Summary of Findings: K-Level Analysis

Purpose: To determine if patients who received prosthetic devices beyond their reported functional limitation assessment indicated on the claims achieved different clinical outcomes and/or Medicare payments over 18-months compared to patients who received the prosthetic devices (i.e., a prosthetic device that matched the patient's reported functional level). We also test the proposition that the cost of higher (more functional) K-level devices is offset by overall lower health care utilization, resulting in lower Medicare payments.

Patients Included: Patients with the following characteristics were included in the analysis:

- Received a prosthetic device that exceeded (or was appropriate for) the functional limitation assessment reported on the claim (e.g., patient assigned as a K-1 or K-2 but received a K-3)[1]
- Contained a 3-month 'clean-period' prior to receipt of prosthetic device that contained no etiological diagnosis
- Had a minimum of 18 months of claims data across all care settings following receipt of initial prosthetic device (referred to as the "post-period")

Results in Brief: **Exhibit 1** shows the distribution of all included patients who received a prosthetic device and the average post-period Medicare payment. Almost two-thirds (64.5 percent) of patients have a K-3 device and an additional 30.9 percent have a K-2 device. It is interesting to note that K-2 patients, on average, have higher Medicare episode payments than K-3 patients, despite K-3 patients having more expensive prosthetic devices.

Exhibit 1: K-Level Distribution (All Devices)

K-Level	Patient Episodes	Percent of Patient Episodes	Average Post-Period Medicare Payment
1	290	3.4%	$79,809
2	2,625	30.9%	$81,513
3	5,483	64.5%	$79,967
4	104	1.2%	$78,664
Total	**8,502**	**100%**	**$80,423**

Source: Dobson DaVanzo custom cohort analysis of Medicare beneficiaries across all care settings (2006-2009)

While the average Medicare episode payment is relatively similar across K-level groups, the distribution of health care spending differs slightly. **Exhibit 2** shows that due to the cost of the device, patients with higher K-levels (more functional) have higher DME utilization, which ranges from 19.6 percent of total Medicare post-period episode spending for K-1 patients (19.6 percent of $79,809) to 42.1 percent for K-4 patients (42.1 percent of $78,664). Among K-2 and K-3 patients – the vast majority of all patients – the distribution across settings is similar, with the largest difference among DME, SNF, and HHA spending.

[1] This analysis is based on administrative claims data. Therefore, clinical information beyond the K-level modifier is not available to determine or validate the patient's reported functional status. This analysis assumes that the highest K-level modifier presented on the claim for the receipt of the base prosthetic device (and add-on codes) accurately reflects the patient's functional status.

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This suggests that patients with K-3 level devices have more expensive devices but lower SNF and HHA spending (in total spending and as a percent), consistent with their likely increased ambulation. It is important to note that despite the higher DME spending among K-3 and K-4 patients, their lower health care utilization offsets the cost of their device, and results in overall lower Medicare spending compared to K-2 patients.

Exhibit 2: Distribution of Average Post-Period Medicare Payment by K-Level and Care Setting (All Devices)

	K-1		K-2		K-3		K-4		Total	
	Average Payment	% of Total Medicare Payment	Average Payment	% of Total Medicare Payment	Average Payment	% of Total Medicare Payment	Average Payment	% of Total Medicare Payment	Average Payment	% of Total Medicare Payment
DMEPOS	$15,649	19.6%	$16,443	20.2%	$21,599	27.0%	$33,153	42.1%	$19,946	24.8%
Physician	$12,357	15.5%	$12,457	15.3%	$10,674	13.3%	$9,608	12.1%	$11,269	14.0%
Inpatient Hospital	$31,269	25.9%	$34,462	27.3%	$35,129	27.7%	$37,281	25.5%	$34,805	27.5%
IRF	$19,078	3.2%	$21,276	3.2%	$20,059	3.4%	$10,678	1.3%	$20,294	3.4%
Outpatient Hospital	$11,609	14.0%	$12,932	15.2%	$12,947	15.4%	$8,838	10.7%	$12,846	15.2%
SNF	$20,948	10.9%	$18,192	8.6%	$16,493	5.8%	$18,265	4.5%	$17,343	6.8%
Home Health	$13,453	9.8%	$12,852	9.8%	$10,163	7.0%	$6,246	3.4%	$11,143	8.0%
Hospice	$22,813	1.1%	$18,766	0.5%	$20,385	0.3%	$27,650	0.3%	$19,974	0.4%
Total	**$79,809**	**100.0%**	**$81,513**	**100.0%**	**$79,967**	**100.0%**	**$78,664**	**100.0%**	**$80,423**	**100.0%**

Source: Dobson DaVanzo custom cohort analysis of Medicare beneficiaries across all care settings (2006-2009)

Due to the difference in health care utilization and Medicare spending across K-levels, this analysis sought to identify patients who received a device with a K-level higher than the patient's reported assessment suggests to determine if better outcomes were achieved. The K-Level "delta" was calculated for each patient, which describes the difference in the K-level device a patient received compared to their indicated functional status. That is, a patient who received an appropriate device (device that matched the patient's K-level) was assigned a delta of "0", while a patient approved for a K-2 device but received a K-3 device was assigned a delta of "1" (or a 'one-level change').

Exhibit 3 shows the distribution of patients by their delta K-level. Approximately 70 percent of patients received an appropriate K-Level device, 23.5 percent received a one-level change (e.g., received K-3 instead of K-2 device), and 6.2 percent received a two or three-level change (e.g., received a K-4 instead of a K-2 device). Patients fit with a device with one K-level change had slightly lower mean payments compared to patients who received an appropriate device ($80,892 vs. $81,115), while patients with a device of a two-level or more change were notably less costly ($70,723, or a 13 percent reduction in spending compared to appropriate devices).

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Exhibit 3: Distribution of K-Level Delta (All Devices)

Delta K-Level	Patient Episodes	Percent of Patient Episodes	Average Post-Period Medicare Payment
0 (appropriate)	5,979	70.3%	$ 81,115
1	2,000	23.5%	$ 80,892
2+	523	6.2%	$ 70,723
Total	**8,502**	**100%**	$ 80,423

Source: Dobson DaVanzo custom cohort analysis of Medicare beneficiaries across all care settings (2006-2009)

The appropriateness of the device one K-level higher than patient's reported assessment appears to have little impact on health care utilization. That is, as shown in **Exhibit 4**, patients who received a device appropriate with their reported K-level assessment (delta of 0) had a similar distribution of spending by care setting compared to patients who received a device that was one K-level higher than their reported assessment (e.g., received a K-3 level device instead of a K-2 device). However, patients who received a device two K-levels higher than their assessment (e.g., received a K-4 level device instead of a K-2 level, or a K-3 level instead of a K-1 level device) had significantly higher DME payments but lower payments across all other care settings (in terms of dollars as well as a proportion), such as physician visits, outpatient care as well as institutional care such as hospitalization, SNF, and IRF stays. This may suggest that providing a higher K-level device to Medicare beneficiaries may result in comparable, or even lower, overall health care utilization as compared to if they received the appropriate level prosthetic device. Furthermore, this indicates that the cost of the prosthetic device is fully amortized during the 18-month episode and does not result in higher overall Medicare spending.

Exhibit 4: Distribution of Average Post-Period Medicare Payment by Delta K-Level and Care Setting (All Devices)

	Delta 0		Delta 1		Delta 2+		Total	
	Average Payment	Percent of Total	Average Payment	Percent of Total	Average Payment	Percent of Total	Average Payment	Percent of Total
DMEPOS	$19,842	24.5%	$19,388	24.0%	$23,267	32.9%	$19,946	24.8%
Physician	$11,399	14.0%	$11,544	14.3%	$8,739	12.4%	$11,269	14.0%
Inpatient Hospital	$35,252	27.6%	$34,428	27.8%	$30,673	24.2%	$34,805	27.5%
IRF	$20,343	3.3%	$20,472	3.6%	$18,810	3.1%	$20,294	3.4%
Outpatient Hospital	$13,303	15.6%	$12,350	14.6%	$9,536	12.9%	$12,846	15.2%
SNF	$17,711	6.8%	$16,889	7.1%	$14,681	5.6%	$17,343	6.8%
Home Health	$11,282	7.8%	$10,838	8.2%	$10,815	8.3%	$11,143	8.0%
Hospice	$19,432	0.3%	$19,246	0.5%	$28,329	0.7%	$19,974	0.4%
Total	**$81,115**	**100.0%**	**$80,892**	**100.0%**	**$70,723**	**100.0%**	**$80,423**	**100.0%**

Source: Dobson DaVanzo custom cohort analysis of Medicare beneficiaries across all care settings (2006-2009)

Beyond the distribution of care across settings, we conducted an analysis using ordinary least square (OLS) and logistic regressions to determine the extent to which receiving a device one level beyond a patient's reported functional limitation assessment (the "delta" level) impacted patient health outcomes and Medicare episode payment. The analysis compared the outcomes of patients fitted with an appropriate device to the outcomes of those patients fitted with a device of a one-level change. This

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analysis controlled for patient demographic and clinical characteristics such as co-morbidities, age, and gender to better isolate the effect of increased K-Level on patient outcomes.

Exhibit 5 present the results of our regression analysis. These data describe the difference in the prevalence of each outcome variable either as a percentage point difference or as a mean difference for each level change in the device compared to a device-appropriate patient. That is, the data presented is not the prevalence of each outcome, rather the difference in prevalence between the patients with a one-level change devices compared to appropriate devices (prevalence for one-level change patients minus prevalence for appropriate patients). With the exception of the prevalence of patient falls, there is no statistically significant difference in the 18-month outcomes of patients fitted with one-level change devices and those with appropriate devices. Thus according to these data, a patient who receives a device beyond their reported functional limitation assessment does not correlate with an adverse clinical outcome (with exception to falls) or different health care costs. However, with each additional K-level device change, patients experience 0.064 more falls. (Falls are relatively infrequent among this population with an average number of falls across all patients as 0.223.) This finding may be attributable to these patients' increased ambulation, but this relationship cannot be tested using administrative claims.

Exhibit 5: Regression Risk Adjusted Difference in Patient Outcomes for Patients Receiving One-Level Device Change Compared to Patients Receiving Appropriate Devices (All Devices)

Outcome Variable	Percentage Point Difference in Probability (1) or Mean Difference in Average Value (2) (Upgrade minus Appropriate)	*P > |T|*
Mortality Rate (1)	-0.14%	0.404
Falls (2)	0.064	0.008*
Fractures (2)	0.030	0.609
ER Visits (2)	0.048	0.322
Physical Therapy Visits (2)	-0.123	0.447
Occupational Therapy (2)	-0.113	0.121
IP Admissions (2)	0.029	0.52
SNF Admission Probability (1)	0.76%	0.599
Total Medicare Payment (2)	-$1,211.89	0.235

(1) The percentage point difference in the probability of the outcome (positive percent indicates upgraded patients are more likely to experience the outcome).

(2) Difference in the average value of the outcome (positive number indicates increased utilization of the outcome)

* Statistically significant

Source: Dobson DaVanzo custom cohort analysis of Medicare beneficiaries across all care settings (2006-2009)

Sub-analyses of High Frequency HCPCS: We replicated the above analysis for a subset of select devices to determine if patient outcomes from receiving a device different than their reported functional limitation assessment varied across different devices. The three most frequently reported O&P devices (representing 82 percent of all services) were included for this sub-analysis: base codes L5301, L5321,

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and L5540. We note that these devices represent the base prosthetic device, not the add-on components that are regulated using the K-level assessments. **Exhibits 6 to 8** present the delta-K regression results for these services.

The results from this sub-analysis suggest that receiving a device with a K-Level that does not align with the assessed functional limitation resulted in different patient outcomes. For base code L5301, there is no statistical difference among the patient cohorts, indicating that receiving a device different than the patient's reported functional limitation does not impact health care utilization or outcomes. Among L5321 users, patients fit with a device beyond their reported limitation level experienced more falls and SNF admissions than patients fitted with an appropriate K-Level device. However, patients with a device beyond their reported limitation level had statistically lower Medicare payments over an 18-month episode period. This may indicate that falls were likely not associated with higher hospitalizations or health care utilization. It may also indicate greater patient mobility resulting in other health improvements and lower Medicare costs. Among L5540 patients who had a reported functional limitation assessment lower than the device prescribed (referred to as "upgrade" in the table), patients experienced statistically more falls and ER visits compared to patients fitted with appropriate K-Level L5540 device; these patients, however, were less likely to have been admitted to a SNF.

Exhibit 6: Regression Risk Adjusted Difference in Patient Outcomes for Patients Receiving One-Level Device Change Compared to Patients Receiving Appropriate Devices (Select Devices)

	L5301 (n = 3,803)		L5321 (n = 1,781)		L5540 (n=1,365)	
Outcome Variable	**Percentage Point Difference in Probability (1) or Mean Difference in Average Value (2) (Upgrade minus Appropriate)**	***P > |T|***	**Percentage Point Difference in Probability (1) or Mean Difference in Average Value (2) (Upgrade minus Appropriate)**	***P > |T|***	**Percentage Point Difference in Probability (1) or Mean Difference in Average Value (2) (Upgrade minus Appropriate)**	***P > |T|***
Mortality Rate (1)	0.04%	0.911	-0.02%	0.961	-0.13%	0.759
Falls (2)	-0.026	0.33	0.140	0.066*	0.102	0.012*
Fractures (2)	-0.143	0.214	0.065	0.55	0.003	0.987
ER Visits (2)	-0.031	0.754	-0.085	0.234	0.343	0.015*
Physical Therapy Visits (2)	0.204	0.519	-0.228	0.362	0.223	0.554
Occupational Therapy (2)	-0.047	0.69	-0.077	0.353	-0.027	0.88
IP Admissions (2)	0.114	0.203	-0.056	0.49	0.058	0.6
SNF Admission Probability (1)	2.15%	0.46	5.18%	0.037*	-5.91%	0.076*
Total Medicare Payment (2)	$2,002	0.326	-$3,508	0.043*	-$401	0.876

(1) The percentage point difference in the probability of the outcome (positive percent indicates upgraded patients are more likely to experience the outcome).

(2) Difference in the average value of the outcome (positive number indicates increased utilization of the outcome)

* Statistically significant

Source: Dobson DaVanzo custom cohort analysis of Medicare beneficiaries across all care settings (2006-2009)

Conclusions: About 30 percent of patients who received a functional limitation assessment received a prosthetic device that exceeded their functional limitation assessment, as reported on the

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administrative claims. Across all codes, patients who received a device beyond their reported functional imitation had similar – if not lower – health care utilization, adverse events, and Medicare episode payment amounts compared to patients who received appropriate devices. However, for certain base devices, there were statistically significant differences among those who received the "upgraded" versus appropriate device. Most notably – among L5321 users – patients with devices beyond their reported functional limitation assessment experienced more falls (possibly due to increased ambulation), but significantly lower Medicare episode payment. Additionally, these results suggest that patients who received high-function (K-4) devices had lower health care utilization and Medicare payments despite the high cost of the prosthetic. This indicates that the cost of the prosthetic was amortized across 18-month period resulting in no additional cost to Medicare, compared to patients who received lower-function devices (K-1 and K-2).