

## CURRENT MINISTRY APPROVAL OF CARDIAC PET &amp; SPECT IN JAPAN

Current Japanese Ministry of Health, Labor, and Welfare  
Approval of Cardiac Positron Emission Tomography

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## Abstract

The current Japanese Ministry of Health, Labor, and Welfare (JMHLW) approvals of cardiac positron emission tomography (PET) include viability, cardiac function, MPI, and detection of inflammatory lesions in cardiac sarcoidosis. The new approval of  $^{13}\text{N}$ -ammonia and  $^{18}\text{F}$ -fluorodeoxyglucose (FDG) for cardiac sarcoidosis have had much impacts on nuclear cardiology community in Japan. Cardiac PET has moved from research PET to clinical PET in Japan.

**Keywords:** Approval • Japanese Ministry of Health, Labor, and Welfare • myocardial perfusion imaging • positron emission tomography

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Japanese Ministry of Health, Labor, and Welfare (JMHLW) initially approved  $^{15}\text{O}$ -labeled gas for left ventricular (LV) functional measurements in 1996. The approval of positron emission tomography (PET) was actually very limited until March 5, 2012. JMHLW currently approves  $^{13}\text{N}$ -ammonia for myocardial perfusion imaging (MPI),  $^{15}\text{O}$ -labeled gas for radionuclide angiography, and  $^{18}\text{F}$ -FDG for myocardial viability and cardiac sarcoidosis testing (Table 1) (1). Recently, most facilities use the hybrid PET/CT scanners. However, the current approval of cardiac PET does still not reimburse PET and simultaneous CT study.

The JMHLW's approval of PET including the use of  $^{18}\text{F}$ -FDG to detect cardiac involvement of sarcoidosis is significant considering that it is not approved in other countries. This approval is likely based on the significant numbers of evidence in Japan showing the usefulness of  $^{18}\text{F}$ -FDG PET in detecting cardiac involvement of sarcoidosis (2).

In the United States, the FDA approved the clinical use of  $^{82}\text{Rb}$  MPI in 1989, and reimbursement by the Centers for Medicare and Medicaid Services (CMS)

began in 1995. Currently, CMS reimbursement applies to  $^{82}\text{Rb}$ ,  $^{13}\text{N}$ -ammonia, and  $^{18}\text{F}$ -FDG (3). The widespread use of  $^{82}\text{Rb}$  must be associated with the approval for clinical use in the United States and Canada (4).  $^{82}\text{Rb}$  has been applied to a limited number of patients with coronary artery disease in Japan for research-based investigations (5). As the next step, approval of  $^{82}\text{Rb}$  for the clinical use is expected.

## Cardiac PET Practice in Japan

The Japanese Isotope Association has conducted a survey of nuclear medicine practice every 5 years since 1982 (6). The total number of  $^{18}\text{F}$ -FDG PET studies was 505,990 in 2012. However, most of the  $^{18}\text{F}$ -FDG PET studies were in oncology (96.3%); cardiac studies accounted for 0.13%.  $^{13}\text{N}$ -ammonia PET MPI was performed in 2,172 studies and numbers for  $^{13}\text{N}$ -ammonia PET MPI showed no significant difference compared to those for the previous survey in 2005.  $^{13}\text{N}$ -ammonia was approved in April, 2012 by JMHLW. The survey was performed in June 2012 and thus the number of

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**Table 1** Japanese Ministry of Health, Labor, and Welfare's approval of use of PET in nuclear cardiology

Test	Date of approval	Indication
<sup>15</sup> O-labeled gas	1996	Diagnosis of heart disease
<sup>18</sup> F-fluorodeoxyglucose	March 8, 2002	Diagnosis of viability (in case of difficult to diagnose myocardial viability using myocardial perfusion SPECT)
	March 5, 2012	Detection of inflammatory myocardial regions in cardiac involvement of sarcoidosis
<sup>13</sup> N-ammonia	March 5, 2012	Diagnosis of ischemic heart disease when other tests are not able to make diagnosis

<sup>13</sup>N-ammonia may not have had significant increase. The number of <sup>13</sup>N-ammonia PET MPI studies is therefore expected to increase in the next survey.

### Japanese Circulation Society Guidelines for Cardiac PET

The Japanese Circulation Society (JCS) guidelines addressed the clinical indication for PET. In the current JCS guidelines, <sup>18</sup>F-FDG PET is class 1 indication for detecting viable myocardium and PET MPI is categorized class I indication for detecting myocardial ischemia (7).

### Future Directions

The current JMHLW approvals of cardiac PET include viability, cardiac function, MPI, and detection of inflammatory lesions in cardiac sarcoidosis. As the next step, new PET MPI tracers are expected to be approved in the future.

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### Conflicts of Interest

None

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