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Title: Positron Emission Tomography (PET) Scanning Technology.

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Aim:

To review and consider the evidence regarding differences between full-ring PET and gamma camera imaging and to issue a decision on the appropriate equipment to use with PET indications currently covered by the Medicare program.

Results and Conclusions:

- Most of the evidence submitted to CMS and available in the scientific literature regarding the diagnostic performance of PET was derived from use of dedicated full-ring PET scanners with bismuth germanate (BGO) crystals. Thus, all the data used to gain recent Medicare coverage approval of FDG-PET for certain oncological and other indications was based on the imaging performance of full-ring systems compared to conventional anatomic imaging.
- Review of the available published studies on camera-based PET shows that these systems miss a non-trivial number of small (2 cm or less), but potentially clinically significant, malignant lesions compared with full-ring PET scanners.
- The clinical utility of PET was premised on the additional information provided by dedicated full-ring PET compared to CT, MRI, and other conventional anatomic imaging studies. CMS has drawn conclusions about the clinical utility of partial-ring scanners based on the evidence for full-ring systems, due to the fundamental design similarities for these two types of systems. However, such design characteristics are significantly different from gamma cameras modified to perform PET.
- Accurate information about sensitivity and specificity for camera-based PET systems is not available. Without studies providing more confident sensitivity and specificity estimates, it is not possible for clinicians to properly interpret the findings from these imaging studies, nor is it possible to determine the clinical significance of diagnostic errors that might result from use of camera-based PET technologies.
- The extension of coverage from full-ring PET to camera-based systems, while anecdotally supported by nuclear medicine experts, cannot be clearly justified based on existing clinical and scientific data.
- Medicare coverage of FDG-PET for new indications (as of July 1, 2001) is limited to use of partial and full-ring PET scanners. Coverage of camera-based systems has been restricted, subject to review over time.

Methods:

- Further studies of the technical and clinical performance of gamma camera-based systems will be necessary to determine whether these systems offer net medical benefit or might inadvertently cause harm.
- Technology in this area is changing rapidly, and CMS is anxious to review any available data comparing the image quality, resolution, sensitivity, and specificity of newer PET scanners to that relating to full-ring PET scanners currently available.
- Standards for PET performance measurement recently released by the National Electric Manufacturers Association (NEMA), the NU 2-2001 standards, may provide a framework for comparing the performance of PET systems with different design features.

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