AMCP

PARTNERSHIP FORUM

No. 3 — 2019

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

Moderator Welcome

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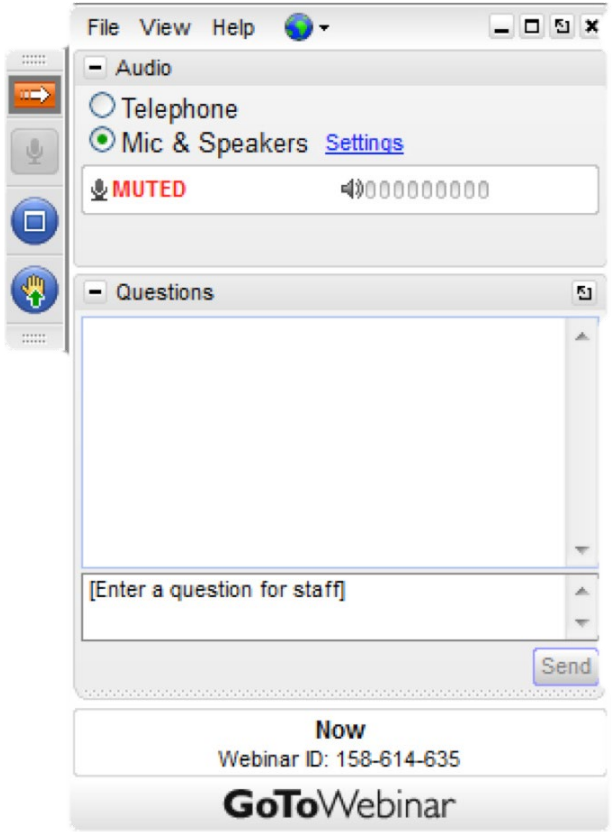

AMCP Partnership Forums

Collaboration for Optimization

The live, hands-on AMCP Partnership Forums bring key decision makers in managed care, integrated care, the pharmaceutical industry, and others together to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes in integrated care and managed care.

Partnership Forums…

- Proactive, collaborative approach
- Provide a voice
- Gain consensus and remove barriers
- Stakeholders work together on common goals and interests
- Have high visibility
- Find common ground and actionable results

2019 Forum Topics

1

Pharmacy and Therapeutics (P&T) Practices: What's Next?

It has been nearly 20 years since AMCP and other stakeholders adopted the Principles for a Sound Formulary System. Since that time, requirements for pharmacy and therapeutics committees (P&T) have been adopted by the Medicare Part D program, health insurance marketplace plans, commercial health plans, Medicaid programs, and other public payers. Changes and evolution in the health care system, including a focus on value-based care, suggest the need for updated recommendations from a broad stakeholder coalition. This Forum will provide a venue to consider P&T practices that reflect the current health care system and provide recommendations to allow for a transparent P&T process in today's health care system.

2

Optimizing Prior Authorization for Appropriate Medication Selection

We will examine how to improve decision making for prior authorization and step therapy based on current market dynamics and considerations to ensure patients receive the most appropriate medications. The forum will develop multi-stakeholder recommendations including: the impact of PA on patient outcomes, the return on investment for technology adoption, and ways to ensure good outcomes through policy and activities by the health care system.

3

What's Next in Managing Risk for Specialty Medications

Current inefficiencies in the health care system create administrative burdens for patients, providers, and payers, and often result in additional unnecessary costs. As a result, the government and private sectors are examining new reimbursement and benefit designs to pay for medications, including re-examining the Medicare Part B and Medicaid programs. Before implementing major changes, however, stakeholders must carefully analyze the potential impact these reforms will have on patient care, access to medications, 340B, and the overall health care system. This forum will make recommendations and considerations for ways that benefit design and reimbursement may evolve without compromising patient access and care.

4

Digital Therapies: What are they and Where do they fit in Pharmacy and Medical Benefits?

Digital therapies with web and designed based applications are emerging as a means to treat conditions by engaging people to improve health and wellness. In some cases, these therapies are preventive to stop a disease or improve outcomes in certain chronic conditions including cancer, diabetes, and heart disease. Other areas for digital therapies have emerged for birth control and to manage opioid addiction. They typically focus on ways to modify a person's environment or behavior to increase patient engagement, improve adherence to medications and possibly reduce hospitalizations or prevent other expensive health interventions. But where do these fit in terms of a pharmacy or a medical benefit for insurance coverage? This partnership forum will consider these important emerging issues to provide recommendations to inform this growing area.

2020 Partnership Forums

1. Helping Patients Anticipate and Manage Drug Costs

2. Preparing for and Managing Rare Diseases

3. Biosimilars: Policy, Practice, and Post Marketing Surveillance to Support Treatment and Coverage Decisions

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Assistant Director, Strategic Market Access and Intelligence
Xcenda

Agenda

- Background
- Forum findings and recommendations
- Next steps and action items
- Q&A

Digital Therapeutics (DTx)

What are they and where do they fit into pharmacy and medical benefits?

Forum Objectives

- Describe digital therapeutics (DTx) 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.
- Outline how payers/managed care organizations may leverage digital therapeutics for value-based care and patient engagement.

Questions and Challenges Facing Stakeholders

Innovators	• Will the business model be accretive to our net margin? • What is the right way to innovate? • How can we transform ourselves to make DTx fit in our organization?
Clinicians	• What DTx are actually therapeutically valuable and how to do I get my patients' access? • How do I stay on top of the therapies that matter? • What will be required of me and my staff?
Payers	• What is the true benefit of the DTx? How can it be proven to add value? • How can we enable the category to lower costs?
Patients	• What has real therapeutic value? • How can I get access and what is the best product? • Will it be safe and effective?
Regulators	• How do we judge quality of technology that is rapidly changing and developed in an agile way?

Digital Therapeutics (DTx)

What are they and where do they fit into pharmacy and medical benefits?

Key Deliverables

- A common understanding of digital therapeutics.
- An outline of the types of evidence payers want from digital therapeutics manufacturers.
- An outline of reimbursement arrangements key stakeholders want with digital therapeutics manufacturers.
- Discuss how digital therapeutics can be integrated into formularies and/or guidelines.
- Additional resources around digital therapeutics.

Why It's Important to Define DTx

Clarifying the Category for Stakeholders

- Differentiates applications with therapeutic value from hundreds of thousands of health and wellness offerings
- Supports payers' planning process for evidence reviews and coverage determinations
- Narrows the number of different options that providers should be aware of
- Clarifies the category for investors, helping quickly define the potential business models, benefits, and challenges for valuation and management
- Defines the barrier to entry between real DTx solutions and "me toos"

Challenges and Opportunities

The Health Care System

- How do DTx differ from existing digital health products?
- What role do DTx play in managing a medical condition; preventing a disorder or disease; optimizing medication use; or treating a disease or disorder?
- What are the evidentiary standards needed for third party payer coverage of digital therapeutics?
- What types of reimbursement and contracting arrangements are appropriate?
- Where do they fit in pharmacy and medical benefits?

Common Definitions of DTx

"Digital therapeutics are evidence-based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease"

– Digital Therapeutics Alliance (2018)

"I would consider digital medicine as something that mimics the same fundamental qualities of drugs, and therefore has the ability to be an industry that can scale to challenge large sections of the pharma industry"

– Peter Hames, CEO, Big Health, Interview with McKinsey (2018)

A digital therapeutic is an intervention based on software as the key ingredient, which has direct impact on a disease. This is what distinguishes this category from the broader term digital health"

– Jorg Land, CEO, Sonormed, Interview with McKinsey, (2018)

"The idea of digital therapeutics or digital medicine is using software experiences to actually get a clinical outcome – a measurable clinical outcome"

– Sean Duffy, CEO, Omada Health at Differential Medicine Conference (2015)

"…digital therapeutics are software products used in the treatment of medical conditions"

– Deloitte, "Digital therapeutics: Improving patient outcomes through convergence" (2019)

"The definition [of digital therapeutics] might include the following requirements:

- Completion of a number of studies among the target population, conducted by independent principal investigators and replicated at multiple sites and/or with different investigators, with trial results (including clinically meaningful outcomes) published in a peer-reviewed journal
- One or more multi-center, randomized, controlled trials
- Ongoing clinical research in the target population involving collection and analysis of real-world evidence to assess safety and effectiveness."

– McKinsey, "Digital Therapeutics: Preparing for takeoff" (2018)

Characteristics of DTx

- Software that delivers a clinical mechanism-of-action, either alone or in combination with other standard-of-care treatments, to improve outcomes
- As with other treatments (e.g., small molecule drugs, biologics, devices), stakeholders expect
  - Appropriate clinical evidence of safety and efficacy
  - Good manufacturing practices

Distinguishing DTx

From Digital Health Products

Demonstrated impact on measurable clinical outcomes

Digital companions → **Replacement therapies**

	Drug + solutions		Pure "replace the pill" digital solutions	
	Drug specific	**Drug agnostic**	**Behavior modifying**	**Physiology modifying**
Description	Drug specific digital solutions	Digital solution that can be used with multiple drugs; not tied to specific drug	Pure digital interventions that lead to patient behaviour modification	Pure digital interventions that impact the underlying physio-logical response of the patient
How they improve outcome	• Adherence tracking • Disease monitoring • Dose optimization	Digital solution that can be used with multiple drugs; not tied to specific drug	Pure digital interventions that lead to patient behavior modification	Pure digital interventions that impact the underlying physiological response of the patient
Business Model	• Primarily B2B	• B2B2C • Some B2C (in US)	• B2C (in US) • Some B2B2C	• B2C (in US) • Some B2B2C

Digital therapeutic solution can also be classified based on Modalities – Semi- interactive (e.g., questionnaires) vs fully interactive (e.g., video game) or text based (e.g., questionnaire) vs multimedia based (e.g., sound based)

Solutions Along the Patient Journey





Focus areas to improve care along the patient journey

Outpatient	**Inpatient**	**Prescription** medication	Home **health**	**New** modalities
• Moving PCP visits to virtual modalities • Reducing price dispersion • Care avoidance from personal health/self-diagnostic tools	• Reduction of re-admissions • Reducing price dispersion • Reducing expensive ER visits	• Reducing price dispersion	• Reducing unit cost of home care through virtualization and tele-health	• Increase in revenue from virtual visits • Percent of value created captured by digital solutions (assumed 10%)

Opportunity for digital therapeutics

• Self-service • Remote patient engagement	• Financial transparency through better tracking of outcomes	• Clinical transparency into use and adherence	• Quantified self wellness • Treatment adherence • Health monitoring and coaching • Social connectivity • Wearables	• Virtual access tools • Remote care

Solutions that are *Not* DTx

Category	Description	Delivery	Examples
Mobile Health (mHealth)	mHealth is the practice of medicine and public health supported by mobile devices.	Software via a mobile device	• Clinician-facing: Mobile Medical Applications - an extension of a medical device, or displaying, storing, analyzing or transmitting patient-specific medical device data. • Consumer-facing: Lifestyle, fitness tracker, nutrition, medication adherence apps
Health Information Technology	Health information technology (HIT) is information technology applied to health and health care. It supports health information management across computerized systems and the secure exchange of health information between consumers, providers, payers, and quality monitors.	Software or platform	• Electronic medical record systems • Electronic prescribing system • Consumer health interface (e.g. MyChart)
Devices, Sensors, Wearables*	Devices that can be worn attached on human skin, or injested, to continuously and closely monitor an individual's activities, without interrupting or limiting the user's motions. These devices are supported by embedded technology for data communication and sensors to interact with both internal and external objects and the environment.	Hardware and software	• Wearable and wireless devices, • Biometric sensors • Diagnostic products • Proprietary algorithms that control the function of physical devices, such as insulin pumps.
Telehealth	The provision of health care remotely by means of telecommunications technology.	Software or platform	• Telehealth platform • Telemedicine platform

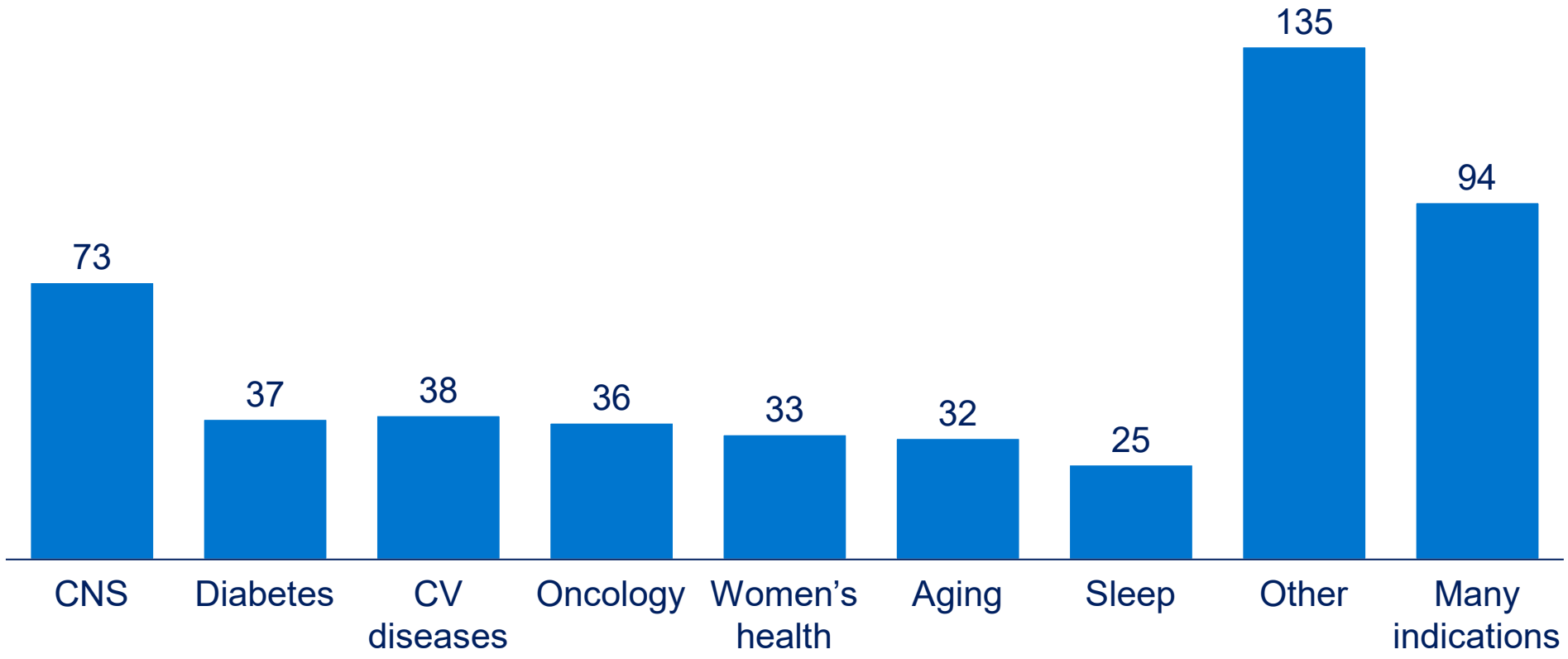
Targets for DTx

Characteristics of Therapeutic Areas

- Chronic conditions needing frequent, high-touch therapeutic interventions
- Diseases without existing treatments or treatments with elevated risk of side-effects (unmet medical needs)
- Complex diseases and diseases for which existing treatments can be enhanced with software
- Benefits from increased interaction with health care providers beyond what is currently practical within the existing health care paradigm
- Low levels of patient adherence that have important implications for patient outcomes
- Benefits from tracking patient data in order to modify or tailor therapy; enable a treat-monitor-treat loop
- Gaps in available therapeutic options
- Diseases associated with stigma that may impact patient willingness to interact with health care providers

Digital Therapeutics Areas of Focus

The adherence segment is targeting chronic diseases where patient engagement is impactful.
The "replace the pill" segment is targeting neurology and psychological disorders.



While most digital therapeutics are focused on specific therapeutic areas some have chosen to be agnostic.

SOURCE: Rock Health Q2 2018

Evidence Requirements

- Will likely be tiered based on medical claim or function
- Should align with standards for clinical evidence
- Evidence of safety and efficacy based on
  - Standardized endpoints for the disease area
  - Appropriate patient population
  - Clinical trials conducted using good clinical practices
- Clinical evidence must be evaluated by appropriate health authorities (e.g., FDA) and receive market authorization (e.g., clearance, approval) with a regulatory label

Regulatory Pathways — United States

- In its infancy and must be tailored for the unique nature of these treatments
- 21st Century Cures Act of 2016 allows some DTx to be approved through the 510(k) pathway
  - Demonstrate that the product is at least as safe and effective as a marketed device
  - Some products have already been approved this way
- De Novo and New Drug Applications (e.g. 505b2 combination products)
- Precertification framework in development

Payer Evaluations

- Understanding value when making coverage determinations. Taking steps to validate products, support reimbursement and widespread adoption
  - Address gaps in care
  - Patient acceptance of the DTx, patient reported outcomes
  - Real-world evidence
  - Logistical issues
- NICE Evidence Standards Framework for Digital Health Technologies is made up of:
  - Effectiveness standards
  - Economic impact standards
- PBMs are further along in establishing digital formularies

https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

Shyra Bias, PharmD Candidate, 2021, Assessing Barriers to Inclusion of Digital Therapeutics on Formulary: A Cross-Sectional Study Across Health Plans, PBMs, and IDNs. Poster presented at AMCP Nexus 2019

Survey Results: Assessing Barriers to Inclusion of Digital Therapeutics on Formulary

A Cross-Sectional Study Across Health Plans, PBMs, and IDNs

What type of evidence would be required for the decision-making process of DTx?

ANSWER CHOICES	RESPONSES	
Disease state classification provided along with tier guidance	41.43%	29
Real world evidence/observational studies	78.57%	55
Randomized controlled trials	64.29%	45
Relevance to current care pathways	68.57%	48
Detailed adverse events/side effect profile	30.00%	21
Information on drug/DTx interactions	25.71%	18
Return on investment (ROI) evaluation	80.00%	56
FDA approval	45.71%	32
Other (please specify)	5.71%	4
Total Respondents: 70	A multiple choice, mixed qualitative-quantitative web-based survey (8/15/19 to 9/3/19)	

Shyra Bias, PharmD Candidate, 2021, Assessing Barriers to Inclusion of Digital Therapeutics on Formulary: A Cross-Sectional Study Across Health Plans, PBMs, and IDNs. Poster presented at AMCP Nexus 2019

Types of Evidence Desired

	Observations and Desired Details
Information security	• Compliance with HIPAA data security requirements.
Usability	• Is there a level of health/digital literacy that is required to receive benefit from the DTx? • Does the DTx operate as intended? • Do all components of the software function as designed?

Types of Evidence Desired

	Observations and Desired Details
Clinical effectiveness	• Pre-market: Must demonstrate safety and efficacy using standard endpoints prior to market authorization by regulatory authority • What impact does the DTx have on clinically accepted, standard endpoints for the disease based on a measurable set of data? • What is a clinically meaningful benefit/result? • How do outcomes in the real world compare with that used for regulatory approval? • What is the impact on patient satisfaction and quality of life? • Level of evidence (e.g., RCT) will depend on the health condition/medical claim

Types of Evidence Desired

	Observations and Desired Details
Engagement (adherence)	• Do patients use the DTx as intended in the real world? • What “dosage” (level of sustained use over time) is required to achieve desired outcomes? • Patient-reported outcomes on use and experience, human factor studies, patient insights • Patient acceptance of the user interface/satisfaction of using the therapeutic • Potential for product updates to alter the user interface and impact engagement

Types of Evidence Desired

	Observations and Desired Details
Safety	• What are the adverse events in clinical trials? • What are adverse events in real-world use? • How do adverse events compare to standard-of-care? • What is the potential for harm? • For example, what is the impact if the patient discontinues another therapy as a result of using the DTx?

Types of Evidence Desired

	Observations and Desired Details
Comparative effectiveness	• How does the DTx compare with other available treatments for the condition? • The level of rigor required will depend on the potential for harm, availability of other therapies, and whether the DTx is considered an adjunct or a replacement (i.e., a stand-alone treatment).

Types of Evidence Desired

	Observations and Desired Details
Cost impact	• Can cost avoidance be demonstrated? • How does the DTx impact total cost of care?
Data access	• Who owns the data? • Who has access to the data? • How is the data used?
Ongoing evaluations	• How will product updates be assessed to provide ongoing assurances of efficacy, safety, and usability?

Benefit Coverage Options

- Novel digital benefit
  - Potential for further system fragmentation and silos
- Incorporate within existing benefit structures
  - Medical benefit and/or pharmacy benefit
- Legislative changes needed for Medicare and Medicaid coverage

Considerations Pharmacy Benefit

- Ability to apply managed care tools, such as a formulary, to support cost-effective care
- Allows use of utilization management structures, such as clinical guidelines and step therapy protocols
- Standard product identifiers for medication products could be applied to DTx to allow coding in pharmacy benefit systems
- Ability to apply value-based contracting

Considerations for Integration in Health Care Delivery

- Channels for patients to access the products
  - Prescription and nonprescription channels; multiple potential platforms for distribution
- Roles of health care providers in optimizing the use of DTx
- Determining how data generated by DTx are managed
  - Capture, integration with existing EHR, and storage
  - Cybersecurity, HIPAA, patient privacy
- Integration of DTx in clinical practice guidelines for various therapeutic areas

Pharmacist Roles Supporting DTx

- Pharmacists' skills can be applied to support use of DTx
- Managed care pharmacists
  - Objectively apprise, evaluate, and select products
  - Utilize patient information to optimize DTx use
- Community pharmacists
  - Recommend DTx
  - Monitor results
  - Counsel and educate patients based on patient's health literacy level
  - Explore coverage options

Recommendations for Advancing DTx Integration

- Expanded educational activities for health care providers
  - Details about DTx products and how to integrate them in practice
- Education for pharmacists to understand, manage, and deploy DTx for appropriate patients
- Integration in clinical practice guidelines to support uptake in practice

Recommendations for Stakeholders

- Develop compendia that list DTx that have received regulatory approval
- Create authoritative resources to inform formulary and coverage determinations
- Implement frameworks of evidentiary standards
- Support ongoing efforts to create effective systems and infrastructures

Summary

- Distinguished from other digital health products based clinical evidence to support a claim
- Require specific sets of high-quality evidence to guide decision making
- A possible new paradigm for reimbursement
  - May be covered by pharmacy and medical benefits.
- Pharmacists are well-positioned to support patients
- Ongoing efforts are needed to provide stakeholder education and to support the development of infrastructures and processes
- Expect to see continued growth in the DTx pipeline

Additional Resources

PROCEEDINGS

AMCP Partnership Forum: Digital Therapeutics—What Are They and Where Do They Fit in Pharmacy and Medical Benefits?

SUMMARY

Digital therapeutics (DTx)—software that delivers a clinical mechanism of action, either alone or in combination with other standard-of-care treatments to improve outcomes—is an emerging class of therapeutic interventions that poses many questions for the health care system. To examine the systems and processes that will support the adoption and utilization of DTx, AMCP convened a multidisciplinary stakeholder forum September 17-18, 2019, in Alexandria, Virginia. The goals of the forum were to (a) define DTx and how managed care organizations evaluate their value; (b) identify where DTx fits within a covered benefit; (c) outline evidentiary standards needed for coverage of DTx; and (d) outline how payers and managed care organizations may leverage DTx for value-based care and patient engagement. Health care leaders representing academia, health plans, integrated delivery systems, DTx manufacturers and industry leaders, pharmaceutical manufacturers, pharmacy benefit managers, employers, federal government agencies, national health care provider organizations, and patient advocacy organizations participated in the forum.

Participants identified characteristics of DTx to develop a better understanding of the spectrum of solutions and how they are distinct from other digital health products, such as mobile health devices, monitoring, care coordination, or electronic health records. The evidence needed to evaluate DTx will likely be tiered based on its medical claim or function and should align with standards for clinical evidence. Clinical evidence must be evaluated by appropriate health authorities (e.g., the U.S. Food and Drug Administration) and receive market authorization (e.g., clearance, approval) with a regulatory label.

Various benefit coverage options were discussed. While some participants suggested that the unique features of DTx 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 outcomes supports integrating DTx within existing benefit structures. They noted that some DTx might be more appropriate for the medical benefit and others might be better aligned with the pharmacy benefit. Finally, many participants observed that, while additional DTx-specific education may be needed, pharmacists are trained to have the knowledge and skills that make them well suited to play a key role in guiding appropriate use of DTx.

J Manag Care Spec Pharm. [Published online March 16, 2020]

Digital therapeutics (DTx)—software that delivers a clinical mechanism of action, either alone or in combination with other standard-of-care treatments to improve outcomes—is an emerging class of therapeutic interventions that poses many questions for the health care system. DTx represents one segment of digital health products and can be distinguished from other products, such as mobile health (mHealth) products or wearable devices, specifically by their demonstrated impact on measurable clinical outcomes. DTx, either as standalone products or for use in conjunction with other treatments, is emerging as a novel treatment modality for a wide range of health conditions. Several have been approved by the U.S. Food and Drug Administration (FDA) for use by patients with various disease states including diabetes, asthma, depression, and substance use disorder. For example, reSET was approved by the FDA for the treatment of substance use disorder. DTx products have a spectrum of different potential functions, including modifying use of medications, modifying patient behavior independent of the use of a pharmaceutical product, and treating a medical condition or affecting the underlying physiological response of the patient. Many also have the capacity to provide data to health care providers.

Generally speaking, characteristics of therapeutic areas that are good targets for DTx include the following:

- Chronic conditions needing frequent, high-touch therapeutic interventions
- Diseases without existing treatments or treatments with elevated risk of side effects (unmet medical needs)
- Complex diseases and diseases for which existing treatments can be enhanced with software
- Diseases that could benefit from increased interaction, for example to support adherence or to track patient data to enable a treat-monitor-treat loop
- Diseases associated with stigma that may affect patient willingness to interact with health care providers

Providers and other stakeholders are using digital health technologies in their efforts to reduce inefficiencies, improve access, reduce costs, increase quality, and make medicine more personalized for patients.[1] DTx has the potential to transform the delivery of health care by allowing for remote patient engagement, better capture and tracking of outcomes, virtual health monitoring to inform treatment, and coaching.

Several market forces are supporting the development and use of DTx. For example, patients are increasingly using digital channels to engage with their health and health care providers, with a high level of patient and caregiver interest in smartphone apps that are designed to affect health. As the health care system increasingly focuses on value and outcomes, DTx allows providers to monitor and intervene with patients between visits and also allows for capturing and tracking data that can be used to evaluate outcomes.

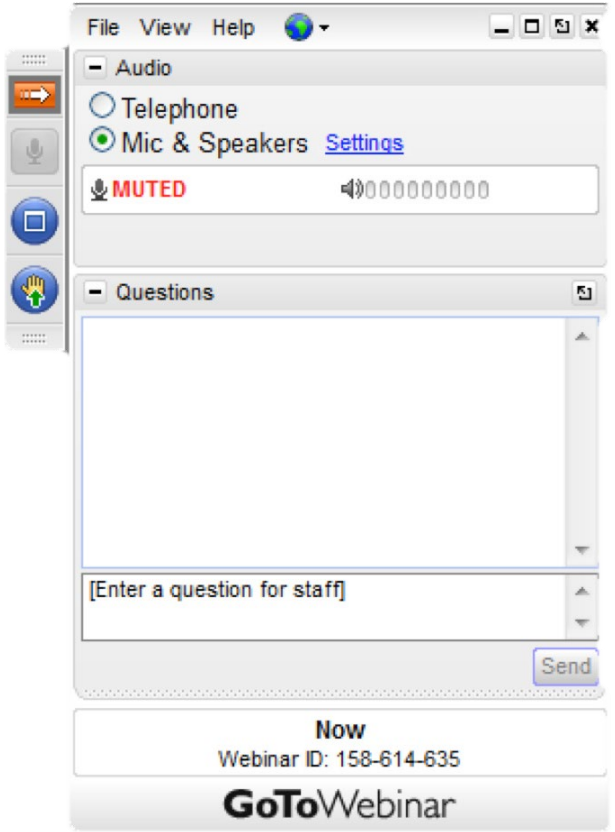
As this emerging product category develops, it poses many challenges and opportunities for the health care system. Adaptations of the existing infrastructures for the delivery of health care products and services will be needed to establish a framework that facilitates optimal utilization of DTx. How does DTx differ from existing digital products in the health care

Full proceedings are available now as *Express EPub Ahead of Print at:* https://www.jmcp.org/doi/full/10.18553/jmcp.2020.19418

DTx Product Fact Sheets

- Digital Therapeutics Alliance Fact Sheet
- Digital Health Industry Categorization

How to Ask Questions



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