

DTx Market and Patient Access Pathways

Digital therapeutics (DTx) deliver validated clinical interventions to patients for a specific disease or disorder. To ensure these products are safe and used by the right patient, at the right time, and in the right manner, DTx products undergo rigorous clinical studies.

How a DTx gains access to the market and how a patient accesses a DTx is highly variable. Regardless of whether a DTx is prescribed by a clinician or undergoes utilization management by a third-party payer (i.e., health insurer, pharmacy benefit manager, employer), DTx products typically undergo some form of an authorization process prior to patient use to ensure appropriate use.

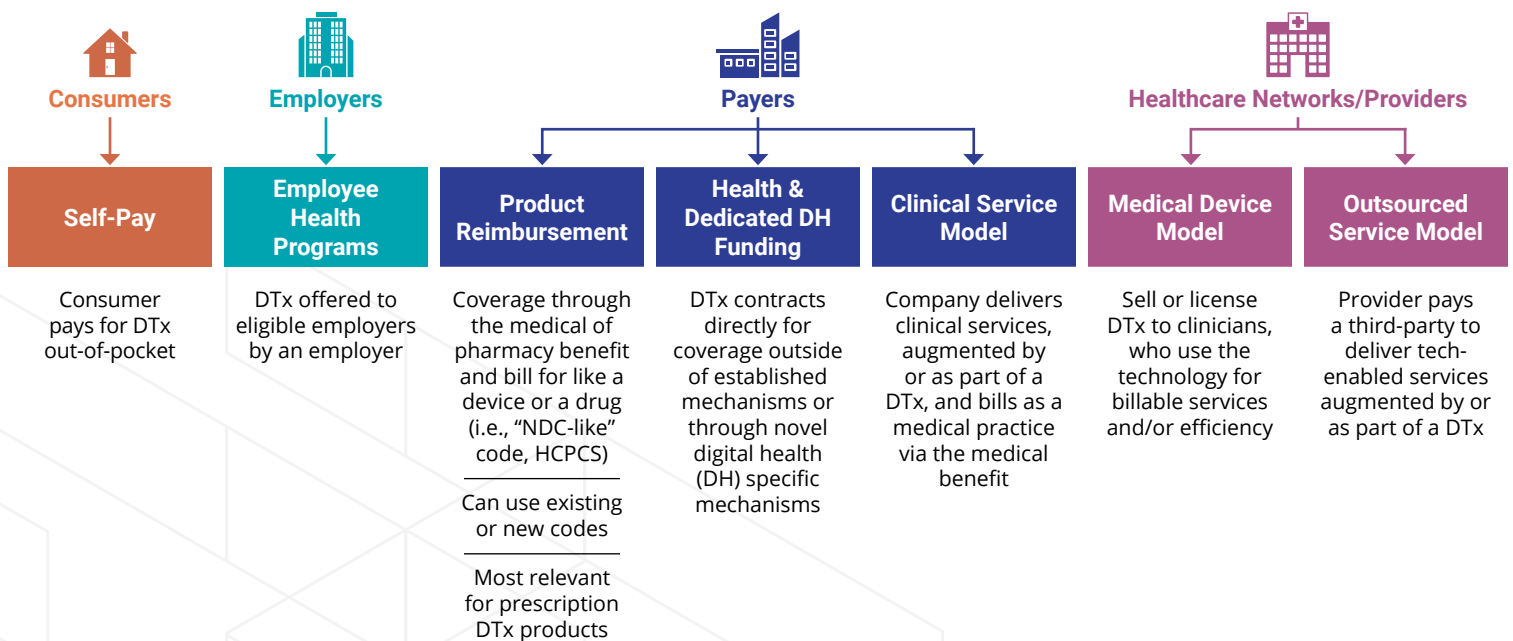
As software products, DTx have different risk/benefit ratios when compared to drugs. DTx generally

have lower adverse event (AE) and safety concerns than drugs and other medical devices. Additionally, DTx products employ rigorous patient activation/onboarding processes, provide detailed instructions for use, and incorporate patient monitoring functions to help maintain positive treatment effect irrespective of the DTx product's market access path.

NOTE: National regulatory bodies perceive DTx regulatory access risk differently. While the US FDA issued enforcement discretion guidance for lower-risk and mental health DTx products, European countries require the CE-mark for all DTx products.

As a unique product class, DTx can follow multiple pathways to reach patients and clinicians, as demonstrated in the figure below.

Current DTx Market Access Pathways



Of the multiple pathways for products to reach patients, as seen in the above figure, some DTx require a clinician prescription, some require a third-party payer (i.e., insurer, PBM, employer) to authorize use, some may be utilized based on the selection of the patient themselves, and some require a combination of the aforementioned options. In nearly all these situations, the product has undergone an

evaluation by at least one third-party, not including regulatory authorities.

Even though international markets adopt different patient access pathways, a government agency—whether regulatory, health technology assessment (HTA), or a health system—will review the product prior to allowing market and patient access to the DTx.