Medical Policy Manual Medicine, Policy No. 175

Digital Therapeutic Products

Effective: January 1, 2025

Next Review: September 2025
Last Review: December 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Digital health products are technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes. A digital therapeutic product is a specific type of digital health product that is practitioner-prescribed software that delivers evidence-based therapeutic intervention directly to a patient to prevent, manage, or treat a medical disorder or disease.

MEDICAL POLICY CRITERIA

Note:

- Member contracts for covered services vary. Member contract language takes precedence over medical policy.
- This policy does not address:
  - Software that is used for the function or control of an FDA-cleared or approved stand-alone medical device (e.g., external insulin pump or pacemaker. See Cross References).
  - Applications operated by a health care practitioner for remote health monitoring.
  - Products not meeting the definition of a digital therapeutic (see Policy Guidelines).

- Products for which coverage is required by a particular health plan under state or federal law (see Policy Guidelines).

The following general Criteria are applied to digital therapeutic products not already addressed in any other Medical Policy (see Cross References).

I. The use of a digital therapeutic product in the treatment or prevention of any health condition is considered **medically necessary** when all of the following Criteria are met:
   A. The digital therapeutic product has been prescribed by a healthcare practitioner providing medical oversight; and
   B. The digital therapeutic product has been approved by the Food and Drug Administration (FDA) for the requested indication; and
   C. High-quality evidence demonstrates the digital therapeutic product improves clinically meaningful net health outcomes as much or more than an established alternative; and
   D. The improved net health outcome provided by the digital therapeutic product is attainable outside of investigational settings.

II. The use of a digital therapeutic product in the treatment or prevention of any health condition is considered **investigational** when Criterion I. is not met.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINE

When a digital health product is a software that delivers evidence-based therapeutic intervention to prevent, manage, or treat a medical disorder or disease, it may be considered as a digital therapeutic product. Digital therapeutics are distinguished from digital medicine and digital health products, such as mobile health products or wearable devices, in that clinical evidence of effectiveness and regulatory oversight are required for digital therapeutic products.[1, 2]

How Digital Therapeutics Differ From Digital Health, adapted from[1-4]

	Digital Health	Digital Medicine	Digital Therapeutics
Definition	Technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations.	Evidence-based software and/or hardware products that measure and/or intervene in the service of human health.	Delivers evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.

	Digital Health		
		Digital Medicine	
			Digital Therapeutics
Clinical Evidence Required?	NO	**YES**	**YES**
Real-World Outcomes required?	NO	NO	**YES**
Regulatory Oversight Required?	NO Do not meet the regulatory definition of a medical device.	VARIES **YES** if classified as medical device.	**YES** As required to support product claims of risk, efficacy, and intended use.

Health Resources and Services Administration Women's Preventive Services Guidelines (HRSA Guidelines) ensure women's access to the full range of FDA-approved contraceptive methods including, but not limited to barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a health care provider.[5]

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

1. Name and manufacturer of the digital therapeutic product
2. Indication for which the digital therapeutic product is being prescribed
3. Relevant billing codes
4. Brief description of how the digital therapeutic product will improve net health outcomes for the patient
5. Medical records related to this request, including but not limited to history and physical exam, conventional testing and outcomes, and treatment provided, if any.

CROSS REFERENCES

1. Insulin Infusion Pumps, Automated Insulin Delivery and Artificial Pancreas Device Systems, DME, Policy No. 77
2. Digital Therapeutic Products for Attention Deficit Hyperactivity Disorder, Medicine, Policy No. 175.01
3. Digital Therapeutic Products for Substance Use Disorders, Medicine, Policy No. 175.02
4. Digital Therapeutic Products for Chronic Low Back Pain, Medicine, Policy No. 175.03
5. Digital Therapeutic Products for Amblyopia, Medicine, Policy No. 175.04
6. Digital Therapeutic Products for Post-traumatic Stress Disorder and Panic Disorder, Medicine, Policy No. 175.05
7. Digital Therapeutic Products for Gait Modulation, Medicine, Policy No. 175.06

BACKGROUND

DIGITAL HEALTH

In 2020 alone, more than 90,000 new digital health applications, an average of more than 250 apps per day, were introduced, bringing the total number of digital health applications available to consumers to over 350,000. Among these applications almost half (47%) focus on the management of a specific disease or health condition.[3] Examples of digital health products currently available include applications that purport to perform cognitive behavior therapy, support weight loss goals, distinguish normal cardiac sinus rhythm and potentially dangerous arrhythmias, and to identify a suspicious mole. In addition, over 80% of adults in the United States own a smartphone.[6] The ability to utilize a personal mobile device, such as a smartphone, as a medical device has substantial potential to impact clinical care and to promote general health and wellness. However, despite the rapid influx of digital health products into the market, there remains no widely accepted framework for the evaluation of efficacy of these products. The use of a digital health product to prevent, manage, or treat a medical disorder or disease must be evaluated in the setting of existing evidence frameworks, as discussed below.

DEFINING DIGITAL THERAPEUTICS

The field of digital health is broad and rapidly changing. Digital therapeutic products fall under the umbrella term of digital health, however, digital therapeutic products are distinguished from digital medicine and digital health products in that clinical evidence of effectiveness and regulatory oversight are required for digital therapeutic products.[1]

The Academy of Managed Care Pharmacy (AMCP) published a review in 2020 which provides the definition of digital therapeutics as: software that delivers a clinical mechanism of action, either alone or in combination with other standard-of-care treatments to improve outcomes.[2]

This review also states, “Digital therapeutics represents one segment of digital health products and can be distinguished from other products, such as mobile health products or wearable devices, specifically by their demonstrated impact on measurable clinical outcomes.” The AMCP provides examples of products that do not meet the definition of a digital therapeutic product, as summarized in Table 1.

Table 1. Products Not Considered Digital Therapeutics[2]

Class	Description	Examples
Mobile Health	The practice of medicine and public health supported by mobile devices	• Clinician-facing: Apps that are for displaying, storing, analyzing, or transmitting patient-specific medical device data • Consumer-facing: Lifestyle, fitness tracking, nutrition, and medication adherence apps
Health Information Technology	• Information technology applied to health and health care • Supports health information management across computerized systems and the secure exchange of health information	• Electronic Medical records • Electronic prescribing systems • Consumer health interface (e.g., MyChart
Devices,	• Devices that can be worn,	• Wearable and wireless devices, (e.g.,

Class	Description	Examples
sensors, wearables	attached on skin, or ingested to continuously and closely monitor an individual's activities • Supported by embedded technology for data communication and sensors to interact with both internal and external objects and the environment	Fitbit, Apple Watch) • Biometric sensors • Diagnostic products • Proprietary algorithms that control the function of physical devices, such as insulin pumps
Telehealth	Provision of health care remotely	• Telemedicine, telehealth platforms

The World Health Organization has developed a classification system to define various types of digital health products.[7] While this system categorizes the different ways digital and mobile technologies are used to support health system needs, it does not provide a definition of therapeutic digital health products, specifically.

The Digital Therapeutics Alliance (DTA) is a global non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics.[1] The DTA provides the following definition of digital therapeutics:

> Digital therapeutics (DTx) 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.
>
> DTx products incorporate advanced technology best practices relating to design, clinical evaluation, usability, and data security. They are reviewed and cleared or certified by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use.
>
> DTx empower patients, clinicians, and payers with intelligent and accessible tools for addressing a wide range of conditions through high quality, safe, and effective data-driven interventions.

Table 2. How Digital Therapeutics Differ From Digital Health, *adapted from*[1-4]

	Digital Health		
		Digital Medicine	
			Digital Therapeutics
Definition	Technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations.	Evidence-based software and/or hardware products that measure and/or intervene in the service of human health.	Delivers evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.

	Digital Health		
		Digital Medicine	
			Digital Therapeutics
Clinical Evidence Required?	NO	**YES**	**YES**
Real-World Outcomes required?	NO	NO	**YES**
Regulatory Oversight Required?	NO Do not meet the regulatory definition of a medical device.	VARIES **YES** if classified as medical device.	**YES** As required to support product claims of risk, efficacy, and intended use.

REGULATORY STATUS

The US Food and Drug Administration (FDA) defines Software as a Medical Device (SaMD) as, "intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."[8]

The FDA notes the following regarding SaMD:

- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms
- "Without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose
- Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device
- SaMD may be used in combination (e.g., as a module) with other products including medical devices
- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software
- Mobile apps that meet the definition above are considered SaMD.

SaMD are reviewed by the FDA under existing 510(k) and DeNovo pathways established for the review of medical devices.

- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device.[9]
- The De Novo process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. De Novo classification is a risk-based classification process. Devices that are classified into class I or class II through a De Novo classification request (De Novo request) may be marketed and used as predicates for future premarket notification [510(k)] submissions.[10]

The Digital Health Center of Excellence (DHCoE) is a resource under the Center for Devices and Radiological Health (CDRH) of the FDA. The DHCoE mission is to complement advances in digital health technology by "providing services to digital health stakeholders to translate digital advances into tools that benefit consumers."[11] The DHCoE notes they support the following:

Empowering Stakeholders

The Digital Health Center of Excellence empowers digital health stakeholders to advance health care by fostering responsible and high-quality digital health innovation by:

Setting and leading strategic direction in digital health technology at the Center for Devices and Radiological Health (CDRH)

Launching strategic initiatives that advance digital health technologies

Building new capacity to oversee and leverage digital health technologies

Providing scientific expertise across the FDA

Providing technological and policy advice to support the FDA decision-making processes

Promoting and showcase existing work across the FDA

Transparently share resources for developers

Connecting Stakeholders

The Digital Health Center of Excellence connects and builds partnerships to accelerate digital health advancements by:

- Fostering collaboration across the FDA in common interest areas
- Facilitating synergies in regulatory science research in digital health
- Facilitating and building strategic partnerships
- Communicating the FDA's research interests
- Advancing international harmonization on device regulatory policy
- Advancing digital health technology international standards
- Providing access to internal and external digital health experts

Sharing Knowledge

The Digital Health Center of Excellence shares knowledge to increase awareness and understanding, drive synergy, and advance best practices by:

- Sharing information to increase awareness of advancements in digital health
- Establishing and promoting best practices
- Creating and disseminating shared resources internally and externally
- Offering training opportunities for the FDA's staff and external stakeholders
- Communicating the FDA's research interests

Innovating Regulatory Approaches

The Digital Health Center of Excellence innovates regulatory approaches to provide efficient and least burdensome oversight by:

- Enabling efficient, transparent, and predictable product review with consistent evaluation quality
- Providing clarity on regulation by developing cross-cutting digital health guidance
- Developing novel, efficient medical device regulatory approaches that are least burdensome while meeting FDA standards

In 2017, the FDA announced the Software Pre-Cert Pilot Program as part of the Digital Health Innovation Action Plan "to develop a new regulatory paradigm that would focus first on the assessment of organizations that perform high-quality software design, testing, and monitoring."[12] In January 2019, the FDA released a Test Plan for the Pre-Cert program as well as a Regulatory Framework for conducting the pilot program.[13, 14] In September 2022, the Software Precertification (Pre-Cert) Pilot Program was completed with the issuance of the Report: The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings.[12] This document includes the following statement:

> Ultimately, the approach to regulating novel, swiftly-evolving medical device software must foster, not inhibit, innovation, while continuing to provide reasonable assurance of safety and effectiveness. These aspects are not mutually exclusive. A flexible, risk based approach to regulation could allow FDA to tailor regulatory requirements more efficiently for devices based on the latest science, the benefits and risks posed by devices, their real-world performance, and their contribution to promoting health equity. It could leverage the capabilities of evolving medical device software so that health care providers, patients, and users can benefit from advancement and innovation, and so that risk for such devices can be reduced through swift software and cybersecurity updates throughout the total product lifecycle, when needed. New legislative authority establishing such an approach could be supplemental to, and not replace, the established regulatory pathways.

PRACTICE GUIDELINE AND POSITION STATEMENT SUMMARY

At this time, no single framework has been adopted by medical or regulatory bodies for evaluation of digital therapeutic products. However, several organizations, both global and national, have initiated efforts to develop a framework for evaluation of digital health products, including those summarized below.

DIGITAL THERAPEUTICS ALLIANCE

The Digital Therapeutics Alliance (DTA), a global non-profit trade association of industry leaders and stakeholders, provides a summary of Industry Core Principals to which all digital therapeutic products should adhere "to demonstrate product integrity and ensure patient safety."[15] These Principals include the statements that digital therapeutic products should:

- prevent, manage, or treat a medical disorder or disease; and
- produce a medical intervention that is driven by software; and
- publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals; and
- be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use; and
- make claims appropriate to clinical evaluation and regulatory status; and
- collect, analyze, and apply real world evidence and/or product performance data.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

The National Institute for Health and Care Excellence (NICE) published an update to the Evidence Standards Framework for Digital Health Technologies (DHTs) in 2022.[4] The framework provides standards for evidence that should be available or developed for DHTs to demonstrate their value in the UK health and care system, specifically. The framework is broken into evidence tiers (minimum evidence standards) based on the functional classification of the technology. Per the definitions above, digital therapeutics fit primarily in the highest evidence tier, C interventions. In 2022, NICE changed evidence tier naming from tiers one, two, and three to A, B, and C to avoid confusion with the European Union's CE (Conformité Européene) marking categories.

Minimum evidence for effectiveness standards for tier C DHTs includes the following:

> High quality intervention study (experimental or quasi-experimental design) showing improvements in relevant outcomes, such as:
>
> - diagnostic accuracy
> - patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life
> - other clinical measures of disease severity or disability
> - healthy behaviors
> - physiological measures
> - user satisfaction and engagement.
>
> Generic outcome measures may also be useful when reported alongside condition-specific outcomes. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention.

XCERTIA

Xcertia, founded in December 2016 by representatives from groups including the American Medical Association, American Heart Association, Healthcare Information and Management Systems Society and digital health nonprofit DHX Group, published a guideline in 2019 that addressed "key areas of guidance to ensure mHealth apps deliver true value in a trusted environment."[16]

These guidelines include the following statement regarding documentation of evidence for the app:

- The app's public description should clearly state which type of research has been performed to validate its content. These can include the following levels of research:
    - I. Systematic review or meta-analysis of randomized control trials
    - II. Randomized control trial/s (number of trials if more than one)
    - III. Quasi-experimental study
    - IV. Case-control or cohort studies
    - V. Systematic reviews of descriptive and qualitative studies
    - VI. Single descriptive or qualitative study
    - VII. Expert medical or academic opinion
- If level of research performed on the opinion [sic] is based on expert or academic opinion (VII) or no study, the app's public description should clearly state, "The effectiveness of the app has not been studied."

THE AMERICAN MEDICAL ASSOCIATION

The American Medical Association Policy on Integration of Mobile Health Applications and Devices into Practice (2017) states; “Our AMA supports the establishment of coverage, payment and financial incentive mechanisms to support the use of mobile health applications (mHealth apps) and associated devices, trackers and sensors by patients, physicians and other providers that:

- support the establishment or continuation of a valid patient-physician relationship
- have a high-quality clinical evidence base to support their use in order to ensure mHealth app safety and effectiveness
- follow evidence-based practice guidelines, especially those developed and produced by national medical specialty societies and based on systematic reviews, to ensure patient safety, quality of care and positive health outcomes
- support care delivery that is patient-centered, promotes care coordination and facilitates team-based communication
- support data portability and interoperability in order to promote care coordination through medical home and accountable care models
- abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services facilitated by the app
- require that physicians and other health practitioners delivering services through the app be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state’s medical board
- ensure that the delivery of any services via the app be consistent with state scope of practice laws.”[17]

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CODES

NOTE: Not all digital health products will have a specific code. These are examples of codes that may be relevant.

Codes	Number	Description
CPT	0770T	Virtual reality technology to assist therapy (List separately in addition to code for primary procedure)
	0771T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older
	0772T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring

Codes	Number	Description
		the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; each additional 15 minutes intraservice time (List separately in addition to code for primary service)
	0773T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; initial 15 minutes of intraservice time, patient age 5 years or older
	0774T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; each additional 15 minutes intraservice time (List separately in addition to code for primary service)
	98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days
	99199	Unlisted special service, procedure or report [when specified as a digital health management software application]
HCPCS	A9291	Prescription digital behavioral therapy, FDA cleared, per course of treatment
	A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
	E1399	Durable medical equipment, miscellaneous [when specified as a digital health management software application]
	E1905	Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software
	G0552	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan
	G0553	First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (dmht) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the dmht device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month
	G0554	Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (dmht) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the dmht device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month

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