



**American Orthotic &  
Prosthetic Association**

November 27, 2018

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-9930-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

Submitted electronically via [www.regulations.gov](http://www.regulations.gov) (CMS-9930-P)

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019

Dear Sir/Madam:

We are writing to provide comments on CMS-9930-P, the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019” proposed rule. This proposed rule was published in the Federal Register on November 2, 2017.

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a trauma, chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA’s comments relative to this proposed rule will be limited to those that address Essential Health Benefits, specifically the provisions of the proposed rule that would enhance the role of individual states as related to essential health benefits.

**Delegation of Excessive Authority to the States Regarding Essential Health Benefits**

In December 2014, AOPA provided extensive comments regarding the CMS proposal to delegate authority on coverage of essential health benefits to individual states. At that time, AOPA expressed its concern relating to the delegation of excessive authority regarding coverage of essential health benefits to the states, through creating the concept of benchmark plans. AOPA pointed out that this was clearly not the original intent of the Patient Protection and Affordable Care Act (PPACA) which was enacted with the purpose of creating consistency

in health care coverage on a national level via a reliable national package of essential health benefits.

Many members of Congress at the time of the 2014 proposed rule, including the then Chairs of the six House Committees and sub-committees that had jurisdiction at the time the PPACA was implemented articulated in a letter to top officials of HHS and CMS that it was clearly Congress' intent that HHS would establish a national policy on what are and are not "essential health benefits." These members were troubled with the approach initially proposed in the Dec. 16, 2011 EHB bulletin, where HHS errantly passed a substantial component of the power to determine Essential Health Benefits to the states, which created state-by-state differences in what is an essential health benefit.

In a letter to Secretary Sebelius, dated Feb. 6, 2012, key committee members (Rep. Waxman, Rep. Levin, Rep. George Miller, Rep. Pallone, Jr., Rep. Stark, Rep. Andrews and Rep. Dingell) expressed their concerns regarding the delegation of EHB to the states. The members stated that:

"When creating the EHB package, we intended this to be a federal decision. We had not anticipated your decision to delegate the definition of the EHB package to states. While we understand the goal of balancing comprehensiveness and affordability, and ensuring an appropriate role for state input, we would reiterate that one of the primary goals of the Affordable Care Act was to create a consistent and comprehensive level of coverage for people across the country. Without very careful protections, we have serious concerns about delegating the decision for EHB to the States and providing even further discretion to insurers."

The comments from key legislators who were part of the creation of the essential health benefits package remain true today and the proposal to further expand the authority of individual states by allowing for more flexibility, whether via selecting "benchmark" plans that will define a state's essential health benefit package, or other devices will most likely only serve the interests of the insurance plans within a state who are looking to reduce costs through the limitation of coverage. The reduction or elimination of health benefits, such as orthotics and prosthetics, which have previously been defined as essential health benefits through the habilitative and rehabilitative services category represents a very small short term savings but may result in significantly higher costs long term due to the lack of prosthetic and/or orthotic intervention. A recent study published by the health economics firm Dobson DaVanzo entitled *Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries*. This study, a copy of which is appended to AOPA's comments showed that Medicare beneficiaries who received a lower extremity orthosis, a spinal orthosis, or a lower limb prosthesis had lower overall healthcare costs, including the cost of the orthotic or prosthetic care, than those that did not receive an orthosis or prosthesis. Expansion of authority to states that would allow them to choose benchmark plans from other states or to select individual categories of essential health benefits for inclusion in their benchmark plans may reduce or eliminate access to orthotic and prosthetic care, ultimately leading to higher long term costs to insurers.

So, succinctly stated, creating “increased flexibility” for state-level changes to **essential health benefits (and particularly one like rehabilitative and habilitative benefits that are explicitly stated in the statute) are bad for our disabled patients—persons with limb loss or chronic mobility impairment—and also bad for the very small business niche (less than 1/3 of 1% of the Medicare spend) comprised of our members who serve these compromised and endangered patients.**

The proposed rule introduces a new section (45 CFR § 156.111) that would allow states additional flexibility in selecting EHB benchmark plans through one of the following three options beginning in 2019:

1. Selecting the EHB benchmark plan of another state;
2. Replacing one or more EHB categories in its EHB benchmark plan with the same categories of benefits from another state’s EHB benchmark plan; or
3. Otherwise select a set of benefits that would become the EHB benchmark plan so long as the benchmark plan does not exceed the generosity of the most generous of among a set of comparison plans.

AOPA believes that expanding the authority of states to allow them to “pick and choose” the benefit packages from other state’s EHB packages is completely inconsistent and incompatible with the intent of the Affordable Care Act and will eliminate any consistency as to which benefits are available to patients under the essential health benefit provisions of the act. In addition to its concern regarding inconsistencies among state benchmark plans regarding what services are covered as essential health benefits, AOPA remains concerned that the proposed rule supports the concept of covering the least amount, lowest cost and quantity/quality of services through selection of benchmark plans that provide the most favorable conditions for the insurer without regard to the needs of the patient. AOPA remains concerned that this minimalistic approach has and will continue to operate to the detriment of patients. This would be even more tragic if it occurred as to prosthetic/orthotic patients with limb loss or chronic limb impairment since the law is intended to provide special protections for persons who are disabled. While the PPACA requires protections from discrimination in benefit design and balance among categories, the actual mechanism for ensuring against such discrimination and ensuring balance has already been proven as insufficient based on HHS’ own acknowledgement of deficiencies regarding coverage of habilitative services under existing benchmark plans .

### **Inclusion of Orthotics and Prosthetics as Essential Health Benefits**

AOPA would also like to take the opportunity to reiterate its understanding that orthotics and prosthetics very clearly have been specifically designated as essential health benefits under the category of habilitative and rehabilitative services initially outlined **in the statute**, and underscored in the HHS Dec. 16, 2011 EHB Bulletin. This is supported by the legislative history, which is replete with statements by leading legislators clarifying that habilitative and rehabilitative services indeed was inexorably intended to include orthotics and prosthetics.

Rep. George Miller, the Chair of the House Education and Labor Committee, and as such a key author of the original bill, stated:

“I am pleased that the essential benefits in the Patient Protection and Affordable Care Act include rehabilitative and habilitative services and devices, as these benefits are of particular importance to people with disabilities and chronic conditions...

The term ‘rehabilitative and habilitative devices’ includes durable medical equipment, prosthetics, orthotics, and related supplies. It is my understanding that the Patient Protection and Affordable Care Act requires the Secretary of Health and Human Services to develop, through regulation, standard definitions of many terms for the purposes of comparing benefit categories, from one private health plan to another. It is my expectation ‘prosthetics, orthotics, and related supplies’ will be defined separately from ‘durable medical equipment.’”

Congressional Record, p.H1882 (March 21, 2010).

In parallel, another legislator, Rep. William Pascarell, a member of the House Ways and Means Committee, the House Committee of jurisdiction at the time the Affordable Care Act was enacted, re-stated the identical standard:

“The term ‘rehabilitative and habilitative devices’ includes durable medical equipment, prosthetics, orthotics, and related supplies. It is my understanding that the Patient Protection and Affordable Care Act requires the Secretary of HHS to develop, through regulation, standard definitions of many terms, including durable medical equipment for purposes of comparing benefit categories from one private health plan to another. It is my expectation ‘prosthetics, orthotics, and related supplies’ will be defined separately from ‘durable medical equipment’ and the Secretary is not to define durable medical equipment for purposes of ‘in-home’ use only.”

Congressional Record, p.E462 (March 23, 2010).

As demonstrated above, there is clear congressional intent that orthotics and prosthetics falls under the statutorily defined EHB category of Rehabilitative and Habilitative services. This intent was confirmed through a direct reference to orthotics and prosthetics in the EHB Bulletin. On the carry-over paragraph from page 4 to page 5 it is stated:

*“For example, across the markets and plans examined, it appears that the following benefits are consistently covered: physician and specialist office visits, inpatient and outpatient surgery, hospitalization, organ transplants, emergency services, maternity care, inpatient and outpatient mental health and substance use disorder services, generic and brand prescription drugs, physical, occupational and speech therapy, durable medical equipment, **prosthetics and orthotics**, laboratory and imaging services, preventive care and nutritional counseling services for patients with diabetes, and well child and pediatric services such as immunizations. As noted in a previous*

*HHS analysis, variation appears to be much greater for cost-sharing than for covered services.”*

[Emphasis added].

Consistency by HHS over the years in regard to interpreting statutorily defined benefits is of dramatic importance—complete reversal of prior policy can be both disruptive and destructive in the lives of “at risk” patients such as this with limb loss, or chronic mobility impairment.

The specific identification of orthotics and prosthetics as an essential health benefit under the umbrella of habilitative and rehabilitative services, consistently in the statute itself, in the **Congressional Record** as well as the EHB bulletin published by the Department of Health and Human Services, clearly indicates the intent to include coverage for orthotic and prosthetics services as essential benefits in every healthcare plan that is to meet the federal criteria of ACA.

In closing, AOPA appreciates the opportunity to submit comments on proposed rule CMS-9930-P. If you have any questions or need any additional information, please contact myself, at (571) 431-0876 or [tfise@aopanet.org](mailto:tfise@aopanet.org), or Joseph McTernan, Director of Coding and Reimbursement Services, Education and Programming at (571)431-0811 or [jmcternan@aopanet.org](mailto:jmcternan@aopanet.org).

Sincerely,

A handwritten signature in dark ink, appearing to read 'T. Fise', is positioned above the typed name.

Thomas F. Fise, JD  
Executive Director

Addendum-Dobson DaVanzo Study

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

***2011 – 2014 Update: Final Report***

**Dobson | DaVanzo**

**Dobson DaVanzo & Associates, LLC Vienna, VA 703.260.1760 [www.dobsondavanzo.com](http://www.dobsondavanzo.com)**

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

*2011 – 2014 Update: Final Report*

Submitted to:  
American Orthotic and Prosthetic Association

Submitted by:  
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Monday, November 13, 2017 — *Final Report*

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# 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 impairment, spinal injury, and lower limb loss. There are few studies of the economic impact or value of O&P services reported in the literature. The American Orthotic and Prosthetic Association (AOPA), initially commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to conduct a retrospective analysis of 2007–2010 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. That analysis focused on the impact on Medicare beneficiaries of receiving lower extremity orthoses, spinal orthoses, and lower extremity prostheses.

This prior custom cohort study of orthotic and prosthetic Medicare beneficiaries was performed based on claims experience over the 2007–2010 period found that the study group of patients who received timely orthotic or prosthetic care had lower or comparable total health care costs than a comparison group of untreated patients over an extended episode of care.<sup>1</sup>

In 2015, AOPA commissioned Dobson | DaVanzo to conduct an update of this analysis, based on Medicare claims from 2011–2014 and including Part D drug claims in addition to Parts A and B. The primary objective of this updated analysis is to validate earlier conclusions on the extent to which Medicare patients who received select orthotic and prosthetic services had less total health care

***This study finds that patients who received O&P services experience better or comparable outcomes than patients who do not, with lower or comparable Medicare payments. These results are confirmative of our initial study, which implies that these findings are stable over time and can be reliably detected with administrative claims data.***

<sup>1</sup> Dobson, Allen, et al. "Economic value of prosthetic services among Medicare beneficiaries: a claims-based retrospective cohort study." *Military medicine* 181.25 (2016): 18-24.

# Executive Summary

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utilization, lower Medicare payments, and/or fewer negative outcomes compared to matched patients not receiving these services. While the data are from Medicare only, the “lessons learned” from this study can inform the economic value proposition of orthotics and prosthetics for other payers.

## Methodology in Brief

This retrospective cohort study investigated the economic and clinical impact<sup>2</sup> of receiving a specified 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<sup>3</sup> from 2011–2014 for patients who met the study’s sampling specifications. Beneficiaries were included in the study group if they had received a specified O&P service between January 1, 2012 and June 30, 2013, and had pre-determined etiological diagnoses of interest. Additionally, patients who received a lower extremity prosthetic were required to have had an amputation within this period. Comparison group patients were selected into the custom cohort based upon the ability to match to a study group patient based on etiological diagnosis, gender age, and state of residence. Up to five comparison group patients were identified for every beneficiary in the study group. In both the study and comparison cohorts, beneficiaries who died within three months of etiological diagnosis were excluded from the dataset.

Using this custom cohort, beneficiaries in the study and comparison groups were further matched one-to-one through propensity score matching techniques that controlled for observable selection bias based on etiological diagnosis, comorbidities, patient characteristics (age, gender, race), and historical health care utilization prior to the etiological diagnosis. Amputees were also matched on whether or when 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 possible adverse outcomes across the study and comparison group patients over 18 months for the lower extremity and spinal orthoses, and over approximately 15 months for the lower extremity prostheses.

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<sup>2</sup> Clinical impact as measured through administrative claims data

<sup>3</sup> 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).

# Executive Summary

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## Summary of Results

Exhibit ES-1 summarizes the results of our analyses for each service group. Within the **lower extremity orthoses** model, 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, fewer falls and fractures, and reduced costs to Medicare (episode payments approximately 8 percent lower than the comparison group, including the cost of the orthotic) ( $p<0.05$ ). Additionally, these patients sustained significantly more outpatient therapy, with significantly shorter stays in inpatient rehabilitation settings ( $p<0.05$ ).

Patients who received **spinal orthoses** had significantly lower Medicare payments over 18 months as compared to those who did not receive the orthotic, as well as fewer acute care hospitalizations, and had higher reliance on outpatient therapy ( $p<0.05$ ). Beneficiaries in the study group saw significantly fewer acute care hospitalizations, as well as significantly shorter lengths of stay in inpatient rehabilitation facilities ( $p<0.05$ ). This could suggest that the use of spinal orthoses allows patients to be less bedbound and remain independent in the community and in their homes. These patients had a similar number of falls and fractures, perhaps resulting from increased mobility. Patients receiving orthoses had significantly fewer emergency room visits ( $p<0.05$ ).

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 comparable or better outcomes than patients who did not receive prostheses. Study group patients were more likely to receive extensive outpatient therapy than comparison group patients ( $p<0.05$ ). Perhaps because of this increased therapy, the study group realized fewer acute care hospitalizations and less long-term facility-based care ( $p<0.05$ ), which offset the cost of the prosthetic. Results suggest that the device was fully amortized by the end of 15 months and the patient could presumably experience higher quality of life and increased independence compared to patients who did not receive the prosthetic.

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 regain stability and mobility. 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 could benefit from and receive the requisite therapy. The increased physical therapy among O&P users allowed patients to become less bedbound and more independent, with fewer emergency room admissions and acute care hospital admissions. This reduction in health care utilization ultimately makes

# Executive Summary

O&P services cost-effective for the Medicare program and increases the quality of life and independence of the patient.

## Exhibit ES-1: Health Care Utilization, Average Use of Therapy, and Patient Outcomes by Cohort (2011–2014)

Health Care Utilization and Outcomes	Study Group	Comparison Group	Difference
<b>Lower Extremity Orthoses (18-month episode; 43,487 pairs)</b>			
Total Average Medicare Episode Payments	\$22,734	\$24,673	-\$1,939 *
Average Medicare PMPM Payment	\$1,263	\$1,371	-\$108 *
Number of Acute Care Hospitalizations	0.52	0.87	-0.35 *
Average Number of IRF Days	0.42	0.47	-0.05 *
Average Number of Outpatient Therapy Visits	12.53	4.93	7.60 *
Number of Fractures and Falls	0.38	0.48	-0.10 *
Number of ER Admissions	0.83	1.22	-0.39 *
<b>Spinal Orthoses (18-month episode; 34,575 pairs)</b>			
Total Average Medicare Episode Payments	\$23,560	\$25,655	-\$2,094 *
Average Medicare PMPM Payment	\$1,309	\$1,425	-\$116 *
Number of Acute Care Hospitalizations	0.40	0.68	-0.28 *
Average Number of IRF Days	0.02	0.03	-0.01 *
Average Number of Outpatient Therapy Visits	6.14	2.06	4.08 *
Number of Fractures and Falls	0.32	0.32	0.00
Number of ER Admissions	0.81	1.03	-0.23 *
<b>Lower Extremity Prostheses (Approximate 15-month episode; 545 pairs)</b>			
Total Average Medicare Episode Payments	\$68,877	\$68,893	-\$16
Average Medicare PMPM Payment	\$4,592	\$4,593	-\$1
Number of Acute Care Hospitalizations	1.23	1.54	-0.31 *
Average Number of IRF Days	2.16	2.10	0.07
Average Number of Outpatient Therapy Visits	26.86	17.97	8.89 *
Number of Fractures and Falls	0.46	0.41	0.05
Number of ER Admissions	2.14	2.03	0.11

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition. PMPM - per-member-per-month payment; IRF - inpatient rehabilitation facility.

\* Statistically significant at  $p < 0.05$

# *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 impairment, spinal injury, and lower limb loss. There are few studies of the economic impact or value of O&P services reported in the literature. The American Orthotic and Prosthetic Association (AOPA), initially commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to conduct a retrospective analysis of 2007–2010 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. That analysis focused on the impact on Medicare beneficiaries of receiving lower extremity orthoses, spinal orthoses, and lower extremity prostheses.

The primary objective of the 2007–2010 study 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 and clinical benefit<sup>4</sup> to government and private payers when a person with limb impairment, spinal injury, or limb loss 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 specified O&P services, compared to similar beneficiaries who did not receive the specified O&P service. This value can be applied directly to the Medicare program, and indirectly, but powerfully, to the beneficiary's quality of life.

This prior custom cohort study of orthotic and prosthetic Medicare beneficiaries performed based on claims experience over the 2007–2010 period found that the study group of patients who received timely orthotic or prosthetic care had lower total health care costs and generally better related clinical outcomes than a comparison group of untreated patients.

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<sup>4</sup> As measured through administrative claims data

# *Introduction*

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AOPA again commissioned Dobson | DaVanzo to conduct an updated analysis based on Medicare claims from 2011–2014 and to include Part D drug claims in addition to Parts A and B. The primary objective of this updated analysis is to validate earlier conclusions on the extent to which Medicare patients who received select orthotic and prosthetic services had less total health care utilization, lower Medicare payments, and/or fewer negative outcomes compared to matched patients not receiving these services. While the data are from Medicare only, the “lessons learned” from this study can inform the value proposition of orthotics and prosthetics for other payers.

In the following chapters, we discuss how we updated our 2007–2010 analysis using Medicare claims data from 2011–2014 to assess whether O&P services improve patient outcomes and reduce costs for Medicare beneficiaries.

# 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 analyses were conducted on a custom cohort claims database requested from the Centers for Medicare & Medicaid Services (CMS).<sup>5</sup> We discuss the methodology for developing the claims database and each of these analytic components in the sections below.

## Custom Cohort Medicare Claims Database

This retrospective cohort study investigated the impact of receiving an O&P service on patient outcomes and Medicare payments. As with the initial 2007–2010 analysis, we focused this updated 2011–2014 analysis on three groups of services:

- lower extremity orthoses;
- spinal orthoses; and
- lower extremity prostheses for patients who underwent an amputation within the 12 months prior to receipt of the prosthetic device.

The O&P services to be included in each of the service groups in this updated study were identical to those used in the 2007–2010 analysis. Appendix A identifies the specific codes from the Healthcare Common Procedure Coding System (HCPCS) included in each group. We requested a custom cohort dataset from CMS with claims across all settings from 2011–2014 for patients who received and did not receive these O&P services. This database served as the analytic sample for all our analyses.

The sampling methodology utilized by CMS to extract the custom cohort database allows our analyses to reflect those Medicare beneficiaries who received the specified O&P

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<sup>5</sup> Data were obtained under DUA #28710.

services between January 1, 2012 and June 30, 2013. Patients were required to have received the O&P service during the specified time period, must have had appropriate etiological diagnoses (discussed more below), and must have survived at least three months post-diagnosis. 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 A.

Health care claims across all care settings<sup>6</sup> from 2011 through 2014 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 2011–2014 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 up to five comparison group patients preliminarily matched to each study group patient.

## Developing Patient Episode Definitions

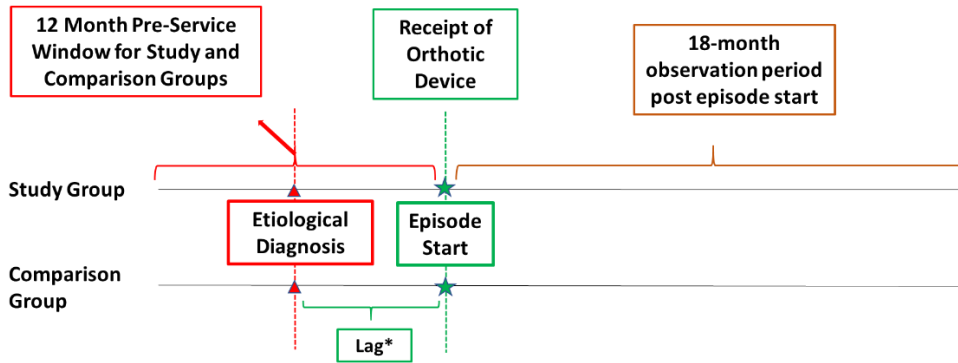
For each of the O&P service groups, we developed patient episodes that would allow for us to capture health care diagnoses, utilization, and expenditures prior to, and after, receipt of the O&P service. The structure for the study group patient episodes was consistent across the orthotic services, as presented in Exhibit 1, but slightly different for prostheses, as presented in Exhibit 2.

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<sup>6</sup> 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).

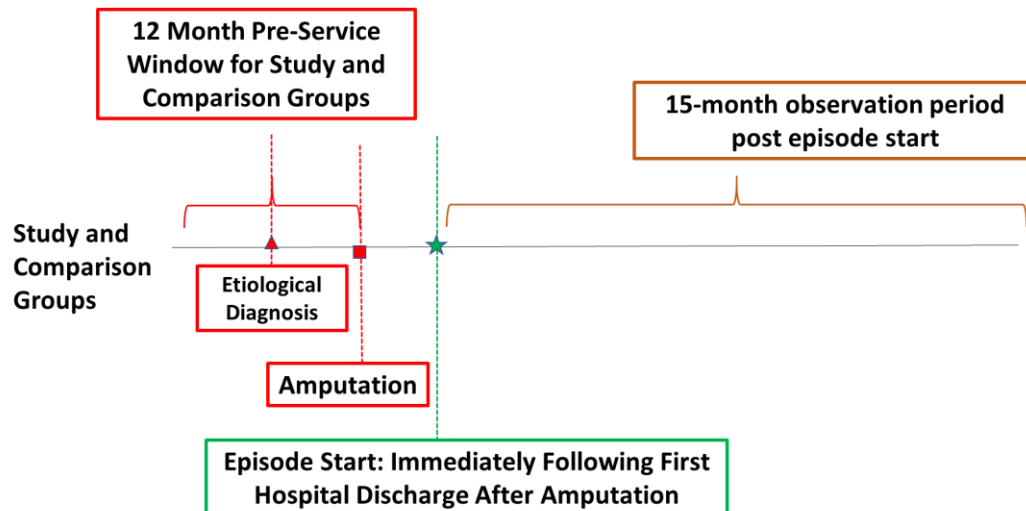


**Exhibit 1: Structure of the Patient Episode Definitions for the Lower Extremity and Spinal Orthotic Models**



\* Lag time between etiological diagnosis and episode start was defined by the average length of time between diagnosis and receipt of orthotic for study group beneficiaries of similar age and gender

**Exhibit 2: Structure of the Patient Episode Definitions for the Lower Extremity Prosthetic Model**



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, 2012 and June 30, 2013. 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 was used to match the O&P users to non-users (study to comparison group) and must have been present during the pre-service window. The etiological diagnosis (as defined by Clinical Classification Software – CCS<sup>7</sup>) was identified with assistance from the study’s clinical committee. The list of etiological diagnoses for each group of services is presented in Appendix A. While patients may have more than one of the etiological diagnoses present at a time, the first one evidenced in the claim was 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 the 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.** For the lower extremity and spinal orthotic models, the post-service period captured the time after receiving the O&P service. Across both orthotic service types, we analyzed the health care utilization and payments for 18 months following receipt of the O&P service. In the prosthetic model, the post-service period captured the time after the hospital discharge following amputation. For this model, we analyzed the health care utilization and payments for approximately 15 months following this hospital discharge.

Based on these constructs, we developed patient episodes for study group patients for each of the service groups. In the next sections, we discuss how we matched study group patients to comparison group patients and how we determined the length of the post-service window.

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<sup>7</sup> 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.

## Developing Patient Cohorts

Based on the patient episode definitions described above, we created 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.

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 prior to the episode of care. In the prosthetic model only, patients were also matched on time to death (where applicable) to further control for selection bias.

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.<sup>8</sup> Literature suggests that applying these techniques to observational studies is sufficient to remove observable selection bias among treatment and comparison groups and can result in findings that mimic RCTs.<sup>9,10,11,12</sup>

## Role of Mortality

In our previous 2007–2010 analysis, we compared the mortality rates of patients who received O&P services to those who did not and found that the mortality rates were very much higher for comparison group patients, particularly during the first three months after etiological diagnosis. Thus, in this updated analysis, patients who died within three months of etiological diagnosis were excluded from the custom cohort. Additionally, mortality after the first three months was particularly important among lower extremity prosthetic patients, as the clinical severity (and risk of imminent death) may have been a driver of whether the patient received a prosthesis. For the prosthetic model, we compared Medicare episode payments across groups more appropriately by matching patients on whether, or when, they died. As a result, mortality across the groups was excluded as a study outcome for the prosthetic model.

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<sup>8</sup> 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

<sup>9</sup> Austin PC: An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivariate Behavioral Research* 46:399-424, 2011

<sup>10</sup> 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

<sup>11</sup> Dehejia R, Wahba S: Propensity score-matching methods for nonexperimental causal studies. *The Review of Economics and Statistics* 84(1):151-161, 2002

<sup>12</sup> Rosenbaum PR, Rubin DB: The central role of the propensity score in observational studies for causal effects. *Biometrika* 70(1):41-55, 1983

## Determining Post-Service Window for Comparison Group Patients in the Lower Extremity and Spinal Orthotic Models

In the lower extremity and spinal orthotic models, the study group patients' post-service window was 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. To ensure the same post-service window for which health care utilization and expenditures were tracked and compared across cohorts, the length of time between etiological diagnosis and episode start for the comparison group was set to the average of the length of time for study group participants of similar age and gender. This ensured that the average length of the pre-window for the study and comparison groups were similar, making the health care expenditures and utilization comparable.

It was not necessary to create a proxy episode start date for the comparison group in the prosthetic model, as for all patients the episode began immediately after the first hospital discharge following the date of the amputation.

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 below shows the number of study group and etiological patients included in each service group before and after matching.

**Exhibit 3: Distribution of Beneficiaries (Study Group and Comparison Group Matches) for each O&P Service Group**

	Lower Extremity Orthotic Model		Spinal Orthotic Model		Lower Extremity Prosthetic Model	
	Study Group	Comparison Group	Study Group	Comparison Group	Study Group	Comparison Group
Number of Patients with O&P service and etiological diagnosis included in Custom Cohort	239,655	255,156	224,994	240,609	13,823	5,959
Number of Pairs after Propensity Score Match	43,487	43,487	34,573	34,573	545	545
Percent of patients represented in the effective sample	18.1%	17.0%	15.4%	14.4%	3.9%	9.1%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries

Our propensity score matching resulted in 43,487 matched pairs of Medicare beneficiaries in the lower extremity orthotic model; 34,575 matched pairs in the spinal

orthotic model; and 545 matched pairs of recent amputees in the prosthetic model. The number of matched pairs in this current study is higher than in our 2007–2010 analysis. This designed increase in sample size resulted from the specifications of the custom cohort database. The relatively small number of beneficiaries included in the lower extremity prosthetic model is because we imposed the requirement that amputation had occurred within 12 months of receipt of the prosthesis, and due to the number of variables used in developing the propensity score match. This excluded long-term users who received replacement prosthetics during the study window.

### **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.

In the 2007–2010 analysis, we used a temporal autocorrelation function 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. The results indicated that we could include the full 18 months of follow up in our episode analysis for the lower extremity and spinal orthotic models. However, for lower extremity prostheses, we found an underlying confounding correlation may have been dominating the effects of the treatment after 12 months. Accordingly, in the 2007–2010 study, we limited the lower prosthetic episodes to 12 months following receipt of the prosthetic device to more precisely measure the treatment effects and outcomes, without introducing the effect of underlying patient conditions. (Additional information on the temporal autocorrelation function is presented in the Appendix B of the 2007–2010 study report.)<sup>13</sup>

However, the effective date of the Affordable Care Act (ACA) intervened since our prior analysis, requiring modifications to the prosthetic episode for this updated 2011–2014 study. The ACA had a significant impact on hospital inpatient and outpatient mix, stay duration, and re-admission policies, among other factors. An initial examination of the 2011–2014 data indicated that a 15-month follow-up period led to a natural break point. To address this, for the current prosthetic model we used an approximate 15-month episode period starting immediately following the first hospital discharge after the amputation, as contrasted to the approximate 3-month waiting period post-amputation

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<sup>13</sup> Dobson, A., et al. "Retrospective Cohort Study of the Economic Value of Orthotic and Prosthetic Services Among Medicare Beneficiaries." Available at <http://52.23.209.174/wp-content/uploads/2014/01/Dobson-Davanzo-Report.pdf>

and an immediately subsequent 12-month episode period we had used for the 2007–2010 analysis.

In summary, we compared the outcomes and Medicare episode payments for up to 18 months following receipt of the lower extremity and spinal orthoses, and for approximately 15 months following amputation for the lower extremity prostheses. Across both study and comparison cohorts and O&P service categories, we compared the average Medicare total payment, distribution of payments by care settings, and outcome measures, such as falls, hospitalizations, and days of rehabilitative/physical therapy. Additionally, within the prosthetic model, 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 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. The use of lower extremity orthoses has been associated with increased mobility, resulting in enhanced quality of life. After our propensity score matching, we identified 43,487 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 B presents the results of the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received lower extremity orthoses were 69 years of age. Most patients were White / Caucasian (84.7 percent), with 29.7 percent of patients being dually eligible for Medicare and Medicaid. Across all matched pairs, 78.2 percent of matched pairs received the orthotic (or needed an orthotic) due to the primary etiological diagnosis of connective tissue disease (32.4 percent); spondylosis, intervertebral disc disorders or other back problems (17.9 percent); other nervous system disorders (16.7 percent); or osteoarthritis (11.3 percent).

Exhibit 4 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). It presents the results of the updated 2011–2014 analysis as well as the results of the initial 2007–2010 analysis for comparison. In general, the results of the 2011–2014 analysis are comparable to those of our earlier study. Although payment amounts differ between the two studies, with only one exception (discussed below) the direction of the difference is consistent.

# Analytic Results

**Exhibit 4: Lower Extremity Orthoses: Spending and Utilization for 18-Month Episode (2008–2010 and 2012–2014**

Care Setting	2007 - 2010 Analysis			2011 - 2014 Analysis		
	n = 34,864 Matched Pairs			n = 43,487 Matched Pairs		
	Study	Comparison	Difference	Study	Comparison	Difference
Physician	\$6,482	\$7,171	-\$688*	\$5,629	\$6,078	-\$449*
DME	\$2,002	\$966	\$1,036*	\$763	\$602	\$162*
Acute Care Hospital / Other Inpatient	\$8,392	\$10,828	-\$2,436*	\$5,640	\$6,212	-\$572*
Long Term Care Hospital	\$366	\$639	-\$273*	\$239	\$294	-\$55
Inpatient Rehabilitation Facility	\$1,178	\$924	\$255*	\$641	\$378	\$262*
Outpatient	\$3,552	\$3,752	-\$199*	\$2,778	\$3,127	-\$349*
Skilled Nursing Facility	\$2,415	\$3,180	-\$765*	\$1,619	\$1,504	\$115*
Home Health	\$2,231	\$1,912	\$320*	\$1,187	\$908	\$279*
Hospice	\$388	\$556	-\$168*	\$319	\$607	-\$288*
Total Part D Drug Spending	--	--	--	\$3,920	\$4,964	-\$1,044*
Total Part D Drug Spending for Part D Users Only †	--	--	--	\$5,563	\$7,322	-\$1,759*
<b>Total</b>	<b>\$27,007</b>	<b>\$29,927</b>	<b>-\$2,920*</b>	<b>\$22,734</b>	<b>\$24,673</b>	<b>-\$1,939*</b>
<b>Average PMPM Across Total Episode</b>	<b>\$1,500</b>	<b>\$1,663</b>	<b>-\$162*</b>	<b>\$1,263</b>	<b>\$1,371</b>	<b>-\$108*</b>
Average Number of Therapy Visits	17.36	12.10	5.26*	12.53	4.93	7.60*
Average Number of Fractures and Falls	1.45	1.52	-0.07	0.38	0.48	-0.10*
Average Number of ER Admissions	1.08	1.20	-0.12*	0.83	1.22	-0.39*
Average Number of Inpatient Admissions	0.62	0.70	-0.08	0.52	0.87	-0.35*
Length of Stay for Inpatient Admissions	--	--	--	2.64	4.77	-2.14*
Average Number of IRF Admissions	0.05	0.04	0.01*	0.03	0.04	0.00*
Length of Stay for IRF Admissions	0.72	0.52	0.20*	0.42	0.47	-0.05*
12-Month Mortality Rate	--	--	--	0.002	0.009	-0.01*

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.

\* Difference is significant at  $\alpha = 0.05$

† Not included in Total

Across the 18-month episode, in this updated analysis the study group patients had a total Medicare payment of \$22,734 compared to \$24,673 for the comparison group – that is, \$1,939 lower for the study group ( $p < 0.05$ ). Significantly fewer admissions to acute care hospitals was a driver of this difference, as the study group patients were admitted 0.52 times during the 18 months, compared to 0.87 times for the comparison group. This lower rate of utilization lowered the total episode payments by \$572 for patients receiving orthoses.

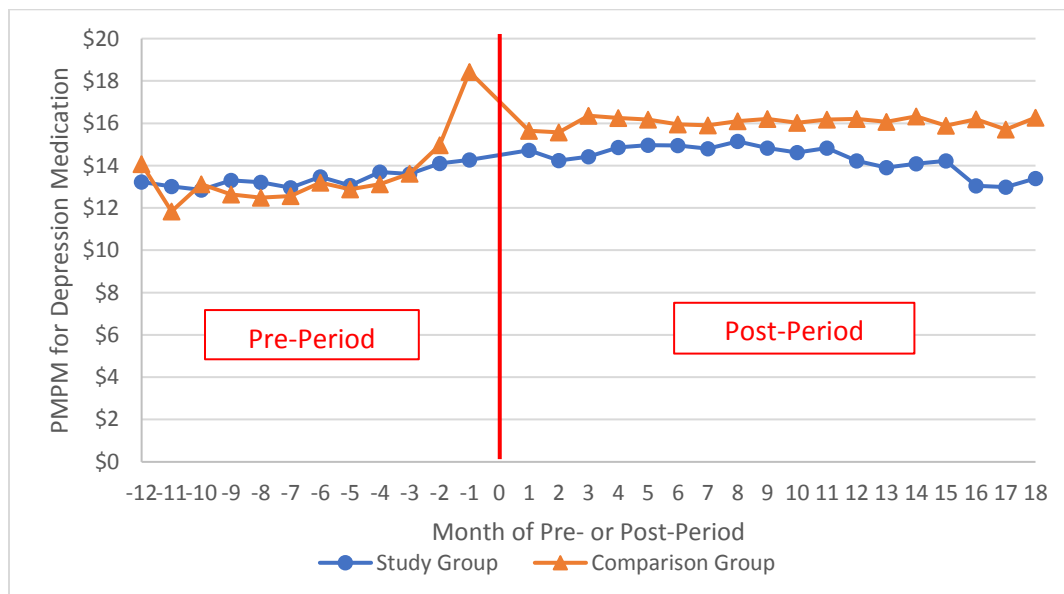


## Analytic Results

In addition, similar to the 2007–2010 analysis, we again found that the lower extremity orthotic study group had significantly lower payments to physicians and outpatient hospitals. Study group beneficiaries also had lower overall Part D drug spending, a significant difference of \$1,759 among beneficiaries using Part D ( $p < 0.05$ ). These findings may suggest overall lower morbidity or comorbidity in patients who receive O&P services.

Although beneficiaries in the study and comparison groups were not matched on Part D drug use, they were matched on comorbidities that likely correspond to prescription drug use, including depression and hypertension. An examination of Part D drugs for depression demonstrates that despite similar spending in the pre-service period (approximately \$13 - \$14 per member per month), in the post-period spending for these drugs increased by approximately \$2 per member per month (to \$16) in the comparison group while remaining constant at \$13 in the study group (see Exhibit 5). This may indicate an increased need for depression-related medication among beneficiaries who do not receive lower extremity orthotics. Spending for hypertension-related medication was similar in both groups during both the pre- and post-periods.

**Exhibit 5. Average Monthly Per Member Per Month Spending for Depression Medication during the Pre- and Post-Periods among Beneficiaries Eligible for Part D**



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

## Analytic Results

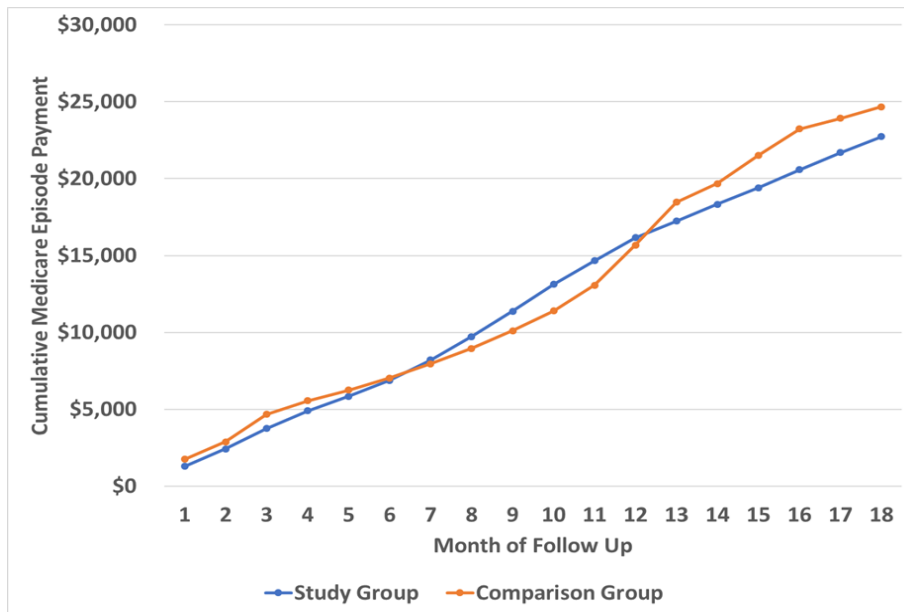
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Beneficiaries receiving the orthotic also demonstrated significantly higher expenditures in most post-acute care settings, including inpatient rehabilitation facilities (\$641 vs \$378), skilled nursing facilities (\$1,619 vs \$1,504), and home health (\$1,187 vs \$908) ( $p < 0.05$ ). These results are similar to those of the 2007–2010 analysis, with the exception of skilled nursing facilities. In the earlier analysis, expenditures in this care setting were \$765 less than the comparison group across the 18-month episode. Higher utilization of post-acute care may be an important reason why acute care hospital admissions and expenditures are significantly lower in the study group. That is, the higher use of post-acute care may eliminate the need for additional or subsequent admission to acute care hospitals, ultimately lowering total episode cost.

Despite having lower total episode payments among the study group patients compared to the comparison group, patients who received lower extremity orthoses received significantly more outpatient therapy than those who did not receive the orthotic (12.53 vs 4.93 visits) ( $p < 0.05$ ). This increased therapy is consistent with Medicare's emphasis on restorative care for beneficiaries, when possible. The higher therapy utilization may also be related to the lower rate of negative outcomes for patients who received O&P services. As shown in Exhibit 4, study group patients experienced significantly fewer falls and fractures (0.38 compared to 0.48) and significantly fewer emergency room (ER) admissions (0.83 vs 1.22) ( $p < 0.05$ ). The results of this analysis suggest that with the receipt of the lower extremity orthotic, study group patients could withstand more intensive therapy that led to increased standing stability, resulting in fewer emergency room admissions, hospitalizations, and lower Medicare payments.

Exhibit 6 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 a period of higher spending in Months 7 to 12, perhaps due to more intensive therapy, the study group patients had lower Medicare episode payments than the comparison group. Thus, over the entire episode the cost of the orthotic was fully amortized through reduced utilization in other settings. These findings are consistent with those of the 2007–2010 analysis.

**Exhibit 6: Lower Extremity Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2012-2014)**



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

**Summary of Findings:** We conclude from this updated 2011-2014 analysis that patients who received lower extremity orthoses had better outcomes, defined as fewer acute care hospitalizations and emergency room admissions, fewer fractures and falls, and reduced overall cost to Medicare. Study group patients achieved better outcomes with Medicare episode payments that were \$1,939 – or 8 percent – less than the comparison group (including the price of the orthotic). Additionally, these patients sustained more rehabilitation. These findings are consistent with those of our initial 2007-2010 study.

## Spinal Orthoses

The second O&P service included in our analysis is spinal orthoses. After our propensity score matching, we identified 34,575 matched pairs among Medicare beneficiaries in the custom cohort database. Beneficiaries were matched on patient demographic and clinical characteristics, and are accordingly risk-adjusted on these dimensions. Appendix B presents the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received spinal orthoses were 67 years old, and 37.6 percent of all matched pairs were female. Most patients were Caucasian (81.2 percent), and 11.8 percent were African American. The most common etiological diagnosis among these beneficiaries was spondylosis (40.1 percent), followed by other connective tissue disease (25.7) percent and other nervous system disorders (15.6 percent).

Exhibit 7 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 patients had significantly lower total episode payments across all care settings (\$23,560 for the study group compared to \$25,655 for the comparison group, a difference of \$2,094). This result is different than that found in the 2007–2010 analysis, which found a nonsignificant difference in total episode spending between the study and comparison groups.

In this updated analysis, a major contributor to the difference in total episode payments between the study and comparison groups was significantly lower payments for Part D drugs in the study group (\$1,598 lower among Part D users only,  $p < 0.05$ ). This could indicate lower prevalence of comorbid conditions and generally better health status among beneficiaries receiving spinal orthoses, compared to those who do not. As mentioned previously, beneficiaries in the study and comparison groups were not matched on Part D drug use but were matched on comorbidities that likely correspond to prescription drug use, including depression and hypertension. Episode spending for these two categories of drugs was similar between the study and comparison groups in this analysis (data not shown).

Study group patients had higher payments for DME services, inpatient rehabilitation facilities, and home health, but lower payments to acute care hospitals, long-term care hospitals and physician offices ( $p < 0.05$ ). This is somewhat different than our earlier analysis, which found lower payments to inpatient rehabilitation facilities for the study group, but higher payments to physician offices. This could indicate a shift toward more intensive facility-based rehabilitative care for beneficiaries receiving orthoses.

Still, the average length of stay in inpatient rehabilitation facilities was significantly lower in the study group, and payments to skilled nursing facilities were comparable between the study and comparison groups across the 18-month episode. This would suggest that while

## Analytic Results

patients who received spinal orthoses required and received more intensive rehabilitation, they were able to recover faster than those without orthoses. Thus, they appear more likely to return home faster and to receive follow up care in the home, as evidenced by higher payments to home health among the study group (\$1,100 vs \$901,  $p < 0.05$ ).

**Exhibit 7: Spinal Orthoses: Spending and Utilization for 18-Month Episode (2008–2010 and 2012–2014)**

Care Setting	2007 - 2010 Analysis			2011 - 2014 Analysis Update		
	n = 6,247 Matched Pairs			n = 34,575 Matched Pairs		
	Study	Comparison	Difference	Study	Comparison	Difference
Physician	\$7,907	\$7,439	\$468*	\$6,291	\$6,570	-\$279*
DME	\$2,605	\$1,288	\$1,317*	\$722	\$621	\$101*
Acute Care Hospital / Other Inpatient	\$11,373	\$11,830	-\$457	\$5,913	\$6,294	-\$381*
Long Term Care Hospital	\$517	\$837	-\$320**	\$190	\$269	-\$79*
Inpatient Rehabilitation Facility	\$990	\$1,188	-\$198**	\$433	\$341	\$92*
Outpatient	\$3,786	\$4,120	-\$334	\$2,734	\$3,294	-\$559*
Skilled Nursing Facility	\$2,188	\$3,175	-\$987*	\$1,234	\$1,281	-\$47
Home Health	\$2,802	\$2,388	\$414*	\$1,100	\$901	\$199*
Hospice	\$431	\$426	\$5**	\$234	\$534	-\$300*
Total Part D Drug Spending	--	--	--	\$4,709	\$5,550	-\$840*
Total Part D Drug Spending among Part D Users Only †	--	--	--	\$6,302	\$7,900	-\$1,598*
<b>Total</b>	<b>\$32,598</b>	<b>\$32,691</b>	<b>-\$93</b>	<b>\$23,560</b>	<b>\$25,655</b>	<b>-\$2,094*</b>
<b>Average PMPM Across Total Episode</b>	<b>\$1,811</b>	<b>\$1,816</b>	<b>-\$5</b>	<b>\$1,309</b>	<b>\$1,425</b>	<b>-\$116*</b>
Average Number of Therapy Visits	14.95	12.91	2.04	6.14	2.06	4.08*
Average Number of Fractures and Falls	2.05	1.56	0.50*	0.32	0.32	0.00
Average Number of ER Admissions	1.35	1.32	0.03	0.81	1.03	-0.23*
Average Number of Inpatient Admissions	0.82	0.78	0.03	0.40	0.68	-0.28*
Length of Stay for Inpatient Admissions	--	--	--	1.84	3.53	-1.69*
Average Number of IRF Admissions	--	--	--	0.02	0.03	-0.01*
Length of Stay for IRF Admissions	0.62	0.68	-0.06	0.24	0.32	-0.07*
12-Month Mortality Rate	--	--	--	0.001	0.008	-0.01*

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.

\* Difference is significant at  $\alpha = 0.05$

\*\* The difference in spending between the study and comparison groups for IRF, LTCH, Other Inpatient and Hospice settings combined was significant at  $\alpha = 0.05$

† Not included in Total

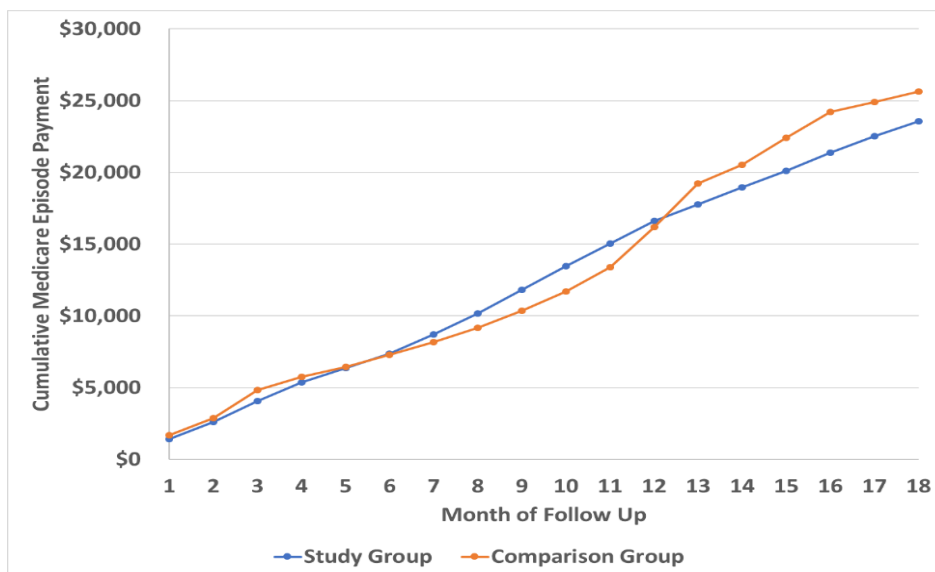
Study group patients who received spinal orthoses experienced the same number of fractures and falls compared to those who did not receive the orthoses. This may have been

## Analytic Results

because patients who received a spinal orthotic received more therapy and therefore may have been more likely to ambulate, increasing the likelihood of falls. The higher prevalence of falls did not relate to a significantly higher rate of emergency room admissions, and the study group in fact had a significantly lower number of emergency room admissions (0.81 admissions for the study group compared to 1.03 for the comparison group,  $p < 0.05$ ).

Exhibit 8 presents the cumulative episode payment for those who received spinal orthoses compared to those who did not by episode month. Similar to the lower extremity orthotic model, this chart indicates that, despite a period of additional cost for the study group between months 7 to 12, the cost of the orthotic was fully amortized over the episode.

**Exhibit 8: Spinal Orthoses: Cumulative Medicare Episode Payment by Cohort (18 Month Episodes from 2012–2014)**



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

**Summary of Findings:** Our analytic results indicated that patients who received spinal orthoses had lower cumulative Medicare payments over 18 months compared to those who did not receive the orthotic. Furthermore, these patients had a higher rate of home-based care and rehabilitation, which could suggest that the use of spinal orthoses allows patients to be less bedbound. These patients had similar prevalence of fractures and falls, which may have been due to the increased ambulation and independence of beneficiaries in the study group. By Month 18, study group patients had Medicare episode payments that were \$2,094 (or 8 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 relatively high Medicare episode payments. Our analysis was limited only 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 545 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. If applicable, they were also matched on timing of death. Appendix B presents the descriptive statistics and the distribution of patients by etiological diagnosis. On average, patients who received lower extremity prostheses were about 66 years of age, and 17.4 percent of patients were female. More than two-thirds of patients included in the matched pairs were Caucasian (68.8 percent), and 24.8 percent were African American. Approximately 5 percent of all matched pairs died within the 15-month episode. Almost one-third of patients had an etiological diagnosis of diabetes mellitus with complication (30.6 percent), while 18.0 percent were diagnosed with chronic ulcer of skin and approximately 17.8 percent were diagnosed with peripheral and visceral atherosclerosis.

Exhibit 9 presents the health care 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 compared across approximately 15 months.

Across the 15-month episode, the study group patients had total Medicare payments across all care settings that were slightly (not significantly) lower than the comparison group (\$68,877 for the study group compared to \$68,893 for the comparison group). About 14 percent of the total episode payment for the study group patients is attributed to the prosthetic (\$9,694 of the total episode payment of \$68,877). The prosthetic device represents an additional cost that was fully amortized within 15 months due to a reduction of care in other settings. This stands in contrast to the 2007–2010 analysis, which found higher total episode payments of \$1,015 among the study group.

## Analytic Results

**Exhibit 9: Lower Extremity Prostheses: Spending and Utilization for Approximate 15-Month Episode (2008–2010 and 2012–2014)**

Care Setting	2007 - 2010 Analysis			2011 - 2014 Analysis Update		
	n = 428 Matched Pairs			n = 545 Matched Pairs		
	Study	Comparison	Difference	Study	Comparison	Difference
Physician	\$7,792	\$11,883	-\$4,092*	\$8,270	\$9,920	-\$1,649
DME	\$18,653	\$2,537	\$16,116*	\$15,323	\$5,018	\$10,305*
Prosthetics Only: L5000 - L5999	--	--	--	\$9,694	\$1,782	\$7,912*
Acute Care Hospital / Other Inpatient	\$18,080	\$28,276	-\$10,196*	\$15,529	\$19,851	-\$4,321*
Long Term Care Hospital	\$1,408	\$4,102	-\$2,694**	\$1,445	\$4,017	-\$2,571*
Inpatient Rehabilitation Facility	\$2,603	\$2,000	\$603**	\$3,476	\$3,415	\$61
Outpatient	\$9,373	\$7,291	\$2,082*	\$8,601	\$8,649	-\$49
Skilled Nursing Facility	\$8,386	\$8,821	-\$435	\$5,783	\$6,630	-\$847
Home Health	\$6,181	\$5,692	\$489	\$5,049	\$4,764	\$285
Hospice	\$715	\$1,572	-\$857**	\$104	\$825	-\$721*
Total Part D Drug Spending	--	--	--	\$5,297	\$5,806	-\$508
Total Part D Drug Spending among Part D Users Only <sup>†</sup>	--	--	--	\$6,576	\$7,143	-\$566
<b>Total</b>	<b>\$73,191</b>	<b>\$72,175</b>	<b>\$1,015</b>	<b>\$68,877</b>	<b>\$68,893</b>	<b>-\$16</b>
<b>Average PMPM Across Total Episode</b>	<b>\$4,066</b>	<b>\$4,010</b>	<b>\$56</b>	<b>\$3,827</b>	<b>\$3,827</b>	<b>-\$1</b>
Average Number of Therapy Visits	56.10	28.90	27.20*	26.86	17.97	8.89*
Average Number of Fractures and Falls	0.90	0.72	0.18	0.46	0.41	0.05
Average Number of ER Admissions	1.55	2.10	-0.55*	2.14	2.03	0.11
Average Number of Inpatient Admissions	1.18	1.51	-0.33	1.23	1.54	-0.31*
Length of Stay for Inpatient Admissions	--	--	--	7.53	11.44	-3.91*
Average Number of IRF Admissions	--	--	--	0.17	0.14	0.02
Length of Stay for IRF Admissions	1.61	1.19	0.42	2.16	2.10	0.07

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.

\* Difference is significant at  $\alpha = 0.05$

\*\* The difference in spending between the study and comparison groups for IRF, LTCH, Other Inpatient and Hospice settings combined was significant at  $\alpha = 0.05$

† Not included in Total

The largest driver of the difference in total episode Medicare payment among the study and comparison group patients was acute care hospitalization. The study group patients had a significantly lower rate of hospitalization than the comparison group patients (1.23 admissions for the study group compared to 1.54 admissions for the comparison group)



## Analytic Results

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( $p < 0.05$ ), resulting in lower episode Medicare payments for acute care hospitalizations (\$15,529 for the study group compared to \$19,851 for the comparison group) ( $p < 0.05$ ). These results are similar to those found in the 2007–2010 analysis.

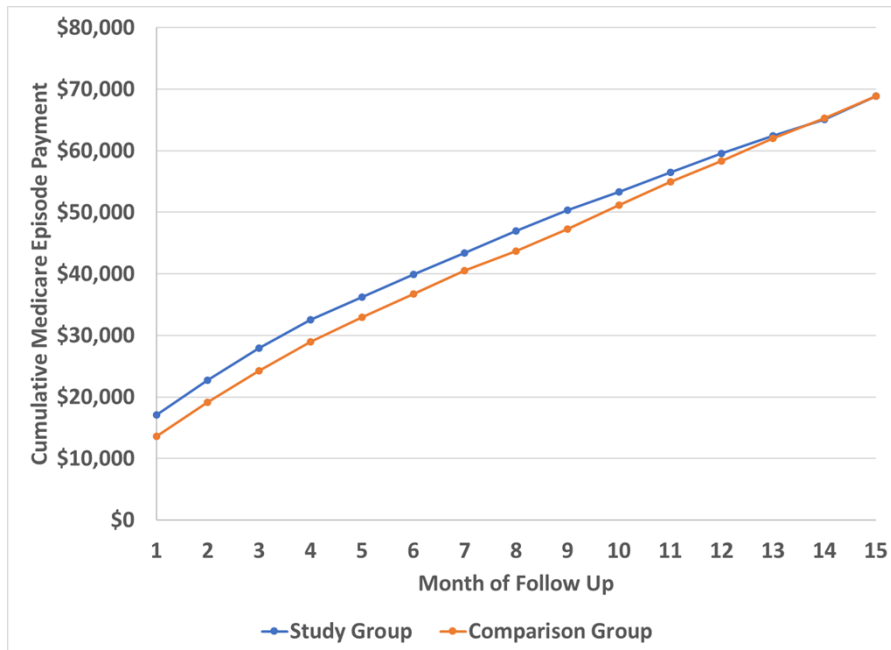
Study group patients had significantly lower expenditures for facility-based long-term care and in-home hospice services than the comparison group patients ( $p < 0.05$ ), but spending differences were not significantly different in other care settings. Expenditures were nominally lower among study group participants in physician offices, hospital outpatient departments, and skilled nursing facilities, which may indicate improved patient clinical stability that is not otherwise captured directly through administrative claims. Expenditures were nominally higher among study group participants for inpatient rehabilitation facilities and home health, which may be an indication of increased therapy. In addition, expenditures were lower for Part D drugs among the study group, although this difference was not significant.

Patients need to be trained and receive extensive therapy to properly use a prosthetic device, and study group patients had considerably higher utilization of outpatient therapy (26.86 visits vs 19.97 visits,  $p < 0.05$ ). Both inpatient and outpatient therapy sessions are critical for patients with prostheses. They must learn 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.

Adverse events or outcomes, defined as the number of fractures and falls and emergency room admissions, were not significantly different between the study and comparison groups, despite evidence of increased ambulation among prosthetic recipients. Given the increased independence of study group patients, the number of falls and fractures was comparable to comparison group patients. Study group patients were admitted to the emergency room nominally more often than comparison group patients, a nonsignificant difference of about 5%.

Exhibit 10 presents the cumulative episode payment for the study and comparison group by episode month. This chart indicates that the cost of the prosthetic was slowly amortized over time; by the end of Month 12, the cumulative Medicare episode payment for the study group was similar to that of the comparison group, indicating that the cost of the prosthetic was fully amortized.

**Exhibit 10: Lower Extremity Prostheses: Cumulative Medicare Episode Payment by Cohort (15 Month Episodes from 2012-2014)**



Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

**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 15 months than those who do not (-\$16). Results suggest that the device was fully amortized by the end of 15 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.

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

Much has changed in health care, and in prosthetic care, since 2010, and patients can face significant barriers in access to prosthetic services. Varying cost pressures caused Medicare payments for all lower extremity prostheses to decline by 6.1 percent between 2010 and 2014. Medicare payments for more advanced prosthetic technology declined by 36.1 percent during this period.<sup>14</sup> 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 or more advanced 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 deemed ineligible for K3 and K4-level devices are at significantly greater risk of adverse events and higher total episode costs when using lower level devices deemed appropriate by CMS.

As shown in Exhibit 11, in this updated 2011–2014 analysis patients fit with K1/K2 devices had a \$16,765 higher total episode Medicare payment than did K3/K4 patients (\$79,314 vs \$62,549,  $p < 0.05$ ). This is somewhat different than the 2007–2010 analysis, which found a nonsignificant difference of \$3,405 (\$81,900 versus \$78,495).

Exhibit 10 shows that in this 2011–2014 analysis, K1/K2 beneficiaries have significantly higher payments for nearly all facility-based care, excluding long term care hospitals. They also have higher payments to physician offices, home health, and outpatient hospitals. This suggests that patients fitted with K1/K2-level prosthetics have poorer health status in general, requiring more medical care than those fitted with K3/K4-levels. It also 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 might expect to see more comparable episode payments among the cohorts in the use of facility and home-based care if K3/K4 prosthetics reduce healthcare expenditures.

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. Patients with K1/K2 devices had significantly more falls and fractures and emergency room admissions. This suggests that receipt of the higher-level prosthetic may be related to better outcomes, defined as the number of fractures and falls or emergency room admissions. This is consistent with a recent report

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<sup>14</sup> Dobson | DaVanzo analysis of DME claims (LDS) for a five percent sample of Medicare beneficiaries; extrapolated to the universe of patients.

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from RAND, which found that microprocessor prosthetic knees are associated with improved physical function and reductions in the incidence of falls and fractures.<sup>15</sup>

**Exhibit 11: K-Level Analysis for Lower Extremity Prostheses: Spending and Utilization by K-Level Cohort\*\* (2008–2010 and 2012–2014)**

Care Setting	2007–2010			2011–2014		
	K1 - K2 (n = 173)	K3 - K4 (n = 173)	Difference	K1 - K2 (n = 137)	K3 - K4 (n = 183)	Difference
Physician	\$8,550	\$8,640	-\$90	\$9,957	\$7,222	\$2,735
DME	\$17,295	\$24,900	-\$7,605*	\$11,871	\$18,346	-\$6,474*
Prosthetics Only: L5000 - L5999	--	--	--	\$7,561	\$11,226	-\$3,665*
Acute Care Hospital / Other Inpatient	\$21,000	\$16,995	\$4,005	\$21,242	\$12,411	\$8,831*
Long Term Care Hospital	\$2,250	\$1,740	\$510	\$1,008	\$1,183	-\$175
Inpatient Rehabilitation Facility	\$2,325	\$2,490	-\$165	\$4,201	\$3,178	\$1,023
Outpatient	\$9,375	\$11,400	-\$2,025*	\$10,251	\$7,537	\$2,714
Skilled Nursing Facility	\$12,255	\$6,240	\$6,015*	\$7,687	\$3,596	\$4,091*
Home Health	\$8,220	\$5,565	\$2,655*	\$7,161	\$3,735	\$3,426*
Hospice	\$615	\$525	\$90	\$133	\$115	\$19
Total Part D Drug Spending	--	--	--	\$5,804	\$5,228	\$576
Total Part D Drug Spending among Part D Users Only <sup>†</sup>	--	--	--	\$6,796	\$6,598	\$198
Total Part D Drug Spending for Pain Medicine among Part D Users Only <sup>†</sup>	--	--	--	\$638	\$1,216	-\$578
<b>Total</b>	<b>\$81,900</b>	<b>\$78,495</b>	<b>\$3,405</b>	<b>\$79,314</b>	<b>\$62,549</b>	<b>\$16,765*</b>
Average Number of Therapy Visits	68.39	40.31	28.08*	34.99	20.78	14.21*
Average Number of Fractures and Falls	0.83	0.86	-0.03	0.87	0.30	0.57*
Average Number of ER Admissions	1.69	1.51	0.18	2.88	1.70	1.18*
Average Number of Inpatient Admissions	1.25	1.12	0.13	1.69	0.87	0.82*
Average Number of IRF Admissions	1.54	1.39	0.14	0.20	0.16	0.05

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2007–2010 and 2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2008 through June 30, 2009 (and matched comparisons), or January 1, 2012 through June 30, 2013 (and matched comparisons) according to custom cohort database definition.

\* Statistically significant at p< 0.05

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

Consistent with our 2007–2010 analysis, this K-level analysis suggests that patients who received K1/K2 devices had higher total episode Medicare payments, despite the initially

<sup>15</sup> Liu H, et al. "Economic Value of Advanced Transfemoral Prosthetics." RAND Corporation. 2017. [https://www.rand.org/content/dam/rand/pubs/research\\_reports/RR2000/RR2096/RAND\\_RR2096.pdf](https://www.rand.org/content/dam/rand/pubs/research_reports/RR2000/RR2096/RAND_RR2096.pdf).

## *Analytic Results*

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lower payments for DME services. This is attributed to the larger reliance on both facility-based care and home health care, perhaps resulting from poorer health status or lower functional status in general. Beneficiaries who received K1/K2 devices also experienced more adverse events, including more falls and fractures, more emergency room visits, and more inpatient admissions.

The difference in Medicare expenditures and adverse events has grown since our initial 2007–2010 analysis, indicating that as fewer patients are granted access to the more advanced K3/K4-level prosthetics, average episode payment is increasing. This suggests that patients with lower level devices may be able to experience fewer adverse events and overall lower episode spending by receiving more advanced devices.

# Discussion

Our previous analysis using data from 2007–2010 indicated that the receipt of O&P services could ultimately reduce health care utilization and spending and increase quality of life. This study updated this prior work using data from 2011–2014 and 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.

Our results suggest that patients who received lower extremity orthoses had significantly fewer acute care hospitalizations, resulting in lower Medicare payments even after including the cost of the orthoses. Additionally, these patients had better outcomes, in that they experienced fewer falls and fractures and 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 lower Medicare payment after including the cost of the orthoses. While patients experienced a comparable number of fractures and falls, these negative outcomes still resulted in fewer emergency room and hospital admissions, ultimately producing lower 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 15-month period, patients who received O&P services reduced their Medicare payments to fully cover the cost of the prosthetic. Through a reduction in acute care hospitalizations and some facility-based care, patients experienced better quality of life at a comparable Medicare episode payment. 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.

Results of our sub-analyses suggest that patients who received a lower-level prosthetic (K1 or K2) experienced more emergency room visits and hospital admissions than those patients who received K3 or K4 devices, and significantly higher episode payments. The disparity between lower-level and higher-level devices has increased since our 2007–2010 analysis. These results may suggest that lower-level patients might benefit from higher level prostheses which provide the additional stability and support needed to reduce the need for facility-based care.

Across all analyses presented above, our results confirm our previous conclusion that O&P services provide value to the Medicare program, as well as a value to the patient. The cost of O&P services is amortized through reduced acute care hospitalizations and care in other settings. These results indicate that claims data can be used to consistently demonstrate the value of O&P services over time.

# Appendix A: 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



## Appendix A: Technical Methodology

Code	Description
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
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 A: 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 A: 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

## Appendix A: Technical Methodology

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 fibula
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
	Amputation of foot at ankle – amputation, ankle through malleoli of tibia and fibula
27888	(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 A: Technical Methodology

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## 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 demographic characteristics and the clinical need for the O&P service. These include: age; gender; race; region; dual eligibility for Medicare and Medicaid; select comorbidities; select diagnostic groups prior to etiological diagnosis based on categories defined by the Clinical Classifications Software (CCS); and, for the prosthetic model only, amputation procedure type following the etiological diagnosis and timing of death (where applicable). All beneficiaries from the study and comparison groups who matched exactly on these variables were selected.

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 upon an expanded selection of the demographic and clinical variables described above. Based on the force-matched pairs identified in the first step, those pairs with the closest propensity scores were selected for the final one-to-one match. 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:

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

where as

$P(X)$  is the probability of receiving an O&P service,

$\beta_0$  is the constant term,

$\beta_i$  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.

# Appendix B: 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 (2011–2014)**

Demographic Characteristic	Study Group	Comparison Group
Number of Beneficiaries	43,487	43,487
Average Age	68.6	68.7
Duals	29.7%	29.7%
Female	43.1%	43.1%
Death (1 Year)	0.2%	0.9%
Caucasian / White	84.7%	84.7%
Black / African American	8.3%	8.3%
Hispanic	4.4%	4.4%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

## Appendix B: Descriptive Statistics

**Exhibit C-2: Etiological Diagnoses for Lower Extremity Orthoses (2011–2014)**

<b>Etiological Diagnosis</b>	<b>Percent of Matched Pairs with Diagnosis</b>
Other connective tissue disease	32.4%
Spondylosis; intervertebral disc disorders; other back problems	17.9%
Other nervous system disorders	16.7%
Osteoarthritis	11.3%
Acute cerebrovascular disease	5.6%
Acquired foot deformities	3.8%
Fracture of lower limb	2.1%
Sprains and strains	2.1%
Multiple sclerosis	1.8%
Joint disorders and dislocations; trauma-related	1.5%
Late effects of cerebrovascular disease	1.3%
Paralysis	1.2%
Other and ill-defined cerebrovascular disease	1.1%
Other congenital anomalies	0.5%
Other acquired deformities	0.4%
Pathological fracture	0.2%
Other CNS infection and poliomyelitis	0.1%
Nervous system congenital anomalies	0.1%
Spinal cord injury	0.1%

Note: Beneficiaries may have more than one etiological diagnosis

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

## Appendix B: Descriptive Statistics

### Spinal Orthoses

**Exhibit C-3: Descriptive Statistics across Matched Pairs for Spinal Orthoses (2011–2014)**

Demographic Characteristic	Study Group	Comparison Group
Number of Beneficiaries	34,575	34,575
Average Age	67.2	67.2
Duals	34.9%	34.9%
Female	37.6%	37.6%
Death (1 Year)	0.1%	0.8%
Caucasian / White	81.2%	81.2%
Black / African American	11.8%	11.8%
Hispanic	5.0%	4.4%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

**Exhibit C-4: Etiological Diagnoses for Spinal Orthoses (2011–2014)**

Etiological Diagnosis	Percent of Matched Pairs with Diagnosis
Spondylosis; intervertebral disc disorders; other back problems	40.1%
Other connective tissue disease	25.7%
Other nervous system disorders	15.6%
Osteoarthritis	7.7%
Other bone disease and musculoskeletal deformities	6.1%
Sprains and strains	2.0%
Other fractures	1.2%
Joint disorders and dislocations; trauma-related	0.7%
Other acquired deformities	0.4%
Other congenital anomalies	0.3%
Pathological fracture	0.2%
Spinal cord injury	0.0%

Note: Beneficiaries may have more than one etiological diagnosis

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.



## Appendix B: Descriptive Statistics

### Lower Extremity Prostheses

**Exhibit C-5: Descriptive Statistics across Matched Pairs for Lower Extremity Prostheses (2011–2014)**

Demographic Characteristic	Study Group	Comparison Group
Number of Beneficiaries	545	545
Average Age	65.9	65.9
Duals	39.2%	39.2%
Female	17.4%	17.4%
Death (1 Year)	4.8%	5.0%
Caucasian / White	68.8%	68.8%
Black / African American	24.8%	24.8%
Hispanic	6.4%	6.4%

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.

**Exhibit C-6: Etiological Diagnoses for Lower Extremity Prostheses (2011–2014)**

Etiological Diagnosis	Percent of Matched Pairs with Diagnosis
Diabetes mellitus with complications	30.6%
Chronic ulcer of skin	18.0%
Peripheral and visceral atherosclerosis	17.8%
Other non-traumatic joint disorders	8.5%
Skin and subcutaneous tissue infections	7.9%
Other circulatory disease	4.9%
Complication of device; implant or graft	3.8%
Complications of surgical procedures or medical care	2.8%
Open wounds of extremities	2.7%
Infective arthritis and osteomyelitis (except that caused by tuberculosis or sexually transmitted disease)	2.1%
Rehabilitation care; fitting of prostheses; and adjustment of devices	1.7%
Gangrene	1.2%
Bacterial infection; unspecified site	0.6%
Crushing injury or internal injury	0.4%
Septicemia (except in labor)	0.4%

Note: Beneficiaries may have more than one etiological diagnosis

Source: Dobson | DaVanzo analysis of custom cohort Standard Analytic Files (2011–2014) for Medicare beneficiaries who received O&P services from January 1, 2012 through June 30, 2013 (and matched comparisons), according to custom cohort database definition.