DTx Prescription vs. Non-Prescription Pathways

Digital therapeutic (DTx) products have the ability to reach patients and caregivers through a variety of patient access pathways. This results in a diverse landscape of possible DTx market access models. In the past, DTx prescription products have been viewed as the only gated patient access path; however, that is not the case. Nearly all patient access to DTx today—including prescription and non-prescription products—involves vetting by a third-party to ensure the right patients have access to the right products.

Patient access to DTx products may be provided via:

GATED		NON-GATED
Prescription Pathway	**Non-Prescription Pathway**	**Non-Prescription Pathway**
▪ Formal prescription from a qualified clinician (in-person or virtual engagement)	▪ Clinician referral for a non-prescription DTx product (in-person or virtual engagement) ▪ Direct authorization by an employer for a non-prescription DTx product ▪ Direct authorization by a payor for a non-prescription DTx product ▪ "Authorized clinical protocol" established by a healthcare decision maker (HCDM) to authorize automatic patient access when necessary qualification requirements are met ▪ "Clinically validated screening tool" that patients use to determine whether they qualify for the therapy	▪ "Over-the-counter" model where no form of third-party authorization is necessary for patient to buy a product ***Note:*** *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*

Product authorization and patient access pathways may differ based on local or national DTx regulatory, Health Technology Assessment (HTA), or payor requirements.