AMCP Principles on Health Plan Coverage for Prescription Digital Therapeutics

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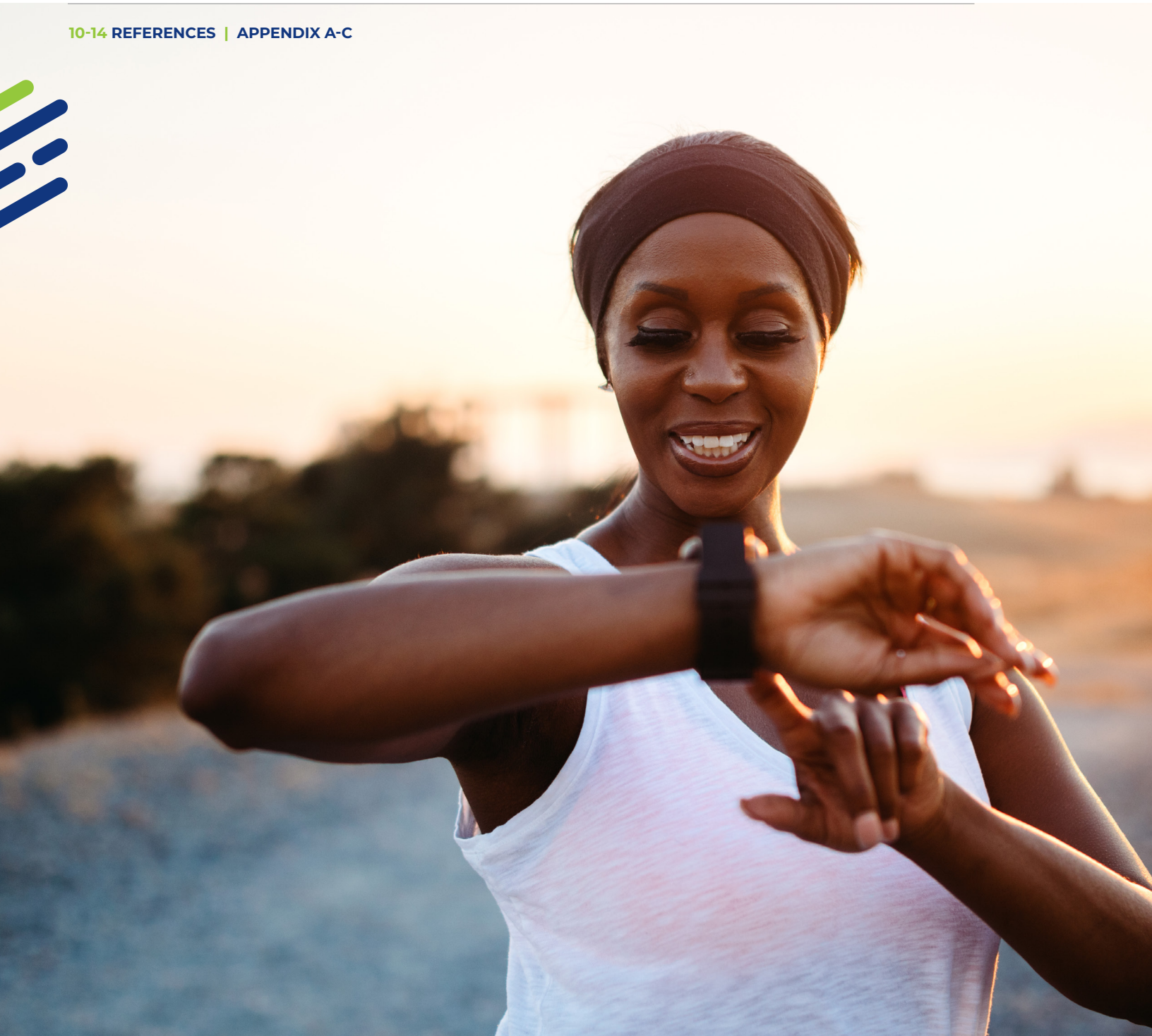
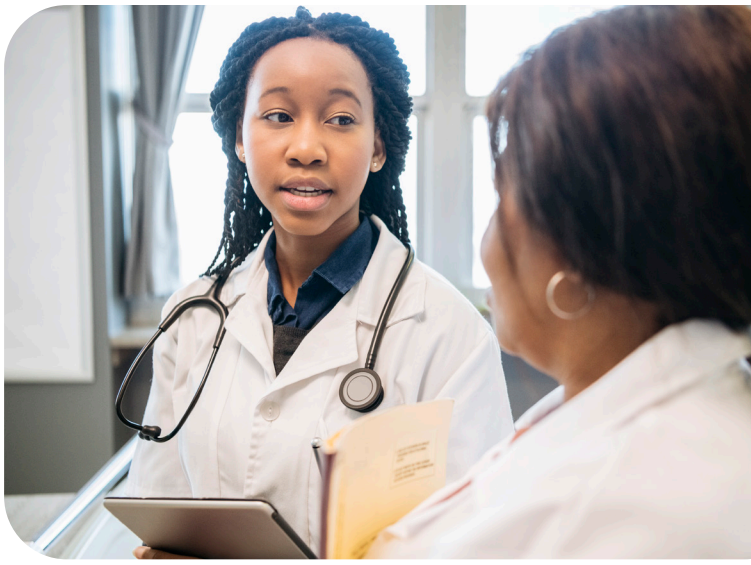
CONTENTS



BACKGROUND

Digital therapeutics (DTx) are defined as health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.[1] Digital health technologies (DHT) such as DTx offer innovative ways to deliver and receive health care. Some of the benefits associated with DTx are the potential for better patient engagement often leading to increased treatment adherence, improved provider monitoring outside of the clinic setting through access to data, and the ability to avoid the stigma associated with some conditions, especially mental health related conditions, for patients needing treatment.[2-4] These benefits, along with many other factors such as the increased adoption of smartphones and tablets, the need for remote care access during the pandemic, and advancements in artificial intelligence and virtual reality, have led to considerable growth in the DTx market.[5]

With some exceptions, DTx that meet the definition of a medical device in section 201(h) of the Federal Food Drug & Cosmetic Act, are regulated by the U.S. Food & Drug Administration (FDA).[6-9] These DTx are brought to market via one of the three medical device evaluation pathways: Premarket Approval, De Novo Classification Request, or Premarket Notification, also referred to as 510(k) clearance.[6-9] Prescription digital therapeutics (PDTs) are those DTx that have been determined by the FDA to require a prescription from a qualified health care professional.[6] Currently, PDTs are available for use in conditions such as attention-deficit/hyperactivity disorder, type 2 diabetes mellitus, nicotine dependence, substance use disorder, amblyopia, and others.[4,10]



While PDTs offer many opportunities, they also require special consideration, which presents coverage and reimbursement challenges. For example, as noted above, only certain DTx are evaluated by the FDA, and of those that are, only some specifically require a prescription.[6-9] They also possess unique features that must be evaluated, such as interoperability between products and existing data systems, ownership and security of the data they generate, and product lifecycle management.[11] Further, uncertainty exists regarding where they fit in the existing benefit category paradigm of medical, pharmacy, and durable medical equipment.[11]

At the direction of the AMCP Board of Directors, definitions and principles related to PDTs were developed with input from the AMCP Professional Practice Committee, AMCP Format for Formulary Submissions Committee, participants of AMCP's 2021 Digital Therapeutics Partnership Forum, and members of the AMCP Digital Therapeutics Advisory Group. These principles address unique aspects of PDTs to support the coverage decision-making process. Additionally, they provide digital health innovators information regarding the needs of decision-makers to appropriately evaluate these products for safety and efficacy.

PRINCIPLES

PRINCIPLE 1: PDTs provide new treatment options and have the potential to close gaps among underserved populations, reduce health care costs, and improve health.

Rationale – PDTs offer innovative ways to deliver and receive health care offering the potential to close gaps like poor access among underserved populations, as well as reduce health care costs, and improve patient health. However, they must be deployed thoughtfully, to avoid exacerbating health inequities.

Commentary – In a study conducted by the Morehouse School of Medicine to assess adoption of DHTs among a cohort of prescribers during the height of the pandemic, the authors highlighted several ways in which these technologies could promote health equity.[12] Among these were convenience and improved access for patients; reduced need to take time off work, secure child and elder care, and find transportation; improved patient engagement through patient portal use; new models for low-acuity care and chronic disease management; enhanced reporting capabilities; and standardized, systematic data collection for health surveillance and interventions. In the same study, prescribers reported their top reasons for implementing DHTs were for ease of workflow integration, to meet patient need, and to improve patient health.[12]

Despite these findings, however, the authors caution that, "…**many individuals and communities still experience inequitable access to DHTs due to many factors, including limited broadband access, challenges related to health and technology literacy, and lack of culturally and linguistically appropriate design and implementation.**"[12] This was echoed in a report commissioned by the U.S. Department of Veterans Affairs on the intersection of digital health and equity.[13] The report focused on four pillars of digital health equity: 1) empowerment and access, 2) accountability and justice, 3) community and leadership, and 4) metrics, which describes the production, collection and sharing of data within the digital health environment. Recommended actions related to these pillars included further research to quantify the impacts of improvements in digital health equity on social determinants of health; increase diversity and representation of underserved populations in positions of decision-making; inclusion of underserved groups and respective community leaders in the technology design phase; and update current policies, standards, and guidelines to improve infrastructure and access, protect medically underserved populations, and enforce greater accountability.[13]

PRINCIPLE 2: FDA clearance, or market approval is required before evaluating a PDT product for coverage and reimbursement.

Rationale – FDA clearance or market approval of a PDT, as it does with a medication, provides a foundation from which payers can further evaluate its safety and efficacy, as well as other product aspects.

Commentary – FDA's process for clearance or premarket approval of a PDT differs from the agency's process for approval of prescription drugs. FDA review and approval are required before any brand or generic drug can be marketed in the U.S. to ensure the drug provides benefits that outweigh its known and potential risks for the intended population. For new drugs, double-blind, randomized, placebo-controlled clinical trials are the gold standard for approval, and the full research, development, and approval process can take as long as 12 to 15 years.

Approval for marketing of PDTs and medical devices can take place via one of three pathways based on risk classification: Premarket Approval, de novo classification, or the 510(k) clearance pathway. According to FDA, "oversight of devices is risk-based, which means that the level of regulatory controls necessary to demonstrate a reasonable assurance of safety and effectiveness is typically matched to the level of risk of the device."[9] Devices designated Class I have the lowest risk and either receive market clearance through the 510(k) pathway or are deemed 510(k) exempt. Those designated Class II have moderate risk and either receive 510(k) clearance or exemption. For 510(k) clearance, the submitter must demonstrate that their device is substantially equivalent to a legally marketed device. This includes submitting information to FDA that demonstrates the device is as safe and effective as the legally marketed device.

Class III devices are those determined to have the highest risk of injury or illness, used in sustaining or supporting life, or have considerable significance in preventing the impairment of human health. Class III devices are required to receive approval via the Premarket Approval pathway, which is the most rigorous for medical devices. The standard in this type of review relies on an independent demonstration of the device's safety and effectiveness.[9] Most premarket approval submissions require some level of human clinical data through a clinical trial. The de novo classification process allows device "types" that have never been marketed in the U.S., but whose safety profile and technology are reasonably well understood to be classified as Class I or II.

Additionally, the FDA provides industry guidance for the clinical evaluation of software as a medical device (SAMD), which is discussed in principle 8 commentary.

For new drugs, double-blind, randomized, placebo-controlled clinical trials are the gold standard for approval, and the full research, development, and approval process can take as long as 12 to 15 years.

PRINCIPLE 3: Coverage and reimbursement pathways for PDTs should be available for both public and private payment programs.

Rationale – Private payers may elect to cover PDTs and other digital health technologies; however, these products do not fit into one of the currently defined benefit categories for Medicare or Medicaid programs. This leaves their beneficiaries, which include some of the most vulnerable individuals, without access to the potential benefits of PDTs.

Commentary – All payment programs require necessary elements to facilitate coverage and reimbursement. For instance, the use of standard pharmacy product identifiers (e.g., National Drug Code numbers, National Council for Prescription Drug Programs compatible codes, or Unique Device Identifiers) allows coding of PDTs within existing payment systems.[14] Additionally, to realize this principle for public payment programs specifically, statutory changes are required to redefine the Medicare and Medicaid benefit categories. Therefore, AMCP supports the Access to Prescription Digital Therapeutics Act of 2023 (S. 723/H.R. 1458), which will add PDTs to the list of services and products eligible for coverage under Medicare and Medicaid, as well as direct the Centers for Medicare & Medicaid Services to establish payment methodologies and product-specific Healthcare Common Procedure Coding System (HCPCS) codes if appropriate.[15,16] AMCP advocates for the creation of a pathway for coverage within Medicare and Medicaid; however, AMCP maintains that payers must have the flexibility to make coverage decisions following the principles employed for medications and outlined within this document. Therefore, if PDTs are to be covered under the Medicare Part D benefit, PDTs should not be classified as a collective therapeutic category based on modality nor should an individual PDT be classified as its own category.

PRINCIPLE 4: Payers should evaluate PDTs using an evidence-based approach that leverages managed care tools, such as formularies and prior authorizations.

Rationale – The best management of PDTs will be achieved by evaluating them within existing utilization management processes. This allows leveraging of managed care tools such as formularies and prior authorizations, which encourage the use of safe, effective, and affordable therapies in appropriate patient populations.[17]

Commentary – Best practice utilization management processes involve evaluation by a committee of experts, which includes reviewing relevant clinical evidence.[18,19] This expert, evidence-based evaluation is the foundation of a sound drug formulary system into which PDTs should be integrated.[18,19] A sound drug formulary system is also an ongoing process in which re-evaluation of products should regularly occur; PDTs, therefore, should also be re-evaluated as appropriate.[11,19] Coverage decision-makers would benefit from specific guidance on what should necessitate evaluation for PDTs.[11]

For additional related commentary, see principles 5 and 6.

PRINCIPLE 5: The P&T Committee or similar body (e.g., Medical Technology Assessment Committee) is the most appropriate body to review PDTs for safety and efficacy.

Rationale – P&T Committees are responsible for developing, managing, updating, and administering the drug formulary system and making decisions based on scientific and economic considerations that achieve appropriate, safe, and cost-effective drug therapy.[17,18] Therefore, as this is already their role, the P&T Committee may be the most appropriate body to review PDTs.

Commentary – P&T Committees are comprised of practicing primary care and specialty physicians, pharmacists, and other health care professionals with the clinical expertise to evaluate a wide variety of drug therapies and other health technologies for the purposes of formulary system management.[18,19] Similarly composed Medical Technology Assessment Committees also are sometimes employed to make coverage decisions regarding devices and other therapies covered under the medical benefit. Because PDTs may be used in place of, or in conjunction with, traditional drug therapies, the P&T Committee or Medical Technology Assessment Committee is uniquely qualified to evaluate PDTs.[10,20] If additional expertise is required for evaluation of privacy and data security specifications for PDTs, P&T Committees should seek external input as they currently do for specialized topics (e.g. oncology).[18,20] This additional expertise may come from, for example, individual data information technology/security experts, a DTx subcommittee, or a separate group such as an innovation center.[18,20]

Because PDTs may be used in place of, or in conjunction with, traditional drug therapies, the P&T Committee or Medical Technology Assessment Committee is uniquely qualified to evaluate PDTs.

PRINCIPLE 6: The P&T Committee or equivalent body has the necessary expertise to recommend coverage policies for PDTs.

Rationale – As part of managing the drug formulary system, P&T Committees also design and implement formulary system policies on utilization and access to medications.[17,18] Therefore, as this is already their role, the P&T Committee may be the most appropriate body to recommend coverage policies for PDTs.

Commentary – In their current capacity, P&T Committees evaluate a wide variety of drug therapies and other health technologies using evidence such as clinical trials, real-world studies, and treatment guidelines.[18,19] This evaluation aids in ensuring covered treatments are safe and effective and determining their appropriate treatment population, which may require specific criteria for coverage to encourage best use.[18,19] Because, as stated previously, PDTs are utilized similarly to other traditional drug therapies, the P&T Committee is also uniquely qualified to recommend criteria for coverage of PDTs as well.[10,20]

PRINCIPLE 7: PDTs should be integrated into clinical guidelines and care management protocols to determine and guide optimal utilization.

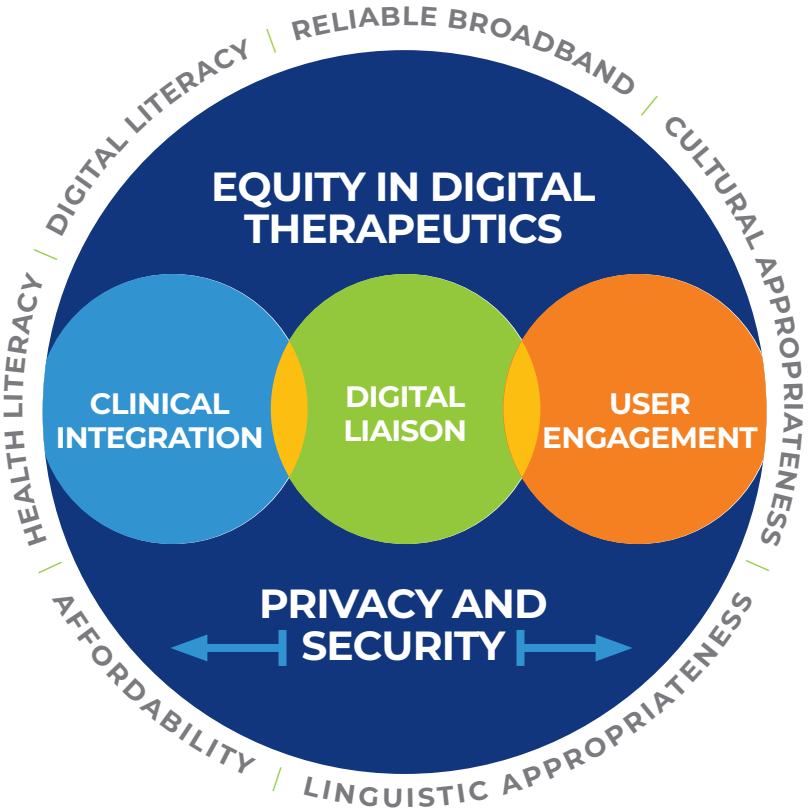
Rationale – It is important for PDTs to be integrated into both clinical guidelines and care management protocols when there is sufficient evidence to support their role in the treatment of a health condition. Clinical guidelines provide necessary information for health care professionals regarding a treatment's place in therapy; additionally, care management protocols can help to ensure this information is appropriately considered in individual patient care.

Commentary – While clinical integration of PDTs takes time, advancements have been made in some therapeutic areas. The Substance Abuse and Mental Health Services Administration (SAMHSA), for instance, provides considerations to assist in realizing greater clinical integration of DTx.[4] These considerations are training mechanisms to ensure providers and care staff are informed, engaged, and supported; ease of integration and exchange of data in interoperable formats from DTx to electronic health records (EHR); communication between patients and providers to determine whether use of digital health interventions is appropriate; and having a digital liaison or designated staff person to oversee all aspects of digital health interventions.[4]

Irritable bowel syndrome (IBS) is another such area. Brain-gut behavior therapy (BGBT) is included in current IBS treatment guidelines; however, its adoption has been limited by cost, therapist availability, patient comprehension of the treatments themselves, patient time investment, and social stigma.[21] DTx may offer solutions to these barriers and there is emerging evidence that they are an effective alternative to in-person BGBT.[21]

PRINCIPLE 8: PDT developers should generate evidence demonstrating the clinical, economic, and patient impact of a product, including its benefits and risks, and should share this evidence with payers.

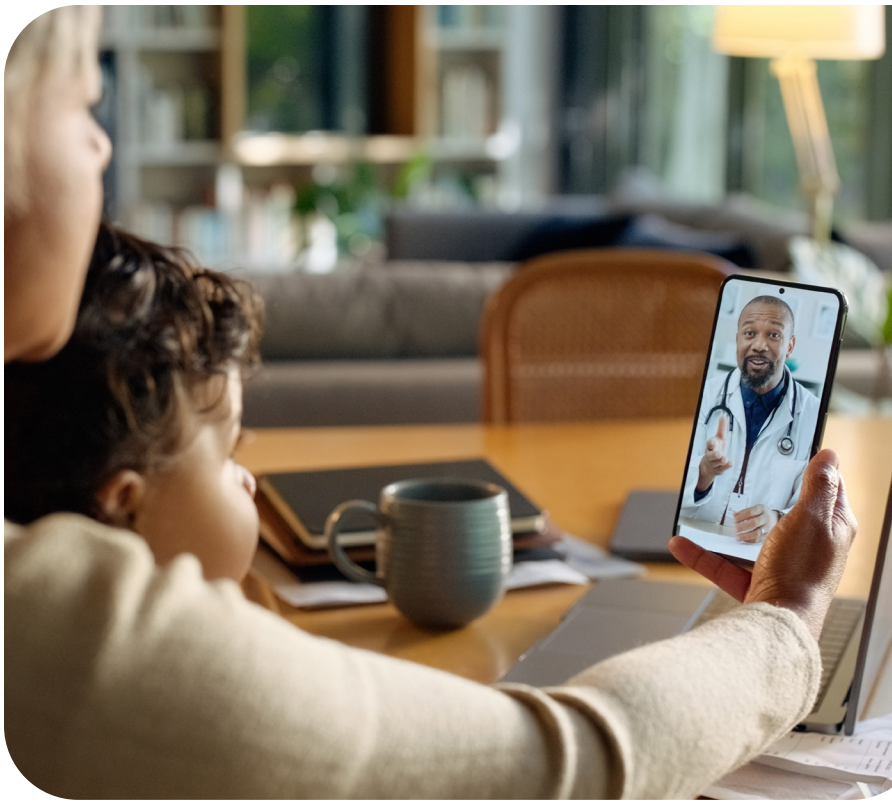
Rationale – The FDA provides industry guidance for the clinical evaluation of SAMD based on principles developed by the International Medical Device Regulators Forum (IMDRF).[22] This and other important DTx product characteristics should be shared with payers as described in the AMCP Format for Formulary Submissions 5.0 (Format 5.0).[20]



Source: The Substance Abuse and Mental Health Services Administration (SAMHSA)

Commentary – While the regulatory oversight of SAMD continues to evolve, the FDA relies on the IMDRF principles in its current approach.[22,23] In these principles, clinical evaluation of SAMD should involve validation of the clinical association between the SAMD ouput and the targeted condition; analytical validation to ensure correct processing of input data to generate accurate, reliable and precise output data; and clinical validation to demonstrate the output data achieves the intended purpose in the target population.[23] IMDRF further states that, "[c]linical evaluation should be an iterative and continuous process as part of the quality management system for medical devices."[23]

Following the integration of DTx into the Format 5.0, communication of their clinical evidence and supplemental information to payers and other stakeholders has been standardized.[20] As it does with other types of products, this aids in the evaluation of benefit/risk profile, alternative options, and place in therapy of DTx products. For example, the Format 5.0 lists three approaches for compiling a DTx dossier based on the intended uses: 1) DTx as a stand-alone therapy, 2) DTx used with other therapies, or 3) DTx co-developed or intended to be used with a specific pharmaceutical product. Format 5.0 also provides topics for which additional information may apply or be needed, such as available formats and versions, instructions for use and intended care setting, real-world evidence, and billing and reimbursement codes.[20] For the full list of topics for which additional information may apply or be needed, see Appendix C.



PRINCIPLE 9: PDT developers must demonstrate that products collect, store, and process user information in a safe, fair, and lawful way.

Rationale – A key function of many PDTs is to collect, store, and process patient data which may include protected health information (PHI); therefore, care must be taken to ensure this occurs in a safe, fair, and lawful way.

Commentary – Stakeholders must have sufficient information to trust that PDT patient data will be managed appropriately. In the Framework to Assist Stakeholders in Technology Evaluation for Recovery – or FASTER – developed by the Agency for Healthcare Research and Quality, clinicians are directed to ask several questions regarding the privacy and security of mental health apps.[4,24] These questions include whether the app meets national standards and regulations for PHI, such as those set by the Health Insurance Portability and Accountability Act and the Children's Online Privacy and Protection Act, and whether the app uses industry standards for secure interoperability if, for instance, it has the capability to send data to an EHR management system.[24]

Additionally, the Format 5.0 addresses key performance indicators for DTx privacy and security as

recommended by the AMCP Digital Therapeutics Advisory Group, which include cybersecurity, data quality, defects, device activation/user adherence, regression testing, releases, rollbacks, and services.[20] The Format 5.0 also provides direction to develop a privacy and data security appendix to contain information on certifications, antivirus software, data backup and recovery solutions, and parental restrictions for minors, for example.[20] For the full list of recommended elements for a privacy and data security appendix, see Appendix C.

PRINCIPLES 10: Significant PDT product updates should be communicated to providers, health care decision makers, and patients, focusing on the update type and whether the mechanism of action is anticipated to change.

Rationale – Developers may periodically release updated versions of PDTs to disseminate product improvements, not all of which will be clinically significant for patients. Updates that relate to clinical effectiveness, safety, or privacy, as examples, should be considered significant, and should be communicated to key stakeholders such as providers, health care decision makers, and patients.

Commentary – The Digital Therapeutics Alliance (DTA) provides a set of DTx Product Best Practices for each of their Industry Core Principles.[25] Among these principles is to apply product deployment, management, and maintenance best practices. To accomplish this, DTx developers should, for example, utilize an end user-focused approach for product deployment and ongoing maintenance; develop appropriate communication and technical support services to account for end user success; account for marketplace feedback, product performance data, product outcomes, and adverse events in ongoing product development efforts; and conduct ongoing risk analyses and mitigation efforts throughout the product lifecycle.[25]

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APPENDIX A: DEFINITIONS

Digital health – A term with a broad scope that includes categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine.[2]

Digital health technologies – Technologies that use computing platforms, connectivity, software, and sensors for health care and related uses.[2] These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products. They may also be used to develop or study medical products.[2]

Digital therapeutics (DTx) – Health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.[1]

Other definitions include:

Products designed to stand alone or work in combination with existing medications or treatments, helping patients prevent, treat, and/or manage their disease while ensuring optimal health outcomes from therapy.[10]

Products that deliver evidence-based therapeutic interventions that are driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.[10]

Prescription digital therapeutics (PDTs) – Digital therapeutics products that have been determined by the FDA to require a prescription from a qualified health care professional.[5]

In the Access to Prescription Digital Therapeutics Act of 2023, a prescription digital therapeutic is defined as a product, device, internet application, or other technology that (1) is cleared or approved under section 510(k), 513(f)(2), or 515 of the FD&C Act; (2) has a cleared or approved indication for the prevention, management, or treatment of a medical disease, condition, or disorder; (3) primarily uses software to achieve its intended result; and (4) is a device that is exempt from section 502(f)(1) of the FD&C Act under section 801.109 of title 21 of the Code of Federal Regulations (or any successor regulation).[13,14]

Software as a medical device (SAMD) – Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.[22]

APPENDIX B: LIST OF AMCP PRINCIPLES FOR PDTS

PRINCIPLE 1	PDTs provide new treatment options and have the potential to close gaps among underserved populations, reduce health care costs, and improve health.
PRINCIPLE 2	FDA clearance or market approval is required before evaluating a PDT for coverage and reimbursement.
PRINCIPLE 3	Coverage and reimbursement pathways for PDTs should be available for both public and private payment programs.
PRINCIPLE 4	Payers should evaluate PDTs using an evidence-based approach that leverages managed care tools, such as formularies and prior authorizations.
PRINCIPLE 5	The P&T Committee or similar body (e.g. Medical Technology Assessment Committee) is the most appropriate body to review PDTs for safety and efficacy.
PRINCIPLE 6	The P&T Committee or equivalent body has the necessary expertise to recommend coverage policies for PDTs.
PRINCIPLE 7	PDTs should be integrated into clinical guidelines and care management protocols to determine and guide optimal utilization.
PRINCIPLE 8	PDT developers should generate evidence demonstrating the clinical, economic, and patient impact of a product, including itsbenefits and risks, and should share this evidence with payers.
PRINCIPLE 9	PDT developers must demonstrate that products collect, store, and process user information in a safe, fair, and lawful way.
PRINCIPLE 10	Significant PDT product updates should be communicated to providers, health care decision makers, and patients, focusing on the update type and whether the mechanism of action is anticipated to change.

FDA=Food & Drug Administration; P&T=Pharmacy & Therapeutics; PDTs=prescriptions digital therapeutics

APPENDIX C: AMCP FORMAT FOR FORMULARY SUBMISSIONS 5.0 EXCERPTS ON DTX

TOPICS FOR WHICH ADDITIONAL INFORMATION MAY APPLY OR BE NEEDED
Functionality
Available format (e.g., app, computer program, website)
Compatibility (i.e., software and/or hardware necessary to utilize product)
Instructions for use and intended care setting
Place in therapy (i.e., is the product intended to be used with certain drugs or classes of drugs? Or could it be used as a stand-alone product?)
Available versions (e.g., different languages or formats)
Availability of technology assistance/support
Real-world evidence
Regulatory codes, classifications, and identifiers
Billing and reimbursement codes

ITEMS TO BE ADDRESSED IN A DTX PRIVACY AND DATA SECURITY APPENDIX
Certifications (e.g., SOC 2, HITRUST, PCI DSS, ITIL, ISO 27001, CIPP)
Data encryption: software supports SSL encryption
Antivirus software
Data protection security measures
Security information and event management solutions (SIEM), web application firewalls (WAF), SECOPS monitoring, managed security providers (MSSPs), security orchestration automation and response platforms (SOAR)
Data backup and recovery solutions
Details on where data are stored
Processes for secure disposal of information technology equipment and media
Intrusion detection systems (IDS) or intrusion prevention systems (IPS) used
Parental restrictions for minors
Data integrity
Cybersecurity
Data privacy processes
Multifactor authentication
Ransomware protection
Other hack prevention methods