[MOHW] Announcement of Plans to Apply National Health Insurance Coverage to DTx devices and AI medical device.

After the 13th National Health Insurance Policy Deliberation Committee meeting (July 26, 2023), the Ministry of Health and Welfare (the "MOHW") announced plans to apply national health insurance coverage to DTx devices and AI (Artificial Intelligence) diagnostic medical devices detailed below. For your reference, the National Health Insurance Policy Deliberation Committee is a committee established by the Ministry of Health and Welfare ("MOHW") pursuant to Article 4 of the National Health Insurance Act to deliberate and decide on important matters concerning national health insurance policy, such as criteria for health insurance medical care benefits, medical care benefit costs, and insurance premiums. Accordingly, the Committee's decision presented policy directives for digital treatment devices and AI (Artificial Intelligence) diagnostic medical devices in the future, and it is expected that further details and guidance will be prepared by the end of 2023.

1. Digital Treatment Devices (DTx);

- Digital therapy devices will be divided between the act of medical service provided by healthcare professionals or compensation for use of digital therapy devices.
- The Committee announced plans to compensate for the act of medical service based on the management/effectiveness evaluation through analysis of prescriptions, and to determine the base amount for the fee for the use of digital therapy devices based on overall cost, requested NHI price amount as well as cases in other jurisdictions etc.

2. Artificial intelligence (AI) imaging devices;

- Artificial intelligence will be compensated in the form of an add-on to the existing NHI reimbursement price by classifying types by similar category as shown in the table below.

Types	Categories
1	Pathology
2	Special imaging (MRI, CT, PET, etc)
3	Endoscope, Ultrasound
4	Type not Classified in 1-3 (simple images, function tests etc)

In order to qualify for NHI insurance coverage in accordance with the policy direction above, companies that import digital health products should be take careful steps in the MFDS's product license approval stage so as not to be incorporated into the "existing technology" classification for NHI reimbursement purposes. For products developed in Korea, after entering the market in the form of "non-reimbursement or selective reimbursement", by fully utilizing the "Integrated Review Procedures for Innovative Medical Devices" or "Evaluation Deferment" procedures, local companies should make efforts to include their products based on the above newly instituted categories. If you have any questions regarding the above, please do not hesitate to contact MDREX (pro@mdrex.co.kr).

Thank you

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