Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries

Final Report

Dobson | DaVanzo

Dobson DaVanzo & Associates, LLC Vienna, VA 703.260.1760 www.dobsondavanzo.com

Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries

Final Report

Submitted to:
American Orthotic and Prosthetic Association
The Amputee Coalition

Submitted by:

Dobson | DaVanzo

Al Dobson, Ph.D.
Audrey El-Gamil
Matt Shimer, Ph.D.
Joan E. DaVanzo, Ph.D., M.S.W.

Friday, July 19, 2013 — *Final Report*

Table of Contents

Executive Summary

Lower extremity and spinal orthotic and prosthetic devices and related clinical services (O&P services) are designed to provide stability and mobility to patients with lower limb loss or impairment and spinal injury. There are few studies of the economic impact or value of O&P services. Even though O&P services currently represent less than 1 percent of Medicare spending, the role of Medicare in the O&P industry will be critical for patients and providers as health care reform is implemented.

This study finds that patients who received O&P services experience greater independence than patients who do not, with better or comparable outcomes and Medicare payments.

The Amputee Coalition and its partner, the American Orthotic and Prosthetic Association (AOPA), commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to conduct a retrospective analysis of Medicare claims data to determine the extent to which patients who received select O&P services had less health care utilization, lower Medicare payments, and/or fewer negative outcomes compared to similar patients who did not receive O&P services. This analysis focuses on the impact on Medicare beneficiaries of receiving:

- lower extremity orthoses,
- spinal orthoses, and
- lower extremity prostheses for patients who received an amputation within 12 months of receiving the prosthetic.

Methodology in Brief

This retrospective cohort study investigated the impact of receiving an O&P service on patient outcomes and Medicare payments. A custom cohort dataset was requested from the Centers for Medicare & Medicaid Services (CMS) that comprised claims across all settings[1] from 2007-2010 for patients who met the study's sampling specifications.

[1] Care settings include: inpatient and outpatient hospitals, long-term care hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, hospice, physician/carrier visits, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Beneficiaries were included in the study group if they had received an O&P service between January 1, 2008 and June 30, 2009, and had pre-determined etiological diagnoses of interest. Additionally, patients who received a lower extremity prosthetic were required to have had an amputation within the preceding 12 months. Comparison group patients who did not receive the O&P service were matched to study group patients (one-to-one) through propensity score matching techniques that control for observable selection bias based on etiological diagnosis, comorbidities, patient characteristics (age, gender, race), and historical health care utilization one year prior to the etiological diagnosis. Patients were also matched on whether they died during the episode to further control for selection bias.

Patient episodes were developed for each of the three O&P services that included at least one year of claims prior to, and at least 18 months following, the receipt of the O&P service (or a proxy date for comparison group patients). We compared health care utilization, Medicare episode payments, and negative outcomes across the study and comparison group patients over 18 months for the lower extremity and spinal orthoses, and over 12 months for the lower extremity prostheses. These time periods were selected based on results of a temporal autocorrelation function, which indicated that beyond these thresholds, the Medicare episode payments can no longer be attributed to the receipt of the O&P service. (Additional information on the temporal autocorrelation function can be found in the Methodology chapter and technical appendix – Appendix B.)

Summary of Results

Exhibit ES-1 summarizes the results of our analyses for each service group. Within the ***lower extremity orthoses***, our analyses suggest that patients who received lower extremity orthoses had better outcomes over 18 months, defined as fewer acute care hospitalizations and emergency room admissions and reduced costs to Medicare (episode payments approximately 10 percent lower than the comparison group, including the cost of the orthotic) ($p<0.05$). Additionally, these patients were able to sustain significantly more rehabilitation, and were able to remain in their homes as opposed to needing placement in facility-based settings ($p<0.05$).

Patients who received ***spinal orthoses*** had comparable Medicare payments over 18 months to those who did not receive the orthotic, and had higher reliance on ambulatory and home-based care (as opposed to facility-based care) ($p<0.05$). This could suggest that the use of spinal orthoses allows patients to be less bedbound and remain independent in their homes. These patients had more falls and fractures, which may be due to their increased ambulation and independence. However, these falls did not result in a higher number of emergency room admissions compared to comparison group patients.

Among ***lower extremity prostheses*** patients, our results indicate that patients who received lower extremity prostheses had comparable Medicare episode payments (including the cost of the prosthetic) and better outcomes than patients who did not receive prostheses. Study group patients were more likely to receive extensive outpatient therapy than comparison group patients ($p<0.05$). The receipt of physical therapy is associated with fewer acute care hospitalizations and emergency room admissions, and less facility-based care ($p<0.05$), which offsets the cost of the prosthetic. Results suggest that the device was nearly amortized by the end of 12 months and the patient could experience higher quality of life and increased independence compared to patients who did not receive the prosthetic.

Exhibit ES-1: Health Care Utilization, Average Use of Therapy, and Patient Outcomes by Cohort (2008-2010)

Health Care Utilization and Outcomes	Study Group	Comparison Group	Difference
Lower Extremity Orthoses (18 month episode; 34,864 pairs)			
Total Average Medicare Episode Payments	$27,007	$29,927	-$2,920*
Average Medicare PMPM Payment	$1,500	$1,663	-$162*
Average Number of IRF Days	0.72	0.52	0.20*
Average Number of OP Therapy Visits	17.4	12.1	5.26*
Number of Fractures and Falls	1.45	1.52	-0.07
Number of ER Admissions	1.08	1.20	-0.13*
Number of Acute Care Hospitalizations	0.62	0.70	-0.08*
Spinal Orthoses (18 month episode; 6,247 pairs)			
Total Average Medicare Episode Payments	$32,598	$32,691	-$93
Average Medicare PMPM Payment	$1,811	$1,816	-$5
Number of Fractures and Falls	2.05	1.56	0.50*
Number of ER Admissions	1.35	1.32	0.03
Number of Acute Care Hospitalizations	0.82	0.78	0.03
Lower Extremity Prostheses (12 month episode; 428 pairs)			
Total Average Medicare Episode Payments	$68,040	$67,312	$728
Average Medicare PMPM Payment	$6,099	$6,015	$85
Average Number of IRF Days	1.61	1.19	0.42
Average Number of OP Therapy Visits	56.1	28.9	27.18*
Number of Fractures and Falls	0.90	0.72	0.18
Number of ER Admissions	1.55	2.10	-0.55*
Number of Acute Care Hospitalizations	1.18	1.51	-0.34*

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition. PMPM - per-member-per-month payment; IRF - inpatient rehabilitation facility; OP - outpatient.
* Statistically significant at p< 0.05

Executive Summary

The results of our analyses suggest that patients who received O&P services were more likely to receive the physical therapy and rehabilitation required for them to remain in the community and avoid facility-based care. The goal of restoring function is emphasized in many of Medicare's covered services (i.e., skilled home health care and inpatient rehabilitation facilities), and therefore supports the targeted use of O&P services for patients who are able to benefit from and receive the requisite therapy. The increased physical therapy among O&P users allowed patients to become less bedbound and more independent, which may be associated with higher rates of falls and fractures, but fewer emergency room admissions and acute care hospital admissions. This reduction in health care utilization ultimately makes O&P services cost-effective for the Medicare program and increases the quality of life and independence of the patient.

Introduction

Lower extremity and spinal orthotic and prosthetic devices and related clinical services (O&P services) are designed to provide stability and mobility to patients with lower limb loss or impairment and spinal injury. While the literature contains considerable evidence of geographic variation in both major amputation rates and the use of orthotic and prosthetic (O&P) services, there are limited studies on the extent to which beneficiaries who receive O&P services experience a reduction in complications and/or costs. There are few studies of the economic impact or value of O&P services. Even though O&P services currently represent less than 1 percent of Medicare spending, the role of Medicare in the O&P industry will be critical for both patients and providers.

The Amputee Coalition and its partner, the American Orthotic and Prosthetic Association (AOPA), commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to conduct a retrospective analysis of Medicare claims data to determine the extent to which patients who received select O&P services had less health care utilization, lower Medicare payments, and/or fewer negative outcomes. This analysis focuses on the impact of receiving lower extremity orthoses, spinal orthoses, and lower extremity prostheses.

This study's primary objective was to determine the economic value of O&P services in terms of the totality of a beneficiary's health care utilization and expenditures. Specifically, the study aimed to determine the financial benefit to government and private payers when a person with limb loss, limb impairment, or spinal injury attains restored mobility through receipt of O&P services. Financial benefit, or economic value, was determined based on the health care utilization and costs for those beneficiaries who received O&P services, compared to similar beneficiaries who did not receive O&P services, for whatever reason. This value can be applied directly to the Medicare program, and indirectly, but powerfully, to the beneficiary's quality of life.

A review of the literature suggests that receipt of O&P services improves patient outcomes on a variety of functional and psychosocial measures, as well as increases quality of life. Additionally, O&P services can reduce health care spending for some patients by

preventing downstream clinical complications and reducing other types of utilization. Based on the literature, it is reasonable to expect the reduction in health care utilization by Medicare beneficiaries with O&P services to at least cover the cost of the O&P service and to improve a variety of patient outcomes. However, more research is needed to understand the relationship between O&P service provision and health care costs.

The use of assistive technology has become more widespread over the past three decades, given the recent growth in the aged population and military service related traumas. Currently, there are approximately two million individuals in the United States who are living with limb loss. The total number of individuals with an amputation, and those using prostheses, is expected to reach 2.4 million by the year 2020. In addition, the total number of persons with paralysis, deformity, or orthopedic impairments that use orthoses is expected to reach 7.3 million by the year 2020.[2]

A brief summary of the literature as it relates to patient outcomes and costs is provided below, and a summary of each studied reviewed is presented in Appendix A.

PATIENT OUTCOMES – FUNCTIONAL ABILITY & PSYCHOSOCIAL ISSUES: While the variability in measures of quality and patient outcomes in research on O&P services can make comparisons difficult, a number of studies have shown that the provision of O&P services led to measurable improvements in the quality of patient care and functional and psychosocial outcomes. Beyond physical health, receipt of O&P services is associated with improved mental health status, in terms of social functioning, general health perception, and role limitation due to emotional problems. Research also suggests that the receipt of O&P services can lead to benefits beyond the reduction of health care utilization and provider payments, such as societal gains including returning to work and reliance on social services. The use of more sophisticated technology has been found to increase the quality of care and patient outcomes

COST BENEFIT AND ECONOMIC VALUE: Long-term savings result when patients receive appropriate prosthetic care. Without prosthetic care, individuals live more sedentary lifestyles, which research has shown to lead to secondary complications, such as diabetes and other related clinical issues and increases in health care utilization and spending.

CURRENT AND FUTURE ACCESS TO O&P SERVICES: Despite research that suggests that O&P services can prevent falls, reduce downstream clinical manifestations such as the development diabetes, and lead to long-term savings in health care spending,

[2] American Academy of Orthotists and Prosthetists. (2006). O&P trends and statistics. Retrieved from: http://www.opcareers.org/assets/pdf/TrendsFINAL.pdf

patients can face significant barriers to access. Creation of parity laws or inclusion of O&P services as ”essential benefits” are likely the only way to ensure appropriate access to patients with disabilities. Several states have found that parity legislation can be implemented with only minimal cost and can produce significant benefit to the patient.

This report includes the methodology and results of a retrospective cohort analysis using four years of Medicare beneficiary claims. In the next chapter, we indicate how our study is designed to test whether O&P services improve patient outcomes and reduce costs for Medicare beneficiaries through conducting a retrospective cohort analysis of recent Medicare claims data.

Methodology

The analytic methodology for this retrospective cohort study consisted of several key components, including: 1) developing patient episodes using the Medicare claims; 2) developing patient cohorts of O&P users and matched comparison groups; and 3) calculating descriptive statistics and analyzing the outcomes associated with specific O&P services on overall patient Medicare episode payments. All of the analyses were conducted on a custom cohort claims database requested from the Centers for Medicare & Medicaid Services (CMS).[3] We discuss the methodology for developing the claims database and each of these analytic components in the sections below. Additional detail is provided in the technical methodology, found in Appendix B.

Custom Cohort Medicare Claims Database

This retrospective cohort study investigated the impact of receiving an O&P service on patient outcomes and Medicare payments. We focused this analysis on three groups of services:

- lower extremity orthoses;
- spinal orthoses; and
- lower extremity prostheses for patients who received an amputation within 12 months of receiving the prosthetic.

In collaboration with a clinical advisory committee, we identified the O&P services to be included in each of the service groups. Appendix B identifies the specific HCPCS codes included in each group.

We requested a custom cohort dataset from CMS with claims across all settings from 2007-2010 for patients who received and did not receive O&P services. This database served as the analytic sample for all of our analyses.

[3] Data were obtained under DUA #21558.

Methodology

The sampling methodology utilized by CMS to extract the custom cohort database allows our analyses to reflect those Medicare beneficiaries who received specified O&P services between January 1, 2008 and June 30, 2009 in accordance with our specification criteria. Patients were required to have received the O&P service during the specified time period and must also have had appropriate etiological diagnoses (discussed more below). As an additional requirement, patients who received a lower extremity prosthetic were required to also have had an amputation within 12 months prior to the receipt of the prosthetic. The codes used to identify an amputation and the etiological diagnoses of interest for each group are included in the technical methodology presented in Appendix B.

Health care claims across all care settings[4] from 2007 through 2010 were obtained for the beneficiaries who met the sampling specifications. Therefore, the database includes one year of claims prior to, and at least 18 months following, the receipt of the O&P service. While, in many cases, patients received more than one O&P service during the 18 month period (either replacement or bilateral services), our analyses were anchored to the first ("index") O&P service during the period.

Within the custom cohort database, CMS also provided Medicare claims from 2007-2010 across all settings for patients that did not receive O&P services. This population served as the basis for our matched comparison group. CMS identified the comparison group patients by matching them to the patients who received O&P services (study group) based on the presence of an etiological diagnosis, gender, age, and beneficiary state of residence. CMS provided us with five comparison group patients preliminarily matched to each study group patient.

EXTRAPOLATION OF CUSTOM COHORT DATABASE TO ALL MEDICARE BENEFICIARIES:
To estimate the proportion of Medicare services (not patients) reflected in our custom cohort database, we compared the O&P utilization by HCPCS code in the custom cohort dataset in calendar year 2008 to the O&P utilization reported in the 100 percent aggregate utilization file released by CMS.[5] It is our estimate that the sample methodology presented above captured virtually all of the lower extremity and spinal orthoses provided to Medicare beneficiaries in 2008, but only captured about 37 percent of the lower extremity prostheses during this period. The low proportion of lower extremity prostheses included in our custom cohort dataset was due to the requirement that the prosthetic must have been provided to a patient within 12 months of his/her amputation. Therefore, while

[4] Care settings include: inpatient and outpatient hospitals, long-term care hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, hospice, physician/carrier visits, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

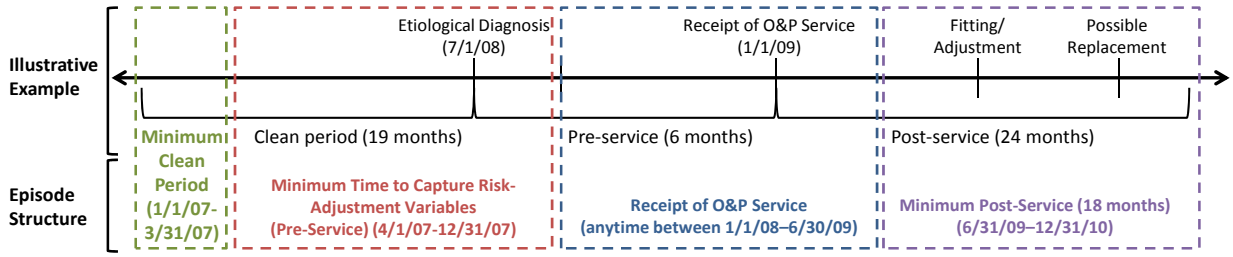
[5] Utilization from the custom cohort dataset was compared to the utilization in the Physician Supplier Procedure Summary Master File for 2008 only.

the results of lower and spinal orthoses can be extrapolated to the entire Medicare population, the results for prosthetic patients can only be extrapolated to other "new prosthetic" users and not the overall prosthetic population.

Developing Patient Episode Definitions

For each of the O&P service groups, we developed patient episodes that would allow for us to capture health care diagnoses, utilization, and expenditures prior to, and after, receipt of the O&P service. The structure for the study group patient episodes was consistent across the groups of services, as presented in Exhibit 3.1.

Exhibit 3.1: Structure of the Patient Episode Definitions for the Study Group with Embedded Illustrative Example



All study group patient episodes contained the following key features:

- **RECEIPT OF O&P SERVICE:** Across all patient episodes, the study group patient must have received the O&P service between January 1, 2008 and June 30, 2009. This allowed us to maximize our sample size, as only patients with 18 months of claims were considered for matching. Furthermore, it allowed for a consistent structure for the remaining episode elements.

- **THE ETIOLOGICAL DIAGNOSIS FOR WHICH THE PATIENT IS RECEIVING THE O&P SERVICE**. The etiological diagnosis was the diagnosis for the condition which ultimately led to the need for the O&P service (likely functional diagnosis), not the diagnosis linked to the claims at the time of receipt of the O&P service. The etiological diagnosis is used to match the O&P users to non-users (study to comparison group) and must be present during the pre-service window. Furthermore, etiological diagnosis is also used to control for mortality across groups (see next section). The etiological diagnosis (as defined by Clinical Classification Software – CCS[6]) was identified with assistance from the study's clinical committee. The list of possible etiological diagnoses for each group of

[6] CCS is developed by the Agency of Healthcare Research and Quality as part of the Healthcare Cost and utilization Project (HCUP). CCS is a diagnosis and procedure categorization scheme that collapses ICD-9s into smaller, clinically meaningful categories.

services is presented in Appendix B. While patients may have more than one of the etiological diagnoses present at a time, the first one evidenced in the claim is used to define them.

- **CLEAN PERIOD PRIOR TO ETIOLOGICAL DIAGNOSIS.** To ensure proper matching to the comparison group, we required a three month minimum clean period for each patient episode prior to the etiological diagnosis to prevent the study group from containing patients with a lengthy history of the etiological diagnosis, which may have impacted the clinical outcome as well as their use of the O&P service.

- **PRE-SERVICE WINDOW PRIOR TO THE RECEIPT OF THE O&P SERVICE.** The etiological diagnosis was identified within 12 months prior to the receipt of O&P services (pre-service window). This pre-service window also allowed us to identify comorbid conditions, patterns of institutional care, and other health care utilization used for risk-adjustment during the matching process.

- **POST-SERVICE WINDOW.** Post-service period captured the time after receiving the O&P service used to track trends in overall health care utilization and expenditures. Across all O&P service types, we analyzed the health care utilization and payments for 18 months following receipt of the O&P service.

Based on these constructs, we developed patient episodes for study group patients for each of the service groups. In the next section, we discuss how we matched study group patients to comparison group patients.

Developing Patient Cohorts

Based on the patient episode definitions described above, we identified two patient cohorts for each O&P service category: those who had the etiological diagnosis and received the O&P services (i.e., the study group), and those who have had the etiological diagnoses but did not receive the O&P service (i.e., the comparison group). The comparison group was matched to the study group through propensity score matching techniques.

Propensity score matching techniques are widely used in observational studies when randomized controlled trials (RCTs) are not possible or able to be generalized to the population, or are unethical or impractical to administer.[7] Literature suggests that applying these techniques to observational studies is sufficient to remove observable

[7] Trojano M, Pellegrini F, Paolicelli D, Fuiani A, Di Renzo V: Observational studies: propensity score analysis of non-randomized data. *International MS Journal* 16:90-97, 2009

selection bias among treatment and comparison groups and can result in findings that mimic RCTs.[8,9,10,11]

We used propensity scores to identify a one-to-one match across study group and comparison group patients based on etiological diagnosis, comorbidities, patient characteristics (age, gender, race), and historical health care utilization one year prior to the etiological diagnosis. Patients were also matched on death to further control for selection bias. That is, if a study group patient died within their episode, they were matched to a similar comparison group patient who died during their post-service window. Following the matching, any matched pair that died within three months of the etiological diagnosis was excluded from the analysis.[12]

Role of Mortality

Prior to matching study to comparison group patients, we compared the mortality rates of patients who received O&P services to those who did not. Results of the analysis indicated that patients who did not receive O&P services had a significantly higher mortality rate than patients who did receive the service. This was particularly important among the lower extremity prosthetic patients, as the clinical severity (and risk of imminent death) may have been a driver of whether the patient received a prosthetic or not. Exhibit 3.2 shows the percent of patients who died by month from etiological diagnosis for the unmatched study and comparison group patients with lower extremity prostheses. Within 24 months of the etiological diagnosis, 73 percent of potential comparison group patients died while only 23 percent of study group patients died. Of the patients who died, 20 percent of potential comparison group patients died within three months of the etiological diagnosis compared to just 1 percent of the study group. Furthermore, of the patients who died, almost 78 percent of potential comparison group patients died within 12 months of the etiological diagnosis, compared to 36 percent of study group patients. To be eligible for matching, study and comparison group patients were required to have an amputation within 12 months of the etiological diagnoses.

[8] Austin PC: An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivariate Behavioral Research* 46:399-424, 2011

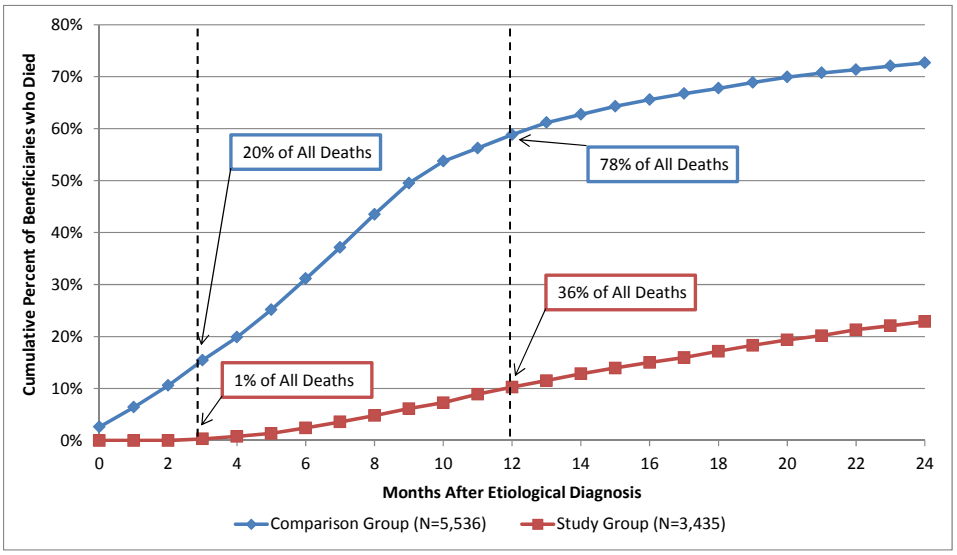
[9] Kuss O, Legler T, Borgermann J: Treatments effects from randomized trials and propensity score analyses were similar in similar populations in an example from cardiac surgery. *J Clin Epidemiol* 64(10):1076-84, 2011

[10] Dehejia R, Wahba S: Propensity score-matching methods for nonexperimental causal studies. *The Review of Economics and Statistics* 84(1):151-161, 2002

[11] Rosenbaum PR, Rubin DB: The central role of the propensity score in observational studies for causal effects. *Biometrika* 70(1):41-55, 1983

[12] Since comparison group patients do not have an index date (date they received the O&P service), etiological diagnosis was the only metric we identified that was consistently defined among the study and comparison group patients.

Exhibit 3.2: Mortality Rate by Month from Etiological Diagnosis for Potential Study and Comparison Group Patients (Prior to Matching)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

These results suggest that patients with severe clinical conditions that may result in death within the short-term may not be referred for O&P services. On the other hand, patients who do receive these services generally have a longer life expectancy following an amputation. While it cannot be confirmed in this study, the timing of the amputation within the patient's disease progression may potentially be related to his/her overall health, mortality, and whether or not he/she receives an O&P service.

By matching patients on whether or not they died, we were able to more appropriately compare Medicare episode payments across groups. As a result, mortality across the groups was excluded as a study outcome.

Determining Post-Service Window for Comparison Group Patients

The study group patients' post-service window is triggered by the receipt of the O&P service. Since comparison group patients did not receive an O&P service, we developed a proxy start date for comparison group patients. In order to ensure the same post-service window for which health care utilization and expenditures were tracked and compared across cohorts, the length of the comparison group's episodes was contingent to the study group. For example, if a patient in the lower extremity orthoses category had an etiological diagnosis two months prior to receiving the O&P service, the comparison group member matched to this patient would have had the first two months following the etiological diagnosis identified as the "pre-service" period and the following 18 months

as the post-period. This ensured that the average length of the pre-window for the study and comparison groups were identical, making the health care expenditures and utilization comparable.

Proper matching of the study and comparison group patients limited the number of episodes included in our study, but helped to ensure that the study and comparison group patients were clinically and demographically similar.

Exhibit 3.3 below shows the number of study group and etiological patients included in each service group before and after matching. Due to the prevalence of lower extremity orthoses among Medicare beneficiaries, 34,864 matched pairs were identified for our analysis. The matching also resulted in 6,247 spinal orthoses matched pairs and 428 lower extremity prostheses. The relatively small number of lower extremity prostheses was due to the required amputation within 12 months of receipt of the prosthetic. As noted above, this excluded long-term users who received replacement prosthetics during the study window.

Exhibit 3.3: Distribution of Pairs (Study Group and Comparison Group Matches) for each O&P Service Group

Matching Step	Group 1: Lower Extremity Orthoses	Group 2: Spinal Orthoses	Group 3: Lower Extremity Prostheses
1) Patients with O&P Service in Custom Cohort Dataset from 1/1/08-6/30/09	278,185	154,553	(excl. req'd amputation) 22,447
2) Patients with O&P service and etiological diagnosis	62,133	13,271	3,435
3) Study group patients able to be matched to comparison group (number of pairs after propensity score match)	35,222	6,341	452
4) Deleted pairs because of missing/inadequate post-service window data	358	94	24
Remaining pairs for analysis (study group and comparison group)	34,864	6,247	428
Percent of patients with O&P service and etiological diagnosis represented in the effective sample (Line 2)	56% (13% of Line 1)	47% (4% of Line 1)	12% (2% of Line 1)

Calculating Descriptive Statistics and Analyzing Impact of O&P Services on Overall Patient Medicare Expenditures

Descriptive statistics were calculated for the study and comparison cohorts after the propensity score matching. As noted above, the two groups were compared to each other based on the distribution of patient characteristics including but not limited to age, gender, race, and comorbidities.

We used a temporal autocorrelation function in order to determine an appropriate episode length that would capture the effects of the O&P service without capturing the effects of other comorbidities or unrelated events. This was a critical analytic step, as once the Medicare episode payments were no longer correlated to the receipt of the O&P service, conclusions could no longer be drawn with regard to the health care utilization and payments for the study group compared to the comparison group.

The temporal autocorrelation function measured the correlation between the Medicare expenditures of a beneficiary's first month (index month) and his/her Medicare expenditures at each month within the episode. As expected, the correlation decreased as the episode length increased as unrelated acute events and underlying chronic conditions began to dominate the overall expenditures of the episode as opposed to the receipt of the O&P service.

For lower extremity and spinal orthoses, the temporal autocorrelation function gradually decreased as episode length increased. The gradual decline over time was to be expected and did not signify any unusual confounding effects. Our results indicated that we could include the full 18 months in our episode analysis. However, for lower extremity prostheses, the correlation dropped rapidly until Month 12, then plateaued for the remainder of the episode length. This plateau in the temporal autocorrelation function signified that an underlying confounding correlation may have been dominating the effects of the treatment after 12 months. As a result, we could not distinguish between the effect of the treatment (receipt of O&P service) and unrelated expenditures after 12 months. Accordingly, we limited the lower prosthetic episodes to 12 months to more precisely measure the treatment effects and outcomes, without introducing the effect of underlying patient conditions. In summary, we compared the outcomes and Medicare episode payments across the prosthetic patients for up to 12 months following receipt of the lower extremity prosthetic, and for up to 18 months following receipt of the lower extremity and spinal orthoses. (Additional information on the temporal autocorrelation function is presented in the technical appendix in Appendix B.)

Across both study and comparison cohorts and O&P service categories, we compared the average Medicare per-member-per-month (PMPM) payment, distribution of payments by

care settings, and outcome measures, such as falls, hospitalizations, and days of rehabilitative/physical therapy. Additionally, we conducted sub-analyses within the study group population to provide comparison of outcomes for patients with lower level prostheses (K1 and K2) compared to higher level prostheses (K3 and K4).

Data Limitations

The key limitation of our methodology was the reliance on administrative data as opposed to clinical data recorded in medical records. The ability to match beneficiaries is limited when using administrative data due to the lack of clinical severity information. While our dataset included all fee-for-service health care utilization and payments, clinical indicators, such as functional status, were not available in the administrative claims. The propensity score matching techniques relied on all patient demographic and clinical characteristics in order to control for observable selection bias among those who received O&P services compared to those who did not. Our propensity score analysis attempted to isolate the effect of receiving an O&P service.

Another limitation of the claims data was the lack of Medicare Advantage discharges and Medicaid long term care-related expenses for dually eligible patients. The relationship of the Medicare to Medicaid payment systems is problematic for analyses that involve episodes of care, as the exclusion of Medicaid claims for dually eligible patients prohibit us from identifying patients who receive care in long-term care facilities as compared to the community. Additionally, with 50 different Medicaid program policies reflected in the data for dual eligibles, there is variability for which we cannot explicitly account.

In the next chapter, we present the results of our study by service category.

Analytic Results

In this chapter, we present the results of our analysis for each O&P service type. We first review the results of the lower extremity and spinal orthoses analyses, and then present the results of lower extremity prostheses analysis.

Lower Extremity Orthoses

Lower extremity orthoses provide patients with stability in their knees, ankles, and feet. Generally, these services are provided to patients who suffer from connective tissue disease, non-traumatic joint disorders and osteoarthritis. The use of lower extremity orthoses have been associated with increased mobility, resulting in enhanced quality of life. After our propensity score matching, we identified 34,864 matched pairs among Medicare beneficiaries in the custom cohort database. Since the matching criteria included patient demographic and clinical characteristics and controlled for observable selection bias, the study and comparison group patients were highly similar.

Appendix C presents the results of the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received lower extremity orthoses were 70 years of age. About 85 percent of patients were Caucasian, with one-quarter of patients being dually eligible for Medicare and Medicaid. Over the 18 month episode, 9.2 percent of patients died. Across all matched pairs, 56.9 percent of matched pairs received the orthotic (or needed an orthotic) due to the primary etiological diagnosis of connective tissue disease (21.5 percent), non-traumatic joint disorder (20.2 percent) or osteoarthritis (15.2 percent). As noted in the methodology, many patients have more than one etiological diagnosis. Our analysis defines each patient by the first etiological diagnosis present in the claims during the pre-service window. While strokes are a common cause for receiving orthoses, the stroke event may have occurred prior to the pre-service window and, therefore, not captured as the etiological diagnosis. We estimate that 18 percent of all study group patients and 17 percent of all comparison group patients had a stroke diagnosis during the pre-service window (regardless of their etiological diagnosis).

Analytic Results

Exhibit 4.1 presents the health care utilization and payments by care setting for those who received O&P services (study group) compared to those who did not (comparison group). Across the 18 month episode, the study group patients had an average PMPM Medicare payment of $1,500 compared to $1,663 for the comparison group – about $162 lower for the study group ($p<0.05$). Significantly fewer admissions to the acute care hospital was a driver of this difference, as the study group patient was admitted 0.62 times during the 18 months, compared to 0.70 times for the comparison group. This difference in utilization resulted in an average difference in PMPM payments of $128. Patients who received O&P services also had fewer skilled nursing facility (SNF) admissions (0.35 admissions compared to 0.44 admissions) and more home health admissions (0.52 compared to 0.47 admissions), indicating that study group patients were more likely to avoid facility-based care ($p<0.05$). The decreased utilization in other care settings may also suggest the overall lower morbidity of patients who receive O&P services. Also, as expected, study group patients had significantly higher durable medical equipment (DME) payments compared to study group patients (given they received the O&P service) (5.76 claims compared to 3.79 claims).

Exhibit 4.1: Lower Extremity Orthoses: Distribution of Claims and PMPM Payments by Care Settings by Cohort (18 Month Episodes from 2008-2010)

	Study Group		Comparison Group		Difference	
Care Setting	Average Number of Claims	Average PMPM	Average Number of Claims	Average PMPM	Average Number of Claims	Average PMPM
Physician	47.92	$360	48.29	$398	-0.37	-$38*
Outpatient	8.23	$197	8.08	$208	0.14	-$11*
DME	5.76	$111	3.79	$54	1.97*	$58*
Acute Care Hospital	0.62	$454	0.70	$582	-0.08*	-$128*
Home Health	0.52	$124	0.47	$106	0.05*	$18*
SNF	0.35	$134	0.44	$177	-0.10*	-$43*
Hospice	0.10	$22	0.13	$31	-0.03*	-$9*
Inpatient Rehabilitation	0.05	$65	0.04	$51	0.01*	$14*
Other Inpatient	0.02	$12	0.03	$19	-0.01*	-$7*
Long-Term Care	0.01	$20	0.01	$35	0.00*	-$15*
Total	**63.57**	**$1,500**	**61.99**	**$1,663**	**1.58***	**-$162***

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

* Statistically significant at p< 0.05

Despite having lower average PMPM payments among the study group patients compared to the comparison group, patients who received lower extremity orthoses received more therapy and more intensive therapy than those who did not receive the orthotic ($p<0.05$). This increased therapy is consistent with Medicare's emphasis on restorative care for beneficiaries, when possible. As shown in Exhibit 4.2, study group patients had higher utilization of inpatient rehabilitation facilities (IRF) and received more outpatient (OP) therapy ($p<0.05$). On average, the study group patients received 0.72 days of care across the 18 month episode compared to 0.52 days in the comparison group. The daily level of therapy intensity required for them to remain in an IRF may suggest that study group patients were able to be better rehabilitated and sustain intensive therapy than those who do not receive the orthotic.

Furthermore, while in the community, study group patients received more than five additional outpatient therapy visits than the comparison group. The high therapy may also be related to the lower rate of negative outcomes for patients who received O&P services. As shown in Exhibit 4.2, while study group patients experienced comparable number of falls and fractures (1.45 compared to 1.54), they experienced significantly fewer emergency room (ER) admissions (1.08 admissions compared to 1.20 admissions) ($p<0.05$). The results of this analysis suggest that despite the receipt of the lower extremity orthotic, study group patients were able to withstand more intensive therapy that led to in increased standing stability, resulting in fewer emergency room admissions, hospitalizations, and lower Medicare payments. By Month 18, the study group patients cumulatively had about $2,920 (or 10 percent) less in Medicare episode payments than comparison group patients ($27,007 compared to $29,927) ($p<0.05$).

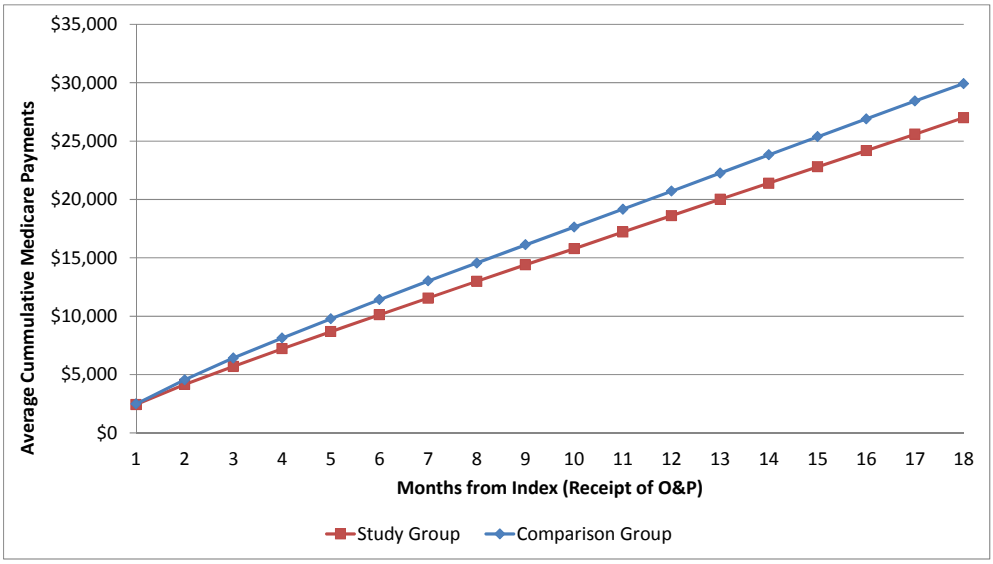
Exhibit 4.2: Lower Extremity Orthoses: Average Use of Inpatient and Outpatient Therapy and Patient Outcomes by Cohort (18 Month Episodes from 2008-2010)

Therapy Use and Outcomes	Study Group	Comparison Group	Difference
Average Number of IRF Days	0.72	0.52	0.20*
Average Number of OP Therapy Visits	17.4	12.1	5.26*
Average Number of Fractures and Falls	1.45	1.52	-0.07
Average Number of ER Admissions	1.08	1.20	-0.13*
Total Average Medicare Episode Payments	$27,007	$29,927	-$2,920*

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.
* Statistically significant at p< 0.05

Exhibit 4.3 presents the cumulative episode payment for those who received the lower extremity orthoses compared to those who did not by episode month. This chart indicates that despite the additional cost of the orthotic in Month 1, the study group patients consistently had lower Medicare episode payments than the comparison group, indicating that the cost of the orthotic was immediately amortized through reduced utilization in other settings. As discussed in the methodology section, even at Month 18, the results of the temporal autocorrelation function suggest that the health care utilization and Medicare payments are related to the receipt of the O&P service.

Exhibit 4.3: Lower Extremity Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2008-2010)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Summary of Findings: Based on the rigorous propensity score matching used to develop the two patient cohorts, we are able to conclude from this analysis that patients who received lower extremity orthoses had better outcomes, defined as fewer acute care hospitalizations and emergency room admissions, and reduced overall cost to Medicare. Study group patients achieved better outcomes with Medicare episode payments that were $2,920 – or 10 percent – less than the comparison group (including the price of the orthotic). Additionally, these patients were able to sustain more rehabilitation, and were able to remain in their homes as opposed to needing placement in facility-based settings.

Spinal Orthoses

The second O&P service included in our analysis is spinal orthoses. These devices are provided to patients with intervertebral disc disorders and other conditions that require spinal alignment and support. After our propensity score matching, we identified 6,247 matched pairs among Medicare beneficiaries in the custom cohort database. These patients were matched on patient demographic and clinical characteristics, and are accordingly risk-adjusted on these dimensions. Appendix C presents the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received spinal orthoses were 71 years old, and more than one-half of all matched pairs were female. About three-quarters of patients were Caucasian, with another 18 percent being African American. Nine percent of patients who receive spinal orthoses died within the 18 month episode. More than half of all patients had an etiological diagnosis of spondylosis, intervertebral disc disorders, or other back problems.

Exhibit 4.4 presents the health care utilization and payments by care setting for those patients who received spinal orthoses (study group) compared to those who did not (comparison group). Across the 18 month episode, the study group and comparison group patients had almost identical average PMPM payments across all care settings ($1,811 for the study group compared to $1,816 for the comparison group) but their utilization within care settings differs. Our analysis suggests that Medicare episode payments are correlated with the receipt of the O&P service at least until 18 months. Therefore, the resulting PMPM Medicare payments over an 18 month time frame can be attributed to the O&P service.

Study group patients had higher utilization of physician and DME services, but lower utilization of SNF and other inpatient facilities, including inpatient rehabilitation, other inpatient (including psychiatric hospitals), and long-term care hospitals ($p<0.05$). This would suggest that while patients who received spinal orthoses had comparable Medicare episode payments to those who did not receive them, they used less facility-based care and appear more likely to have remained in the home and received home health care or an outpatient visits than comparison group patients. The receipt of the orthotic was attributed to a difference in the PMPM payments due to DME services of $73 ($145 for the study group compared to $72 for the comparison group; $p<0.05$). This suggests that the cost of the spinal orthoses was fully amortized over the 18 month episode in addition to the reduction in utilization across the other care settings.

Exhibit 4.4: Spinal Orthoses: Distribution of Claims and PMPM Payments by Care Settings by Cohort (18 Month Episodes from 2008-2010)

	Study Group		Comparison Group		Difference	
Care Setting	Average Number of Claims	Average PMPM	Average Number of Claims	Average PMPM	Average Number of Claims	Average PMPM
Physician	56.11	$439	50.32	$413	5.79*	$26*
Outpatient	8.03	$210	8.28	$229	-0.25	-$19
DME	7.43	$145	4.86	$72	2.58*	$73*
Acute Care Hospital	0.82	$621	0.78	$636	0.03	-$15
Home Health	0.75	$156	0.57	$133	0.18*	$23*
SNF	0.33	$122	0.44	$176	-0.10*	-$55*
IRF, LTCH, Other Inpatient, and Hospice	0.19	$118	0.20	$157	-0.01	-$39*
Total	**73.67**	**$1,811**	**65.45**	**$1,816**	**8.21***	**-$5**

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.
* Statistically significant at p< 0.05

While the average PMPM payment for those who received spinal orthoses is similar to those who did not (a difference in total Medicare episode payment of $5, or just 0.3 percent), the outcomes for the two groups vary. Study group patients who received spinal orthoses experienced more fractures and falls compared to those who did not receive the orthoses ($p<0.05$) (Exhibit 4.5). These outcomes may have been related to the increased independence of patients (and no longer bedbound), in that patients who received a spinal orthotic were more likely to ambulate, increasing the likelihood of falls. The higher prevalence of falls did not appear to relate to a significantly higher rate of emergency room admissions (1.35 admissions for the study group compared to 1.32 for the comparison group). (Given that the focus of spinal orthoses is to provide stability, we did not compare the use of therapy as an outcome measure.)

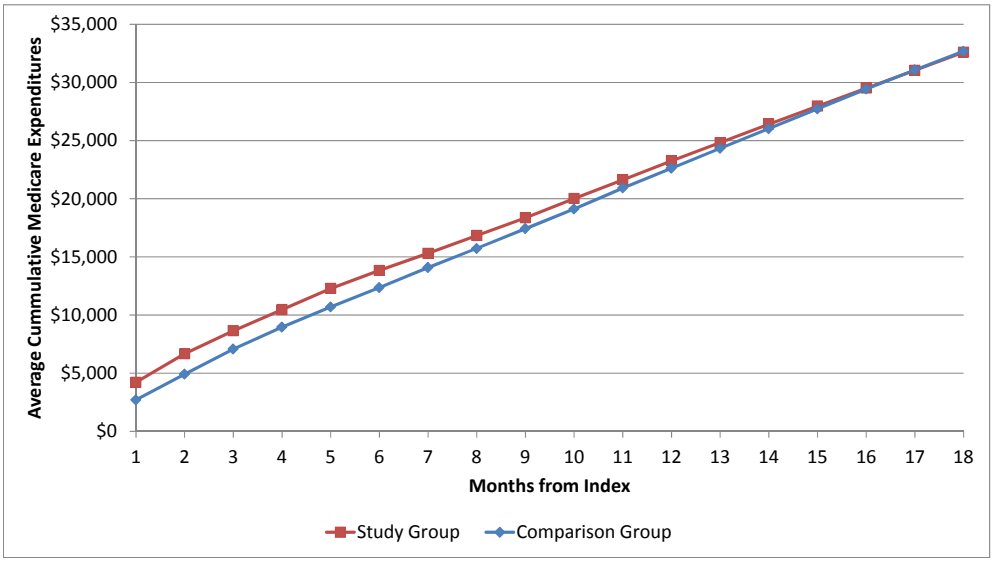
Exhibit 4.5: Spinal Orthoses: Average Use of Inpatient and Outpatient Therapy and Patient Outcomes by Cohort (18 Month Episodes from 2008-2010)

Outcomes	Study Group	Comparison Group	Difference
Average Number of Fractures and Falls	2.05	1.56	0.50*
Average Number of ER Admissions	1.35	1.32	0.03
Total Average Medicare Episode Payments	$32,598	$32,691	-$93

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.
* Statistically significant at p< 0.05

Exhibit 4.6 presents the cumulative episode payment for those who received spinal orthoses compared to those who did not by episode month. This chart indicates that the additional cost of the orthotic in Month 1 was not fully amortized until Month 18 through the reduction of other health care services. By Month 18, study group patients had Medicare episode payments that were $93 lower than comparison group patients.

Exhibit 4.6: Spinal Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2008-2010)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Summary of Findings: Our analytic results indicated that patients who received spinal orthoses had comparable cumulative Medicare payments over 18 months to those who did not receive the orthotic. Furthermore, these patients had a higher rate of ambulatory and home-based care (as opposed to facility-based care), which could suggest that the use of spinal orthoses allows patients to be less bedbound and remain independent in their homes. These patients had a slightly higher prevalence of fractures and falls, which may have been due to their increased ambulation and independence. By Month 18, study group patients had Medicare episode payments that were $93 (or 0.3 percent) lower than comparison group patients.

Lower Extremity Prostheses

The final O&P service included in our analysis is lower extremity prostheses, which is associated with high Medicare episode payments. Our analysis was only limited to patients who received an amputation within the 12 months prior to the receipt of the O&P service. While lower extremity prostheses are often provided to younger (not Medicare eligible) beneficiaries due to trauma or disease progression, we only investigated the impact of prostheses on Medicare beneficiaries with a recent amputation. Prosthetics require significant training and effort on the part of the user to properly and safely use the device. Due to the high cost to the Medicare program, there may be a selection bias among certified O&P personnel and physicians to only fit patients with the physical mobility and motivation to ambulate with a prosthetic. Furthermore, patients with high clinical severity and those in the last year of life may be less likely to receive a prosthetic device.

Due to the low incidence of new prostheses among Medicare beneficiaries, our propensity score matching resulted in 428 matched pairs of recent amputees who received a prosthetic matched to a new amputee who did not. These patients were matched on patient demographic and clinical characteristics, and are accordingly risk-adjusted. Appendix C presents the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received lower extremity prostheses were about 73 years of age and only one-third of patients were female. More than two-thirds of patients included in the matched pairs were Caucasian, and about another quarter of patients were African American. Almost one-half of all matched pairs died within the 12 month episode. Almost one-half of patients had an etiological diagnosis of diabetes mellitus with complication (24.3 percent) or peripheral and visceral atherosclerosis (22.2 percent). Another 15.0 percent had skin and subcutaneous tissue infection.

Exhibit 4.7 presents the health care utilization and payments by care setting for those who received lower extremity prostheses (study group) compared to those who did not (comparison group). As discussed in the methodology, the results for lower extremity prostheses were only compared across 12 months, as opposed to the 18 months used for lower extremity and spinal orthoses. This shorter episode length was analyzed as the results of the temporal autocorrelation function suggested that the Medicare episode payments were no longer related to the receipt of the O&P service after 12 months and were driven by underlying trends across the patient populations. Therefore, conclusions on the impact of the prosthetic on Medicare episode payment could not be drawn beyond 12 months.

Across the 12 month episode, the study group patients had average PMPM Medicare payments across all care settings that were only slightly (not significantly) higher than the comparison group ($6,099 for the study group compared to $6,015 for the comparison

group). About one-quarter of the total PMPM payment for the study group patients is attributed to the prosthetic ($1,554 of the total PMPM of $6,099). The prosthetic represents an additional cost that was nearly amortized within 12 months due to a reduction of care in other care settings.

The second largest driver of PMPM Medicare payment among the study group patients (and the largest among the comparison group patients) was the acute care hospitalization. The study group patients had a lower rate of hospitalization than the comparison group patients (1.18 admissions for the study group compared to 1.51 admissions for the comparison group), resulting in lower PMPM Medicare payments for acute care hospitalizations ($1,498 for the study group compared to $2,338 for the comparison group) ($p<0.05$).

Similar to the trends evidenced in the other O&P services analyzed in this report, study group patients appear more likely to have remained in the home and receive outpatient visits and less likely to receive facility based care including IRF, LTCH, Other Inpatient, and hospice services than the comparison group patients ($p<0.05$). Among lower extremity prosthetic patients, study group patients had higher outpatient visits (11.37 visits compared to 9.52 visits; $p<0.05$) and comparable home health admissions (1.29 admissions compared to 1.18 admissions), and SNF admissions (1.48 admissions compared to 1.81 admissions) than comparison group patients. Study group patients also had lower Medicare payments for physician visits, which may indicate patient clinical stability that is not captured through administrative claims ($649 PMPM compared to $990 PMPM; $p<0.05$) (Exhibit 4.7).

Exhibit 4.7: Lower Extremity Prostheses: Distribution of Claims and PMPM Payments by Care Settings by Cohort (12 Month Episodes from 2008-2010)

	Study Group		Comparison Group		Difference	
Care Setting	Average Number of Claims	Average PMPM	Average Number of Claims	Average PMPM	Average Number of Claims	Average PMPM
Physician	53.94	$649	60.68	$990	-6.75	-$341*
DME	14.02	$1,554	9.00	$211	5.02*	$1,343*
Outpatient	11.37	$781	9.52	$608	1.86*	$173*
SNF	1.48	$699	1.81	$735	-0.33	-$36
Home Health	1.29	$515	1.18	$474	0.11	$41
Acute Care Hospital	1.18	$1,498	1.51	$2,338	-0.34*	-$839*
IRF, LTCH, Other Inpatient, and Hospice	0.35	$402	0.55	$658	-0.20*	-$256*
Total	**83.63**	**$6,099**	**84.26**	**$6,015**	**-0.63**	**$85**

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.
* Statistically significant at p< 0.05

Unlike the orthoses discussed above, patients need to be trained and receive extensive therapy to properly use a prosthetic device. One driver of the difference in the PMPM payment is the use of therapy. Study group patients had considerably higher utilization of both outpatient therapy (56.1 visits compared to 28.9 visits) (Exhibit 4.8). These sessions – both inpatient and outpatient therapy – are critical for the patients with the prosthetic to help teach them balance and mobility with their new device. Additionally, the high use of therapy may be associated with increased ambulation, which suggests that the study group patients with prostheses were less bedbound than the comparison group.

The negative outcomes, defined as the number of fractures and falls and emergency room admissions, were also comparable or higher for the study group patients. Despite the increased independence of study group patients, the number of falls and fractures were comparable to comparison group patients. However, study group patients were admitted to the emergency room less often than comparison group patients (1.55 admissions compared to 2.10 admissions; $p<0.05$). Across the entire 12 month episode, study group patients had an average Medicare episode payment that was comparable (only $728 higher, or 1 percent) to the comparison group, including the cost of the prosthetic.

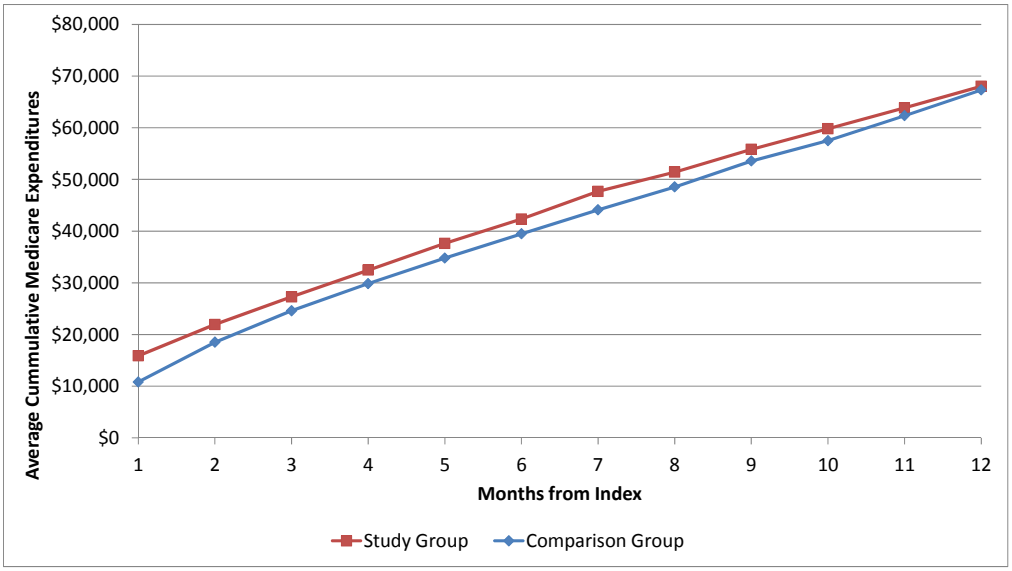
Exhibit 4.8: Lower Extremity Prostheses: Average Use of Inpatient and Outpatient Therapy and Patient Outcomes by Cohort (18 Month Episodes from 2008-2010)

Therapy Use and Outcomes	Study Group	Comparison Group	Difference
Average Number of IRF Days	1.61	1.19	0.42
Average Number of OP Therapy Visits	56.1	28.9	27.18*
Average Number of Fractures and Falls	0.90	0.72	0.18
Average Number of ER Admissions	1.55	2.10	-0.55*
Total Average Medicare Episode Payments	$68,040	$67,312	$728

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Exhibit 4.9 presents the cumulative episode payment for the study and comparison group by episode month. This chart indicates that the cost of the prosthetic in Month 1 was slowly amortized over time; by the end of Month 12, the cumulative Medicare episode payment for the study group was $728 (1 percent) higher than the comparison group patient, indicating that the cost of the prosthetic was nearly fully amortized. Due to the correlation between the monthly payments each month after the receipt of the prosthetic, we were unable to draw conclusions beyond Month 12.

Exhibit 4.9: Lower Extremity Prostheses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2008-2010)



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Confirmation of Results under Separate Methodologies

We studied the economic impact and value of lower extremity prostheses using two additional methodologies, which validated our findings. The results across all three methodologies were consistent with those presented above. The first methodology conducted the study using the standard analytic files made available through CMS for a five percent sample of Medicare beneficiaries from 2007-2009. While the results were comparable to those shown above, the small sample size prohibited us from generalizing the results beyond the small sample of patients we derived from the five percent sample.

Following the receipt of the custom cohort database which provided both more patients and one more year of data (2010), we matched and analyzed patients. This second methodology using the custom cohort dataset did not control for patient death in the propensity score matching and only used nine months of a pre-service window period to risk-adjust the two patient populations.

Finally, in an attempt to improve our initial two analyses, our third methodology controlled for patient death and extended the episode pre-service period to 12 months (reflected in this final report). Despite the methodology selected, the results were consistent in that patients who received lower extremity prostheses had slightly higher Medicare episode payments at the end of 12 months with the cost of the prostheses nearly fully amortized. The study group patients who received prostheses experienced fewer acute care hospitalizations and emergency room admissions. This suggests that there is value for the patient in receiving lower extremity prostheses. Despite the initial costs for prostheses, Medicare can provide them to its beneficiaries at a minimal net cost due the reduced health care utilization in all other (non-DME) care settings. Without the use of a prosthetic, comparison group patients have higher Medicare payments across all other settings. Ultimately, the costs of the prostheses are nearly amortized over the 12 month period, resulting in comparable Medicare payments across the two groups.

Sensitivity Analyses: Outcomes and Medicare Episode Payments by K-Level

We compared the Medicare episode payment and outcomes for patients who were assigned a lower-level prosthetic due to their limited function (K1 and K2 devices) to patients assigned higher K-Level devices (K3 and K4 devices). This task investigated whether patients who received lower level prostheses had more negative outcomes and adverse events than those with higher-level devices. While these results are not risk-adjusted, the goal of the analysis was to determine if less capable and independent beneficiaries who are denied K3 and K4 devices are at significantly greater risk of adverse events when using lower level devices.

As shown in Exhibit 4.10, patients fit with K1/K2 devices had a comparable average Medicare PMPM payment to K3/K4 patients ($5,460 PMPM compared to $5,233). Despite the comparable Medicare PMPM payment, K1/K2 patients had more SNF admissions suggesting that patients with lower level devices were more likely to use facility-based care (2.02 SNF admissions for K1/K2 patients compared to 0.84 SNF admissions for K3/K4 patients; $p<0.05$). However, the number of acute care hospitalizations was comparable across K1/K2 and K3/K4 patients (1.25 admissions compared to 1.12 admissions).

The fact that patients who received a K3/K4 prosthetic had comparable Medicare PMPM payments despite significantly higher DME payments ($1,660 PMPM compared to $1,153, $p< 0.05$) suggests that patients who should receive a K1/K2 prosthetic due to lower functional status are not being fit with K3/K4 prosthetics. If K1/K2-level patients were receiving K3/K4-level prosthetics, we would expect to see higher PMPM payments among the K3/K4 cohort in the use of facility-based care, and would expect to see overall higher PMPM payments due to the higher DME costs for the prosthetic.

Exhibit 4.10: K-Level Analysis for Lower Extremity Prostheses: Distribution of Claims and PMPM Payments by Care Settings by K-Level Cohort (12 Month Episodes from 2008-2010)**

	K1-K2 (n=173)		K3-K4 (n=173)		Difference	
Care Setting	Average Number of Claims	Average PMPM	Average Number of Claims	Average PMPM	Number of Claims	Average PMPM
Physician	54.54	$570	55.24	$576	-0.71	-$5
DME	12.64	$1,153	15.42	$1,660	-2.79*	-$506*
Outpatient	12.05	$625	11.21	$760	0.84	-$135
SNF	2.02	$817	0.84	$416	1.17*	$401*
Home Health	1.44	$548	1.21	$371	0.23	$176*
Acute Care Hospital	1.25	$1,400	1.12	$1,133	0.13	$266
Hospice	0.21	$41	0.11	$35	0.10	$6
Inpatient Rehabilitation	0.10	$155	0.12	$166	-0.01	-$10
Long Term Care, Other Inpatient	0.05	$150	0.03	$116	0.02	$34
Total	**84.31**	**$5,460**	**85.31**	**$5,233**	**-1.01**	**$227**

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

* Statistically significant at $p< 0.05$

** Analysis does not include all 428 lower extremity prostheses study group patients as not all prostheses were billed with a K-level.

In comparing patient outcomes across cohorts, results indicate that patients with lower level devices had comparable IRF days but more outpatient therapy days ($p<0.05$) than patients with higher-level devices (Exhibit 4.11). However, it is interesting to note that patients with K1/K2 devices had comparable number of falls and fractures and emergency room admissions. This suggests that receipt of the higher level prosthetic is not related to better outcomes, defined as the number of fractures and falls or emergency room admissions.

Exhibit 4.11: K-Level Analysis for Lower Extremity Prostheses: Average Use of Inpatient and Outpatient Therapy and Patient Outcomes by Cohort (18 Month Episodes from 2008-2010)

Therapy Use and Outcomes	K1-K2	K3-K4	Difference
Number of Beneficiaries	173	173	0
Average Number of IRF Days	1.54	1.39	0.14
Average Number of OP Therapy Visits	68.39	40.31	28.08*
Average Number of Fractures and Falls	0.83	0.86	-0.03
Average Number of ER Admissions	1.69	1.51	0.18

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.
* Statistically significant at $p< 0.05$

This preliminary K-level analysis suggests that patients who received K1/K2 devices had comparable Medicare PMPM payments despite the lower payments for DME services. This is likely attributed to the larger reliance on SNF and home health care. Further research is warranted to match patients on clinical and demographic characteristics to determine whether the need for facility-based care can be avoided through higher level devices for more frail individuals. Based on the descriptive results presented above, our analyses indicate that patients with lower level devices may be able to experience reduced facility-based care by receiving more advanced devices.

Summary of Findings: The results of our analysis indicate that patients who received lower extremity prostheses were more likely to receive extensive outpatient therapy than comparison group patients. The receipt of physical therapy was associated with fewer acute care hospitalizations, emergency room admissions, and less facility-based care ($p<0.05$), which nearly offset the cost of the prosthetic. As a result, patients who received prosthetics had comparable cumulative Medicare payments over 12 months than those who do not ($728, or just 1 percent higher). Results suggest that the device was nearly amortized by the end of 12 months and the patient could experience better quality of life and increased independence compared to patients who did not receive the prosthetic at essentially no additional cost to Medicare or the patient.

Discussion

The literature indicates that the receipt of O&P services could increase a patient's mobility, ultimately reducing their health care utilization and increasing their quality of life. Based on this possibility, this study investigated the economic impact and value of three O&P services: lower extremity orthoses, spinal orthoses, and lower extremity prostheses. Using propensity score matching techniques to compare clinically and demographically similar patients who received O&P services to those who did not, we were able to determine the economic impact and value of these services on the Medicare population. This study excludes other sources of economic value and outcomes, such as the ability for patients with O&P services to return to work or become more independent from social services.

Our results suggest that patients who received lower extremity orthoses had significantly fewer acute care hospitalizations and fewer admissions to facility-based care settings, resulting in lower Medicare payments even after including the cost of the orthoses. Additionally, these patients had better outcomes, in that they experienced fewer emergency room admissions. Therefore, we conclude that providing lower extremity orthoses can improve a patient's quality of life while reducing Medicare spending.

The analysis for spinal orthoses indicated that patients can experience better quality of life, possibly through increased independence, at a comparable Medicare payment after including the cost of the orthoses. While patients experienced more fractures and falls, these negative outcomes resulted in comparable emergency room and hospital admissions, ultimately producing comparable Medicare episode payments.

The final service category, lower extremity prostheses, represented the most clinically complex population with by far the highest Medicare episode payments. Our analyses show that over a 12 month period, patients who received O&P services reduced their Medicare payments to nearly cover the cost of the prosthetic. Through a reduction in acute care hospitalizations, physician visits, and facility-based care, patients experienced better quality of life at a comparable Medicare episode payment. Despite a comparable

number of fractures and falls among lower extremity prosthetic users, the rate of emergency room admissions was lower than those who did not receive the service. Part of the savings due to reduced facility-based care was offset by extensive physical therapy and rehabilitation to teach patients how to properly use their prostheses.

If used properly, lower extremity prostheses have the potential to increase quality of life and reduce facility-based care for newly amputated Medicare beneficiaries. Providers must consider the patients overall well-being and physical ability prior to prescribing a lower extremity prostheses.

Results of our sub-analyses suggest that patients who received a lower-level prosthetic (K1 or K2) experienced comparable emergency room visits and hospital admissions than those patients who received K3 or K4 devices. While additional analyses are warranted, these results may suggest that lower-level patients could benefit from higher level prostheses to provide the additional stability and support needed to reduce the need for facility-based care.

Across all analyses presented above, our results suggest that O&P services provide value to the Medicare program, as well as a value to the patient. The cost of the O&P services are nearly, if not completely, amortized through reduced acute care hospitalizations and facility-based care. Therefore, patients are receiving care in the community and avoiding facility-based care, at a comparable or lower total cost to the Medicare program.

Appendix A: Literature Detail

Appendix A: Literature Detail

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
1	Practice Analysis of the Disciplines of Orthotics and Prosthetics – Core Competencies for Orthotic and Prosthetics.	American Board for Certification in Orthotics and Prosthetics, Inc. (ABC), (2000)	Core O&P competencies developed based on an ABC study in 2000.	Competencies include: • Patient assessment • Formulation of the treatment plan • Implementation of the treatment plan • Follow-up treatment plan • Practice management • Promotion of competency and enhancement of professional practice • Individual and cultural differences • Communication • Critical inquiry/clinical decision making • Education • Outcomes assessment/evaluation • Administration • Consultation	• There are a broad range of core competencies that are applicable to and can be used as guidelines for the O&P profession.
2	The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: A systematic review.	Bus SA, Valk GD, van Deursen RW et al., (2008)	Assesses literature on the effectiveness of footwear and offloading interventions in preventing/healing foot ulcers or reducing foot pressure in diabetics.	• Plantar pressure reduction is achieved through different modalities (i.e., casts, walkers, therapeutic footwear), but the diversity of methods limits comparison of study results. • The evidence to support the use of footwear and surgical interventions is sparse. • Research literature on the use of footwear for plantar foot ulcers has lagged behind clinical practice, leading clinicians to recommend interventions based on opinion/past experience rather than published literature.	• The systematic review supports the use of non-removable devices for healing plantar foot ulcers. • However, more high-quality studies are necessary to confirm the benefits of footwear and offloading interventions. • Without more robust, well-controlled studies, the most effective modalities may not be identified, accepted, or adopted in diabetic foot practice.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
3	Microprocessor-controlled prosthetic knees: A technology assessment.	California Technology Assessment Forum (CTAF), (2007)	Reviews the scientific evidence for the use of microprocessor-controlled prosthetic knees for individuals with trans-femoral amputations.	• The C-leg, Rheo knee, and the IP line of prostheses are all class I 510(k) exempt devices. • This search cross-referenced key words "microprocessor prosthetic knee" and "amput" from 1966 to 2007. Twelve studies were analyzed to compare microprocessor to other prosthetic knees (1 IP, 1 Rheo, and 10 C-leg). • The majority of the studies found a small but statistically significant decrease in energy expenditures using a microprocessor prosthetic knee. • Microprocessor knees also confer a higher level of function, with fewer falls and more ability to traverse complex terrain. • The C-leg specifically led to higher overall satisfaction through improved stair/hill descent, which led to fewer falls and less frustration with falls.	• Although IP, Rheo, and C-leg have all been studied, the only one studied for actual functional outcomes is the C-leg. The other two study "intermediate" markers—energy expenditure and walking dynamics. • Despite the benefits of a microprocessor-controlled prosthetic knee, it does require that the prosthetist be trained in fitting/setting and to train the patient to use the knee, which is resource-intensive. • It appears that healthy, active adults with a trans-femoral amputation for a non-vascular cause (i.e., trauma, tumor) derive functional benefit from wearing microprocessor knees, however the only adequately studied one is the C-leg.
4	Psychological status of diabetic people with or without lower limb disability.	Carrington AL, Mawdsley SKV, Morley M, et al., (1996)	Compares quality of life between diabetics with chronic foot ulceration or lower limb amputations and diabetic controls.	• Foot problems are the most common cause of hospital admissions among diabetic patients in Great Britain. • In a study of 6,000 diabetics, 2% had foot ulcers and 2.5% were amputees. • The Foot Questionnaire showed that chronic foot ulceration in diabetics is related to a significantly worse attitude toward their foot care than the diabetic amputees and controls.	• As diabetic amputees reported higher quality of life than diabetics with chronic foot ulcers, more services—such as social/psychological counseling—should be available for immobile/semi-immobile diabetics. • Counseling should be provided to those who are socially isolated/depressed due to foot problems, whether an amputee or with an ulceration.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
5	The health status of diabetic patients receiving orthotic therapy.	Davies S, Gibby O, Phillips C, et al., (2000)	Compares the self-reported health status of a group of diabetic patients receiving orthotic therapy with those not receiving therapy; sample of 280 people was recruited with type I and II diabetes.	• The impact of diabetes on health-related quality of life has been investigated greatly in recent years. • Studies have found that the quality of life in mobile diabetic amputees was better than that of the diabetic foot ulcer patient. • Patients fitted with prostheses are encouraged to be mobile, whereas those with an ulcer are not. Therefore, those with a prosthetic are less sedentary and do not experience secondary health complications.	• The orthotic intervention resulted in increased both physical and mental health scores at six and 12 months. • The use of specialist footwear for patients with at-risk feet (as a result of diabetes) resulted in improvement in health status and should become part of the treatment plan for such patients.
6	Assessing the state of clinically applicable research for evidence-based practice in prosthetics and orthotics.	Geil MD, (2009)	Describes the current state of the evidence-based process for O&P.	• Clinically applicable research has assessed treatment effectiveness, altered clinical patient interaction, led to new technologies development, and changed longstanding clinical opinion. However, obstacles remain in the application of research to practice. • A gap exists between the perceived research needs and clinically applicable research currently in production. • A Northwestern University survey indicated that although 98% of respondents view research as important, 78% lack the ability/resources to carry out work. • Currently, O&P specific literature assessments are being performed by the American Academy of Orthotists and Prosthetists.	• Evidence-based process in O&P relies on a progression of stages of research, from gathering evidence to measuring effectiveness. • Research needs include clinical care, management (i.e., timing of orthotic management, appropriate prescription), and better understanding of components/function (i.e., prosthetic knees, socket suspension). • Main solutions offered include: 1) practitioners must consume published research, and 2) researchers must be aware of the need for evidence as identified by practitioners.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
7	Improving health care quality with outcomes management.	Heinemann AW, Fisher WP, Gershon R, (2008)	Examines the need for valid outcome measures and quality improvement in rehabilitation practice.	• Health tracking has been shown to provide returns on investment of $1.44 to the federal government for every dollar invested. • A higher return results when potential insurance-cost reductions, saved workplace productivity, and the human value of improved health are considered. • In a survey by the Amputee Coalition of America, 75% felt excluded in the care process, saying they received no educational materials. • The four principles for quality improvement are: 1) the value of clear expectations routinely checked against observation; 2) the need for therapeutic validity; 3) patient-centered care and assessment but systems that are clinic-based and clinician-managed; and 4) evidentiary basis and comparability.	• As the need to evaluate and measure rehabilitation practice has grown in past years, so has the need for valid, reliable and change-sensitive outcome measures. • Health status and patient satisfaction are the primary outcomes of interest for rehabilitation care, yet patients are not often included in the process. • Currently, O&P quality improvement measures are not developed with the kind of care and precision as in other industries, and new technologies for precision measurement create new opportunities for informing quality improvement efforts. • By establishing common product definitions and comparable outcome measures, the cost/quality equation for O&P could be rebalanced.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
8	Development and application of the Orthotics and Prosthetics User Survey: Applications and opportunities for health care quality improvement.	Heinemann AW, Gershon R, Fisher WP, (2006)	Describes the development of the Orthotics and Prosthetics Survey (OPUS) as an instrument for evaluating goals of O&P providers.	• The O&P service delivery system needs a means of measuring and enhancing health care quality given the fragmentation of the industry. • No industry-wide instrument is accepted for quality improvement. • The Orthotics and Prosthetics National Office Outcomes Tool (OPOT) was built around a generic health-related quality of life instrument, the Medical Outcome Study, and included 13 questions on satisfaction. • OPUS goals include: 1) reduction of activity limitations; 2) enhancing quality of life; and 3) assuring patient satisfaction with services and devices.	• While psychometric analyses were conducted in OPOT, the instrument was not sensitive to change in lower extremity function. • OPUS was developed to measure: 1) lower extremity functional measure; 2) health-related quality of life; 3) follow-up evaluation of device satisfaction; and 4) follow-up evaluation of services satisfaction. • The gap of measuring patient activation persists. Patient activation must be triggered, meaning: 1) belief in the importance of taking an active role in health care; 2) confidence in taking action; 3) active participation; and 4) persistence under stress.
9	Patient and professional perspectives on prescribed therapeutic footwear for people with diabetes: A vignette study.	Johnson M, Newton P, Goyder E, (2006)	Uses a qualitative study to discuss patient/health professional views of therapeutic footwear for people with diabetes-related foot complications.	• Interviews were conducted with 15 patients and 15 health professionals using a “vignette” technique. • While health professionals realized therapeutic footwear prescription was important to patients, perspectives of expectations and reality of prevention differed. • Patients often have difficulty finding fitting shoes when feet are constantly changing shape. • For prevention/healing of foot ulceration, continuous use of therapeutic footwear is advised.	• Due to available therapeutic shoes, patients have difficulty changing their shoe-wearing behavior according to guidelines. • Patient perspectives must be taken into account in footwear provision. • More style choices might encourage more appropriate use of footwear as well as the concept of concordance before patient is prescribed therapeutic shoes. • Changes in professional practice are needed if patient requirements/values are taken into account.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
10	The effect of specialist footwear on the quality of life of patients with lower leg ulcers.	Leigh R, Barker S, (2007)	Assesses whether there is change in QOL for patients with lower limb wounds, when provided with specialist medical footwear.	• In patients with foot/lower limb ulcers, wearing Kerraped specialist footwear resulted in improved quality of life across physical symptoms/daily living (10.7%) and wellbeing (11.1%) within two weeks. • There was a slight increase in improved social life (2.4%).	• This study showed improvement in two key quality of life domains resulting from specialist footwear for patients with lower limb wounds, both in primary and secondary care. • The availability of specialist footwear increases postural stability for patients, therefore reducing the likelihood of falls and improves the probability of healing faster. • Using specialist medical footwear such as Kerraped could result in marked improvements in health-related quality of life.
11	Advocates seek better insurance coverage for amputees needing limb prostheses.	Mitka A, (2008)	Describes the economic environment differing between military/veteran and non-military amputees.	• The budget for the VA's Prosthetics and Sensory Aids Service was a proposed $1.39 billion for 2008, up from $1.12 billion in 2006. • Cost still remains an issue, so states are pushing for "prosthetic parity" legislation, which requires insurers to cover prostheses like other medical conditions. • Currently, nine states have passed this legislation: California, Colorado, Indiana, Maine, Massachusetts, New Hampshire, New Jersey, Oregon, and Rhode Island. • However, America's Health Insurance Plan (AHIP) opposes mandating coverage for specific conditions because it makes it harder for employers to offer health insurance.	• Overall, the O&P industry must improve the limited documentation for the benefits of prosthesis use. Lack of documentation has inhibited the ability of amputee advocates to raise insurance coverage levels. • If insurance companies do not know a new system will provide greater functionality, they do not want to front the cost.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
12	Assessing satisfaction with orthotic devices and services: A systematic literature review.	Peaco A, Halsne E, Haftner BJ, (2011)	Identifies and appraises patient-reported outcome instruments that have been used to assess satisfaction with orthotic devices and services; advocates for measures that are suitable for an O&P clinical environment.	• A systematic search of medical databases was conducted using the combination of the terms "satisfaction" and "orthotic." • Fourteen publications met the selection criteria and were chosen for review from 1989 to 2009. • This systematic literature identified four formal outcome measures and seven ad hoc measures.	• "Formal measures" included the SERVQUAL questionnaire to assess satisfaction. It was derived from a model of service quality developed in 1985. The 99 items were consolidated into 22 questions spanning 5 "domains" of service quality including: 1) reliability, 2) assurance, 3) tangibles, 4) empathy, and 5) responsiveness. • OPUS was developed by a multidisciplinary advisory team that selected three areas of focus: 1) functional status of limb, 2) health-related quality of life, and 3) client satisfaction. • The Quebec Users' Evaluation of Satisfaction with Assistive Technology (QUEST) was developed in 1996 to evaluate satisfaction with assistive technology (i.e. devices) and the accompanying provision of service. It contains 27 items that represent "factors most likely to influence the degree of user satisfaction". • The SRS-22 was also originally developed to measure surgical rather than orthotic outcomes and may not be an ideal solution for all O&P applications.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
13	The diabetic foot: Quality of life.	Price P, (2004)	Investigates the health-related quality of life for patients with foot complications resulting from diabetes.	• The health quality of life may be worse for those with diabetic foot lacerations compared to those with amputation because of the fear of infection, reoccurring ulceration and lifelong disability. • The data on this important outcome measure must be improved upon so that preventative care and treatment options are provided to patients. • Patients with foot ulceration may need support to adjust to the changes developing due to complications (including depression).	• A UK study found that patients attending a specialist foot clinic and received orthotic interventions had significantly improved health-related quality of life unlike those not attending the clinic who faced decline. • This shows how quality of life can be improved through interventions. • This paper concludes that addressing all aspects of the diabetic foot is probably best accomplished through use of a multidisciplinary team to work through all stages of patient management.
14	U.S. Food and Drug Administration regulation of prosthetic research, development, and testing.	Resnik L, Klinger SL, Krauthamer V, et al., (2010)	Presents an overview of the FDAs regulatory requirements to inform those working to develop and test new prosthetic devices.	• Prosthetic manufacturers and designers need to understand FDA regulations and requirements before performing clinical studies with prosthetic devices. • Most prosthetic components are classified as class I (i.e. minimal risk and general controls for risks). • Nearly all class I devices are exempt from premarket notification by the FDA.	• Physical medicine device classification: o I: socket components, external limb components, food drop orthosis, limb braces o II" C-leg microprocessor, powered external limb overload warning device o III: stair climbing wheelchair • Because today's advances in prosthetic engineering introduce new technologies/uses, many of these new developments will require premarket notification submissions. • As a result, the developers/manufacturers must be familiar with the regulation governing these devices so they can perform studies evaluating risks and benefits.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
15	Effects of lower limb prosthesis on activity, participation, and quality of life: A systematic review.	Samuelsson KAM, Toytari O, Salminen AL, et al., (2012)	Summarizes and evaluates findings from studies on effectiveness of lower limb prostheses in terms of activity, participation, and quality of life, and secondarily in terms of user satisfaction, use/non-use, and/or cost-effectiveness.	• Out of 818 identified publications, 8 met inclusion criteria. • The primary outcomes where change in activity, participation and/or quality of life and the secondary outcomes were user satisfaction, use/non-use in real life contexts, and cost-effectiveness were secondary outcomes. • Results were inconsistent except for quality of life and use/non-use where the study found an improvement in a microprocessor-controlled knee versus a non-microprocessor-controlled knee.	• There was overall inconsistency in both results and study quality. • This systematic review of the literature highlights the need for high-quality research studies reflecting effectiveness of different prosthesis interventions for daily living and quality of life.
16	Barriers to the implementation of evidence-based practice in orthotics and prosthetics.	Stevens PM, (2011)	Describes evidence-based practice, different theories regarding its application, and how medical information can be deemed “useful” to an O&P practitioner.	• Usefulness of medical information is a product of its relevance and validity divided by the work required to obtain it. • Relevance is based on the frequency of a given program or concern within an O&P practice. • Validity of a piece of information is a piece of information representing the likelihood that it is true.	• Evidence-based practice is no more than the incorporation of useful, literature-derived medical information into clinical practice. • Although traditional secondary knowledge sources of useful information exist, additional sources that are more accessible and current are necessary. • As more information sources are developed in the O&P community, the findings of the evidence will better inform daily patient care.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
17	Living with an amputation: What it means for patients and their helpers.	Thompson DM, Haran D, (1984)	Compares social/emotional problems between 134 single-leg amputees with 109 of their main helpers.	• Used the Day Amputee Activity Score, Goldberg GHQ, Townsend's Social Isolation scale, and Forder's concept of Felt Need in the study. • Most of the patients were male, and caretakers were mostly female. • Peripheral vascular disease was the most frequent reason for the amputation. • Respondents reported unmet need for information on financial help, employment, and social activity. • Both caretakers and amputees were socially isolated.	• Respondents knowledge of available services must be improved. • Both the social work profession and the Artificial Limb Centre are under-utilized enough in order to help with the psychosocial adjustment to loss of a limb.
18	Knee replacement underused, says panel.	Vastag B, (2004)	Discusses knee replacement advantages and disadvantages.	• About 1 percent of prosthetic knees loosens or fails each year, leading to more surgery or even amputation. • Failure rates are higher among obese, males, young patients, and those with co-morbidities. • Younger patients tend to wear out their artificial knees and older patients endure more complications in surgery and longer recovery times. • Knee replacement surgeries are now one of the single largest expenditures of Medicare.	• The NIH's Office of Medical Applications of Research convened a consensus conference due to this growth in knee surgeries. • Despite overwhelming endorsement of total knee replacement, the NIH Committee found substantial gaps in outcomes research. • The Committee recommends that the government funds a registry of knee replacement surgeries to track the effect of different rehabilitation strategies.

Evidence Reviewed: Quality					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
19	Effectiveness of different types of footwear insoles for the diabetic neuropathic foot.	Viswanathan V, Madhavan S, Gnanasundaram S, et al., (2004)	Compares the effectiveness of different types of footwear insoles in the diabetic neuropathic foot.	• Patients who were using therapeutic footwear showed lower foot pressure. • Those who used nontherapeutic footwear showed increased foot pressure. • New lesions were higher in those using their own footwear (33%) compared with those who were provided footwear (4%).	• Therapeutic footwear is useful to reduce new ulcerations and therefore the amputation rate in the diabetic population.
20	Coping with a leg amputation.	Walters J, (1981)	This article describes the impact of an amputation in four phases of loss adjustment.	• The four phases of loss adjustment are: 1) impact, 2) retreat, 3) acknowledgement, and 4) reconstruction. • Most of leg amputations are secondary to a disease, such as diabetes or heart disease. • Amputation causes a change in body image, but the loss of a leg is perhaps the most serious alteration of body image. • Not only can physical appearance be changed, but the mobility can be seriously compromised as well.	• To adjust to one's new body image, an amputee must receive both physical care and emotional support.

Evidence Reviewed: Cost					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
21	The economic benefits of prosthetic coverage; Prosthetic coverage: Saving money and saving lives.	Amputee Coalition of America	Cost of prosthetic coverage, caps on O&P, states that have passed prosthetic parity legislation, and benefits from prosthetic care.	• Companies are imposing caps of one limb per lifetime, $2,500 per lifetime, and $500 per year. • Most states currently choose the federal Medicare law as the minimum coverage standard. • Colorado found the cost to be $0.12 PMPM. • California estimated a cost of between $0.15 and $0.25 PMPM. • Massachusetts estimated a cost of between $0.28 to $0.35 PMPM.	• Every dollar spent on rehabilitation, such as prosthetic care, can save more than $11 in disability benefits. • The "non-fiscal" benefits include reduced pain, decreased dependence, and lessened diabetes-related infection, which all lead to savings in medical costs. • Long-term savings result from prosthetic care. • Without prosthetic care, individuals live more sedentary lifestyles which leads to secondary complications, such as diabetes-related complications leading to $264,000 in costs (for example, becoming an amputee at age 55 and living until age 77).
22	A report to the 2006/2007 California state legislature: Analysis of Assembly Bill 2012 – Orthotic and Prosthetic Devices	California Health Benefits Review Program, (2006)	Impact of CA mandate on O&P costs, savings, benefits.	• There were over 14 million individuals under age 65 with coverage for O&P devices. • The CA mandate offers coverage on a group basis for O&P devices when they are prescribed, ordered and furnished by specific providers. • Prior, prosthetics were only covered if prescribed by the physician, but now adds surgeons and podiatrists to the coverage.	• This mandate does not impact the total cost of health care. • Because the savings are less than 0.01% of total premiums in the small group market, employers would not respond much to such a small potential savings.

Evidence Reviewed: Cost					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
23	Review and evaluation of proposed legislation to mandate coverage for certain prosthetic devices – H. 376	Commonwealth of Massachusetts – Division of Health Care Finance and Policy, (2005)	Impact of MA mandate on O&P costs, savings, benefits.	• Requires "all" health insurers except Medicare and other government programs to provide coverage for those employed in the Commonwealth with certain medically necessary prosthetic devices. • Coverage would be comparable to Medicare. • Four MA commercial insurers currently cover a range of unlimited coverage to $1,500 annual limits for O&P devices.	• Compass Health estimates a five-year cost of $5.3 million to $9.0 million (mid-range $6.5 million). • Premiums would increase by an average $0.41 per member per month.

Evidence Reviewed: Cost					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
4	Prosthetic and orthotic adult benefit.	Department of Health Care Policy and Financing Medical Policy and Benefits, (1999)	Impact of CO mandate on O&P costs, savings, benefits.	• The 1997 Medicaid Omnibus Bill provided an optional service of prosthetic devices, including medically necessary augmentative communication devices to eligible adult Medicaid clients. • The funding of $978,994 was appropriated in FY 1998/99 (starting July 1, 1998). • Determinations of appropriate benefit are being made through the guidelines/criteria developed by Medicare's O&P program. • For example, using Medicare guidelines, the benefit would cover a lower limb prosthesis when the client would reach/maintain a defined functional state within a reasonable period of time, and is motivated to ambulate. • Clinical assessments are also used in determination of medical necessity and the potential for successful use of prostheses. • Traumatic amputation accounted for 80% of all units utilized.	• Colorado found that this provision results in both fiscal and quality of life benefits. • These include pain reduction, decreased dependence, and reduced change of diabetic-related infection. • The net savings (after expenditures for the new adult benefit services) were $195,482, or $1,777.60 per client. • If this average was applied to those not included in the study group, the estimated net savings for FY 1998/99 would be $448,666.

Evidence Reviewed: Cost					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
25	A report to the Joint Standing Committee on Insurance and Financial Services of the 124th Maine Legislature: Review and evaluation of LD 20.	Department of Professional and Financial Regulation - State of Maine, (2010)	Impact of Maine microprocessor amendment on O&P costs, savings, benefits.	• In 2004, Maine mandated that insurance companies cover prosthetic devices for all/part of an arm or leg. • Amendment LD20 extends coverage for prosthetics employing microprocessors. • 11 other states that have adopted prosthetic mandates do not exclude microprocessors. • There are at least four manufacturers of microprocessors in Maine. • This service is required roughly 78 times (aged <65) per year for new/replacement prosthetics, with 20 not covered by insurance.	• Under Medicare rules, prosthetics are eligible for replacement every five years. • 28% of microprocessor prosthetics are covered by insurance. • A microprocessor knee costs $32,000 more than a traditional prosthetic knee. • Anthem estimated a State of Maine (SOM) Employee Plan would cost $0.11 PMPM. • Harvard Pilgrim estimated a 0.1% of claims cost, or $0.30 PMPM. • The Department (State of ME) estimates a 0.05% premium increase, or $0.15 PMPM. • This new mandate would affect 20 Maine amputees initially, and 50 going forward yearly.
26	Evaluation of Senate Bill 931: Mandated Coverage of Prosthetic Devices.	Joint Legislative Audit and Review Session of the Virginia General Assembly, (2007)	Impact of VA mandate on O&P costs, savings, benefits.	• There are between 37,450 and 50,952 amputees in Virginia (according to national prevalence rates). • Virginia's proposed mandate would require Medicaid to offer prosthetic coverage at comparable levels to Medicare. • Medicaid only pays for the "minimal applicable component necessary for the activities of daily living".	• Per member per month (PMPM) costs were only estimated between $0.02 and $0.08. • The mandate would not have a significant impact on the cost of healthcare in VA and may reduce overall costs. • Without prosthetic devices, individuals may lead a more sedentary lifestyle, leading to more secondary health complications.

Evidence Reviewed: Cost					
Ref. #	**Title**	**Author(s), Year**	**Description**	**Findings**	**Conclusions**
27	A Study of Assembly Bill of A-2774.	Mandated Health Benefits Advisory Commission, (2005)	Impact of NJ mandate on O&P costs, savings, benefits.	• This bill requires health plans to reimburse O&P devices on the same level as Medicare reimbursement. • Approximately 2.4 million (out of 8.5 million NJ population) persons would benefit from this bill. • Actuarial consultant NovaRest postulates that coverage can result in use of increased expensive appliances, supportive services, and replacements.	• This bill would increase premium costs by an average of 0.025% (or $0.25 of $1,000 of premium). • While an increase in premium can cause some to drop coverage, only an estimated 0.2% will drop with every 1% increase. • The mandate would increase the availability of O&P devices, reduce the financial burden for beneficiaries, and increase mental health and employability; however the quantity of such improvements is unknown (although qualitatively supported).
28	Methods to estimate and compare VA expenditures for assistive devices to Medicare payments.	Render RL, Taylor P, Plunkett J, et al., (2003)	Compares Veterans Health Administration (VA) annual expenditures for assistive devices at six VA hospitals with payments for the same devices in the private sector.	• Currently, disabled people account for 15 to 20% of America's non-institutionalized population, with more than 13 million (roughly 6% of all residents) using or needing assistive devices (1990). • Adaptive technology is not included in Medicare's benefit package. However, the VA's benefit package includes all four groups of assistive technologies. • The U.S. spent $18.5 billion on DME in CY 2000, with a third paid for by the government (through Medicare, Medicaid, and the VA). • Private sector payments are estimated by applying Medicare geographically adjusted rates, or by inflating VA costs by 30 percent.	• VA spent $30.6 million at the six sites, and hypothetical private sector payments were an estimated $49.8 million. • Unlike Medicare, the VA contracts through a competitive bidding process to provide assistive devices and dispense devices it has purchased. • Competitive bidding results in much lower expenditures. However, generalizing these cost savings to the private sector or federal programs requires further study.

References

1. American Board for Certification in Orthotics and Prosthetics, Inc. (2000). Practice analysis of the disciplines of orthotics and prosthetics – core competencies for orthotic and prosthetics: 1-2.
2. Bus SA, Valk GD, van Deursen RW et al. (2008).The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: A systematic review. *Diabetes Metabolism Research and Review* 24(1): 162-180.
3. California Technology Assessment Forum (CTAF). (2007). Microprocessor-controlled prosthetic knees: A technology assessment.
4. Carrington AL, Mawdsley SKV, Morley M, et al. (1996). Psychological status of diabetic people with or without lower limb disability. *Diabetes Research and Clinical Practice* 32: 19-25.
5. Davies S, Gibby O, Phillips C, et al. (2000). The health status of diabetic patients receiving orthotic therapy. *Quality of Life Research* 9(2): 233-240.
6. Geil MD. (2009). Assessing the state of clinically applicable research for evidence-based practice in prosthetics and orthotics. *Journal of Rehabilitation Research and Development* 46(3): 305-314.
7. Heinemann AW, Fisher WP, Gershon R. (2008). Improving health care quality with outcomes management. *American Academy of Orthotists and Prosthetists* 4(4): 1-8.
8. Heinemann AW, Gershon R, Fisher WP. (2006). Development and application of the Orthotics and Prosthetics User Survey: Applications and opportunities for health care quality improvement. *Journal of Prosthetics and Orthotics* 18(6): 80-85.
9. Johnson M, Newton P, Goyder E. (2006). Patient and professional perspectives on prescribed therapeutic footwear for people with diabetes: A vignette study. *Patient Education and Counseling* 64: 167-172.
10. Leigh R, Barker S. (2007). The effect of specialist footwear on the quality of life of patients with lower leg ulcers. *Wounds UK* 3(4): 19-23.
11. Mitka A. (2008). Advocates seek better insurance coverage for amputees needing limb prostheses. *Journal of the American Medical Association* 299(18): 2138-2139.
12. Peaco A, Halsne E, Haftner BJ. (2011). Assessing satisfaction with orthotic devices and services: A systematic literature review. *Journal of Prosthetics and Orthotics* 23(2): 95-105.
13. Price P. (2004). The diabetic foot: Quality of life. *Clinical Infectious Disease* 39, Supplement No. 2: 129-131.
14. Resnik L, Klinger SL, Krauthamer V, et al. (2010). U.S. Food and Drug Administration regulation of prosthetic research, development, and testing. *American Academy of Orthotists and Prosthetists* 22(2): 121-126.
15. Samuelsson KAM, Toytari O, Salminen AL, et al. (2012). Effects of lower limb prosthesis on activity, participation, and quality of life: A systematic review. *Prosthethetics and Orthotics International* 36(2): 145-158.
16. Stevens PM. (2011). Barriers to the implementation of evidence-based practice in orthotics and prosthetics. *American Academy of Orthotists and Prosthetists* 23(1): 34-39.
17. Thompson DM, Haran D. (1984). Living with an amputation: What it means for patients and their helpers. *International Journal of Rehabilitation Research* 7(3): 283-292.
18. Vastag B. (2004). Knee replacement underused, says panel. *Journal of the American Medical Association* 291(4): 413-414.
19. Viswanathan V, Madhavan S, Gnanasundaram S, et al. (2004). Effectiveness of different types of footwear insoles for the diabetic neuropathic foot. *Diabetes Care* 27(2): 474-477.
20. Walters J. (1981). Coping with a leg amputation. *American Journal of Nursing*: 1349-1352.
21. Amputee Coalition of America. The economic benefits of prosthetic coverage; Prosthetic coverage: Saving money and saving lives.

22. California Health Benefits Review Program. (2006). A Report to the 2006/2007 California State Legislature: Analysis of Assembly Bill 2012 – Orthotic and Prosthetic Devices: 1-24. Accessed from: http://www.chbrp.org/docs/index.php?action=read&bill_id=63&doc_type=3
23. Commonwealth of Massachusetts – Division of Health Care Finance and Policy. (2005). Review and Evaluation of Proposed Legislation to Mandate Coverage for Certain Prosthetic Devices – H. 376: 1-32. Retrieved from: www.mass.gov/Eeohhs2/docs/dhcfp/r/pubs/mandates/prosthetics.pdf
24. Department of Health Care Policy and Financing Medical Policy and Benefits. (1999). Prosthetic and Orthotic Adult Benefit: 1-10. Retrieved from: http://www.amputee-coalition.org/advocacy/research/co_parity_medicaid_full_report.pdf
25. Department of Professional and Financial Regulation - State of Maine. (2010). A Report to the Joint Standing Committee on Insurance and Financial Services of the 124th Maine Legislature: Review and Evaluation of LD 20: 1-30. Retrieved from: http://www.maine.gov/pfr/legislative/documents/LD020_Microprocessor_Prosthetic_Study_Final.pdf
26. Joint Legislative Audit and Review Session of the Virginia General Assembly. (2007). Evaluation of Senate Bill 931: Mandated Coverage of Prosthetic Devices: 1-44. Retrieved from: http://jlarc.state.va.us/reports/Rpt358.pdf
27. Mandated Health Benefits Advisory Commission. (2005). A Study of Assembly Bill A-2774: 1-29. Retrieved from: http://www.nj.gov/dobi/division_insurance/mhbac/a2774report.pdf
28. Render RL, Taylor P, Plunkett J, et al. (2003). Methods to estimate and compare VA expenditures for assistive devices to Medicare payments. *Medical Care* 41(6): 70-79.

Appendix B: Technical Methodology

In this appendix, we provide additional information on our methodology related to creating patient episodes, identifying and matching patient cohorts, and tracking and comparing patient outcomes.

Creating Patient Episodes

With the assistance of the clinical committee, we identified O&P services to be included in the custom cohort dataset for each of the O&P groups and the etiological diagnoses required for each study and comparison group patient. The HCPCS codes included in the study reflect the base O&P service to ensure that a patient episode is not created for an existing O&P user. For each of the O&P services, we identify the HCPCS used to trigger the episode (index event) and the etiological diagnoses that are required to be present before the receipt of the service.

Lower Extremity Orthoses

Exhibit B-1: Lower Extremity Orthoses Used as Episode Trigger

Code	Description
L1970	Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated
L1960	Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated
L1940	Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated
L2036	Knee Ankle Foot Orthosis, Full Plastic, Double Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated
L1932	Afo, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment
L1990	Ankle Foot Orthosis, Double Upright Free Plantar Dorsiflexion, Solid Stirrup, Calf Band/Cuff (Double Bar 'Bk' Orthosis), Custom-Fabricated
L1971	Ankle Foot Orthosis, Plastic Or Other Material With Ankle Joint, Prefabricated, Includes Fitting And Adjustment
L1930	Ankle Foot Orthosis, Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment
L1845	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Includes Fitting And Adjustment

Code	Description
L1844	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated
L1846	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated
L1843	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Includes Fitting And Adjustment

Exhibit B-2: Lower Extremity Orthoses Etiological Diagnoses

Etiological Diagnosis (CCS Category)
Other connective tissue disease
Other non-traumatic joint disorders
Osteoarthritis
Spondylosis; intervertebral disc disorders; other back problems
Other nervous system disorders
Acute cerebrovascular disease
Diabetes mellitus with complications
Acquired foot deformities
Sprains and strains
Fracture of lower limb
Joint disorders and dislocations; trauma-related
Paralysis
Late effects of cerebrovascular disease
Other and ill-defined cerebrovascular disease
Other congenital anomalies
Multiple sclerosis
Other acquired deformities
Other CNS infection and poliomyelitis
Pathological fracture
Nervous system congenital anomalies
Spinal cord injury

Appendix B: Technical Methodology

Spinal Orthoses

Exhibit B-3: Spinal Orthoses Used as Episode Trigger

Code	Description
L0631	Lumbar-Sacral Orthosis Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May I
L0637	Lumbar-Sacral Orthosis Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Re
L0486	Thoracic-Lumbar-Sacral Orthosis Triplanar Control, Two Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symph
L0639	Lumbar-Sacral Orthosis Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebra

Exhibit B-4: Spinal Orthoses Etiological Diagnoses

Etiological Diagnosis (CCS Category)
Spondylosis; intervertebral disc disorders; other back problems
Other non-traumatic joint disorders
Osteoarthritis
Other connective tissue disease
Other nervous system disorders
Other bone disease and musculoskeletal deformities
Sprains and strains
Other fractures
Other acquired deformities
Pathological fracture
Other congenital anomalies
Joint disorders and dislocations; trauma-related
Spinal cord injury

Appendix B: Technical Methodology

Lower Extremity Prostheses

Exhibit B-5: Lower Extremity Prostheses Used as Episode Trigger

Code	Description
L5050	Ankle, Symes, Molded Socket, Sach Foot
L5301	Below Knee, Molded Socket, Shin, Sach Foot, Endoskeletal System
L5321	Above Knee, Molded Socket, Open End, Sach Foot, Endoskeletal System, Single Axis Knee
L5400	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment, Suspension, And One Cast Change, Below Knee
L5420	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment And Suspension And One Cast Change 'Ak' Or Knee Disarticulation
L5450	Immediate Post Surgical Or Early Fitting, Application Of Non-Weight Bearing Rigid Dressing, Below Knee
L5460	Immediate Post Surgical Or Early Fitting, Application Of Non-Weight Bearing Rigid Dressing, Above Knee
L5500	Initial, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5505	Initial, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5510	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5520	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5530	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5535	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, No Cover, Sach Foot, Prefabricated, Adjustable Open End Socket
L5540	Preparatory, Below Knee 'Ptb' Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Model
L5560	Preparatory, Above Knee- Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5570	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5580	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5585	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Prefabricated Adjustable Open End Socket
L5590	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon No Cover, Sach Foot, Laminated Socket, Molded To Model
L5595	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Patient Model

For lower extremity prostheses, patients were also required to have an amputation within 12 months of receiving the prosthetic. Comparison group patients were also required to have an amputation following the etiological diagnosis. The amputation CPT codes used are contained below.

Exhibit B-6: Amputation Codes Required for Lower Extremity Prostheses Study and Comparison Group Patients

CPT	Description
27590	Amputate leg at thigh
27591	Amputate leg at thigh – with immediate fitting technique including first cast
27592	Amputate leg at thigh – open, circular (guillotine)
27594	Amputation follow-up surgery – secondary closure of scar revision
27596	Amputation follow-up surgery – reamputation
27598	Amputate lower leg at knee – disarticulation at knee
27880	Amputation of lower leg – through tibia and fibia
27881	Amputation of lower leg – with immediate fitting technique including first cast
27882	Amputation of lower leg - open, circular (guillotine)
27884	Amputation follow-up surgery – secondary closure of scar revision
27886	Amputation follow-up surgery – reamputation
27888	Amputation of foot at ankle – amputation, ankle through malleoli of tibia and fibula (e.g., syme, Pirogoff type procedures), with plastic closure and resection of nerves
27889	Amputation of foot at ankle – ankle disarticulation

Exhibit B-7: Lower Extremity Prostheses Etiological Diagnoses

Etiological Diagnosis (CCS Category)
Diabetes mellitus with complications
Peripheral and visceral atherosclerosis
Skin and subcutaneous tissue infections
Other non-traumatic joint disorders
Chronic ulcer of skin
Other circulatory disease
Complication of device; implant or graft
Open wounds of extremities
Gangrene
Septicemia (except in labor); rehabilitation care; complications of surgical procedure

Appendix B: Technical Methodology

Identifying and Matching Patient Cohorts

As described in the methodology section, we used propensity score matching techniques to match study group patients to comparison group patients. This involved a two-step process

First, patients were matched many-to-many across cohorts on a series of variables that control for clinical need for the O&P service. These include: the etiological diagnosis leading to the need for O&P services, whether the patient died during the episode window, and, for lower extremity prostheses, amputation procedure code following the etiological diagnosis.

Second, following the initial match, propensity score techniques were used to refine the match of patients across settings. This statistical method is used to reduce observable selection bias between the two cohorts and is used in this study to isolate the impact of site of service on all three types of patient outcomes. The propensity score indicated the probability of a patient receiving an O&P service based on their demographic and clinical characteristics.

A propensity score for each patient was calculated based on patient demographic characteristics and clinical characteristics. Patient demographic characteristics included age; gender; race; and dual eligibility for Medicare and Medicaid. Clinical characteristics included: comorbidities; prior healthcare utilization based on BETOS codes; prior use of institutional settings; receipt of care from specialists; and HCC score.

An optimized match was approximated by iteratively matching patients with an increasing caliper width. For instance, patients were first matched within 0.0001 of their propensity scores (i.e., a patient with a propensity score of 0.4312 would only be matched to someone with a 0.4311 or 0.4313). The remaining patients were then matched within 0.001 of their propensity scores, and so on. The final caliper width of 0.01 was consistent with the literature, which traditionally uses matches within 0.2 standard deviations of the logit function that determined their propensity score.[13] Therefore, our iterative approach is more rigorous than the standard caliper width supported by the literature. The rigor of the matching techniques isolated the effect of site of service from other observable causal effects. Patients who were not able to be matched were excluded from the analysis. The logistic regression used to calculate the propensity score follows the following functional form:

[13] Austin PC: Optimal caliper widths for propensity-score matching when estimating differences in means and differences in proportions in observational studies. *Pharm Stat* 10:150-161, 2011

$$P(X) = \frac{1}{1+e^{-(\beta_0+\sum \beta_i x_i)}},$$

where as
P(X) is the probability of receiving an O&P service,
β_0 is the constant term,
β_i is the coefficient of the i-th explanatory variable, and
x_i is the value of the i-th explanatory variable.

This function will always evaluate between zero and one.

Tracking and Comparing Patient Outcomes

Following the propensity score matching, we conducted a temporal autocorrelation function to determine the appropriate episode length needed to capture the effects of the O&P service without capturing the effects of other comorbidities or unrelated events.

As presented in the methodology section of the main report, this is a critical analytic step, as once the Medicare episode payments were no longer correlated to the receipt of the O&P service, conclusions could no longer be drawn with regard to the health care utilization and payments for the study group compared to the comparison group.

The temporal autocorrelation function measured the correlation between the Medicare expenditures of a beneficiary's first month (index month) and his/her Medicare expenditures at each month within the episode. As expected, the correlation decreased as the episode length increased as unrelated acute events and underlying chronic conditions began to dominate the overall expenditures of the episode as opposed to the receipt of the O&P service.

The temporal autocorrelation function is defined as,

$$A(t) = \frac{\langle (X_1-\mu_1)(X_t-\mu_t)\rangle}{\sigma_1\sigma_t},$$

where X_t is the Medicare episode payments for a beneficiary after *t* months,
μ_t is the mean Medicare episode payments of all beneficiaries after *t* months, and
σ_t is the standard deviation of the Medicare episode payments after *t* months.

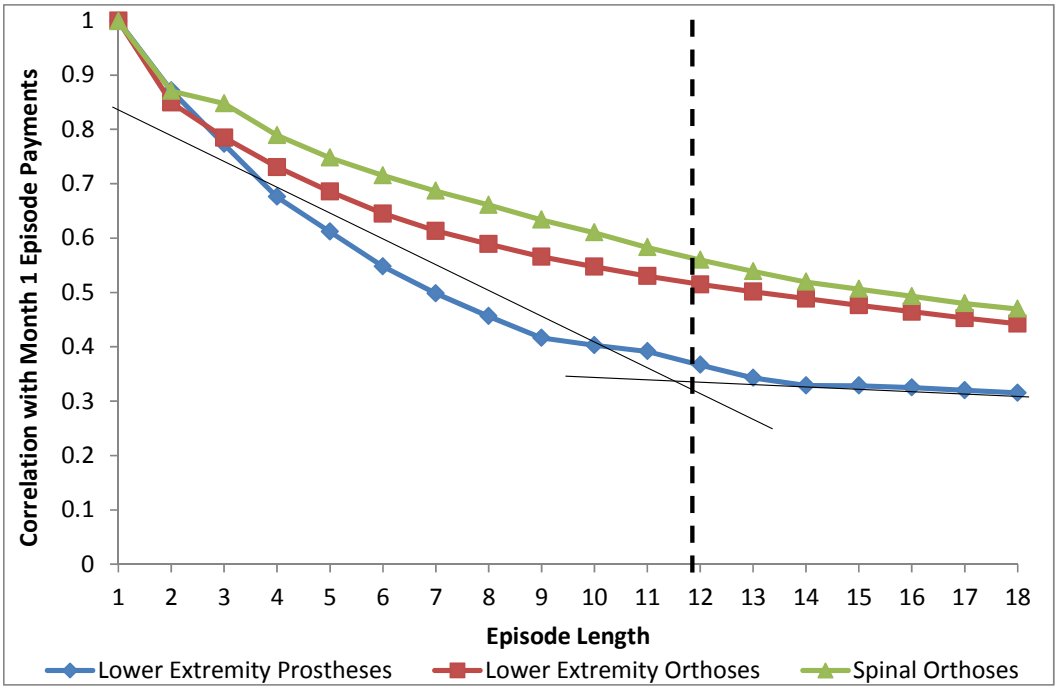
The angled brackets denote the average across all beneficiaries.

The result of the temporal autocorrelation function for each O&P service is presented below. For the lower extremity and spinal orthoses, the decline in the correlation between

the Medicare episode payment each month and month 1 payments was gradual and continuous. As expected, there were no dislocations or breaks as the episode window approached 18 months. Therefore, we were comfortable analyzing the patient outcomes and Medicare episode payments for the study and comparison groups across the 18 month episode.

For the lower extremity prostheses patients, there appeared to be two distinct slopes in the autocorrelation function (indicated by the illustrative – not calculated – trend lines). The first slope was significantly steeper than the slope of the orthotics, and would likely approach a correlation of 0.0 around 18 months. However, around month 12, there was a second trend line that was virtually flat. This plateau represented an underlying confounding correlation that became dominant at month 12. The intersection of these two trend lines at month 12 represented the point at which we could not distinguish between the effect of the treatment (receipt of O&P service) and unrelated expenditures. As a result of this analysis, we limited the lower prosthetic episodes to 12 months to more precisely measure the treatment effects and outcomes, without introducing the effect of underlying patient conditions.

Exhibit B-8: Results of Temporal Autocorrelation Function for All Three O&P Services



Once the episode length is determined, we compared the patient outcomes across groups. There were three types of outcomes for which the study and comparison groups were compared. First, the groups were compared on utilization and PMPM payments for each care setting.

Second, clinical and functional indicators were used, including use of inpatient rehabilitation facilities (IRF) and outpatient therapy, prevalence of fractures and falls, and emergency room and hospital admissions. Lastly, average cumulative episode payment was the final outcome measure and was compared across groups.

The definition for each outcome is included below.

Outcome	Definition
Utilization among each care setting	Average number of days or visits within each care setting
Per-member-per-month (PMPM) payment by setting	Sum of the payments divided by the sum of the member months
Inpatient (IRF) therapy	Average number of IRF days per episode
Outpatient therapy	Average number of outpatient therapy visits defined by revenue centers 0420, 0421, 0423, 0424, 0429, 0430, 0431, 0433, 0434, and 0439
Fractures and falls	ICD-9:E88X and 800 - 829
Emergency room and hospital admissions	Revenue center 045X
Average cumulative episode payment	Sum of the PMPM

Appendix C: Descriptive Statistics

Appendix C shows the descriptive statistics for each of the O&P groups following the propensity score matching.

Lower Extremity Orthoses

Exhibit C-1: Descriptive Statistics across Matched Pairs for Lower Extremity Orthoses (2008-2010)

Demographic Characteristic	Study Group	Comparison Group	Percentage Point Difference
Number of Beneficiaries	34,864	34,864	0.00
Average Age	70.8	70.9	-0.10
% Duals	24.3%	24.1%	0.00
% Female	53.4%	56.0%	-0.03
% Death	9.2%	9.2%	0.00
% Black	10.0%	10.6%	-0.01
% White	85.5%	84.0%	0.02
% Hispanic	1.9%	2.1%	0.00

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Appendix C: Descriptive Statistics

Exhibit C-2: Etiological Diagnoses for Lower Extremity Orthoses (2008-2010)

Etiological Diagnosis (CCS Category)	Percent of Matched Pairs
Other connective tissue disease	21.5%
Other non-traumatic joint disorders	20.2%
Osteoarthritis	15.2%
Spondylosis; intervertebral disc disorders; other back problems	8.9%
Other nervous system disorders	8.2%
Acute cerebrovascular disease	4.9%
Diabetes mellitus with complications	4.6%
Acquired foot deformities	4.0%
Sprains and strains	3.5%
Fracture of lower limb	3.1%
Joint disorders and dislocations; trauma-related	1.8%
Paralysis	1.1%
Late effects of cerebrovascular disease	0.7%
Other and ill-defined cerebrovascular disease	0.5%
Other congenital anomalies	0.5%
Multiple sclerosis	0.5%
Other acquired deformities	0.5%
Other CNS infection and poliomyelitis	0.2%
Pathological fracture	0.1%
Nervous system congenital anomalies	0.1%
Spinal cord injury	0.1%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Appendix C: Descriptive Statistics

Spinal Orthoses

Exhibit C-3: Descriptive Statistics across Matched Pairs for Spinal Orthoses (2008-2010)

Demographic Characteristic	Study Group	Comparison Group	Percentage Point Difference
Number of Beneficiaries	6,247	6,247	0.00
Average Age	71.2	71.1	0.10
% Duals	33.9%	26.9%	0.07
% Female	59.7%	55.5%	0.04
% Death	9.0%	9.0%	0.00
% Black	17.0%	18.7%	-0.02
% White	75.5%	72.9%	0.03
% Hispanic	3.1%	3.1%	0.00

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Exhibit C-4: Etiological Diagnoses for Spinal Orthoses (2008-2010)

Etiological Diagnosis (CCS Category)	Percent of Matched Pairs
Spondylosis; intervertebral disc disorders; other back problems	52.0%
Other non-traumatic joint disorders	10.7%
Osteoarthritis	9.7%
Other connective tissue disease	9.4%
Other nervous system disorders	5.6%
Other bone disease and musculoskeletal deformities	5.0%
Sprains and strains	3.6%
Other fractures	2.5%
Other acquired deformities	0.5%
Pathological fracture	0.5%
Other congenital anomalies	0.3%
Joint disorders and dislocations; trauma-related	0.2%
Spinal cord injury	0.1%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Appendix C: Descriptive Statistics

Lower Extremity Prostheses

Exhibit C-5: Descriptive Statistics across Matched Pairs for Lower Extremity Prostheses (2008-2010)

Demographic Characteristic	Study Group	Comparison Group	Percentage Point Difference
Number of Beneficiaries	428	428	0.00
Average Age	72.9	72.5	0.40
% Duals	40.2%	45.3%	-0.05
% Female	36.7%	37.6%	-0.01
% Death	45.6%	45.6%	0.00
% Black	22.7%	29.9%	-0.07
% White	70.8%	64.0%	0.07
% Hispanic	3.3%	3.5%	0.00

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.

Exhibit C-6: Etiological Diagnoses for Lower Extremity Prostheses (2008-2010)

Etiological Diagnosis (CCS Category)	Percent of Matched Pairs
Diabetes mellitus with complications	24.3%
Peripheral and visceral atherosclerosis	22.2%
Skin and subcutaneous tissue infections	15.0%
Other non-traumatic joint disorders	12.2%
Chronic ulcer of skin	11.9%
Other circulatory disease	4.4%
Complication of device; implant or graft	3.5%
Open wounds of extremities	2.6%
Gangrene	2.3%
Septicemia (except in labor); rehabilitation care; complications of surgical procedure	1.6%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), according to custom cohort database definition.