

DIGITAL THERAPEUTICS

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Summary of Changes

Additions:

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

Clarifications:

 Policy was restructured to first specify any digital therapeutics that may be considered medically necessary (inclusions), and second to indicate that all other digital therapeutics not expressly named as inclusions are considered not medically necessary for any indication or use, and are experimental, investigational, or unproven (exclusions).

I. POLICY/CRITERIA

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.

- For biofeedback see *Biofeedback, Medical Policy No. 91002*.
- For continuous glucose monitors and insulin pumps see *Continuous Glucose Monitoring and Insulin Pumps, Medical Policy No. 91466.*
- For durable medical equipment, see *Durable Medical Equipment, Medical Policy No. 91110*.
- For telemedicine and virtual services see *Telemedicine/Virtual Services*, *Medical Policy No. 91604*
- 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,

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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. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, services, devices, 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, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 42542 42543 42546 42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 5100-87572--,00.html, 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

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Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. 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.)

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- 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.

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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

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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 videobased 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 ($\underline{K180173}$). 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

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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 $8.6\% \pm 2.1\%$ with 29.3% of the patients with HbA1c >9%. With d-Nav, HbA1c decreased to $7.3\% \pm$ 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 Medical Care in Diabetes (2022)

- "Systems that combine technology and online coaching can be beneficial in treating prediabetes and diabetes for some individuals" (level of evidence, B [supportive evidence from well-conducted cohort studies])
- "Diabetes technology, when coupled with education and follow-up, can improve the lives and health of people with diabetes; however, the complexity and rapid change of the diabetes technology landscape can also be a barrier to patient and provider implementation."

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

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sample sizes and of longer duration are needed to gather and assess evidence of sustainable effectiveness over time."

V. CODING INFORMATION

CPT/HCPCS CODES that may apply

- 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

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- 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)
- 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*)

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