DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

DEVELOPED WITH EVERSANA™

SOUTH KOREA Regulatory

Category Name

Digital Therapeutics (recognized as a subset of Software as a Medical Device (SaMD), which is a subset of Medical Devices)

Responsible Regulatory Agency

Ministry of Food and Drug Safety (MFDS)

Classification	Major Submission Dossier	Technical document Review Organization	Authority	Pathway
1 (Very Low)	Abbreviated Technical document	–	NIDS	Listing
2 (Low)	Technical document & Evidence Report	NIDS	NIDS	Certification
3 (Moderate), 4 (High)	Technical document & Evidence Report	MFDS	MFDS	Approval

*NIDS: National Institute of Medical Device Safety Information. NIDS is an MFDS affiliated public organization and is responsible for the listing of Class 1 medical devices and the certification of Class 2 medical devices.

	Class 1: Listing	Class 2: Certification	Class 3-4: Approval
Product Risk Classifications			
Regulatory Review	Exempt	NIDS	MFDS
Pre-Submission Opportunities	Cost: • 1,097,000 KRW (Approx. 746 USD) (clinical investigation plan and/or clinical investigation result report) / Timeline: 70 days • 524,000 KRW (Approx. 356 USD) (others) / Timeline: 55 days		
Guidelines To Be Met	• Guidance on the Review and Approval of Digital Therapeutics (DTx) (English version) • Guidance on the Clinical Trials Design of Digital Therapeutics (DTx) (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Insomnia Improvement (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Alcohol Use Disorders Improvement (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Nicotine Use Disorder Improvement (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Depressive Disorder Improvement (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Panic Disorder Improvement (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Eating Disorder Improvement (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for ADHD Improvement (Korean version) • Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for Mild Cognitive Impairment Improvement (Korean version)		
Other Guidelines	• Guidance on Review and Approval for Medical Device Software (Korean version) • Guidance on the Application of Real World Evidence of Medical Device (Korean version) • Guidance on Review and Approval for Cybersecurity of Medical Device (Korean version)		
Product Recognition	Listed	Certification	Approval
Approximate Timing For Process Completion	Immediate	Within 80 working days	Within 80 working days
Cost	85,000 KRW (approximately 39 USD)	2,530,000 KRW (approximately 1,720 USD)	1,495,000 KRW (approximately 1,016 USD)

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SOUTH KOREA Reimbursement

Prescription Required?	Required for reimbursement by public health insurance.
Public Insurance Coverage	In 2023, DTx has been given 3-year temporary registration for national reimbursement under Health Insurance and Review Assessment (HIRA) or National Health Insurance Service (NHIS). Reimbursement will be selective for prescribed patients within research or clinical trial institutions that was appointed by NECA. Temporary registration is for select medical instructions to establish clinical evidence, such as effectiveness. Upon evaluation after 3 years, the final decision on official registration for national reimbursement will be made. Details provided in HIRA Guidance (Korean Version)
Private Health Insurance	Not at this time.
Employer-Sponsored Healthcare	Not at this time.
Consumer-Funded	In the event that a DTx product has not been approved for reimbursement, patients may opt to pay out of pocket for an improved quality of life. Medical institutions are required to disclose the non-reimbursed product price on the HIRA website. Details provided in HIRA Guidance (Korean Version)

Note: This document represents pathways that continue to evolve. It does not provide legal advice.