DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

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 & Class 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
Pre-Submission Opportunities	Optional opportunity for manufacturers to determine specific guidelines that are necessary for product approval.
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. Current guidelines.
Other Required Guidelines	Alignment with ISO standards related to product privacy and data security.
Product Recognition	Approved
Approximate Timing For Process Completion	4–12 months
Cost	Submission Fee (including product review and GCP&CLP compliance inspection): 13,016,900 JPY (approximately $113,910 USD) *Note: Fees may 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, payors 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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