Gaps in the delivery of rehabilitation medical equipment in the digital age

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1. Introduction

“This equipment has been deemed not medically necessary.” If you have read or been told this, you are likely a patient or healthcare provider trying to navigate the ordering process for durable medical equipment [DME] and complex rehab technology (CRT). Often, the people behind the organizations making this determination do not have a full understanding of the medical as well as the functional needs of persons with disabilities. DME refers to everything from ventilators to the tips of crutches; CRT is a subset of DME and refers to individually configured wheelchairs, seating and positioning systems, and other adaptive equipment [1].

Gaps in delivery affect all DME, but when CRT equipment is involved, the negative impact on the patient can be increased due to the highly customized nature of the technology. When something is deemed medically unnecessary and therefore will not be paid for by insurance, patients and families often still feel the need for the item and thus seek alternatives for the requested equipment. If denied by a third party payor, some charities will still provide for new DME. At other times, nonprofit organizations and communities will facilitate the delivery of donated DME. Usually, families have tried everything before resorting to equipment that is homemade. This equipment usually serves the original intended purpose but at a much lower cost than purchasing the DME from a medical equipment vendor. These methods of obtaining DME have become almost a pipeline, one that has been widened considerably through crowdfunding websites that can lead to funding in a pinch and social media platforms that are perfect for sharing engaging stories of children using the homemade devices. The growing collection of ‘feel-good’ stories on social media has created a niche, which can be used to get end-user feedback on a frustrating process or possibly serve third world countries and other areas with limited resources. However, this niche should not replace rehabilitation equipment evaluations. While appreciating any DME feel-good story, rehabilitation providers should be somewhat incredu-
lous that the device was not obtained through traditional equipment clinics and ask, “Why didn’t the insurance company pay for it?”

2. Background

When DME is not funded, insurance companies tell providers and patients that the requested DME is not medically necessary. The lack of funding is attributed to the lack of perceived need; insurance companies might be accused of valuing the bottom line over the patient’s well-being when they do not fund DME as ordered by a medical provider. However, it is an oversimplification to place this blame solely on health insurance organizations, even privately operated ones. Providers, policy makers, and insurance companies have all contributed to the main issue: a misinterpretation of ‘medical necessity’ itself.

The meaning of ‘medical necessity’ has changed over time. Before insurance companies and managed care, medical necessity was synonymous with provider medical decision-making. Slowly, physicians found that medical need determinations became a shared endeavor with insurers due to the complexities of socioeconomic reform and operations outsourcing for near-term productivity increases [2,3]. The concept of ‘medical necessity’ was then overly defined and applied liberally to the justification of all aspects of clinical practice, including diagnostics and interventions [4].

For children under the age of 21 with Medicaid, section 1905(r) of the Social Security Act mandates a standard for medical necessity as defined by the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guide, first developed in 1967 [5]. DME and other medical interventions and services are “medical necessity” if they “correct or ameliorate” defects and physical and mental illnesses or conditions [5]. The guide for EPSDT goes further to say:

“A service need not cure a condition in order to be covered under EPSDT.

Services that maintain or improve the child’s current health condition are also covered in EPSDT because they ‘ameliorate’ a condition. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. The common definition of ‘ameliorate’ is to “make more tolerable.” [5]

Despite the clarity of this definition, the interpretation of ‘amelioration’ still seems to be nebulous in practice. Moreover, when local government and companies recap this federal definition of medical necessity they pick and choose what part of the definition they want to use; one group found that of the 33 states with managed Medicaid, only 18 of those states had online access to their managed model contracts, and of those, only 13 model contracts contained the language “to correct and ameliorate” [6]. The American Academy of Pediatrics attempted to provide a foundation for defining medical necessity and its implementation by reinforcing the EPSDT standard and adding that it is the universal expectation that children should have access to optimal growth and development [7]. However, the relationship between optimal development and properly prescribed DME continues to be under-characterized.

In 2015, Stanley wrote a compelling explanation of the issues with CRT funding by highlighting the failures of coding, coverage, and/or payment policies as root causes of the obstacles to obtaining CRT funding [1]. This three-tiered approach can also be applied here to unfunded DME, but her work focused on adult patients and Medicare. She did highlight how Part B Medicaid coverage of equipment also includes the concept of the device needing to be used in the home setting only, which is concerning given that life is not lived solely in one’s house [1.8]. Many scholars agree the original purpose of the ‘in home’ qualification by Congress was to differentiate this category from the ‘in hospital or nursing home’ category, not to preclude the value of ‘in community’ use [1]. However, insurance companies frequently deny helpful features because they are deemed convenience items for community use only.

Even after the implementation of the EPSDT, providers and patients did not have appropriate access to rehabilitation technology. The Technology Related Assistance to Individuals with Disabilities Act of 1988 yielded further support for statewide programs to provide technology-related assistance for individuals of all ages with disabilities [9]. Later, the Individuals with Disability Education Act (IDEA), from 1997 and revised in 2004, required that children be considered for assistive technology, another subset of DME, defined as any item, piece of equipment, or product system that is used to increase, maintain, or improve the functional capabilities of the child [9]. With these pieces of legislation, we see medical necessity of equipment described in broad sweeping terms, yet it seems to be narrowly applied in practice today.
The do-it-yourself (DIY) model for assistive technology does have advantages that researchers have identified. Patients feel empowered by making their own equipment solutions and the benefits of saved time and money are usually favorable [10–12]. Patients also often provide insights to tailor existing devices to individual needs and may even find a role for a completely new type of device [10–12]. This is especially true for those with rare diseases; a recent survey of nearly 500 physicians who treat adults and children with rare diseases found that 90% of respondents felt a need for innovative diagnostic and therapeutic devices for their patients [13]. However, most of the advantages to a DIY equipment evaluation are specific to process improvements not process overhaul – DIY models are not a near-term answer to the inefficiency and obstacles of the rehabilitation equipment evaluation process [14].

Returning to our primary question, why are the companies who insure children whose stories appear in these viral videos not funding this rehabilitation equipment? Given that there are many potential answers to this question, it may be helpful to classify them so that we have a road map for addressing all types of insurance denials resulting in unfunded DME (see also Table 1).

2.1. The DME is not actually necessary

While the hope is that all equipment that is ordered is deemed medically necessary, we know that is not the case. At times, the equipment may be truly be an item developed for convenience or the equipment is inappropriate to address the identified functional goals. At other times, research may even show that some cohorts do not require certain DME and yet providers still request these products because they are under-informed, unconvincing, or unwilling to change their practice [15]. Yet another case occurs when a family is requesting a device and the provider does not have a strong opinion on its necessity, but is willing to help the family try to get insurance to pay for it, essentially relying on the insurance company to deny the order if it is inappropriate. The insurance companies should not have to be a safeguard for inappropriate prescribing practices, but often they are.

Practice inefficiencies account for other medically unnecessary DME orders. Some charities and non-profits require an equipment denial statement before providing other funding. For complicated pieces of DME such as a power wheelchair, the vendors sometimes embed requests for convenience items or cosmetic customization. The result is often a partial denial of the order to exclude the unnecessary items. These items are then paid for by the family, a charity, or are abandoned altogether.

Accurate and current rates of DME adoption and abandonment are not well reported, but conservative estimates suggest at least one third of all assistive technology is abandoned [16,17]. Many possible reasons for device abandonment exist, including the lack of consumer input or interdisciplinary approach as well as other personal or environmental factors that were missed in the evaluation [18–20]. Regardless of the reasons for abandonment, it is clear that the diagnostic process by which DME is ordered can, and should, be improved. Inappropriately ordered equipment wastes resources, because usually the orders go unfulfilled, but still add otherwise unneeded layers of review and processing. Inappropriate orders that are fulfilled are even more wasteful and could potentially be detrimental to the patient. The viral videos of homemade examples of DME replacements only compound this issue, as patients and parents become motivated to make their own versions of devices that may not have been appropriate in the first place.

2.2. The DME is necessary, but the order did not have sufficient documentation

Despite training that is currently deemed sufficient, many providers are not aware of resources that can help improve their evaluation and justification of DME, especially with CRT. Raising the par level of this training would help, but the central issue may be the sheer volume of equipment needs and lack of standard training requirements on equipment justification. Even with extra training, professionals ordering the products may be unsure what insurance companies require for a successful letter of medical necessity. This uncertainty may result from a lack of knowledge on the professional’s part or a lack of transparency by the insurance company regarding algorithms for equipment approvals. For example, providers in some regions expect a power wheelchair with a standing feature to be denied initially no matter how much data is provided. In other cases, insufficient documentation can be the result of human error or oversight, such as incorrect reporting of functional status or omitted demographic information. All denials related to insufficient documentation create delays in the process due to the time required to complete written and peer-to-peer appeals or attend fair cause hearings. Additionally, many families
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are not told that they have the right to appeal these decisions; if they are told, they are not sure when and how to conduct appeals. Some vendors and providers also do not fully understand their role in the appeals process. Finally, addressing equipment appeals can require a significant amount of time, which families may be able to find the time to support, but vendors and providers often cannot because that time is not reimbursable. Due to productivity constraints and the lack of accountability for outcome quality, providers and vendors often fail to complete paperwork or phone calls for appeals in the allotted time windows; this failure directly benefits the insurance company bottom line, which then incentivizes more denials. Improved quality control and tracking could help shorten these delays and decrease the number of missed appeal windows, but there is no separate funding to support such processes. However, the financial implications of better outcomes with shorter delays may show that the quality control would fund itself. These delays caused by
insufficient documentation create a vacuum of equipment need that patients are addressing with DIY options.

2.3. The DME is necessary and the order had sufficient documentation

Sometimes a device is truly medically necessary for a child, but it is not funded because it is not a covered benefit on the insurance company’s plan. It is important to help educate patients with functional impairments and their families on how to assess if a given insurance program will meet their needs. Another interesting case occurs when a family is required to sign a form saying that they will pay the difference if a device is not fully funded; the fear of getting this bill leads some families to cancel the order for a device that would have otherwise been appropriate [1]. Also, when two similar devices are ordered in close succession, the insurance company will not fund the more recent one without further justification until a prescribed amount of time has elapsed. Another issue for some families is that the co-pay for a necessary device is still exorbitant, which begs the question of why the device needs to be so expensive [21]. Finally, two functionally distinct types of equipment are sometimes incorrectly lumped together and the more expensive device is denied. Even if providers and families try to appeal for these equipment categories to be more distinct, some families will seek homemade innovations rather than wait for this appeal process.

2.4. The DME is not necessary under the current rules, even though it is clearly necessary to patients and providers

A lack of research and poorly developed rules and regulations will continue to result in the denial of some DME and CRT that is clearly medically necessary for patients. However, the absence of research cannot continue to be a stand-alone justification for a denial. Many patients and families feel that their insurance company does not understand the true nature of the functional challenges they face. What insurance calls a convenient, capricious, or luxurious request, families see as the pathway to safely and effectively accessing daily activities necessary for physical/mental health and improved quality of life. When current rules and regulations allow denials of needed devices, those rules and regulations must be revised. Rehabilitation providers and organizations who serve persons with functional impairments and their families must engage with the policy makers addressing these rules and regulations and our professional organizations should support this engagement. Those who provide care for these patients and families have a responsibility to educate decision makers by advocating for equipment that improves health and function. The value of DME is missed when we have to defend functional benefits mislabeled as convenience. The value of DME is missed when we have to defend the necessity of mobility and activities outside of the home setting. The value of DME is missed when we have to defend the need for safety equipment even when the patient also has nursing support in the home. The value of DME is missed when we have to defend how working towards independence in some areas of life, even while dependent in others, is still valuable to a child.

3. Applying the International Classification of Functioning, Disability and Health (ICF)

Since medical necessity is a malleable concept, we must seek a new way of defining and defending medical necessity in certain cases with DME and CRT. For too long, the definition of medical necessity has relied on inexact policy wording that allows for interpretation of words such as ‘amelioration’ and ‘function.’ One way to decrease the chance for misinterpretation of medical necessity would be to incorporate elements of the International Classification of Functioning, Disability and Health (ICF) in order to show the expected benefit of equipment for persons with disabilities [22]. The use of ICF criteria in assessing the medical need allows for the valuation of impairment, participation, and activity domains equally, whereas our current system overvalues impairment interventions. For children in particular, participation is vital to daily function and basic childhood development, especially for those with disabilities [23].

The ICF framework and terminology has been shown to be useful for medical device development [24], clinical practice [25–29] and outcome measures [30, 31], as well as other research methodologies [32,33]. This framework provides a broader understanding of how to measure medical necessity. For example, acute interventions and lifesaving procedures are easy to understand as ‘necessary’ when they have short-term outcomes or positively affect large populations. The benefits can be quantified easily when a surgical tumor procedure improves the five-year survival rates in patients...
with brain cancer or a medication brings down blood pressure readings. However, interventions for a small number of people with qualitative and quantitative benefits in multiple domains are more difficult to demonstrate as medically necessary, but the ICF can capture the complexities of these benefits. A cane can result in improved mobility effectively lowering the risk of a fall, but it also promotes flexibility, cardiovascular fitness, weight control, social interaction, vocational integration and community productivity, thus having a greater sum influence on domains of health outcomes than the medication that simply lowers blood pressure. The attempts to quantify medical value of equipment fail to capture the full extent of functional benefits, because our funding structure does not yet capture benefits from multiple domains of life. Though work has been done in this area, the usefulness of the ICF will not be fully realized until more research and policy addresses the ICF as a coding and billing model in healthcare [34,35].

4. Summary of proactive strategies

The problems causing difficulty obtaining DME and CRT are many and patients not having the equipment they need for safe and effective mobility and function in daily activities have serious short- and long-term consequences. Clearly, insurance policies need to be revisited and revised based on functional needs. More training and standardization of training requirements for professionals prescribing and evaluating this equipment is also worthy of exploration. One way to be individually proactive to access current resources like the Assistive Technology Standards and Knowledge Center though the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) [36,37].

The cost of the equipment itself also requires review and continued oversight. While economics of the market pull of a device as well as the cost to companies and vendors can be complex, some CRT costs four times more than the standard cost of new passenger vehicles. Providers should support policies that either reduce or subsidize the costs of this equipment for our patients. Even if insurance companies will not pay for some types of new equipment, exploring the role of equipment donation/sharing programs could be helpful. These programs are usually charity-based and do not have standardized regulations or the funds to allow for significant safety testing. If either institutions or insurance companies were to help support such programs, we may be able to improve outcomes, save money, and most importantly have a clear process to certify used DME and CRT as functional and safe.

Providers should also attempt to distinguish policy issues as either coding, coverage, and/or payment obstacles and advocate for changes to national coverage determination laws [1]. One such law that has been considered since 2016, and as of 2019 has not yet passed, is H.R. 2408: Ensuring Access to Quality Complex Rehabilitation Technology Act of 2019, which would create a pathway for specific CRT coding, significantly improving access to this equipment [38]. Providers can follow and support this law and other similar initiatives at http://www.access2crt.org/ [39].

Finally and most importantly, providers must actively listen to and collaborate with their patients to advocate for medical necessity, sometimes on a case-by-case basis. The ICF is one tool to help in that process, but the key is that only patients and their providers can truly define the medical need when considering the complex intersection of technology, equipment, and function.

5. Conclusion

Knowing why the insurance company did not pay for the device featured in an online feel-good story is sadly the tip of the iceberg. In fact, the digital age has only further highlighted gaps that have been growing in the equipment delivery model since before social media was a cultural concept. For the sake of our patients, we have to ask: Is this do-it-yourself approach safe for the child? Is this new device truly achieving the function of the original? A hackathon is a portmanteau of the words “hack” and “marathon” often used to describe computer-programming competitions in colleges, and the world is having a DME hackathon. While ingenious and innovative, the results of this hackathon are not necessarily safe, equitable, or just. The ideas are out there, but many of our patients will not be able to access them. Some of these feel-good stories are harbingers of larger systematic issues that must be addressed by proactive changes in the definition of medical necessity and funding policies. For providers, every DME or CRT do-it-yourself replacement video is a chance to ask a new question: what could rehabilitation medicine have done to prevent the need for this?

References

[1] Stanley RJ. Medicare and complex rehabilitation technol-


[33] van der Willik D, Dijkstra PU, Postema K, Verkerke GJ, Hi-


