Key Insights

MDIC Commercial Payer Council

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MDIC
Medical Device
Innovation Consortium

Contents

Key Insights

from the MDIC Commercial Payer Council

The MDIC Commercial Payer Council held its first quarterly session on January 30, 2024. MDIC's Health Economics and Patient Value (HEPV) program served as a neutral convener, bringing together executives representing an integrated healthcare delivery network and payer, a device company, a health plan, a health technology assessment organization, and a law firm, as well as consultants involved in health policy, market access, and reimbursement.

The experts shared their perspectives and insights on two key topics:

1. **Navigating Medicare Advantage**
2. **Reimbursement for digital health technologies**

The following key insights are intended to help individuals working in device and digital health technology companies develop a strategy and a pathway for working with commercial payers.

Navigating Medicare Advantage

For the first time in Medicare's history, more than half of all eligible people with Medicare, or 30.8 million people in 2023, were enrolled in private Medicare Advantage plans. Medicare Advantage plans are offered by private health insurance companies that receive payments from the federal government to provide Medicare-covered services.[1]

In 2022, 99% of Medicare Advantage enrollees had a plan that required prior authorization for some services.[2] Prior authorization can be viewed as imposing a significant burden on providers, suppliers, and patients, as it frequently results in denials and necessitates appeals. Ultimately, the prior authorization process can create barriers and delay access to necessary care.

The MDIC Commercial Payer Council's expert insights and perspectives on navigating Medicare Advantage cover:

- Prior authorization requirements
- Navigating prior authorizations
- Tips for pursuing appeals.

Many services covered by Medicare are not addressed by an NCD or an LCD.

Recommendations on Navigating Medicare Advantage

- **Provide complete data on the technology's efficacy and cost-effectiveness.**
- **Consider data for total patient population and/or targeted subgroups as appropriate.**
- **Where possible, use peer-reviewed, published literature as evidence of efficacy and cost-effectiveness.**
- **When appealing a denial, cite sources (e.g., Medicare claims database) showing where the item or service has been covered. This demonstrates that the item or service is not "experimental or investigational".**

Prior Authorization Requirements

Commercial payers operate under a "medical necessity" standard rather than Medicare's standard of "reasonable or necessary." This distinction can make attaining prior authorization approval more challenging for Medicare Advantage (MA) patients.

MA plans are required to provide at least the same level of benefit coverage as original Medicare. MA plans must follow Medicare's National or Local Coverage Determinations (NCD or LCD). However, in absence of written policy, MA plans may defer to their commercial policy processes.

[1] KFF. 10 Reasons Why Medicare Advantage Enrollment is Growing and Why It Matters. January 30, 2024. https://www.kff.org/medicare/issue-brief/10-reasons-why-medicare-advantage-enrollment-is-growing-and-why-it-matters/. Accessed 4/13/2024.

[2] KFF. Medicare Advantage in 2023: Enrollment Update and Key Trends. August 9, 2023. https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/. Accessed 4/13/2024.

Prior authorization to determine appropriate care and prevent inappropriate utilization is permissible; however, some payers may use prior authorization as a strategy to delay or avoid covering expensive care.

Tips for Pursuing Appeals

When payers deny prior authorization, organizations should pursue an appeal, using an iterative process and providing new evidence as it becomes available. Bear in mind that incomplete data on a technology's clinical or cost effectiveness may result in additional delays.

When appealing a coverage policy or an individual denial:

- Know ahead of time if an NCD or LCD applies.
- Be sure to point the MA plan to the applicable Medicare policy.
- Engage the patient or policy holder. Plans are often more responsive when the patient has a voice.
- If the appeal fails despite a Medicare policy being in place, engage the Medicare Pharmaceutical and Technology Ombudsman. More information can be found here: https://www.cms.gov/center/special-topic/ombudsman/medicare-pharmaceutical-and-technology-ombudsman.
- Analyze the total patient population and/or targeted subgroups as appropriate that could benefit from the technology.
- Demonstrate the efficacy and cost-effectiveness of the technology in the total patient population.

Key Consideration: Determine if an NCD or LCD is Applicable

The percentage of Medicare services addressed by LCDs or NCDs can vary based on the scope of services and the healthcare needs of Medicare beneficiaries. Generally, a significant portion of Medicare services fall under the purview of LCDs and NCDs, as these determinations guide coverage decisions and reimbursement policies.

However, it's important to note that not all Medicare services require LCDs or NCDs for coverage determination. Some services may be covered based on statutory requirements, Medicare regulations, clinical guidelines, or established medical standards without the need for specific LCDs or NCDs.

Analyze whether a payer has previously covered the item or service. Data from claims databases or other validated sources demonstrating payment can support that the item or service meets the applicable payer standard for coverage.

> ***"If you do have an NCD or an LCD, you have a significant advantage."***
>
> Law firm representative

Be aware that your approach may require engaging with a number of decision-makers, whether the payer is Medicare or commercial. For Medicare, it may require engaging with a number of Medicare Administrator Contractors (MAC) Medical Directors. On the commercial side, the same payer may have a number of medical directors overseeing different or regional plan lines of business.

> ***Start at the most important MACs and make your case. Knock down the dominoes one by one. Or if you have a really good study, talk to all of them at the same time."***
>
> Law firm representative

Other Insights About Navigating Prior Authorization

Engage in the Process

Note that sometimes an authorization from the patient or policyholder is required. Follow the requirements of the plan for the appeals process. Contact the ombudsman for help reaching the right people, if necessary, or when the plan is consistently resistant to following Medicare guidelines.

Work with Medicare Administrative Contractors

Medicare Administrative Contractors (MACs) are commercial payers that are contracted with Medicare to administrate coverage and claims. Sometimes they share Medical Directors (MD) or often meet together on issues. Get to know respective MAC MDs as they are often easier to engage with than those on the the commercial side.

Expect combined payer/ provider organizations to follow Medicare coverage decisions

Combined payer/provider organizations are very likely to follow Medicare's coverage decisions. One key reason to follow Medicare is to avoid confusing providers.

> ***If it's acceptable for patient A, it should be acceptable for patient B."***
>
> Integrated healthcare delivery network and payer representative

Reimbursement for Digital Health Technologies

Digital health refers to the broad use of digital technologies, information, and communication tools in healthcare delivery and management. Digital therapeutics are a subset of digital health focused specifically on using software-based interventions to prevent, manage, or treat medical conditions. Lack of an explicit and consistent framework for reimbursement by Medicare and commercial payers is seen as hindering patient access to digital therapeutics.

The MDIC Commercial Payer Council's expert insights and perspectives on digital health technologies cover:

- Key payer challenges and considerations in policy
- Value proposition for digital therapeutics and other digital health technologies
- Patient compliance and adherence
- Usability of digital therapeutics and other digital health technologies.

Key Payer Challenges and Considerations

While the tremendous promise and potential of digital health technologies are widely recognized, rapid adoption may create challenges for Medicare and commercial payers.

Lack of a consistent framework for reimbursement

Neither Medicare nor commercial payers have a straightforward path from development and commercialization to reimbursement, even for technologies authorized by the FDA. This provides industry with an opportunity to work with commercial payers to develop the framework.

Recommendations on Reimbursement for Digital Health Technologies

- **Provide data that demonstrates better health outcomes with use of digital therapeutics and other digital health technologies.**
- **Generate real-world evidence to demonstrate value.**
- **Demonstrate that digital health technology is unique and impactful, particularly with respect to a digital therapeutic.**
- **Understand the approach with Medicare versus commercial plans may be different.**
- **Engage patients and caregivers to generate compliance and adherence evidence, which is a key concern on the part of payers.**
- **Work with hospitals, physicians, surgery centers and home care agencies to embed digital health technologies into practice patterns to improve care and potentially offset other expenses.**
- **Consider the usability of digital health technologies, particularly digital therapeutics, by patients, caregivers, and physicians.**

A Medicare benefit category for digital therapeutics has not been defined.[3] Medicare does have codes for certain digital therapeutics that commercial payers can use, however, lack of CMS-established payment for the codes implies that digital therapeutics are not a Medicare benefit under the existing statutory framework of the Social Security Act.

Remote patient monitoring codes (RPM), on the other hand, are recognized under the Medicare Physician Fee Schedule as "Incident To" services, providing a pathway for Medicare payment for those specific services as defined by CPT®. The same is true for AI services that have been granted CPT® codes. Other digital health technologies may not have separate coding or payment; however, their costs may be considered packaged within the payment for the associated service.

Regardless of the payment or coding pathway, providing data for the entire patient population demonstrating meaningful outcomes is very important when seeking coverage.

While CMS's position on digital health technologies, including digital therapeutics may be evolving, the Social Security Act limits its actions. Commercial payers do not have the same limitations. However, they are not likely to cover digital therapeutics that have not been cleared or authorized by the FDA.

[3] Learn more about Medicare benefit category regulation here https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coverage/medicare-coverage-items-and-services. Accessed 4/13/2024.

Communication of the Value Proposition for Digital Therapeutics

Payers are skeptical about the value of digital therapeutics and want to know about the return on investment they would achieve by covering them. Industry must develop a compelling clinical and economic value proposition when seeking coverage and reimbursement. This is especially important for apps, which are rarely tested prior to coming into the market and are often not regulated by the FDA.

Evidence that the digital therapeutic space is unique and impactful

It is critical to demonstrate that the digital therapeutic is unique and impactful. Uniqueness is necessary due to the risk of substitution with a free, yet less effective, alternative.

Key Parts of the Value Proposition for Digital Therapeutics

- **Evidence that the digital therapeutic is unique and impactful**
- **Real-world evidence, demonstrating:**
  - compliance, adherence, and outcomes from patients and caregivers
  - transitions of care from hospital to home as treatment
- **Digital therapeutics as fundamental to efficient and cost-effective care**

Real-World Example: Balancing Cost Versus Compliance with an Addiction App

Pear Therapeutics demonstrated that people who used its addiction app would have 10% higher attendance at outpatient or group therapy meetings. The list price of the app was approximately $1,500 for 12 weeks, however, a 10% increase in compliance wasn't worth the cost of the app.

Real-world evidence

The strength or weakness of the evidence for a digital therapeutic is key to demonstrating and communicating value to a payer. Presenting real-world evidence such as the following may fill any gaps:

- From patients and caregivers demonstrating compliance, adherence, and outcomes
- About transitions of care where patients discharged from a hospital are effectively using a digital therapeutic at home as part of their treatment.

Highlight digital therapeutics as fundamental to efficient care

Payers are concerned that digital therapeutics that are billed separately will add cost, not value.

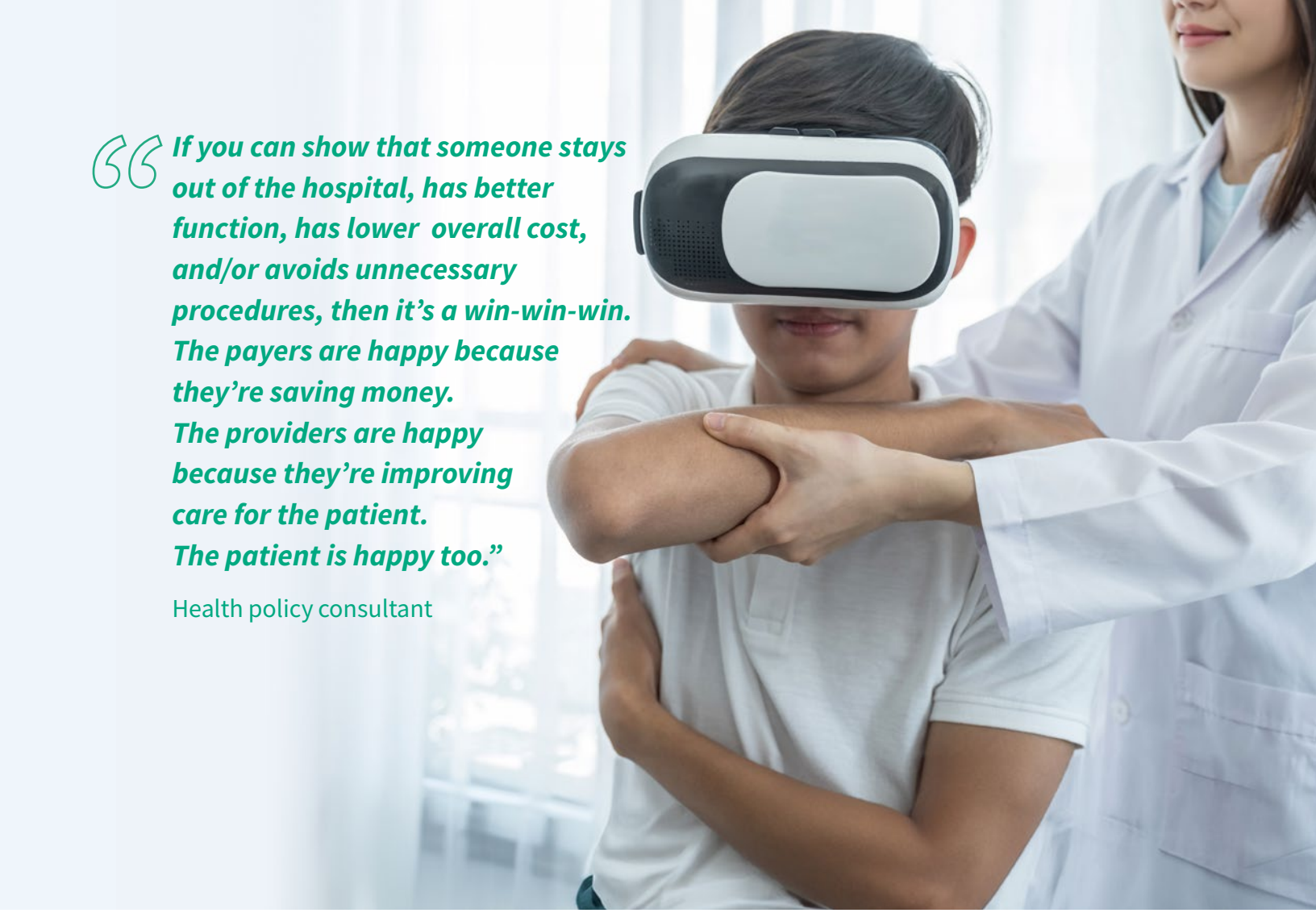
Embedding digital therapeutics into practice patterns that facilitate more efficient care and substitute for other current expenses may encourage payers to cover digital therapeutics.

Consider embedding digital therapeutics into practice patterns of hospitals, physicians, surgery centers, and home care agencies. This is a potential pathway to demonstrating the value to providers within the context of how they are paid, which will support adoption, even in the absence of additional reimbursement from payers.

> ***"Embedding digital therapeutics into practice patterns "makes it much easier to make the value proposition, because there's a clear line of sight to the endpoint value."***
>
> Integrated healthcare delivery network and payer representative

Real-World Example: Embedding a Digital Blood Pressure Monitor into Practice Patterns

Digital blood pressure monitors help patients control their blood pressure. If the monitor is connected to the patient's primary care practice, and the physician is responsible for the patient's outcomes, then someone in the practice will follow up to encourage appropriate use. The value of the digital blood pressure monitor becomes clear and persuasive when the patient is engaged in using the monitor by embedding it into practice patterns.



> ***If you can show that someone stays out of the hospital, has better function, has lower overall cost, and/or avoids unnecessary procedures, then it's a win-win-win. The payers are happy because they're saving money. The providers are happy because they're improving care for the patient. The patient is happy too."***
>
> Health policy consultant

Separation of Medicare and commercial payers

Since Medicare does not cover prescription digital therapeutics, the best approach is to separate Medicare from commercial payers when seeking coverage and reimbursement.

Patient Compliance and Adherence

Compliance and adherence has always been an issue for payers. It is more of a challenge with digital therapeutics.

Since most digital therapeutics actively engage patients or caregivers, industry must gather data directly from them about their use. Companies that provide evidence of compliance, adherence, and successful outcomes from a digital therapeutic will rise to the top.

Usability of Digital Therapeutics

Digital therapeutics are the most successful when the manufacturer/developer consider the patient's voice as well as their ability to integrate into the care continuum early. Considerations include connectivity, EHR integration, how patients actually use the digital therapeutic, and the physician's workflow.

Industry should consider these things during the development of the device, not after its launch. For physicians, the digital therapeutic must fit into their workflow in a reasonable way and offer data that are meaningful in managing the patient and improving outcomes.

MDIC Medical Device Innovation Consortium

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About the MDIC Commercial Payer Council

The MDIC Commercial Payer Council is part of MDIC's Health Economics and Patient Value (HEPV) program. This initiative aims to create predictability and transparency of evidentiary requirements for coverage and improve pathways for coverage, coding, and payment to speed patient access and amplify the patient voice in selection of treatment options.

For more information about the MDIC Commercial Payer Council, please email Harry Kotlarz, Vice President, HEPV at hkotlarz@mdic.org.