



PARTNERSHIP FORUM

No. 3  2019



EXECUTIVE SUMMARY

Digital Therapeutics: What are They and Where do They Fit in Pharmacy and Medical Benefits?

Digital therapeutics are innovative products that are being approved to treat a wide range of disease states, including diabetes, asthma, depression, substance use disorder, and many other conditions. As this emerging product category develops, it poses many questions for the health care system. How do these therapeutics differ from existing digital products in the health care space? What role do digital therapeutics play in preventing a disorder or disease, optimizing medication use, or treating a disease or disorder? What are the evidentiary requirements needed for third-party payer coverage of digital therapeutics? And where do they fit in pharmacy and medical benefits?

To examine these questions and explore how to develop systems and processes that will support the adoption and utilization of digital therapeutics, AMCP convened a multidisciplinary stakeholder forum September 17-18, 2019, in Alexandria, Va.

THE GOALS OF THE FORUM WERE TO:

- Describe digital therapeutics and how managed care organizations evaluate their value.
- Identify where digital therapeutics fit in within a coverage benefit.
- Outline evidentiary standards needed for coverage of digital therapeutics.

AMCP Partnership Forums are designed to address current market challenges and opportunities by bringing together key-decision makers in managed care, integrated care, the pharmaceutical industry, and others to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes.

CONTACT INFO

675 N Washington Street | Suite 220
Alexandria, VA 22314

703 684 2600 | www.amcp.org | [@amcporg](https://twitter.com/amcporg)

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Participants identified characteristics of digital therapeutics and how they are distinct from other digital products, such as mobile health devices. Key characteristics of digital therapeutics that were clarified include a general description, approval and validation processes, and levels of evidentiary standards for safety and efficacy to support regulatory approval and coverage by payers. Other issues that will need to be addressed include patient access, product delivery, and coding and reimbursement.

There was general agreement that certain features of a digital therapeutic, such as data privacy and security, are basic requirements for coverage by payers. Features that will need to be evaluated for coverage and formulary decisions include safety and

“*...this is the perfect time for us to come together at an AMCP Partnership Forum to talk about how we facilitate that [utilization], how do we make sure that if clinicians prescribe and patients need treatment that these get into standard of care, in clinical workflow. And how do payers think about managing them and reimbursing for them in a way that ultimately provides benefit to the entire health care system.*

Yuri Maricich, MD
Chief Medical Officer, Pear Therapeutics

WATCH FOR FOLLOW-UP

AMCP will publish detailed findings and recommendations from this Partnership Forum an upcoming issue of the *Journal of Managed Care & Specialty Pharmacy*. The proceeding document will be used in AMCP's ongoing efforts to find innovative and collaborative solutions to support the adoption and utilization of digital therapeutics in health care practice. These efforts will include:

- More education around digital therapeutics.
- Continued discussion on digital therapeutics and their role in improving patient health.
- Further defining the role of the pharmacy benefit and evidentiary standards with digital therapeutics.
- Exploring the possibility of working with key stakeholders on the development of a compendia.

NEXT FORUM TOPIC—

What's Next for Specialty Medication Benefit Design and Reimbursement

December 10–11, 2019
Hilton Mark Center
Alexandria, VA

efficacy, as well as the usability of the therapeutic. The evidence needed to evaluate digital therapeutics will be tiered based on its medical claim or function. For example, those intended to replace a pharmaceutical product for the treatment of a condition may require more evidence than those intended to monitor a condition.

Many digital therapeutics are distinct from pharmaceutical products in several respects. For example, iterative changes can be expected as a result of regular updates to software and operating platforms. Therefore, strategies for evaluating digital therapeutics in the real world must include ongoing assessments of the products as updates are implemented.

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Collection and interpretation of data from digital therapeutics must also be considered, including who is responsible for analyzing and interpreting results.

Various benefit coverage options were discussed. While some participants suggested that the unique features of digital therapeutics could be best addressed by a novel digital benefit, others argued that creating an additional benefit would result in further health care system fragmentation. They observed that the increasing focus on compensating providers for value supports integrating digital therapeutics within existing benefit infrastructures. They noted that some digital therapeutics, such as those delivered by physicians, might be more appropriate for the medical benefit, while others, such as those delivered by patients, might be better aligned with the pharmacy benefit.

Finally, many participants observed that pharmacists have knowledge and skills that make them well-suited to play a primary role in the management of digital therapeutics.

“ *Some of the themes that have emerged, in which there is absolute consensus, is the need to validate, the need to develop evidence, share it, and what appears to be a strong willingness on the part of payers is to see these kinds of therapeutics as part of the benefits package. Challenging and really rather optimistic so far.* ”

Caroline Popper, MD, MPH
President, Popper and Company

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