DTx Intended Uses & Mechanisms

Digital therapeutic (DTx) product intended uses can be classified broadly into the following categories based on the clinical outcome(s) they intend to achieve:

DTx INTENDED USES	DESCRIPTION	EXAMPLE PRODUCT
DTx designed to produce behavioral change	Digital product that employs various mechanisms to change or alter a patient's behavior	Cognitive behavioral therapy (CBT) delivered via a patient app designed to improve patient attention, a key outcome for ADHD patients
DTx designed to produce physiologic change	Digital product that employs various mechanisms to change or impact a patient's physiology	Video and audio stimuli directly alter brain chemistry and serotonin production to reduce depressive symptoms
DTx designed to help with disease and/or condition management	Digital product that helps patients manage their disease and impacts clinical outcomes	Connected device and app designed to support patients and their self-management of diabetes and lower A1c levels

Note: *Digital therapeutics may have more than one intended use.*

Mechanisms that digital therapeutics utilize to achieve intended use(s) can include, but are not limited to:

DTx MECHANISMS	DESCRIPTION	EXAMPLE PRODUCTS
Behavioral therapy	Clinically validated behavioral therapy delivered digitally, as opposed to in person	▪ Cognitive Behavioral Therapy (CBT) delivered via an app ▪ Immersive biopsychosocial approach delivered via an app
Biofeedback	Direct sensing of and feedback on patient biometrics via a connected device or app	▪ Breathing pattern recognition via a connected device ▪ Psychophysiological feedback via a connected device
Cognitive training	Clinically validated mental exercises delivered digitally, as opposed to in person	▪ Sensory stimuli and simultaneous motor challenges designed to target neural systems in the brain via a connected device ▪ Pattern recognition and response via an app
Neurological stimulation	Direct neurostimulation tailored via a digital solution in response to the patient, patient state, biometrics, etc.	▪ Non-invasive neuromodulation via a connected device ▪ Auditory-motor entrainment via a connected device

DTx MECHANISMS	DESCRIPTION	EXAMPLE PRODUCTS
Physiologic stimulation	Direct physiologic stimulation tailored via a digital solution in response to the patient, patent state, biometrics, etc.	▪ Audio stimulation via a connected device ▪ Visual stimulation via a connected device ▪ Vibrotactile feedback via a connected device
Software-determined medication dose modification	Software-based solution that provides prompts on or directly adjusts a recommended dose of medication	▪ Insulin dose recommendations via a connected device and app ▪ Trigger-initiated inhaler recommendations via a connected device and app
Software-directed disease management	Software-based solution that provides prompts, reminders, and recommendations to support patients in self-management of their disease and/or condition	▪ Cancer treatment symptom management recommendations via an app ▪ Respiratory disease trigger management recommendations via a connected device and app
Software-led, disease-specific clinical coaching/ rehabilitation	Software-based solution that guides patients through clinically validated exercises and techniques digitally, as opposed to in person	▪ Physical therapy rehabilitation via a software program and connected device ▪ Optometry rehabilitation via a software-program ▪ Pelvic floor muscle training (PFMT) via a software program

Note: *Digital therapeutics may incorporate one or more mechanisms to achieve their intended uses.*