Japan’s medical device reimbursement policy
-changes for the past 3years and future trend-

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Two types of reimbursement rule for medical devices

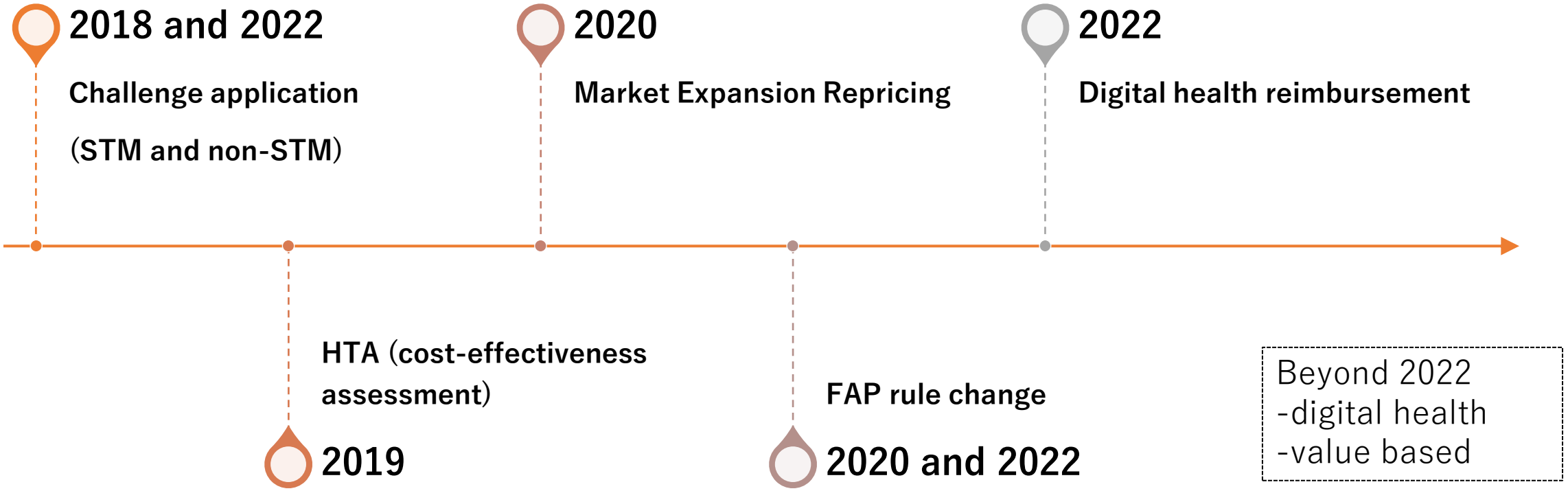
STM (Special Designated Treatment Material:　Device fee)

- Prices individual medical devices (functional category), for example, implant and disposal device types such as pacemakers and artificial joints

Non-STM (Technical fee)

- Incorporates price as part of the technical fee for diagnostic devices such as CT/MRI scanners, or medical devices to be used repeatedly

Health policy changes for the past 3 years and future



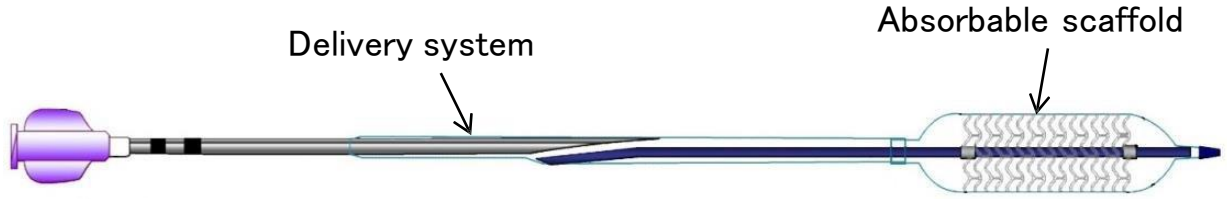
Challenge application rule was created in 2018

Support for products that need to be evaluated based on actual use

- Some of the insured medical materials are implanted in the body for a long period of time or involve highly innovative technologies, and it may be difficult to verify the final evaluation items before the product is listed in the insurance system.
- For such products that require evaluation based on actual use, a new system (challenge application) will be established to allow reevaluation of the applicability of a new functional category after the product is listed in the insurance system, based on actual use, for the parts that could not be evaluated at the time of product introduction. NEW!

Absorbable cardiac stent

: The stent is biodegradable and disappears in about three years, whereas conventional metal stents remain in the body.



The benefits of biodegradation and disappearance are expected to be realized after a longer period of time.

- Reduction of events after a long period of time
- Preservation of treatment options at the time of re-treatment, etc.

Successful examples of challenge application

Medtronic Advisa MRI: 3% improvement premium

At the time of reimbursement listing, there were no clinical data to prove the usefulness of the “Reactive ATP function”

Subsequently, a large-scale clinical study on the Reactive ATP function was conducted, and the results of this study were published

Boston Scientific RESONATE CRT-D: 5% improvement premium

The median battery life of the battery-powered CRT-D was 9.9 years through the remote monitoring system, compared to 4.8 years for the conventional battery-powered CRT-D