DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

DEVELOPED WITH EVERSANA™

JAPAN Regulatory

DTx products in Japan are recognized as medical devices. They are subject to regulatory oversight by the Pharmaceuticals and Medical Devices Agency (PMDA) and Ministry of Health, Labor, and Welfare (MHLW). Following regulatory approval, MHLW evaluates products for potential reimbursement.

Category Name	Software as a Medical Device (SaMD)
Responsible Regulatory Agency	Pharmaceuticals and Medical Devices Agency (PMDA) and Ministry of Health, Labor, and Welfare (MHLW)
Product Risk Classifications	**Class II, III, IV**
Regulatory Review	All DTx products that qualify as Class II, III, and IV medical devices qualify for regulatory review. **- Class II products & III with Certification Standard (CS) products require certification by a Registered Certification Body (RCB)** *Note: Products that are outside the scope of CS or do not comply with CS are reviewed by PMDA and approved by MHLW* **- Class III & IV products require PMDA review and Minister's approval** - DTx has SaMD version of rebalancing notification (2-step approval scheme for SaMD) available
Pre-Submission Opportunities	Various pre-consultation slots with PMDA are available.
Guidelines To Be Met	Manufacturers engage with PMDA for an initial product review prior to receiving final approval from MHLW. New, innovative products require higher levels of evidence through clinical trials. Products that are similar to medical devices that are already on the market do not require the same degree of clinical evidence. Applicable guidelines include Reliability Standards (Enforcement Regulations of the Pharmaceutical Affairs Law), Essential Principles and QMS Ministerial Ordinance.
Other Required Guidelines	ISO/IEC standards for conventional medical devices may also apply.
Product Recognition	Approved
Approximate Timing For Process Completion	Certain SaMD products undergo a priority review process completed within 6 months; Aiming to ensure SaMD reviews will be finalized within 6 months as part of five-year plan (2024–2028)
Cost	Submission Fee (including product review and GCP&CLP compliance inspection): 13,016,900 JPY (approximately $82,305 USD + travel fee) for a novel Class II/III product *Note: Fees differ depending on the product class*

JAPAN Reimbursement

Prescription Required?	Prescription required for public insurance coverage.
Public Insurance Coverage	Ministry of Health, Labor, and Welfare (MHLW) evaluates product pricing annually. To achieve coverage as a technical fee* in Japan: - Aim to receive support for coverage from the appropriate medical society - Submit an Insurance Coverage Request Form to Social Insurance Union of Societies related to Internal Medicine / External Medicine - Undergo a health economic evaluation to negotiate with MHLW *Many SaMD products are reimbursed as a technical fee in Japan, but another path as a Special Treatment Medical Device is also possible
Private Insurance Coverage	Not common due to universal health insurance coverage. However, payers may be receptive to new therapies that target conditions that impact large populations.
Employer-Sponsored Healthcare	Not common due to universal health insurance coverage. However, employers may be receptive to offering disease prevention programs.
Consumer-Funded	Not common due to universal health insurance coverage. However, consumers may be interested in paying out of pocket for a product that improves their quality of life.

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

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