

Japan approves reimbursement for Edwards' Sapien XT valve

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Singapore: Edwards Lifesciences, makers of heart valves and hemodynamic monitoring, has announced that Japan's Central Social Insurance Medical Council (Chuikyo) has approved the recommendation by the Japanese Ministry of Health, Labor and Welfare's (MHLW) expert review panel to provide reimbursement for the Edwards Sapien XT transcatheter aortic heart valve. The reimbursement is scheduled to go into effect on October 1.

This decision follows regulatory approval of the Sapien XT valve in June. With this approval, Chuikyo established a reimbursement of approximately \$46,000 (4.53 million Yen) for when the Sapien XT valve is used in the treatment of patients with severe symptomatic aortic stenosis. The reimbursement rate for medical devices in Japan covers the cost of the device as well as taxes, certain hospital fees and distribution expenses.

"We are very pleased that the Japanese government has moved swiftly to provide reimbursement for the Sapien XT valve, to enable the country's clinicians to treat transcatheter aortic valve replacement patients with the latest therapy," said Mr Larry L Wood, Edwards' corporate vice president, transcatheter heart valves.

The Sapien XT valve is the first commercially available transcatheter valve in Japan. In the United States, the Sapien XT valve is not commercially available; it is an investigational device being studied as part of a randomized, pivotal clinical trial.