STUDY: HIGHER STANDARD OF CARE FOR PATIENTS WITH LIMB LOSS, CHRONIC LIMB IMPAIRMENT OR SPINAL INJURIES SAVES MEDICARE MONEY IN MOST CASES

Even Though Devices Are Often Costly, Long-Term Bill for Taxpayers Ends Up Lower Or Only Slightly Higher; Win, Win: Findings Indicate Patients Also Benefit from Higher Quality of Life and Increased Independence.

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Dobson-DaVanzo Cost Effectiveness Study

Key Findings: Taxpayers end up paying more over the long term in most cases when Medicare patients are not provided with replacement lower limbs, spinal orthotics, and hip/knee/ankle orthotics, according to major new study commissioned by the Amputee Coalition and conducted by Dr. Allen Dobson, health economist and former director of the Office of Research at CMS (then the Health Care Financing Administration).

Executive Summary: While prospective, blinded, and randomized studies are the cornerstone of research, there is also much to be learned from retrospective studies, particularly when the database is as large and powerful as the entire Medicare database. Over two years ago, the Amputee Coalition commissioned, and with financial assistance in the form of multiple support grants totalling roughly $250,000 by AOPA, a leading expert, Allen Dobson, PhD, the former Research Director for the Medicare program, and his colleagues in the firm of Dobson-DaVanzo, were retained to assess cost effectiveness of prosthetic and orthotic care. The study used the Medicare Claims database for all Medicare claims data for patients with conditions that justified the provision of lower limb orthoses, spinal orthoses, and lower limb prostheses. The research design separated patients with similar etiologies (that is, triggering conditions, diseases or health events) into two groups for each of the three therapies (studying equal comparative groups of those receiving these therapies, vs. those who did not). This coupled with the study's unprecedented access, via special permission from Medicare, to have access to every Medicare payment for these patients over 4 years permitted the researchers to determine their cost history for medical care following their O&P intervention.

The conclusions for both orthotics cases show the cumulative Medicare costs over the 18 months following receipt of the orthotic intervention were less than the population that did not receive the treatment. With respect to the prosthetic intervention, the cumulative cost comparison demonstrated that in the initial 12 months, the cohort that received the prosthesis had about 1% higher costs compared to the population that did not receive the device. This means that prosthetic patients could experience better quality of life and increased independence compared to patients who did not receive the prosthesis at essentially no additional cost to Medicare or to the patient. These results should logically apply to private insurance patients as well.

Detailed Summary of the Study/Research: Available online at http://www.amputee-coalition.org, the unprecedented study looks at nearly 42,000 paired sets of Medicare beneficiaries with claims from 2007-2010. The paired patients either received full orthotic and prosthetic care or they did not get such care. Lower extremity and spinal orthotic and prosthetic devices and related clinical services are designed to provide stability and mobility to patients with lower limb loss or impairment and spinal injury.

The study's key finding: Patients who received orthotic or prosthetic services have lower or comparable Medicare costs than patients who need, but do not receive, these services. According to the study,

Medicare could experience 10 percent savings ($2,920 less) for those receiving lower extremity orthoses and similar cost efficiencies for patients receiving spinal orthoses and lower extremity prostheses.

What offsets the initially high cost of some orthotic and prosthetic devices? These devices are associated with higher rates of physical therapy and rehabilitation, allowing patients benefiting from them to remain in the community and avoid costly facility-based care. Patients are generally able to become less bedbound and more independent, which may be associated with fewer emergency room (ER) admissions and acute care hospital admissions. The reduced use of hospital services and facility-based care offsets the cost of the devices, producing Medicare savings and better quality-of-life outcomes for patients.

Report author Dr. Allen Dobson said: "**Looking at full costs and other outcomes (including use of out-patient therapy, number of falls, ER admissions, and acute hospitalizations) over a 12-18 month period, our study concludes that patients who received the orthotic and prosthetic services experienced greater independence than patients who do not, with better or comparable health outcomes and generally lower Medicare payments."**

Susan Stout, interim president & CEO, Amputee Coalition, said: **"Every person who has suffered limb loss, and who has received a prosthetic device appropriate for their needs, knows the value of the device for them personally. This study provides nationwide data which helps to corroborate this patient experience, and also points us to the need for more research regarding the value of prosthetics from both a quality of life and a financial perspective."**

Lower extremity orthoses for the hip, knee, or ankle are typically used to prevent deformities, enhance walking, alleviate pain and protect limbs. A spinal orthotic device is an external apparatus that is applied to the body to limit the motion of, correct deformity in, reduce loading on, or improve the function of a particular spinal segment of the body. Examples include soft cervical collars, halo vests, and lumbar vests. Lower extremity prosthetics are artificially replaced limbs located at the hip level or lower.

This is a clear win for patients and a win for taxpayers. Not only do patients who get full orthotic and prosthetic (O&P) treatment benefit the most, but it also ends up costing taxpayers less in most cases. The goal of restoring function is emphasized in many of Medicare's covered services, and therefore supports the targeted use of O&P services for patients who are able to benefit from and receive the requisite therapy. The increased physical therapy among O&P users allowed patients to become less bedbound and more independent, which may be associated with higher rates of falls and fractures, but fewer emergency room admissions and acute care hospital admissions. This reduction in health care utilization ultimately makes O&P services cost-effective for the Medicare program and increases the quality of life and independence of the patient.

DETAILED STUDY FINDINGS

- Patients who received lower extremity orthoses had better outcomes over 18 months, defined as fewer acute care hospitalizations and emergency room admissions and reduced costs to Medicare (episode payments approximately 10 percent lower than the comparison group, including the cost of the orthotic). Additionally, these patients were able to sustain significantly more rehabilitation, and were able to remain in their homes as opposed to needing placement in facility-based settings. The study looked at 34,864 pairs of patients, with the full-care group costing $27,007 on average and the group provided lesser care costing $29,927 on average.

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

patients. The study looked at 6,247 pairs of patients, with the full-care group costing $32,598 on average and the group provided lesser care costing $32,691 on average.

- Among lower extremity prostheses patients, the study results indicate that patients who received lower extremity prostheses had comparable Medicare episode payments (including the cost of the prosthetic) and better outcomes than patients who did not receive prostheses. Results suggest that the device was nearly amortized by the end of 12 months and the patient could experience higher quality of life and increased independence compared to patients who did not receive the prosthetic. The study looked at 428 pairs of patients, with the full-care group costing $68,040 on average and the group provided lesser care costing $67,312 on average.

Steps Going Forward: As with any good study, this one raised some new questions, even as it answered some prevailing ones. Several additional potential areas for analysis were identified. Questions about the key gaps in scientific evidence and outcomes data about O&P services were formulated to improve the standard of care and address payer policies. This is landmark work as for the first time; AC, with support from AOPA, is compiling authoritative answers to questions advanced by payers to demonstrate scientifically that O&P intervention improves patient outcomes.

(I) Prospective, Comparative Effectiveness Study Areas:

a. K1 and K2 ambulators—the Dobson DaVanzo study has demonstrated that K1-2 patients cost Medicare more than K3-4 patients, with the former having more ER admissions and higher reliance on facility-based care. It recommends that "further research is warranted to match patients on clinical and demographic characteristics to determine whether the need for facility-based care can be avoided through higher level devices for more frail individuals." It appears that a suitable RFP could and should be developed for a comparative effectiveness study to explore this question in a more in-depth prospective study.
b. The largest dollar volume and fastest growing orthotic code is L0631. It has been the topic of a recent OIG report, and according to the Dobson-DaVanzo study, the vast majority of back braces under this code are being provided by medical supply facilities without an O&P professional. Further, the largest percentage explosion in volume of this code has been at the physician office and/or physical therapist, indicating a prospect that volume increases may be driven, at least in part, by non-clinical considerations. Can the therapeutic value of these L0631 back braces be demonstrated in a prospective study? (This is likely a two-step process, first garnering Medicare data on how the type of provider [orthotist, therapist, physician office, manufacturer's rep, others] impact outcomes, from such further information as may be obtainable from the Medicare database, as a prelude to a prospective research study).

(II) Retrospective Explorations, Using Medicare Database, Similar to Dobson-DaVanzo Study:

a. What is the relationship between lower back pain and surgical procedures and therapies for patients with spinal orthoses?
b. In the first Dobson-DaVanzo custom cohort study because of the absence of Part D data on medication used by the custom cohort pairs, questions on mental health, use of antidepressants, pain medications, etc., and other questions could not be answered. Securing access to Medicare Part D data to round out the cost data as well as the evidence of possible impacts of O&P treatments on medication use is extremely important.