NO. 91645-R2

DIGITAL THERAPEUTICS

Effective date: 03/01/2026 **Last reviewed**: 02/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy addresses only digital therapeutics. Digital therapeutics (DTx) are health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a therapeutic medical intervention. The criteria in this policy are not applicable to the medical, behavioral health, or pharmacological therapies/treatments, or medical devices used in conjunction with digital therapeutics.

Related policies:

- For biofeedback see Biofeedback # 91002
- For continuous glucose monitors and insulin pumps see Continuous Glucose Monitoring and Insulin Pumps # 91466
- For durable medical equipment, see Durable Medical Equipment # 91110
- For telemedicine and virtual services see Telemonitoring # 91604

SUMMARY OF CHANGES – R2

Additions:

- New Policy scope section
- New Medical/Professional Society Guidelines section
- New Government Regulations section listing applicable CMS NCDs or LCDs
- New FDA/Regulatory section

I. MEDICAL NECESSITY CRITERIA

A. **Inclusions**: The following digital therapeutics are considered medically necessary when used according to their labeling:

1. **d-Nav® System (Hygieia, Inc.)** when used by adults with Type 2 diabetes as an aid in optimizing insulin management. Use of the d-Nav® System requires a prescription.

B. **Exclusions**: All other digital therapeutics (DTx), including the DTx software and any associated ancillary components, that are not expressly listed as inclusions, are considered not medically necessary for any indication or use, and are experimental, investigational, or unproven due to insufficient evidence in current published peer-reviewed literature to support clinical utility and efficacy. This includes, but is not limited to the following:

1. Non-prescription digital therapeutics (e.g., over-the-counter).
2. Prescription digital therapeutics (PDTs), including those that are prescribed for direct-to-consumer or stand-alone use (without the guidance/participation of a healthcare provider).
3. Digital therapeutics that are used in conjunction with, and/or to enhance another device or treatment.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

According to the Digital Therapeutics Alliance (DTA), digital therapeutics is 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." The International Organization for Standardization (ISO) published ISO/TR 11147: Health informatics—Personalized digital health—Digital therapeutics health software systems. This publication was developed by ISO's *Technical Committee (TC) 215—Health Informatics* in June 2023, and the definition of digital therapeutics was subsequently adopted by the Digital Therapeutics Alliance. Under this definition, wellness products that deliver interventions to patients but do not claim to treat or alleviate a disease do not qualify as a digital therapeutic (DTx).

DTx can integrate with ancillary components to form a DTx system by using general purpose hardware or platforms (i.e. smartphone, tablet, computer, watch, headset), input or output components (i.e. wearables, sensors), pharmaceuticals, or patient or clinician support components necessary for DTx functioning, or by using patient- and context-specific data to generate a medical intervention. DTx can function independently or in addition to other interventions, such as integrating with other digital health technology (DHT) components (i.e. monitoring, diagnostic, clinical decision support) as part of a multi-functional DHT product or tandem medical interventions (i.e. clinician-delivered therapies, pharmaceuticals, medical devices, DHTs).

Digital Health Technologies (DHTs)

Digital Health Technologies (DHTs) are defined by the US FDA as "computing platforms, connectivity, software, and sensors [used] for health care and related uses." The definition is broad and can include technologies that serve a variety of purposes, including facilitating low-acuity patient wellness, operationalizing patient data, and even delivering a standalone intervention.

Digital Therapeutics is but one category of DHTs. DHT categories include:

1. Industry and Admin-Facing:

    - Non-Health System Software/Digital Health (DH) solutions: Health Information Technology (HIT) and digital health (DH) solutions for non-hospital/ health system stakeholders (i.e., pharma, medtech, payors, employers, pharmacy, etc.)
    - Health System Operational Software: Enterprise HIT intended to provide nonclinical system benefits and support (i.e., operational, financial)

2. Health Care Provider-Facing:

- Health System Clinical Software: Enterprise HIT and digital health solutions intended to provide clinicians with support managing their patient populations

3. Patient-Facing:

    - Health & Wellness: Disease-agnostic solutions that capture, store, and sometimes transmit health data and promote general well-being and healthy living
    - Patient Monitoring: Solutions intended to monitor specific patient health data that may be used to inform management of a specific disease, condition, or health outcome
    - Care Support: Solutions intended to support patient self-management of a specific diagnosed medical condition through education, recommendations, and reminders
    - Digital Diagnostics: Validated digital tools for detecting and characterizing disease, measuring disease status, response progression, or recurrence
    - Digital Therapeutics: Health software intended to treat or alleviate a disease by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact

For a product to be considered a digital therapeutic:

1. The product must provide an intervention that is used in the context of healthcare.
2. The intervention must treat, manage, or prevent a disease or disorder.
3. The software must be responsible for providing the intervention to the patient via a technology platform, medical device, pharmaceutical, etc.
4. The product has:

    - Been designed and manufactured using quality best practices.
    - Engaged end users in product development and usability processes.
    - Incorporated patient privacy and security protections.
    - Applied product deployment, management, and maintenance best practices.
    - Published trial results inclusive of clinically meaningful outcomes in peer-reviewed journals.
    - Been reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use.
    - Made claims appropriate to clinical evaluation and regulatory status.
    - Collected, analyzed, and applied real-world evidence and/or product performance data to patient care.

A product is generally considered to NOT be a digital therapeutic if any of the following apply:

1. The product does not provide an intervention that is used in the context of healthcare.
2. The intervention is primarily used for general health promotion, wellness, or fitness.
3. The intervention solely informs, monitors, diagnoses, or provides a clinician with insight.
4. The intervention does NOT treat, manage, or prevent a disease or disorder.
5. A clinician has sole responsibility for delivering the intervention (independent of the software) to the patient.
6. A standalone medication or pharmaceutical provides the intervention (independent of software).
7. ANY of the criteria listed in 4. i. – viii above are NOT met.

Digital therapeutics are available either via prescription or as non-prescription (OTC) products. Currently authorized DTxs deliver therapeutic interventions using a range of approaches, devices, and technologies. DTx includes products (e.g., applications connected to continuous glucose monitoring systems with or without insulin pumps) that use a broad range of software and hardware technologies and require some level of FDA approval. Sometimes only one part of a device may require such approval, as is the case with the software component of the Fitbit device (Google LLC, Mountain View, CA) that detects irregular heart rhythms and notifies both the patient and provider. (Shafai et al., 2023)

Common areas of therapeutic application for DTxs include diabetes (i.e. insulin dose management), behavioral health (i.e. CBT, anxiety, depression), pain management, disorders of gut brain interaction (i.e. irritable bowel syndrome), and Alzheimer's disease.

The FDA currently regulates digitally delivered treatments that meet the definition of software as a medical device (SaMD), meaning "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." SaMD products, like all medical devices, are evaluated for their perceived potential risk and are assigned to 1 of 3 classes: class I (low risk, general controls), class II (moderate, general and special controls), and class III (high risk, general controls and premarket approval).

Prescription Digital Therapeutics

DTx that require clinician initiation and oversight are called prescription digital therapeutics (PDTs). PDTs undergo additional and more rigorous regulatory scrutiny because they treat serious diseases and are only available via a prescription by a licensed clinician. Although the first FDA-authorized PDTs were issued as class II devices based on their indications (requiring special controls), different DTx may end up in different risk classes based on their area of treatment.

The FDA determines whether a prescription is required to provide reasonable assurance of appropriate clinical use given the severity of the disease in question and the risks of treating patients with the device. Such controls may include special labeling requirements, written guidelines, performance standards, premarket data requirements, postmarket surveillance, and patient registries. Authorized SaMDs (approved or cleared) receive a label from FDA, similar to a drug, that describes indications for use, medical claims, appropriate patient populations, safety and warnings, instructions for patients and clinicians, and the supporting clinical safety and effectiveness data.

After a clinician prescribes a PDT, the patient downloads the digital therapeutic and is then usually guided through the activation steps. Patients may be assisted with these steps, either in person or via phone or online “chat” functions. Once a password is set up, patients can begin working and learning in the PDT. The patient-facing mobile application may be associated with a clinician-facing “dashboard” for monitoring and managing patient progress during the prescription. In many applications, PDT content is conveyed to patients via a sequence of self-guided interactive lessons that parallel the structure and approach of face-to-face sessions. Lessons can be delivered via text, personalized goal setting, graphical feedback based on inputted symptoms, animations and illustrations to enrich comprehension, quizzes to test and enhance user knowledge, video vignettes to promote user identification with material, or video-based expert explanations. In addition to completing interactive learning modules reinforced by quiz questions, patients can often record disease symptoms, triggers, and patterns. During the course of treatment, patients continue to see their prescribing clinician either in person or virtually as needed. PDT prescriptions can range from weeks to months, with options to renew prescriptions at the discretion of the treating clinician. (Shafai et al., 2023)

Non-Prescription Digital Therapeutics

Non-prescription, or over-the-counter (OTC) digital therapeutics are available without clinician initiation and oversight. While the first software-based therapeutics were PDTs, nonprescription digital treatments are similar and some have received FDA market authorization. (Watson et al., 2023). In order for a product to be an OTC DTx; efficacy, safety, and usability data is necessary to ensure a medical product will not be abused or cause harm to a patient. For OTC digital therapeutics, no form of third-party authorization (i.e. clinician prescription or health plan authorization) is necessary for the patient to buy and use the product.

Digital Therapeutics Used in Conjunction With Another Device/Treatment

DTx can be used as a standalone therapy or in conjunction with more conventional treatments such as pharmacological or in-person therapy, or with certain hardware or other sensory or mechanic devices. When used as part of a system with ancillary components, the treatment depends on the collection and processing of digital

measurements. Because of the digital nature of the methodology, data can be collected and analyzed as both a progress report and a preventative measure. (Kampouraki, 2024)

An example of a digital therapeutic that involves the use of a device is Freespira (Freespira Inc.), which is available by prescription only and indicated as adjunctive treatment for panic disorder and/or posttraumatic stress disorder (PTSD) (K180173). It is a biofeedback device, which according to its regulatory guidance is an "instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters MEDICAL POLICY No. 91002-R10 Biofeedback Page 3 of 6 … so that the patient can control voluntarily these physiological parameters" (21CFR882.5050). Under the direction of a licensed healthcare provider, patients are trained to use the Freespira sensor and the Freespira mobile application to participate in breathing exercises with the intent of normalizing their respiratory rate and exhaled carbon dioxide levels. Sessions of breathing exercises are conducted twice daily, 17 minutes each for 4 weeks at home (K180173). The Freespira website contends that the device thereby "normalizes CO2 and respiratory rates in a single 28-day treatment for adults and adolescents" with the intent of preventing panic attacks (Freespira Inc., 2022).

d-Nav (Hygieia)

d-Nav is a prescription digital therapeutic that combines an FDA-cleared mobile app enabled by AI technology, and virtual clinical support to make autonomous adjustments to a patient’s insulin prescription based on their historical and current glucose levels. (Digital Therapeutics Alliance, 2024) d-Nav seeks to address gaps in insulin titration which can lead to inadequate glycemic management.

In a multicenter, randomized controlled trial, 181 patients aged 21-70 with type 2 diabetes mellitus (DM) and a hemoglobin A1C (HbA1c) of 7.5%-11% on the same insulin regimen for at least 3 months were randomly assigned to either d-Nav with healthcare professional support or healthcare professional support alone. The primary outcome was mean change in hemoglobin A1C from baseline to 6 months. Safety was assessed by the frequency of hypoglycemic events. At baseline, mean HbA1c was 8.7% (SD 0.8; 72 mmol/mol [SD 8.8]) in the intervention group and 8.5% (SD 0.8; 69 mmol/mol [SD 8.8]) in the control group. The mean decrease in HbA1c from baseline to 6 months was 1.0% (SD 1.0; 11 mmol/mol [SD 11]) in the intervention group, and 0.3% (SD 0.9; 3.3 mmol/mol [9.9]) in the control group (p=0.96) (Bergenstal et al., 2019)

In another study, a single center embedded the d-Nav technology and its dedicated clinical support and studied treatment efficacy/safety in the first 600 patients and use of cardiorenal-risk reduction pharmacotherapy. The authors found that patients used d-Nav for 8.2 ± 3.0 months with 82% retention. Age was 67.1 ± 11.5 years and duration of diabetes was 19.8 ± 11.0 years. During the last 3 years before d-Nav, glycated

hemoglobin (HbA1c) had been overall higher than 8% and at the beginning of the program it was as high as 8.6% ± 2.1% with 29.3% of the patients with HbA1c >9%. With d-Nav, HbA1c decreased to 7.3% ± 1.2% with 5.7% of patients with HbA1c >9%. During the first 3 months, d-Nav reduced total daily dose of insulin in one of every five patients due to relatively low glucose levels to minimize the risk of hypoglycemia. Glucagon like peptide 1 (GLP-1) receptor agonists or dual GLP-1 and Glucose-dependent insulinotropic polypeptide (GIP) receptor agonists were prescribed in about a half of the patients and sodium glucose cotransporter 2 inhibitor in a third. The frequency of hypoglycemia (<54mg/dL) was 0.4 ± 0.6/month and severe hypoglycemia 1.7/100-patient-years. (Warren et al., 2024)

Guidelines/Position Statements

American Diabetes Association: Diabetes Technology: Standards of Care in Diabetes (2026)

- *Diabetes technology, coupled with education, follow-up, pharmacotherapy as needed, and support, can improve the lives and health of people with diabetes; however, the complexity and rapid evolution of the diabetes technology landscape can also be a barrier to implementation for people with diabetes, their care partners, and the health care team.*
- Recommendation **7.28**: *Consider combining technology (CGM, insulin pump, and/or diabetes apps) with online or virtual licensed coaching to improve glycemic outcomes in individuals with diabetes or prediabetes. (Level of Evidence: **B** [Supportive evidence from well-conducted cohort studies]*

Diabetes digital app technology: benefits, challenges, and recommendations. A consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group (Fleming et al., 2020)

- *While the available studies of app-based interventions show promise for promoting healthy behaviour and managing complex diseases, such as diabetes, they are extremely limited in both quantity and quality. The studies [previously mentioned in this section] all report their respectively assessed apps as improving or showing promise in improving short-term outcomes. However, all of these studies also conclude that more rigorous, larger sample and longer-term RCTs are required to distinguish the effect of these apps from possible concomitant effects. In principle, well-designed studies with larger sample sizes and of longer duration are needed to gather and assess evidence of sustainable effectiveness over time.*

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Diabetes Association	Standards of Care in Diabetes – 2026 (December 2025) 7. Diabetes Technology
European Association for the Study of Diabetes (EASD)	Diabetes digital app technology: benefits, challenges, and recommendations. A consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group (December 2019)
International Organization for Standardization (ISO)	ISO/TR 11147:2023(en). Health informatics—Personalized digital health—Digital therapeutics health software systems. (2023)
Digital Therapeutics Alliance	Digital Therapeutic Definition—June 2023 DTA's Adoption & Interpretation of ISO's DTx Definition

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
d-Nav® System (Hygiea, Inc.)	K181916	02/04/2019

Regulatory Considerations for Prescription Drug Use-Related Software: *This guidance describes how FDA intends to apply its drug labeling authorities to certain software outputs that are disseminated by or on behalf of a drug sponsor for use with a prescription drug or a prescription drug-led, drug-device combination product (hereafter referred to as a "combination product") that is assigned to the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research as the lead center.*

Digital Health Advisory Committee: *advises the Commissioner of Food and Drugs on issues related to digital health technologies (DHTs), providing relevant expertise and perspective to improve the FDA's understanding of the benefits, risks, and clinical outcomes associated with the use of DHTs.*

Guidances with Digital Health Content: *The guidance documents listed here are FDA guidances with Digital Health content and are intended to provide clarity on the FDA's regulation of digital health products.*

Policy for Device Software Functions and Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff (September 2022): Communicates *how the Agency intends to apply its regulatory oversight to certain software, including device software functions and mobile medical applications (MMAs) intended for use on mobile platforms or on general-purpose computing platforms.*

Digital Health Center of Excellence: *Goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation.*

VI. CODING

CPT/HCPCS Codes

0687T Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
0688T Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified healthcare professional, with report, per calendar month
0704T Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment
0705T Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days
0706T Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified healthcare professional, per calendar month
0731T Augmentative AI-based facial phenotype analysis with report
0740T Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; initial set-up and patient education
0741T Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days
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 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 healthcare professional other than the physician or other qualified healthcare 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 healthcare professional other than the physician or other qualified healthcare 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)
99199 Unlisted special service, procedure or report (when specified as a mobile-based health management software application., *(Explanatory notes must accompany claim)*
A9291 Prescription digital cognitive and/or behavioral therapy, FDA-cleared, per course of treatment
A9292 Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
A9293 Fertility cycle (contraception & conception) tracking software application, FDA cleared, per month, includes accessories (e.g., thermometer)
A9294 Prescription digital cognitive and/or behavioral therapy, biofeedback, fda cleared, per course of treatment
A9999 Miscellaneous DME supply or accessory, not otherwise specified (when specified as a mobile-based health management software application *(Explanatory notes must accompany claim)*
E1399 Durable medical equipment, miscellaneous (when specified as a mobile-based health management software application. *(Explanatory notes must accompany claim)*
E1905 Virtual reality cognitive behavioral therapy device (CBT), including preprogrammed 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
T1505 Electronic medication compliance management device, includes all components and accessories, not otherwise classified (when specified as a mobile-based health management software application. *(Explanatory notes must accompany claim)*

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will

supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Guidelines/Position Statements:

1. American Diabetes Association Professional Practice Committee for Diabetes*; 7. Diabetes Technology: Standards of Care in Diabetes—2026. *Diabetes Care* 1 January 2026; 49 (Supplement_1): S150–S165. https://doi.org/10.2337/dc26-S007
2. Digital Therapeutics Alliance. DTA's Adoption & Interpretation of ISO's DTx Definition. Available at https://dtxalliance.org/wp-content/uploads/2023/06/DTA_FS_New-DTx-Definition.pdf (Accessed December 8, 2025).
3. Fleming GA, Petrie JR, Bergenstal RM, Holl RW, Peters AL, Heinemann L. Diabetes digital app technology: benefits, challenges, and recommendations. A consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. Diabetologia. 2020 Feb;63(2):229-241. doi: 10.1007/s00125-019-05034-1. PMID: 31802144.
4. The International Organization for Standardization. ISO/TR 11147:2023(en). Health informatics—Personalized digital health—Digital therapeutics health software systems. (2023). Available at: https://www.iso.org/standard/83767.html (Accessed December 8, 2025)

Additional references:

5. Bergenstal RM, Johnson M, Passi R, Bhargava A, Young N, Kruger DF, Bashan E, Bisgaier SG, Isaman DJM, Hodish I. Automated insulin dosing guidance to optimise

insulin management in patients with type 2 diabetes: a multicentre, randomised controlled trial. Lancet. 2019 Mar 16;393(10176):1138-1148. doi: 10.1016/S0140-6736(19)30368-X. Epub 2019 Feb 23. PMID: 30808512; PMCID: PMC6715130.
6. Digital Therapeutics Alliance. What is a DTx? Available at: https://dtxalliance.org/understanding-dtx/what-is-a-dtx/ (Accessed December 8, 2025).
7. Hayes Inc. Evolving Evidence Review. Freespira Digital Therapeutic (Freespira Inc.) for Treatment of Panic Disorder. Hayes Inc.; Jun 14, 2024
8. Kampouraki, Dina. “Digital Therapeutics (DTx) | European Data Protection Supervisor.” Www.edps.europa.eu, 11 Mar. 2024, www.edps.europa.eu/press-publications/publications/techsonar/digital-therapeutics-dtx_en.
9. Phan P, Mitragotri S, Zhao Z. Digital therapeutics in the clinic. Bioeng Transl Med. 2023 May 3;8(4):e10536. doi: 10.1002/btm2.10536. PMID: 37476062; PMCID: PMC10354777.
10. Shafai G, Aungst TD. Prescription digital therapeutics: A new frontier for pharmacists and the future of treatment. J Am Pharm Assoc (2003). 2023 Jul-Aug;63(4):1030-1034. doi: 10.1016/j.japh.2023.03.012. Epub 2023 Apr 3. PMID: 37019379.
11. Watson A, Chapman R, Shafai G, Maricich YA. FDA regulations and prescription digital therapeutics: Evolving with the technologies they regulate. Front Digit Health. 2023 Apr 17;5:1086219. doi: 10.3389/fdgth.2023.1086219. PMID: 37139487; PMCID: PMC10150093.
12. Warren M, Bergenstal RM, Hager M, Bashan E, Hodish I. A Scalable Application of Artificial Intelligence-Driven Insulin Titration Program to Transform Type 2 Diabetes Management. Diabetes Technol Ther. 2024 Aug;26(8):556-565. doi: 10.1089/dia.2024.0041. Epub 2024 May 31. PMID: 38452101

Past review dates: 11/2024, 02/2025, 02/2026

AMA CPT Copyright Statement: All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

The name “Priority Health” and the term “plan” mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.