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:

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

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| 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 |
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| 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.*