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CureApp receives world-first approval of digital therapeutic app for hypertension

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World's first medical device regulatory approval of digital therapeutic app for hypertension



Japan's CureApp has received the medical device regulatory approval of an digital therapeutic (DTx) app for hypertension. This marks the first time a standalone software app supporting doctors and patients has received medical device regulatory approval in Japan, and is the first app addressing hypertension to be approved in the world. Preparations are now underway to receive reimbursement and launch the app in 2022.

This app provides direct treatment guidance that has been tailored to each individual patient, including advice on diet, exercise, sleep, and other aspects of their lifestyle, and information intended to encourage behavioral improvements based on information entered by the patient, via their smartphone.

The version of the app available to physicians allows physicians to check a patient's daily progress toward implementing lifestyle changes, and is intended to contribute in a meaningful way toward improving the quality of medical care provided within a limited time frame.

The FY2022 revision of the national medical payment system added the "Addition of Medical Management of Software as a Medical Device, etc.", and this marks the first case of a standalone software application acting as a doctor and patient aid receiving pharmaceutical approval. This is also the first time in the world medical device regulatory approval has been granted for DTx in the field of hypertension.