes any disposable components and the expected life or the replacement frequency recommended for the disposable components.

1. Describe the item fully in general terminology. What is it? What does it do? How is it used? Describe the patient population for whom the product is clinically indicated. Descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles on the item may be included in the information packet submitted for review, but they do not replace the requirement to fully respond to this question and fully describe the item. For drugs and biologicals, include: A) indications for use, B) action, C) dosage and route of administration, D) package insert and, E) how supplied.

2. Describe how the item/product is primarily and customarily used to serve a medical purpose.

7A) Identify similar products and their manufacturers. (If a drug -list other drugs by trade name marketed under the same active ingredient category/generic name.) 7B) Identify significant differences between this item and other products listed above. (Include differences in item cost; material; product design; how it is used; different mechanism of operation, differences in function/treatment provided to a patient; clinical indication; and clinical outcome.) 7C) Complete item 7C only if you are making a claim of significant therapeutic distinction). Claims of significant therapeutic distinction when compared to the use of other, similar items, must be described in detail. Articulate the clinical theory behind the claim, including differences in the product or its operation as it compares to currently coded products. Specify how the product results in a significantly improved medical outcome or significantly superior clinical outcome. (Please refer to the HCPCS decision tree for additional information.) Provide the best available information related to your claim. Include copies of all articles that result from your systematic analysis of the available literature. Information submitted should be as complete as possible. Unfavorable articles should be provided with any appropriate rebuttal or explanation. If the articles submitted cause you to exceed the overall 40-page limit, then submit one reference copy of each article and 35 copies of the application.

Answer each of the questions A), B), and C) below: A) List any 3rd party payers that pay for this product B) List any codes that are currently being billed to those payers for this product.

C) Explain why existing code categories are inadequate to describe the item.

9. A) Is this product prescribed by a health care professional? B) If yes -who prescribes the product and in what setting(s) is the product prescribed?

10. A) Is the item useful in the absence of an illness or injury? B) Explain:

11a.) Provide the date that the item/product was cleared for marketing by the FDA. If the product is exempt from FDA review and classification, please explain the basis for the exemption.

b.) Attach copy of the FDA approval letter including the 510(k) summary for those items that are approved using the 510(k) process. Also, if an item is cleared using the 510(k) process, identify the HCPCS codes, if applicable, that describe the predicate products listed in the 510(k) submission and explain why these codes do not adequately describe the item that is the subject of the HCPCS recommendation. In other words, if an item is listed as being substantially equivalent to another item(s) in an application for FDA marketing clearance, why is it not equivalent or comparable for coding purposes?

c.) For drugs and biologicals only: In order for an application for a code for a drug/biological can be considered timely and complete: FDA approval documentation may be submitted after the code application, but no later than March 31, 2013, provided all other application materials are complete and submitted by the deadline of January 3, 2013, and provided the application for marketing approval has been submitted to the FDA by September 30, 2012. Applicants awaiting FDA clearance for drugs or biologicals at the January 3rd submission deadline must submit with the application documentation evidencing submission for FDA approval, along with the date the application was submitted to the FDA.

12A) When was the item/product marketed in the United States?

Note For drugs and biologicals, the date of first sale is required.

12B) For all items that are not drugs and not biologics, the applicant must submit 3 months of marketing experience following the FDA approval date. For the 3 months prior to submitting this coding recommendation, what is the total number of units sold in the U.S. and the total dollar amount in sales (Medicare, Medicaid

and private insurance)? Do not estimate or provide projections -the information

provided must represent actual volume of sales for the product for the period of time

indicated. Note: For drugs and biologicals, information regarding the number of units

sold is not required.

13. Identify the percent of use of the item across the following settings. For drugs/biologicals, provide the percentage of use for the setting in which this product is or would be administered.

Physician's Office: _____

Freestanding Ambulatory Care Clinics: _____ Patient's Home by patient: _____ Patient's Home by Health Care Provider: _____ Nursing Home/Skilled Nursing Facility: _____ Hospital Inpatient Facilities: _____ Hospital Outpatient Facility: _____ Other-(identify): _____ TOTAL VOLUME OF USE ACROSS ALL SETTINGS SHOULD EQUAL 100%

14. What is the Manufacturer's Suggested Retail Price (MSRP) or list price of the item?

This question must be answered for all items, except drugs/biologicals.

HCPCS Coding Recommendation submitted by:

* Please provide a **complete** mailing address and **direct dial** phone number. We use this information to contact applicants regarding upcoming meetings, questions regarding applications, and to make notifications of the status of applications.

Name: Name of Corporation/Organization: Mailing Address (street): City, State, Zip Telephone Number and extension: FAX Number: E-Mail Address:

I attest that the information provided in this HCPCS coding recommendation is accurate and correct to the best of my knowledge.

_____ Date: _____

Signature of Applicant

Is applicant the manufacturer? Y/N If not, the manufacturer must sign the following attestation:

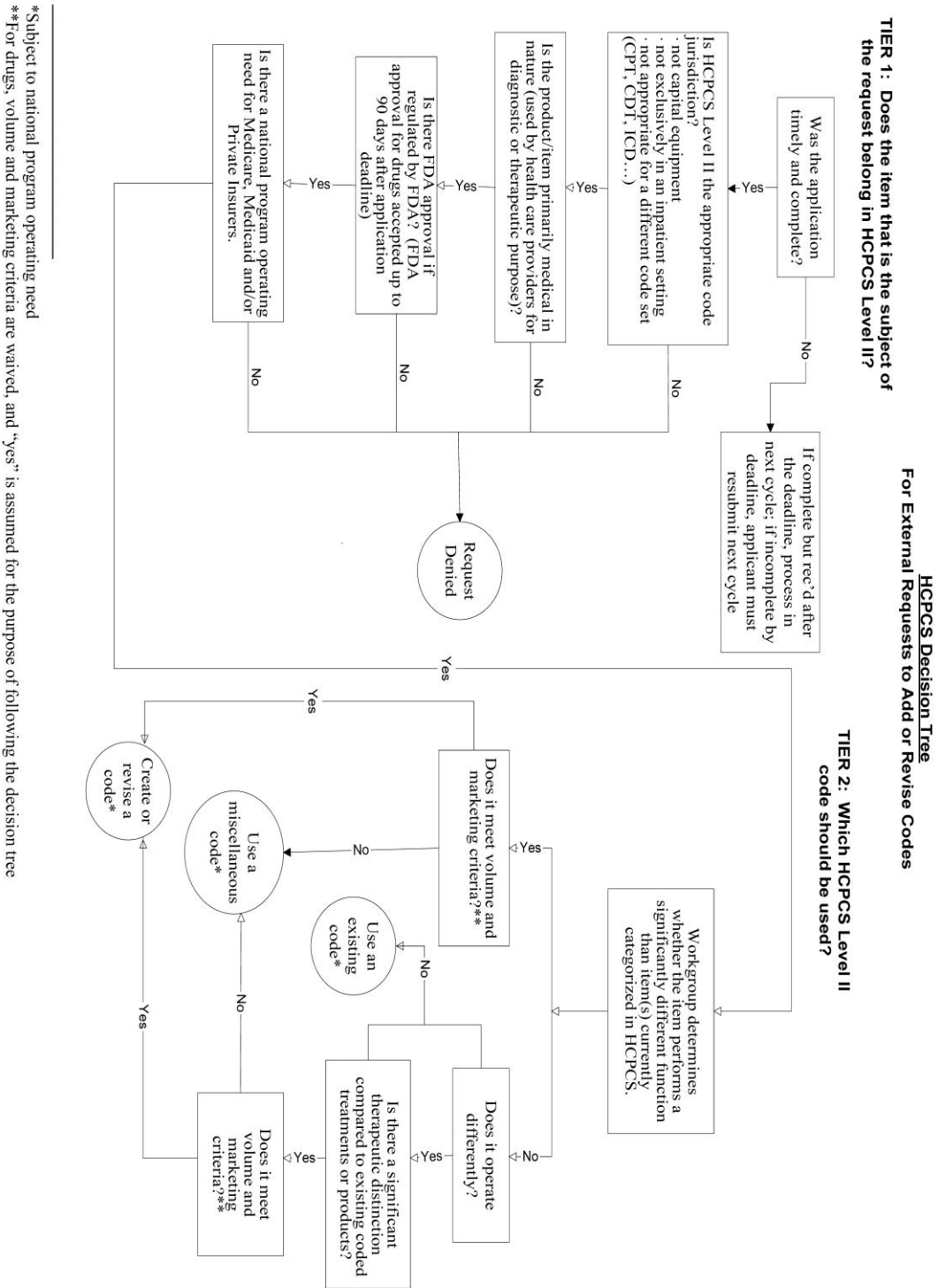
I attest that the information describing the product is accurate. _____

_____ Date: _____

Signature of Manufacturer

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1042**. The time required to complete this information collection is estimated to average 11 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

HCPCS Revision/Addition Flow Chart



*Subject to national program operating need
 **For drugs, volume and marketing criteria are waived, and "yes" is assumed for the purpose of following the decision tree

Figure 4: HCPCS Revision/Addition Flow Chart (cms.gov)

Definitions and Clarifications of HCPCS Flow Chart

Tier 1:

HCPCS 2 is the appropriate code jurisdiction: Item is not within the jurisdiction of CPT, CDT, ICD or DRG coding.

Primarily Medical in nature: Item is primarily and customarily used to serve a medical purpose and is not useful in the absence of a medical condition or injury.

FDA approved if regulated: See the online Medicare Benefit Policy Manual #100.2, Chapter 15 – Covered Medical and Other Health Service, Section 50.4.1 – Approved Use of Drug. Does not apply if regulated items are not yet approved. Note: FDA approval for drugs accepted up to 90 days after the application deadline.

National Programmatic Need: At least one insurance sector, public (Medicare or Medicaid) or private (commercial insurers) identified a program operating need to separately identify the item and that need is common across the sector, (i.e., nationally, as opposed to one or a handful of individual insurers or states). Does not apply if item identification is statutorily required.

Tier 2:

Existing or similar code: Describes a similar function to previously coded products

Volume and marketing criteria: There must be sufficient claims activity or volume (3% of affected population), as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code and establishing policy and system edits.

Note: Marketing data requirements waived for drugs only.

Performs a different function: Does something completely different to the patient. Examples: suction for a different purpose; static vs. dynamic; swing vs. stance.

Operates differently: Performs the same or similar function to other items, using a different mechanism. Examples: mechanical vs. electronic; automatic vs. manual regulating; extrinsic vs. intrinsic lubrication.

Significant Therapeutic Distinction: Improved medical benefit when compared with the use of other, similar items, e.g., significantly improved medical outcome or significantly superior clinical outcome. Requests for modifications to the HCPCS Level II code set based on such claims are reviewed on a case-by-case basis, taking into consideration clinical information provided by the applicant and other commentators that supports or refutes the claim(s) made by the applicant. In submitting a request, an applicant should provide the best available information supporting his or her claim. Greater weight will be given to more methodologically rigorous and scientifically reliable evidence. Note that process indicators (such as improved compliance, convenience and personal preference) are considered significant distinctions only to the extent that they result in demonstrably improved clinical outcomes.

Revised: October 16, 2006

Some Health Insurance Quotes

Aetna				
Plan	Category		In Network	Out of Network
Open Access Managed Choice 1500	Deductable	Individual	\$1,500	\$3,000
		Family	\$3,000	\$6,000
	Coinsurance Maximum	Individual	\$1,500	\$7,000
		Family	\$3,000	\$14,000
	Max Out-of- Pocket	Individual	\$5,000	\$10,000
		Family	\$10,000	\$20,000
	D.M.E.	Coinsurance	40%	50%
\$2000 per calendar year max				
Specialist Visit	Copay/ Coinsurance	\$45	50%	
Physical Therapy	Coinsurance	40%	50%	
	24 visits per year			
Open Access Managed Choice 2500	Deductable	Individual	\$2,500	\$5,000
		Family	\$5,000	\$10,000
	Coinsurance Maximum	Individual	\$2,500	\$5,000
		Family	\$5,000	\$10,000
	Out-of-Pocket Maximum	Individual	\$5,000	\$10,000
		Family	\$1,000	\$20,000
	D.M.E.	Coinsurance	40%	50%
\$2000 per calendar year max				
Specialist Visit	Copay/ Coinsurance	\$45	50%	
Physical Therapy	Coinsurance	20%	50%	
	24 visits per year			
Open Access Managed Choice 5000	Deductable	Individual	\$5,000	\$10,000
		Family	\$10,000	\$20,000
	Coinsurance Maximum	Individual	\$5,000	\$2,500
		Family	\$10,000	\$5,000
	Out-of-Pocket Maximum	Individual	\$10,000	\$12,500
		Family	\$20,000	\$25,000
	D.M.E.	Coinsurance	20%	50%
\$2000 per calendar year max				
Specialist Visit	Copay/ Coinsurance	\$45	50%	
Physical Therapy	Coinsurance	20%	50%	
	24 visits per year			

Table 5: Aetna Health Insurance Quotes¹⁵

Assurant (default non-customized plans)				
Plan	Category		In Network	Out of Network
Value Plan	Deductible	Individual	\$5,000	\$6,000
		Family	\$5,000	\$6,000
	Coinsurance Maximum	Individual	\$4,000	\$10,000
		Family	\$8,000	\$20,000
	Out-of-Pocket Maximum	Individual	\$9,000	\$16,000
		Family	\$23,000	\$38,000
	D.M.E.	Coinsurance	50%	50%
Deductible & Coinsurance Maximum				
Specialist Visit	Coinsurance	50%	50%	
Physical Therapy	Coinsurance	50%	50%	
	unlimited visits			
OneDeductible PPO HAS	Deductible	Individual	\$5,000	\$5,500
		Family	\$10,000	\$11,000
	Coinsurance Maximum	Individual	\$0	\$1,000
		Family	\$0	\$2,000
	Out-of-Pocket Maximum	Individual	\$5,000	\$6,500
		Family	\$10,000	\$13,000
	D.M.E.	Coinsurance	100%	80%
Deductible and Coinsurance Maximum				
Specialist Visit	Coinsurance	100%	80%	
Physical Therapy	Coinsurance	100%	80%	
	unlimited visits			
PPO X-tra Plan	Deductible	Individual	\$5,000	\$6,000
		Family	\$5,000	\$6,000
	Coinsurance Maximum	Individual	\$2,500	\$10,000
		Family	\$5,000	\$20,000
	Out-of-Pocket Maximum	Individual	\$7,500	\$16,000
		Family	\$20,000	\$38,000
	D.M.E.	Coinsurance	50%	50%
Deductible & Coinsurance maximum				
Specialist Visit	Coinsurance	50%	50%	
Physical Therapy	Coinsurance	50%	50%	
	unlimited visits			

Table 6: Assurant Health Insurance Quotes²⁸

Anthem Blue Cross Blue Shield				
Plan	Category		in network	out of network
Premier	Deductable	Individual	\$500 - \$10,000	\$500 - \$10,000
		Family	\$1,000 - \$20,000	\$1,000 - \$20,000
	Coinsurance Maximum	Individual	\$0 - \$3,000	\$7,500
		Family	\$0 - \$6,000	\$15,000
	Out-of-Pocket Maximum	Individual	\$3,500 - \$10,000	\$8,000 - \$17,500
		Family	\$7,000 - \$20,000	\$16,000 - \$35,000
	D.M.E.	Coinsurance	0 - 20%	30%
Deductable & Coinsurance Maximum				
Specialist Visit	Copay/ Coinsurance	\$40	30%	
Physical Therapy	Coinsurance	0 - 20%	30%	
	20 visits per year			
SmartSense	Deductable	Individual	\$750 - \$12,000	\$750 - \$12,000
		Family	\$1,500 - \$24,000	\$1,500 - \$24,000
	Coinsurance Maximum	Individual	\$0 - \$4,000	\$7,500
		Family	\$0 - \$8,000	\$15,000
	Out-of-Pocket Maximum	Individual	\$4,750 - \$12,000	\$8,250 - \$19,500
		Family	\$9,500 - \$24,000	\$16,500 - \$39,000
	D.M.E.	Coinsurance	0 - 50%	30 - 50%
Deductable & Coinsurance Maximum				
Specialist Visit	Copay/ coinsurance	\$30 for first three	30 - 50%	
Physical Therapy	Coinsurance	0 - 50%	30 - 50%	
	20 visits per calendar year			
Lumenos HAS Plus	Deductable	Individual	\$1,500 - \$5,950	\$1,500 - \$5,950
		Family	\$3,000 - \$11,900	\$3,000 - \$11,900
	Coinsurance Maximum	Individual	\$0 - \$1,000	\$3,500 - \$5,950
		Family	\$0 - \$2,000	\$7,000 - \$11,900
	Out-of-Pocket Maximum	Individual	\$2,500 - \$5,950	\$5,000 - \$11,900
		Family	\$5,000 - \$11,900	\$10,000 - \$23,800
	D.M.E.	Coinsurance	0 - 20%	30 - 40%
Deductable & Coinsurance Maximum				
Specialist Visit	Coinsurance	0 - 20%	30 - 40%	
Physical Therapy	Coinsurance	0 - 20%	30 - 40%	
	20 visits per calendar year			

Table 7: Anthem Blue Cross Blue Shield Health Insurance Quotes¹³

Medicare		
Plan	Category	Costs
Part B	Deductable	\$140
	Coinsurance Maximum	N/A
	Max Out-of-Pocket	N/A
	D.M.E	20% of the Medicare approved cost plus the difference between the approved cost and the actual cost. 60 visits per year for physical therapy
	Specialist Visit	
	Physical Therapy	

Table 8: Medicare Coverage¹⁴

A Description of each K Level and the Amputee Mobility Predictor Tool

K-Level 0	Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance quality of life or mobility.
K-Level 1	Has the ability or potential to use a prosthesis for transfers or ambulation in level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator.
K-Level 2	Has the ability or potential for ambulation with the ability to transverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
K-Level 3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.
K-Level 4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Table 9: Description of K Levels²⁹

AMPUTEE MOBILITY PREDICTOR ASSESSMENT TOOL – AMPnoPRO

Instructions: Testee is seated in a hard chair 40-50cm height with arms. The following maneuvers are tested with or without the prosthesis. Advise the person of each task or group of tasks prior to performance. Please avoid unnecessary chatter throughout the test and no task should be performed if either the tester or testee is uncertain of a safe outcome. One attempt only per item. Maximum of 2 days allowed to complete assessment.

The right limb is: PF TT KD TF HD intact The left limb is: PF TT KD TF HD intact

NAME: _____ ASSESSOR: _____ DATE: _____ TIME: _____

			Comments
1. Sitting Balance Sit forward without backrest, with arms folded across chest for 60s.	Cannot sit upright independently for 60s Can sit upright independently for 60s	=0 =1	
2. Sitting reach Reach forwards and grasp the ruler using preferred arm (Tester holds ruler 26cm beyond extended arm midline to the sternum, or against the wall, intact foot midline)	Does not attempt Cannot grasp or required arm support Reaches forward and successfully grasps item	=0 =1 =2	
3. Chair to chair transfer 90° Chair height between 40-50cm, allowed to use aid but no armrests	Cannot do or requires physical assistance Performs task but unsteady or needs contact guarding Performs independently	=0 =1 =2	
4. Arises from chair—single effort Chair height between 40-50cm, tester asks patient to cross arms over chest. If unable, uses arms or assistive device	Unable without physical assistance Able, uses arms/assistive device to help Able without arms	=0 =1 =2	
5. Arises from chair—multiple effort Chair height between 40-50cm, multiple efforts allowed without penalty	Unable without physical assistance Able but requires > 1 attempts Able to rise in one attempt	=0 =1 =2	
6. Immediate standing Balance (1st 5 secs) Standing on one leg, timing commences at initial hip extension	Unable Able, but requires use of arms for support Able without arm support	=0 =1 =2	
7. Standing balance :30seconds 1 st attempt do not use arm support, if unable, may use arm support on 2 nd attempt	Unable Able, but requires use of arms for support Able without arm support	=0 =1 =2	
8. (Amypro only)			
9. Standing balance: standing reach Reach forward and grasp the ruler 26cm beyond preferred arm midline to the sternum or against a wall	Unable Able, but requires use of arms for support Able without arm support	=0 =1 =2	
10. Standing balance: nudge test Standing on one leg, tester gently pushes on subjects sternum with palm of hand 3 times (ONLY if safe to do so)	Begins to fall, needs catching catches self using arms for support Steady, toes come up for equilibrium reaction	=0 =1 =2	
11. Standing balance: eyes closed 30sec.	Unsteady or uses arm support Steady without arm support	=0 =1	
12. Standing balance: picking object off the floor Object is placed 30cm in front of patient, midline	Unable Able, but requires use of arms for support Able without arm support	=0 =1 =2	
13. Stand to sit Patient is asked to sit in chair with arms crossed over chest. If unable, allow use of hands	Unable, or falls into chair Able, but uses arms for support Able, without use of arms	=0 =1 =2	
14. Initiation of gait Patient is asked to hop with an aid and observed for hesitancy	Any hesitancy or multiple attempts to start No hesitancy	=0 =1	
15. Hopping 8 meters a) Step length b) Foot clearance (discourage deviations incl. Circumduction, foot sliding or shuffling)	a) Does not advance 30cm on each hop Advances minimum of 30cm each hop b) Unable to clear foot without deviations Clears foot on every step	=0 =1 =0 =1	
16. Step continuity	Stopping or discontinuity between hops Hops appear continuous	=0 =1	
17. Turning 180° turn to sit in chair	Unable to turn without physical assistance No assistance, 4 or more hops to turn No assistance, 3 or less hops to turn	=0 =1 =2	
18. Variable cadence Patient is asked to hop 4 metres, and repeat a total of 4 times. Speeds are to vary from slow, fast, fast and then slow (ONLY if safe to do so)	Unable to vary cadence Able to vary cadence, but asymmetrical step lengths used or balance compromised Able without asymmetry or balance compromise	=0 =1 =2	

19. Hopping over an obstacle The patient is asked to hop over an obstacle 10cm high	Unable Able, but catches foot or appears unsafe Able, safe and independant	=0 =1 =2	
20. Stairs Patient is asked to ascend and descend at least 2 steps without holding the rail using crutches. If unable, patient may use the rail.	Ascending; Unable Able using the rail Able without the rail Descending; Unable Able using the rail Able without the rail	=0 =1 =2 =0 =1 =2	
21. Assistive device selection	Bed bound Wheelchair Frame Crutches	=0 =1 =2 =3	

Score ___/39

K Classification	AMPnoPRO score	Key AMP Tasks
K0	?	Items 1,2,3,4,5,6,7 <ul style="list-style-type: none"> Ability to sit or stand without difficulty
K1	?	Items 4,6,7,9,10,13,14 <ul style="list-style-type: none"> Able to sit to stand Moderate standing balance Can't displace COM over BOS Initiates gait, possibly hesitant Uses an assistive device Probably low endurance
K2	?	Items 7,9,10,15,16,17 <ul style="list-style-type: none"> Able to maintain standing balance Ability for limited displacement of COM over BOS Able to maintain balance with assistance when nudged Able to take a full stride with at least one foot Maintains step continuity and can complete a 3 step turn without intervention
K3	?	Items 9,10,12,15,16,17,19,20 <ul style="list-style-type: none"> Ability to maintain single limb balance Able to displace COM without difficulty Able to maintain balance without assistance when nudged Able to alter COM and correct without difficulty Gait demonstrates equal strides, good continuity, varied cadence Ability to turn independently with less than 3 steps Able to step over obstacles and climb stairs
K4	?	Items 9,15,16,17,18,19,20 <ul style="list-style-type: none"> Ability to maintain single limb balance with both legs Able to perform most tasks at the highest level with good balance Gait is symmetrical with the ability to clearly vary cadence and negotiate turns, obstacles and stairs independently

Table 10: The Amputee Mobility Predictor Tool²⁹

Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices



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Analysis of Assembly Bill 2012-Amended: Orthotic and Prosthetic Devices

Estimated Monthly Premium Impact of SB 931

	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
Individual (standard)	10	\$0.18	\$1.00	\$0.12
Individual (optional)	0 -- --			
Group (standard)	14	\$0.24	\$1.73	\$0.11
Group (optional)	3	\$0.11	\$22.29	\$0.11

Source: Bureau of Insurance Survey of Insurance Providers, 2007

- Other states that have reviewed similar mandates have estimated the premium impact on the consumer to be between \$0.12 and \$0.35 per premium per month. Estimates for Virginia were even lower; with per premium per month impacts between \$0.02 and \$0.08.
- Several of these studies also found a potential cost savings in both private and public sector health insurance from reduced spending on associated complications, physical rehabilitation, and coverage provided under State Medicaid programs.
- Costs to insurance companies will most likely increase as a result of providing increased coverage for prosthetic devices. However, establishing a baseline level of coverage has the potential to reduce costs associated with individual coverage appeals related to current restrictions on prosthetic care.

Key Findings

- Mandating coverage defined in SB 931 will establish a minimum level of coverage for individuals requiring prostheses and increase individual access to certain device types.
- The availability of prosthetic devices can improve the physical and psychological functioning of persons with amputations, injuries, and congenital physical disabilities by enabling them to exercise and perform other activities of daily life.
- In addition, most amputees with prostheses return to some form of work and show a reduction in secondary conditions that can result from their disability.
- Mandating this benefit is not expected to have an impact on an individual demand for prosthetic devices.
- Given that the population affected by this mandate would be under 65, the potential social impact of the proposed mandate would be the ability of individuals to more fully contribute to society.
- Qualitative data suggests that use of prosthetic devices increases the quality of life for the user. This has the potential to reduce the cost of additional complications or amputations, as well as the incidence of compounding disease related to increased sedentary lifestyle.

For more information about our efforts in the state, contact the Advocacy Department at 202/742-1885 or state@amputee-coalition.org. To get involved in our federal campaign, contact us at 202/742-1886 or federal@amputee-coalition.org.



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Social Need Consistent With Role of Insurance

- Based on the premise that the role of health insurance is to promote public health, encourage the use of preventive care, and to provide protection from catastrophic financial expenses for unexpected illness or injury, the proposed mandate appears consistent with the role of health insurance.
- Prosthetic devices are restorative in nature, and often allow a user to regain a level of social functionality comparable to their pre-amputation condition.
- While these devices do not treat the initial reason for the amputation, they may prevent additional medical complications.

Cost of Secondary Complications

Without prosthetic care, many individuals will lead a more sedentary lifestyle which may lead to secondary complications depending on procedures used and the patient's lifespan, including:

- costs of medications for diabetes-related complications;
- instances of heart attack due to peripheral vascular disease, for which surgical treatment and hospitalization can cost from \$75,000 to \$200,000;
- development of knee or hip problems from being unable to walk correctly, for which surgery can cost from \$80,000 to \$150,000 or more; and
- crutch overuse leading to wrist, elbow and shoulder problems, which can cost between \$7,500 and \$25,000.

Mandating coverage may reduce the overall costs of health care due to a reduction in secondary complications.

Prepared for: Virginia Special Commission on Mandated Health Benefits

Prepared by: Joint Legislative Audit Review Commission, 2007

For more information about our efforts in the state, contact the Advocacy Department at 202/742-1885 or state@amputee-coalition.org. To get involved in our federal campaign, contact us at 202/742-1886 or federal@amputee-coalition.org.

Prosthetic Designers/Manufacturers Interview Questions

Please answer the following to the best of your ability. If at any point you feel uncomfortable answering a question, you may feel free to skip it.

Customer Base

1. Approximately how many people use the **name of device**?
2. What companies purchase the **name of device**?
3. Approximately how many companies purchase the **name of device**?

How much do companies pay for each **name of device**?

Costs

4. Approximately how much do the components and materials in each **name of device** cost?
5. Approximately what does it cost to manufacture and assemble each **name of device**?
6. Approximately what percent of each **name of device**'s cost goes towards paying employees?

Research and Development

7. What kind of equipment did you use in order to test the **name of device**?
8. How much did it cost?
9. Did you get investors in order to help fund the R&D or manufacture of the **name of device**?
10. If so how much did they contribute?

Patents

11. Did you purchase a patent for the **name of device**?
12. Did you obtain investors in order to purchase your patent?
13. If so how much did they invest?

FDA

14. Did your company face any losses during the FDA approval process?
15. What's the Future for Prosthetics?
16. With the decreasing price of technology in mind, do you think that robotic prosthetics will become available to the average user?

Robotic Prosthetic User Survey

<https://docs.google.com/spreadsheets/formResponse?pli=1&formkey=dDk1bGNXTVdoM1JWRi15Yk5qWjU2OFE6MQ&ptok=4035386664722204212&ifq>

Please only fill out this survey if you currently use, or have previously used, a robotic prosthetic device. For the purpose of this project, any electronically powered prosthetic is considered robotic. A few examples include the C-Leg, Rheo Knee, i-Limb, Proprio Foot, and myoelectric prosthetics. I am part of a project team at Worcester Polytechnic Institute that is currently investigating the high prices of robotic prosthetics. I would be extremely pleased if you filled out the following survey, so that my team and I might gain a better perspective on the financial challenges amputees face. Your responses will be kept completely anonymous.

1. Please specify your level of amputation.
2. What is the name of the robotic prosthetic you use/have used?
3. Would you rather use a traditional prosthetic or a robotic one?
Why?
4. Are you pleased with the function of your robotic prosthetic?
Why?
5. Do you feel there is a prosthetic that would better suit your needs?
6. If so, please give a description or the name of the prosthetic.
7. Was price a major factor when choosing your robotic prosthetic?
8. If so, how did it affect your decision?

Prosthetic Price

9. What was the total out-of-pocket expense for your prosthetic? How much did you personally pay?

10. What was the total cost of your robotic prosthetic? How much would it have cost you without health insurance or other aid?

11. What health insurance provider did you have when you purchased your prosthetic?

12. Approximately what percent of the cost did your health insurance cover?

13. If you received any other financial aid, who provided it? Type the names of any sources of aid you received. (Veteran's Affairs, Barr Foundation, Limbs for Life, etc.)

14. If you received any other financial aid, how much of the cost did it cover?

15. On a scale of 1-5, was the price of your robotic prosthetic reasonable or unreasonable?

Physical Therapy and Associated Costs

16. What was the total out-of-pocket expense for your physical therapy?

17. If you required physical therapy, what was the total cost? How much would it have cost you without health insurance or other financial aid?

18. Approximately what percent of the cost did your health insurance cover?

19. If you received any other financial aid, how much of the cost of physical therapy did it cover?

Warranty

20. How long is the warranty for your robotic prosthetic?

21. What's the average amount of time you use a robotic prosthetic for before it needs to be replaced or repaired?

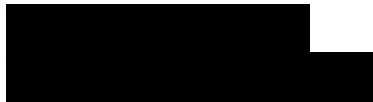
Are you paying too much for your robotic prosthetic?

My project group at Worcester Polytechnic Institute is currently investigating the high prices of robotic prosthetics.

My group partners and I are collecting survey data and conducting interviews with amputees, health insurance representatives, prosthetists, and manufacturers, in order to find a means for reducing the cost of these prosthetics.

Your help would be greatly appreciated in aiding this effort. We would love to hear about any of your experiences with your robotic prosthetic and we would be grateful if you would be willing to answer a brief questionnaire. Any data collected will be kept strictly anonymous.

Contact me at:



Daniel Topping
Worcester Polytechnic Institute
Biomedical Engineering
Class of 2013

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