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Medicare and Complex Rehabilitation Technology: A 20-Year Review

The Impact of Medicare Legislation and Regulation on Complex Rehabilitation Technology Access and Innovation

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The objectives of this article are to compile and detail the last 20 years of legislation and regulation related to durable medical equipment in the Medicare program and to analyze the resulting impact of these changes on access to Complex Rehabilitation Technology; to demonstrate how these legislative and regulatory changes impact medical care and outcomes for people with disabilities; and to draw conclusions regarding implications and necessary changes to the Medicare program.

Key words: Complex Rehabilitation Technology, innovation, Medicare, mobility

In the United States, third party payers, primarily Medicare, Medicaid and the Veterans Administration, fund the vast majority of wheeled mobility and seating technology. The Medicare program is widely accepted as the model that other payers use as a basis to establish their own coverage and pricing policies. Therefore, it is Medicare legislation and regulation regarding products classified as durable medical equipment (DME), of which Complex Rehabilitation Technology (CRT) is a subset, which is the focus of this article. Medical equipment needed at home to treat or ameliorate a beneficiary's illness or injury is covered under the DME benefit. To qualify as DME, the equipment must (1) withstand repeated use, (2) primarily serve a medical purpose, (3) generally not be useful to a person without an illness or injury, and (4) be appropriate for use in the home.

While CRT is not officially defined, legislation has been introduced in Congress H.R. 942—Ensuring Access to Quality Complex Rehabilitation Technology Act of 2013 and a companion bill, S. 948 with the same title that contains a clear definition. In both cases, CRT is defined as an item that "is designed and configured for a specific qualified individual to meet the individual's unique medical, physical, and functional needs related to a medical condition; and capacities for basic activities of daily living and instrumental activities of daily living; is primarily used to serve a medical purpose and is generally not useful to a person in the absence of illness or injury; and requires certain services to ensure appropriate design, configuration, and use of such item, including an evaluation of needs and capacities and matching of the features and functions of CRT items to the qualified individual who will use such an item; and configuring, fitting, programming, adjusting, or adapting the particular complex rehabilitation technology item for use by such individual."[1]

Until recently, as technology advanced to meet the unique needs of people with disabilities, no one questioned whether CRT is appropriately classified as DME. Without question, CRT products have advanced to meet the needs of individuals who, prior to innovation, had no choice but to use standard technology or build something in their garage. In the early 1980s, it was not unusual to see a person with a disability use the same wheelchair that had been used to meet a temporary mobility need for a person recovering from hip surgery.

To understand the impact of Medicare legislation and regulation on CRT access and innovation, one must first understand the policies that govern access to medical equipment. Using an analogy of a 3-legged stool, coding, coverage, and payment policies are the 3 legs that allow or limit access to technology. With a stool, if 1 or more of the legs are missing the stool is not stable. The same is true for technology, if one of these important policies does not support appropriate access, people with disabilities will not be able to obtain the products and related services they require. Take almost any year between 1994 and 2014 there will be at least one, often more, significant Medicare legislative or regulatory change that impacted coding, coverage, or payment for CRT. In some years the change was minimal, in others it was substantial.

The *cumulative* change over the 20-year time period and the impact it has had on access to CRT is what this article covers. To accomplish understanding you must get deeper in the details of the Medicare program and specifically coding, coverage, and payment policies than most might enjoy. But, if you can allow yourself to read, not skim, these details, it will provide not only an understanding

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of these policies and hopefully, or more importantly, an understanding of the changes that are required to remove barriers to access and innovation.

The following pages will cover the origin of the Medicare program, the population of Medicare beneficiaries and how the program has evolved. The real focus will be the 3 legs of access—coding, coverage, and payment. Specifically, this article will cover the processes and evolution caused by legislation and regulation, as well as changes needed to these policies and their processes to ensure that people with disabilities are ensured access to the technology that levels the playing field, improves function, and increases independence and quality of life.

MEDICARE BACKGROUND

Currently approximately 50 million people are enrolled in the Medicare program; almost 8 million qualify on the basis of disability rather than age.[2] In 1965, Medicare was enacted as Title XVIII of the Social Security Act, extending health coverage to almost all Americans 65 years or older. Medicare was implemented on July 1, 1966, with more than 19 million individuals enrolled. In 1972, Medicare eligibility was extended to 2 million individuals under the age of 65 with long-term disabilities and to individuals with end-stage renal disease. Also in 1972, Medicare was given the authority to conduct demonstration programs.[3] In 1977, The Health Care Financing Administration, later renamed as the Centers for Medicare and Medicaid Services (CMS), was established to administer the Medicare and Medicaid programs.

Knowing that the Medicare program is funded through separate mechanisms helps to explain why it often appears that policy decisions for one program was made without consideration of implications to another. The mechanisms by which these programs are funded can have an important effect on Medicare legislation (Table 1).

CODING OF TECHNOLOGY

As described earlier, coding is possibly the most important leg of the 3-legged stool. The importance stems from the fact that coding is the foundation for which coverage and payment are developed. If coding is flawed the policies built on them are too. For CRT, there are very few codes that recognize the unique nature of this technology. As a result, the coverage and pricing policies fail to support access to this important technology.

Durable medical equipment is billed to Medicare through a national code set, the *Healthcare Common Procedure Coding System* (HCPCS). It was established in 1978 to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. The HCPCS consists of level I Current Procedural Terminology codes used to report medical procedures and services. This code set is administered by the American Medical Association. Durable medical equipment, prosthetics, orthotics, and suppliers are represented by level II, an alphanumeric coding system and level III, referred to as local codes; these codes were developed and used by non-Medicare payers to meet their unique needs where current level I or level II codes were deficient. A national code set is necessary for Medicare, Medicaid, and other health insurance programs to ensure that insurance claims are processed in an orderly and consistent manner. Initially, use of the HCPCS was voluntary, but with the implementation of

TABLE 1 Medicare Part A Versus Part B

Part A: Hospital Insurance	Part B: Medical Insurance
Most people don't pay a premium because they or a spouse already paid for it through their payroll taxes while working	Most people pay a monthly premium.
Helps cover inpatient care in hospitals, including critical access hospitals and skilled nursing facilities (not custodial or long-term care). Also helps cover hospice care and some home health care.	Helps cover doctors' services and outpatient care. Helps cover some other medical services that Part A doesn't cover, such as some of the services of physical and occupational therapists, and some home health care. Part B helps pay for these covered services and supplies when they are medically necessary.[3] Medical equipment needed at home to treat a beneficiary's illness or injury is covered under Part B, and specifically the DME benefit.
The Hospital Insurance (HI) Trust Fund is funded through	The Supplementary Medical Insurance (SMI) Trust Fund is funded through
• payroll taxes paid by most employees, employers, and people who are self-employed	• funds authorized by Congress Premiums from people enrolled in Medicare Part B (Medical Insurance) and Medicare prescription drug coverage (Part D)
• other sources, like income taxes paid on Social Security benefits, interest earned on the trust fund investments, and	• other sources, like interest earned on the trust fund investments
• Medicare Part A premiums from people who aren't eligible for premium-free Part A	

the Health Insurance Portability and Accountability Act of 1996 (HIPAA), use of the HCPCS for transactions involving health care information became mandatory for all payers, not just Medicare.

In October of 2003, the secretary of Health and Human Services (HHS) delegated authority under the HIPAA legislation to CMS to maintain and distribute HCPCS level II codes. As stated in 42 CFR Sec 414.40 (a) CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

Within CMS, there is a HCPCS Workgroup, an internal workgroup composed of representatives of the major components of CMS, as well as representatives from relevant Federal agencies and private insurance. The CMS HCPCS Workgroup establishes permanent National HCPCS codes annually. In addition, the CMS HCPCS Workgroup may occasionally establish temporary HCPCS codes on a quarterly basis, prior to the next annual HCPCS code update.

Temporary HCPCS codes are for meeting, within a short time frame, urgent national program operational needs of a particular insurance sector that are necessary to implement their programs and policies. These codes are established at the discretion of CMS. For example, Medicare may need additional codes before the next scheduled annual HCPCS update to implement newly issued coverage policies or legislative requirements.

The HIPAA required CMS to adopt standards for coding systems that are used for reporting health care transactions. The CMS published, in the Federal Register on August 17, 2000 (65 FR 50312), regulations to implement this part of the HIPAA legislation. These regulations provided for the elimination of level III known as local codes by October 2002, at which time, only level I and level II code sets could be used. The elimination of local codes was postponed, as a result of section 532(a) of the Benefits Improvement and Protection Act (BIPA), which continued the use of local codes through December 31, 2003.[4]

Local codes were extremely important to non-Medicare payers, such as Medicaid and private insurers. These codes allowed program staff to identify technology on the basis of the specific needs of their enrollees. The loss of local codes forced Medicaid programs and other non-Medicare payers to cross-walk local codes to existing level II HCPCS codes where possible and identify gaps in the level II code set. Many Medicaid program staff reached out to manufacturers and others in the industry to assist by submitting code applications to CMS in an effort to obtain adequate codes for technology orphaned by the elimination of local codes.

A strong and coordinated effort followed; manufacturers submitted individual code applications and industry coalitions assembled ad hoc workgroups involving multiple stakeholder groups to develop and submit comprehensive coding proposals for entire categories of products, such as standing devices and manual wheelchairs (MWC). These efforts to obtain new codes to represent current technology and definitions to identify the features and clinical application of that technology did not produce the needed HCPCS codes.

Looking back, this was a clear turning point; HCPCS codes became increasingly generic grouping dissimilar technologies with different clinical applications. Unfortunately, most of the decisions made by the HCPCS workgroup resulted in heterogeneous grouping of CRT and DME. The result subsequently led to decreased reimbursement for CRT technology since, in most cases, Medicare has a fee schedule for each code. The payment section to follow will provide more details regarding how payment (Medicare fee schedule) is developed and why homogeneous grouping of products within a code is fundamental to ensure access.

In the years following HIPAA legislation, changes in level II code definitions and how products were grouped continued to change. Some of the changes were in response to applications submitted by manufacturers and associations, and others were based on efforts of Medicare contractors. Code definitions changed to enable codes to represent a larger array of products (Table 2).

In addition to the development and management of the HCPCS code set, Medicare contracted other services related to the code set such as product classification, assignment of products to codes and to assist in assessing the need for new codes or revisions to existing codes, as well as to perform necessary data analysis including utilization. The Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) was the initial contractor to provide these services and more.

The SADMERC was contracted to do the following.

- Report and analyze claims data
- Provide data analysis support to the 4 DMERCs.
- Support Medicaid programs with product coding and classification
- Provide guidance to manufacturers and suppliers on the proper use of the HCPCS
- Perform a variety of national pricing functions for DMEPOS services,
- Assist CMS with the DMEPOS fee schedules,
- Analyze DMEPOS fees to identify unreasonable or excessive reimbursement amounts, and,
- Review and assess existing HCPCS codes for product categories to ensure coding accurately represented current technology for categories with high utilization and high cost; primarily those categories targeted for inclusion in the competitive bidding program.

In August of 2008, the contract transitioned to the Pricing, Data Analysis and Coding (PDAC) Contractor. In many ways, the PDAC contract mirrored the SADMERC contract with important distinctions. The PDAC is not contracted

TABLE 2 Complex Rehabilitation HCPCS Code Change History

Effective Date	Code and Description	Change	Comments	Reimbursement Change
Safety belts/Pelvic straps/Positioning belts				
Jan 1, 2005-Present	E0978	Positioning belt/safety belt/pelvic strap, each	Single code now represents seat belts, pelvic straps, and positioning belts; 2-point and 4-point attachments.	2005 fee schedule amount—$42.70. 2014 fee schedule when provided with standard MWCs—$40.25, when provided with CRT MWCs, $46.71. No billing for this code with PWCs. Supplier must use a KE pricing modifier when billing this item with a CRT MWC.
Jan 1, 2004	K0031 Safety Belt/Pelvic Strap, each	Cross-walked K0031 to E0978- Safety belt/pelvic strap, each		2004 fee schedule amount—$42.70
Oct 1, 1993	K0031 Safety Belt/Pelvic Strap, each	Cross-walked E0978 and E0979—merged into 1 single code	Code descriptor not only merges all types of safety belts, now includes pelvic straps; 2-point and 4-point attachments.	Oldest available fee schedule (Jan 1998) reimbursement for K0031—$40.73 each
Jan 1, 1986-Sept 30, 1993	E0979 Belt, safety with Velcro closure	Code genesis		Prior to 1993, suppliers reimbursement was based on supplier's submitted charges.
Jan 1, 1986-Sept 30, 1993	E0978 Belt, safety with airplane buckle	Code genesis		Prior to 1993, suppliers reimbursement was based on supplier's submitted charges.
Heel loop				
Jan 1, 2004-Present	E0951 Heel loop/Holder, each	Cross-walked K0034 and K0035 to E0951 and descriptor changed to Heel Loop/Holder any type, with or without ankle strap	Adaptive Equipment Systems Submitted a Request to establish a code for a rigid foot positioner, trade name: Adaptive Equipment Systems Shoe Holder. Request denied. Manufacturer instructed to use E0952 and E0951 (Heel Loop/Holder) for submitting claims.	2014 fee schedule when provided with standard MWCs and all PWCs, $17.89 when provided with CRT MWCs, $20.76 and supplier must use KE pricing modifier when billing.
Oct 1, 1993-Dec 31, 2003	K0034 Heel loop, each	Code genesis		Oldest available fee schedule (Jan 1998) reimbursement for K0034—$17.97
Oct 1, 1993-Dec 31, 2003	K0035 Heel loop w/ ankle strap, each	Code genesis		Oldest available fee schedule (Jan 1998) reimbursement for K0035—$24.71

(*Continues*)

TABLE 2 Complex Rehabilitation HCPCS Code Change History (*Continued*)

Effective Date	Code and Description	Change	Comments	Reimbursement Change
Toe loop				
Jan 1, 2004-Present	E0952 Toe loop/Holder	Cross-walked K0036 to E0952 and descriptor changed to Toe Loop/Holder, each	Adaptive Equipment Systems Submitted a Request to establish a code for a rigid foot positioner, trade name: Adaptive Equipment Systems Shoe Holder. Request denied. Manufacturer instructed to use E0952 and E0951 (Heel Loop/Holder) for submitting claims.	
Oct 1, 1993-Dec 31, 2003	K0036 Toe loop, each	Cross-walked E0952 to K0036		Oldest available fee schedule 1998-
1986-Sept 30, 1993	E0952 Toe loop, each			Prior to 1993, suppliers reimbursement was based on supplier's submitted charges.
Handrim—without projections				
Jan 1, 2008-Present	E2205	Long descriptor change—Handrim without projections, any type, (including ergonomic or contoured) replacement only	Adds ergonomic handrims (e.g. Natural-Fit Handrim) still no reimbursement	2008 Replacement fee schedule $32.67. 2014 fee schedule—$35.72 each
Jan 1, 2005	E2205	Handrim any type, replacement only	No longer reimbursed with initial issue of wheelchair- loss of $32.67 each (based on 2005 fee schedule).	2005 replacement fee schedule $32.67
Oct 1, 1993-Dec 31, 2004	K0059	Plastic-coated handrim, each		2004 fee schedule $31.72 each
Oct 1,1993-Dec 31, 2004	K0060	Steel handrim, each		2004 fee schedule $27.75
Oct 1,1993-Dec 31, 2004	K0061	Aluminum handrim, each		2004 fee schedule $39.37
Handrim—with projections				
Jan 1, 2007-Present	E0967	Handrim, Any type with projections, each replacement only	No longer reimbursed with initial issue of wheelchair- Loss of $65.69 each based on 2007 fee schedule)	Replacement only; fee schedule $65.69 each
Jan 1, 2004	E0967	Handrim, Any type, with projections, each	Combined K0062 and K0063- Increase of $4.68 over K0062 and reduction of $15.77 compared to K0063	$65.69 each
Oct 1, 1993-Dec 31, 2003	K0062	Handrim with 8-10 vertical projections		2003 fee schedule—$61.01 each
Oct 1, 1993-Dec 31, 2003	K0063	Handrim with 12-16 vertical projections		2003 fee schedule—$81.46

Abbreviations: CRT, Complex Rehabilitation Technology; MWC, manual wheelchairs; PWC, power wheelchairs.

to evaluate codes for the purpose of developing comprehensive coding proposals, or provide code verification for Medicaid programs; the PDAC only code verifies on the basis of Medicare guidelines.

These differences in the 2 contracts is worthy of mention because the impact on access is significant. The SADMERC historically played an important role in CMS' efforts to prepare for the DME competitive bidding program mandated by Congress. The SADMERC was to ensure that codes represented current and homogeneous technologies. The SADMERC staff systematically reviewed products, identifying key characteristics and developing proposals for code additions, deletions, or definition changes and developing criteria and requirements for HCPCS codes. In several situations related to CRT, the SADMERC staff recognized differences in this technology compared to standard DME. On the basis of the product differences, and the fact that utilization was typically low for the Medicare population, manufacturers were often instructed that their products should be billed using miscellaneous codes (eg, K0108, E1399).

In many cases, the PDAC staff has initiated reviews of SADMERC coding decisions and reversed earlier decisions. The result is that many CRT items are now grouped with DME items into a single HCPCS code (Figure).

Furthermore, in many cases when unique HCPCS codes have been requested to represent CRT, the CMS HCPCS workgroup decision has been to change or expand the definition of similar HCPCS code to state "any type" to allow a CRT item to be grouped with DME.

The result is an inability to distinguish or segregate technology based on technological differences or clinical application. This strategy for coding products has also resulted in inadequate reimbursement, frequently reimbursement is below a supplier's cost to buy the product let alone provide the related services. Ultimately, the cumulative result of declining reimbursement is a reduction or elimination of access to CRT.

An additional way that coding negatively affects access is through bundling of options and accessories (a basic equipment package) with the base wheelchair. A basic equipment package identifies items provided at the same time as the base wheelchair and bundles them into the fee schedule for the base. These items are then no longer billable separately unless replaced or repaired. These types of coding changes are not viewed by CMS as pricing changes; however, decisions that render items no longer separately billable without a corresponding increase to the fee schedule, clearly result in reimbursement cuts (Table 3).

For example, as recent as 2004, special MWC handrims such as plastic coated were billable with initial issue of the wheelchair. The current policy for MWCs lists handrims as bundled with the base wheelchair and only billable to Medicare if they are replaced. Plastic-coated handrims are an up-charge from the basic features with a manufacturer's suggested retail price (MSRP) around $100.00. Projection handrims are also an up-charge, with a MSRP ranging from $240 to $315. Effective in 2007, these wheelchair accessory items were bundled with the base wheelchair. Since there was no subsequent update to the fee schedule for MWC bases when these accessories were bundled with the base, the net result is a reduction in reimbursement. The 2014 fee schedule for plastic-coated handrims is $35.72 each or $71.44 for a pair. Projection handrims are $71.82 each or $143.64 for a pair when replaced, but no additional funding is allowed when provided at initial issue.

IMPLICATIONS

The loss of ability for payers to develop their own local codes to meet their programmatic needs and the needs of their beneficiaries was significant. Many payer organizations (eg, Medicaid, private payers, Tricare, etc) lack the human or financial resources to focus on coding and its impact on access. The CMS has focused toward the program operating needs of the Medicare program in the development of the code set. The result has been a move toward generic codes. This has left behind the needs of Medicaid programs and private payers that serve different populations (eg, pediatrics, working age adults, etc). Consequently specialized and individualized products serving special populations with relatively small numbers become outliers, orphans or worse, grouped with standard technology; the result, as a general rule, is systematic underfunding of CRT products.

Furthermore, bundling of accessories and options with base codes simplifies claims processing for payers, but without modifications to the fee schedule also reduce reimbursement. For CRT bundling of technologies will not work because each CRT system is configured to meet the medical and functional needs for a specific person. Every person does not need the same "bundle" of CRT items so therefore bundling of items in a CRT system, providing items that may not be needed or used, may result in waste or denied access if the reimbursement of the wheelchair system is insufficient to allow provision of additional accessories.

CHANGES NEEDED

Payers need an unbiased method to obtain the codes essential to meet their unique programmatic needs and the needs of their beneficiaries without arbitrary thresholds or requirements. For example, if 1 state Medicaid program desires a code to define a very unique pediatric device, they should be able to obtain a code, no questions asked. The program may require a code to track utilization to develop a specific coverage policy or merely because the item is very expensive and there is a desire to track coverage while ensuring access for the appropriate population.

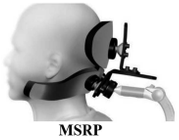
HCPCS Code	Long Description	Fee Schedule	SPA Pricing[b]	Example 1 DME	Example 2 CRT	Example 3 CRT
E0950	WHEELCHAIR ACCESSORY, TRAY, EACH	FLOOR $83.28 KE[a] $96.63 CEILING $97.98 KE $113.68	$64.00 – $86.00	Wood, plastic, Acrylic  MSRP $98 - $210	Viewline+, Top Drop Clamps, PVC Rim, Controller Cut-out  MSRP $399 (X-Large)	Padded, Upholstered Tray w/Cut-out  MSRP $374 - $430 (W/Hardware)
E0955	WHEELCHAIR ACCESSORY, HEADREST, CUSHIONED, ANY TYPE, INCLUDING FIXED MOUNTING HARDWARE, EACH	FLOOR $161.98 KE $187.94 CEILING $190.57 KE $221.10	$104.55 – $150.00	Whitmyer® Single Pad Headrest  MSRP $205 - $450	Whitmyer® Heads Up  MSRP $$355 - $675	Whitmyer® Dual Sub-Occipital Headrest  MSRP $415 - $715
E0995	WHEELCHAIR ACCESSORY, CALF REST/PAD, EACH	FLOOR $24.35 KE $28.26 CEILING $28.65 KE $33.25	NA – NA	Calf Rest Pad  MSRP $36	Single Calf Pad  MSRP $130	Divided Footbox  MSRP $400
E0978	WHEELCHAIR ACCESSORY, POSITIONING BELT/ SAFETY BELT/PELVIC STRAP, EACH	FLOOR $34.35 KE $39.70 CEILING $40.23 KE $46.71	$16.80 – $27.67	Pelvic Belt  MSRP $25 - $85	Padded, Push-Button Pelvic Belt  MSRP $87 - $92	4-Point, Padded, Push-Button Pelvic Belt  MSRP $112 - $116
E0951	HEEL LOOP/HOLDER, ANY TYPE, WITH OR WITHOUT ANKLE STRAP, EACH	FLOOR $15.21 KE $17.65 CEILING $17.89 KE $20.76	$10.94 – $14.70	Heel Loop  MSRP $30	Ankle Strap  MSRP $130 - $138	Shoe Holder, Ankle Holder  MSRP $265
E0960	WHEELCHAIR ACCESSORY, SHOULDER HARNESS/STRAPS OR CHEST STRAP	FLOOR $72.89 KE $84.57 CEILING $85.75 KE $99.49	$48.85 – $80.00	Chest Belt  MSRP $64 (Non-padded) $80 (Padded)	Anterior Trunk Support, Contour-Style, Dynamic  MSRP $130	Anterior Trunk Support, Zipper-Open, Dynamic  MSRP $150

Figure. Inadequate coding examples. [a]Billing modifier for wheelchair accessories when provided on bases not included in the competitive bidding program or bases not impacted by 9.5% cut to the Medicare fee schedule in 2009 to off-set the cost of a 18 month delay in the CB program; [b]Single Payment Amount for a given competitive bid area. For the Figure, the SPA is the highest and lowest for all areas.

New HCPCS codes must be granted for new technology if the technology

- performs a different function (does something clinically different for the patient) than a previously coded product; OR
- operates differently; OR
- is a distinct technology (eg, components, materials of construction, structural features, size, mechanism of action are distinctly different from existing technology); OR
- meets a distinct patient or clinical need (eg, there is a distinct patient population that benefits from the use of this device, or there are significant clinical

TABLE 3 Impact of Policy and Coding Decisions on Reimbursement

Example K0005 Ultra-Light Wheelchair and Related Accessories

Initial HCPCS Code	Descriptor/ Definition	Fee Schedule Date	Fee Schedule Amount	Current HCPCS Code	Status	2014 Fee Schedule	Impact-Based on Last Available Fee Schedule
K0005	Ultra lightweight adult wheelchair			K0005	Valid code	$2021.71	
K0062	Handrim with 8-10 oblique projections each	2003	$ 61.01	E0967	Billable replacement only	…	$122.02
K0055	Seat depths, 15, 17, 18 for high strength lightweight and ultra lightweight manual wheelchairs	2003	$ 95.10	Code deleted	Coding guidelines changed—all manual wheelchairs include all seat widths, depths and seat to floor heights	…	$95.10
K0054	Seat widths 10, 11, 12, 15, 17, 20 for high strength lightweight and ultra lightweight manual wheelchairs	2003	$ 104.64	Code deleted	Coding guidelines changed—all manual wheelchairs include all seat widths, depths and seat to floor heights	…	$104.64
K0056	Seat height less than 17 or equal to or greater than 21 for lightweight or ultra lightweight manual wheelchairs	2003	$ 95.10	Code deleted	Coding guidelines changed—all manual wheelchairs include all seat widths, depths and seat to floor heights	…	$95.10
K0035	Heel loop with ankle strap, each	2003	$ 25.90	E0951	Valid code—descriptor changed to state with or without ankle strap—New fee schedule developed	$20.76	$10.28
K0030	Solid insert		$ 95.15	E0992	Not separately billable	…	$95.15
E0192	Pressure equalizing cushion	2004	$ 387.01	E2603	Coding changes in 2004—fee schedule developed using gap-filling methodology—Valid code	$165.77	$221.24
					Total	$2208.24	$743.53
					Impact	25.18% reduction in reimbursement	

Abbreviation: HCPCS, Healthcare Common Procedure Coding System.

indications or uses that are distinct from existing codes.)
- Bundling of accessories and options should be limited in scope and only if the items are routinely provided with the base. Otherwise, these options should be billed only when needed.

COVERAGE

Medicare coverage is established through the National Coverage Determinations and local coverage determination (LCD) processes. The vast majority of these policies are made at the regional level by clinicians at the CMS contractors responsible for paying Medicare claims. National Coverage Determinations are made through an evidence-based process defined by CMS. In some cases, CMS' own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development and Coverage Advisory Committee. In the absence of a national coverage policy, an item or service may be covered at the discretion of the CMS contractors based on a LCD.

Section 522 of the BIPA of 2000 created the term "local coverage determination". An LCD is a decision by a Medicare administrative contractor, fiscal intermediary or carrier whether to cover a particular item or service on a Medicare administrative contractor–wide, intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (ie, a determination as to whether the item or service is reasonable and necessary). Prior to this legislation, Medicare contractors used local medical review policies (LMRP) to establish coverage of particular items or services. The difference between LMRPs and LCDs is that LCDs consist of only "reasonable and necessary" information, while LMRPs may have contained benefit category and statutory exclusion provisions. Now, any non-reasonable and necessary language a contractor wishes to communicate to providers is now published in a corresponding policy article.

Codes describing what is covered and what is not covered can be part of the LCD. The HCPCS coding guidelines are not elements of LCDs and instead are published in corresponding policy articles.

Local coverage determination changes are made for many reasons. The contractors for Medicare may decide changes are needed to address utilization concerns prompted by data analyzed by the DME PDAC. Changes may also be made on the basis of a request for reconsideration that is submitted by stakeholders or to address changes in medical practice. In the LCD development process, the medical directors are instructed to use an evidence-based process.

As stated in the Medicare Program Integrity Manual regarding the development of LCDs, "Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
  - Scientific data or research studies published in peer-reviewed medical journals;
  - Consensus of expert medical opinion (ie, recognized authorities in the field); or
  - Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage."[5]

Frequently, CRT coverage policies include lists of covered diagnoses or diagnosis codes referred (diagnostic based coverage policies). While the use of specified diagnoses can create a very concise coverage policy, simplify claims processing, and support automated claims processing, for people who do not have a specified diagnosis yet have a medical need for technology, there exists no Medicare program review process to allow a medical professional to independently review and approve coverage on an individual consideration basis. Instead, a supplier must interpret and apply the policy, inform the person that they do not meet the coverage requirements, and obtain a signed form from the individual, or their legal representative, indicating they will accept financial responsibility in case the claim is denied.

If a Medicare beneficiary does not have the financial means to cover the costs, they may be unable to obtain the equipment they need. In addition, when a Medicare beneficiary is a qualified Medicaid beneficiary as well, accepting personal financial responsibility may not be allowed (State

legislation and regulation would determine). In these cases, if Medicaid follows Medicare policy regarding coverage, it would be unlikely that the person would receive the needed technology.

These issues also illustrate why well-defined HCPCS codes are critical to enable the establishment of meaningful coverage policies that enable appropriate access. If codes were established to segregate DME from CRT, it would provide the necessary foundation for appropriate coverage development for both categories of products. Coverage policies developed using homogeneous HCPCS for CRT products could allow appropriate access for the small group of people with disabilities that need it without increasing risk of overutilization by the broader group of Medicare beneficiaries.

One additional coverage issue has denied access to appropriate technology for decades known as the "In the Home" restriction. The legislation that defines DME includes a requirement that the item must be appropriate for use in the home. Significant evidence exists to demonstrate that Congress was merely distinguishing medical equipment paid for in hospital and nursing home stays from equipment used by people living at home. For decades, the Medicare program has interpreted this legislation to limit access to DME to only equipment needed to move around inside the 4 walls of a person's home. This has had several profound effects.

- If a person is capable of ambulating short distances inside their home or the device they need inside their home differs from what they need outside their home, they will not receive Medicare reimbursement for any technology to assist their mobility outside their home.
- Use of technology appropriate for inside the home use, which means flat level surfaces, is often not adequate or even dangerous for use outside the home-community use. When technology is pushed to perform in settings it was not designed for repairs and premature replacement can increase and can be costly. To make the situation even more devastating, repairs have become increasingly difficult or impossible to obtain due to regulatory requirements and inadequate reimbursement.

IMPLICATIONS

Three issues regarding coverage have reduced access to technology for people who have a medical need for it; demands for evidence that exceeds what is reasonable for CRT, the use of diagnostic specific coverage policies without a process that allows individual consideration for those with a medical and functional need but without a listed diagnosis that is specified in the coverage policy, and CMS's interpretation of language in legislation that requires DME to be appropriate for use in the home.

CHANGES NEEDED

To ensure that people with disabilities are able to access technology that meets their needs and to promote continued innovation in this area, a number of important changes are needed. Health care is changing, innovative ideas for the delivery of health care is being considered, and efforts continue to reduce cost while increasing quality of care and outcomes. For CRT specifically, there is a strong need for the following changes.

A hierarchy of evidence for CRT that answers the important questions regarding when and if coverage of a device is appropriate, and is achievable. A consensus conference that includes all stakeholders could provide a platform for this work to begin.

The HCPCS codes must be developed for CRT to facilitate the development of adequate coverage policies that promote access for people with disabilities.

A process must be implemented within the Medicare program that allows for individual consideration for people with a medical need for technology but do not have a diagnosis that is required by the coverage policy for the device.

The CMS must modify its interpretation for "in the home" to allow for consideration of community access, self-care, and independence when determining whether there is a medical need for technology.

PAYMENT

The Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203) established a fee schedule to be used when computing reimbursement for DME and Prosthetic and Orthotics (PO) under Medicare. For DME, the legislation established 5 payment categories[6]:

- inexpensive and other routinely purchased items;
- items requiring frequent and substantial servicing
- customized items;
- other items of DME, frequently referred to as "capped rental" items; and
- oxygen and oxygen equipment

For most DMEPOS items and services, fee schedule payments prior to January 1, 1989, were made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment for most DMEPOS items and services is now based on the lower of the actual charge for the item or a fee schedule amount. The part B deductible and 20% coinsurance both apply to the DMEPOS items and services described earlier.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (eg, July 1, 1986, through June 30, 1987). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee

schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items or supplier and MSRP lists. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

It is important to understand that all products within a single code have the same maximum reimbursement. Once a fee schedule amount is determined for a specific HCPCS code, any product within that same HCPCS code will not be reimbursed more than the maximum fee schedule assigned to that code. For example, the ultra-lightweight MWC code K0005 represents products with a range of MSRP from $1900 to $3595. Products assigned to this code vary in material, product weight, features, adjustability, as well as available options and accessories.

To be considered a *customized* DME item, "a covered item (including a wheelchair) must be: 1) Uniquely constructed or substantially modified for a specific beneficiary according to a physician's description and orders; and 2) So different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes. For example, a wheelchair that is custom fabricated, or substantially modified, so that it can meet the needs of wheelchair-confined, conjoined twins facing each other is unique and cannot be grouped with any other wheelchair used for the same purpose. It is a one-of-a-kind item, fabricated to meet specific needs. Conversely, items that: 1) Are measured, assembled, fitted, or adapted in consideration of a patient's body size, weight, disability, period of need, or intended use (i.e., custom fitted items); or

2) Have been assembled by a supplier, or ordered from a manufacturer, who makes available customized features, modification or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician do not meet the definition of customized items. These items are not uniquely constructed or substantially modified and can be grouped with other items for pricing purposes. The use of customized options or accessories or custom fitting of certain parts does not result in a wheelchair or other equipment being considered as customized."[7]

Pricing category changes also affect access. Effective April 1, 2014, CMS reclassified CRT items previously classified as routinely purchased to capped rental. Regulation states that an item is classified as routinely purchased if the item was purchased by Medicare at least 75% of the time between July 1, 1986, and June 30, 1987. For CRT, the reclassification affected adult manual tilt-in-space wheelchairs, pediatric MWC, power assist systems, and speech generating devices. Essentially, since the technology was not available or there was no evidence that these items had been billed to the Medicare program during the timeline established in regulation, these items were reclassified as capped rental.

Historically, most of the reimbursement cuts have been the result of legislation.

- Balanced Budget Act of 1997—Eliminated Medicare DME schedule updates for 1998-2002.
- Balanced Budget Refinement Act of 1999—Provided for Medicare DME updates for 2001 and 2002 based on Consumer Price Index- Update (CPI-U) minus 2%.
- Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) BIPA of 2000—Allowed for full 2001 CPI-U update and 2002 1-year temporary increase.
- Medicare Prescription Drug Improvement and Modernization Act of 2003—Eliminated Medicare DME fee schedule updates for 2004-2008, reduced certain items (including power wheelchairs [PWCs]) by the difference between Medicare and federal employees health benefits program and directed the Secretary of HHS to establish and implement programs under which competitive acquisition areas are established throughout the United States for the furnishing of competitively prices items and services based on bids.
- Deficit Reduction Act of 2005—Reduced capped rental maximum period from 15 months to 13 months and added a requirement that once the capped rental period has been reached, the title for the equipment transfers to the beneficiary. Prior to this change, suppliers could bill Medicare 1 month's rental every 6 months to cover repairs and maintenance while they also maintained ownership of the equipment and could pick it up if the medical need changed or the beneficiary died. During the rental period, suppliers are required to maintain and repair the equipment.
- Medicare Improvements for Patients and Providers Act of 2008—terminated all contracts under the first round of DME competitive acquisition program, set to start July 1, 2008. Required the Secretary of HHS to rebid the first round in 2009 and delayed the second round of bidding until 2001. To pay for the cost of the program delay, the act required a 9.5% reduction in the fee schedule for all round 1 DME items and services both inside and outside of competitive acquisition areas. Since CRT PWCs were included in the initial round of competitive bidding, although exempted from future rounds by this legislation, the 9.5% cut to pay for the delay was applied to these products.
- The Patient Protection and Affordable Care Act of 2010—Eliminated the purchase option for standard PWCs, modified how power mobility payments are paid during the rental period. Beginning with

calendar year 2011, Section 3401 of The Affordable Care Act requires that the increase in the CPI-U be adjusted by changes in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity. The amendment specifies the application of the multifactor productivity may result in an update "being less than 0.0 for a year, and may result in payment rates being less than such payment rates for the preceding year." In addition, required the Secretary of HHS to expand the number of areas to be included in Round 2 of competitive bidding from 79 to 100 of the largest metropolitan statistical areas and to use competitively bid prices in all areas by 2016.[8]

To illustrate the impact of the legislation on access to complex rehab technology, the tables below apply the changes to actual HCPCS codes representing ultralightweight MWCs and CRT PWCs (referred to by Medicare and the HCPCS code set as group 3 power mobility devices (Tables 4 and 5).

IMPLICATIONS

Again, the foundation for appropriate payment is adequate codes to represent homogeneous technology. But, even

TABLE 4 Ultra Lightweight Manual Wheelchair Actual Fee Schedule Changes Versus Consumer Price Index—Update (CPI-U)[a]

HCPCS Code K0005				
	Actual Fee Schedule Changes	**Actual % Change Over Previous Year**	**CPI-U % Change**	**Fee Schedule Change if CPI-U Update**
Oldest available fee schedule 1998	$1763.39			
1999	$1763.39	0	1.7	$1793.36
2000	$1763.39	0	2	$1829.23
2001	$1768.68	0.3	3.7	$1896.91
2001	$1888.62	6.78		
Temporary (1 year) update only 2002	$1839.21	–2.6	3.2	$1957.61
2003	$1848.76	0.5	1.1	$1979.14
2004	$1848.76	0	2.1	$2020.70
2005	$1848.76	0	3.3	$2087.39
2006	$1848.76	0	2.8	$2145.83
2007	$1848.76	0	4.3	$2238.11
2008	$1848.76	0	2.7	$2298.54
2009	$1941.20	5	5	$2413.47
2010	$1941.20	0	–1.4	$2379.68
Multifactor productivity adjustment reduction of 1.2 2011	$1939.26	–1	1.1	$2405.85
Multifactor productivity adjustment reduction of 1.2 2012	$1985.80	2.4	3.6	$2492.27
Multifactor productivity adjustment reduction of 0.9 2013	$2001.69	0.8	1.7	$2534.83
Multifactor productivity adjustment reduction of 0.8 2014	$2021.71	1	1.8	$2580.46

[a]K0005—Ultra lightweight adult manual wheelchair <30 pounds; –22% or –$567.76 lower reimbursement comparing 2014 fee schedule to what the fee schedule would have been with all CPI-U updates since 1998.

TABLE 5 Power Mobility Fee Schedule Changes[a]

HCPCS Code K0011/K0848 Fee Schedule Changes				
Year of Fee Schedule	**Actual Fee Schedule**	**Actual % Change Over Previous Year**	**Consumer Price Index—Update (CPI-U)**	**Fee Schedule Amount With Full CPI-U**
Oldest available fee schedule 1998	$5052.00			
1999	$5052.00	0	1.7	$5137.88
2000	$5052.00	0	2	$5240.64
2001	$5067.20	0.3	3.7	$5434.54
2001	$5410.70	6.78		
Temporary (1 year) update only 2002	$5270.30	–2.6	3.2	$5608.45
2003	$5295.50	0.5	1.1	$5670.14
2004	$5295.50	0	2.1	$5789.21
2005	$5122.60		3.3	$5980.25
2006	$5122.60	0	2.8	$6147.70
Code change—K0848	$5433.60			
2007	$5433.60	0	4.3	$5667.24
2008	$5433.60	0	2.7	$5820.26
2009	$4782.40	–9.5	5	$6111.27
2010	$4782.40	0	–1.4	$6111.27
2011	$4777.53	–0.1	1.1	$6178.49
2012	$4892.20	2.4	3.6	$6400.92
2013	$4931.33	0.8	1.7	$6509.73
2014	$4980.66	1	1.8	$6626.91

[a]K0848—Group 3 standard weight capacity power wheelchair; Fee schedule difference –$1646.25 or 24.48% reduction comparing 2014 fee schedule to what the fee schedule would have been with all CPI-U updates since 1998.

with appropriate coding, the mechanism for updating the fee schedule to reflect annual changes has reduced or been eliminated for a decade or more by legislation.

When new technology is developed, it reflects costs at that time and has no connection with 1986/87. To develop a fee schedule for new and emerging technologies, the formula for establishing the fee schedule must not include freezes or reductions to the annual fee schedule updates required by Congress for existing codes.

CHANGES NEEDED

This is another area where policies have not evolved as necessary to align with medical practice. To protect access to CRT, changes in the methodology used to develop the fee schedule is needed. There are a couple of viable options; apply gap-filling but eliminate the use of freezes or reductions to the annual fee schedule updates required by Congress for existing codes, or develop a new formula for establishing pricing for new technologies or new HCPCS codes that more adequately reflects current costs.

SUMMARY

The CRT industry is a relatively young industry born out of the unmet needs of people with long-term disabilities. Innovation for these technologies often occurred in garages or basements by family or friends with a desire to assist those they loved to get out of bed, spend more time engaged in activities, increase function and independence, improve their ability to access their community, return to school or work, facilitate self-care or even allow them to care for others (ie, children or parents), and much more. Gradually these innovative products moved out of garages and into manufacturing facilities that adhere to Food and Drug Administration requirements and improved access to technologies for more people.

Unfortunately coding, coverage, and payment policies for these important technologies have not kept pace. The

result is that access to CRT has declined; manufacturers have been forced to reduce options, features, and customization to accommodate inadequate reimbursement. The cumulative result is unmet needs. Stakeholders have networked for solutions to facilitate provision of CRT, but overtime reimbursement has continued to drop, costs to manufacture have increased, costs related to the services needed to provide technology has escalated, and the ability to continue to provide technology has declined dramatically.

Efforts are currently underway to establish a separate benefit category within the Medicare program that would segregate CRT and DME and provide a clean slate to begin to develop coding, coverage, and payment that meets the needs of people with long-term disabilities.[9] In hindsight, one could ask whether this should have been done in 1972 when the Medicare program was expanded to include people younger than 65 years with a permanent disability. However, at that time the number of people with permanent disabilities was approximately 2 million and CRT did not yet exist.

Today, the number of people who qualify for Medicare based on a permanent disability is approximately 9 million. In addition, there is an industry of manufacturers and suppliers of CRT, a large group of physical and occupational therapists who focus on wheeled mobility and seating and supplier companies that employ credentialed assistive technology professionals. A lot has changed regarding CRT products and services over the last 20 years. It is imperative that funding policies change to ensure access to CRT for people with disabilities.

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Resilience in Older Adults: Erratum

In the article that appeared on pages 155–163 of the July–September 2014 issue, please note that the references and acknowledgment of work for what is referred to as the Resilience Model (the definitions of the components of this model and the description of the model appear in Figure 1) were inadvertently omitted. Please note that this model was developed by and published initially by Richardson, Neiger, Jensen, and Kumpfer: Richardson, GE, Neiger, BL, Jensen S, Kumpfer, KL. The resiliency model. *Health Education*. 1990;21(6):33-39.

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