CLINICAL EDITORIAL

Technology for Unmet Needs - Why It's Increasingly Difficult to Get Innovative Technology to Those Who Need It

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Manufacturers of medical devices in the U.S. market are aware of the myriad of regulatory policies that must be followed, especially those enforced by the Food and Drug Administration. This article will not address the FDA regulatory processes except to mention that following the policies closely and consistently is crucial. The Center for Medicare and Medicaid Services processes and resulting decisions have increasingly limited access to innovative technologies for the people who need them. This isn't the agency's intent, but it can be the unintended consequence of its processes. The influence of Medicare decisions is far-reaching. Many third-party payers routinely follow Medicare coding and coverage policies. And most, including Medicaid, routinely use the Medicare fee schedule as the base from which to discount.

Background

There are four necessary steps for a medical device to successfully be reimbursed by third party payers (not including the Veterans Affairs).

1. Medicare Benefit Category Assignment — A Healthcare Common Procedure Coding System code can be assigned without a benefit category, however, Medicare will not reimburse for an item without it.
2. Assignment of a Level II HCPCS code.
3. Adequate reimbursement.
4. Published coverage policy, or one that is well understood and consistently adhered to.

Benefit category assignment

Anyone may submit a request for Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics and Supplies benefit category determination. This can be done in one of two ways: as part of a HCPCS Level II code addition or revision or as part of a request for a National Coverage Determination. The process should be chosen carefully and advice from experts could prove invaluable. The timeline varies between the two processes, as does the level of scientific evidence required for each, as NCDs are made through an evidence-based process.

Assignment to a HCPCS code

Durable medical equipment is billed to Medicare through HCPCS.. It was established in 1978 to provide a standardized coding system. However, the use of these codes was voluntary beyond Medicare, and Medicaid and commercial payers had the ability to create unique codes to meet the needs of their enrollees and their program's operating needs.

With the implementation of the Health Insurance Portability and Accountability Act of 1996, use of the HCPCS for transactions involving health care information became mandatory for all payers, not just Medicare. Then, in October of 2003, the Secretary of Health and Human Service delegated authority under the HIPAA legislation to CMS to maintain and distribute HCPCS Level II codes and establishing uniform national definitions.[1]

Medicare fee schedule development

When a new HCPCS code is approved, a payment modifier and in most situations, a Medicare fee schedule will be established.

Continuity of Pricing — This is applied when Medicaid has paid for the item in the past under an existing HCPCS code. While manufacturers could seek a new HCPCS code for an item with features that exceed existing code requirements, a motivator could be to obtain reimbursement that covers the additional features and their associated cost. However, the continuity of pricing would prevent the assignment of a higher fee schedule.

Comparability — This method is used when the technology for which the new code was created is determined to be comparable to those in an existing code based on physical, mechanical and electrical components,

function and intended use, and additional attributes and features. Based on CMS policy, there is no prioritization among these categories, and the analysis may be completed based on the item, subcomponents of the item or a combination of items. It is important to note that a new item does not have to be comparable within each category to be considered comparable.

Gap-Fill Process — This method is used when neither of the above are applicable. This involves the use of verifiable reimbursement amounts paid for the item by commercial (non-Medicare) payers. There is a complex formula that CMS has utilized for years that involves deflating and inflating the prices and determining the adjusted median paid amount. Without losing readers in the process details, the ultimate fee schedule amount is routinely 30% lower than the median price.

The Medicare influence on access

Medicare has always influenced how other payers view technologies. Over time, legislation, regulation and the evolution of managed care has increased the ways that CMS and Medicare policy influences access for all. It is important for all stakeholders to understand the required processes and how they influence access. CMS has implemented important changes to the various processes over the last decade. Many of these changes were the result of stakeholder advocacy. A good example is CMS' policy change that allows HCPCS applications on a biannual basis for DMEPOS as opposed to one-time a year.

It has become increasingly important for manufacturers to have evidence regarding the clinical significance of new technology. As budget pressures increase, we can expect the push for evidence to escalate. To improve prompt access to innovative technology, manufacturers would benefit from verifying their product development timelines, including the necessary regulatory processes, and determine the evidence required.

REFERENCE

1. All policy details are available on the CMS website at www.cms.hhs.gov

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Rita Stanley has 43 years of experience associated with durable medical equipment/Complex Rehab Technology and Assistive Technology. Stanley joined RxFunction Inc. as vice president of government relations in October 2022. Prior to that, she established Merriman Innovation Consulting, LLCS, a company primarily focused on health policy with an emphasis on improving access to innovative technology. Stanley has a strong understanding of coding, coverage and payment policies and believes that coding is the foundation for coverage and payment. She is engaged in efforts to improve the HCPCS coding system. Stanley was the founding president of NCART and currently serves as the RESNA liaison. Stanley also serves on the RESNA board of directors, is the president-elect of the RESNA executive board and chairs its government affairs committee. Stanley also serves on the Alliance for HCPCS coding reform and is a Friend of iNRRTS. Stanley has experience and insight that allows her to understand where policies are preventing adequate access to technologies and has dedicated her career to understanding the processes and strategies available to bring meaningful reform.