

**CMS recommends coverage for  
RAI scan negative, Tg positive (>10 ng/mL) thyroid cancer**

**Summary**

**The Centers for Medicare and Medicaid Services (CMS) issued a decision memorandum in April 2003 recommending coverage for FDG PET scanning in patients with thyroid cancer of follicular cell origin previously treated by thyroidectomy and RAI ablation who have serum Tg > 10 ng/mL.**

The process began in December 2000, when CMS issued a decision document that specifically excluded thyroid cancer coverage for FDG PET scanning, which was already approved for most other head and neck cancers but. In response to this decision, the Standards of Care Committee of the American Thyroid Association, in cooperation with The Endocrine Society and AACE, filed a written request for reconsideration of coverage of FDG PET scanning in thyroid cancer in June 2001. During the course of the review process, CMS (1) requested additional information from the ATA, (2) referred the topic to the Agency for Healthcare Research & Quality for a technology assessment, and (3) received additional information and support for the request for reconsideration from the Society of Nuclear Medicine. Details of the review process and final decision can be found at <http://www.cms.hhs.gov/ncdr/memo.asp?id=70>.

It is important to note that before any new or modified policy can take effect, CMS must first issue a manual instruction, program memorandum, CMS ruling, or Federal Registry Notice giving specific directions to our claims-processing contractors. That issuance, known as the National Coverage Determination (NCD) includes an effective coverage date. The start date for coverage has not yet been determined but should be announced soon.

**Specifics of Requested Indications**

While we are pleased with decision of CMS to recommend coverage for patients with elevated serum Tg and negative RAI scans, we also see several other roles for FDG PET scanning in the management of thyroid cancer patients. Therefore, the request for reconsideration of coverage letter submitted in June 2001 recommended that CMS consider expanding coverage for FDG PET scanning in thyroid cancer for the following indications.

- Initial staging (post-surgical) of thyroid cancer of histological subtypes that are known to concentrate I-131 poorly, and therefore not allow for reliable whole body iodine-131 scans. *[CMS Decision: Evidence not adequate to recommend approval for coverage].*
- Re-staging of recurrent or residual thyroid cancer of follicular cell origin in patients with elevated serum thyroglobulin levels, where standard imaging tests have failed to localize metastatic origins. *[CMS Decision: Evidence is adequate to recommend approval for coverage].*
- Re-staging of recurrent or residual medullary thyroid cancer in patients with elevated serum calcitonin, where standard imaging test have failed to localize metastatic lesions. *[CMS Decision: Evidence not adequate to recommend approval for coverage].*
- Identifying (prognosis on) patients with metastatic thyroid cancer of follicular cell origin at highest risk of death over the following three years. *[CMS Decision: Evidence not adequate to recommend approval for coverage].*

In order for CMS to recommend coverage for a specific diagnostic test, the item or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” In rare diseases, most published studies are retrospective, include only relatively small sample size, and often do not directly address the clinical management implications of positive or negative findings.

In thyroid cancer, even though the published data is largely retrospective, CMS determined that there was sufficient evidence to recommend coverage of FDG PET scanning in patients with serum Tg >10 ng/mL with negative RAI scanning. The rationale behind using a Tg > 10 ng/mL (either suppressed or stimulated) arose from the observation by Hooft et al (1) that most patients included in the studies of Tg positive, RAI scan negative patients had serum Tg levels well above 10 ng/mL. Furthermore, the true positive rate for FDG PET was on 11% when the Tg was less than 10 ng/mL, 50% when the Tg was 10-20 ng/mL, and 93% when the Tg was greater than 100 ng/mL (2).

While many centers are now using FDG PET scanning in the initial staging of patients with tumors that are unlikely to concentrate RAI (3), the published reports specifically

addressing this issue are insufficient to allow a determination by CMS that coverage is reasonable and necessary. Likewise, the published reports on the utility of FDG PET in medullary thyroid cancer are inadequate for policy decision making.

The CMS did note that FDG PET scanning does provide powerful prognostic information (4). However, they felt that this information was unlikely to alter patient management and was therefore deemed not to be reasonable and necessary and was not further addressed in the decision memorandum.

### **Future Directions**

This process has emphasized the need for well-designed, prospective studies that specifically address the role of FDG PET scanning in thyroid cancer. In order to gain FDG PET scanning approval for the other indications listed above, additional studies that specifically address the impact of these scans on clinical management decision making in these various subpopulations of patients will be required. This is likely to be quite a challenge since these patients represent only a small fraction of a disease that is already relatively uncommon. In all likelihood, multicenter studies will be required to adequately address these important issues.

1. Hooft L, Hoekstra O, Deville W, et al. Diagnostic Accuracy of 18F-Fluorodeoxyglucose positron emission tomography in the followup of papillary or follicular thyroid cancer. *JCEM* 86: 3779-3786, 2001.
2. Schluter B, Bohuslaviziki KH, Beyer W, et al. Impact of FDG PET with differentiated thyroid cancer who present with elevated thyroglobulin and negative 131I scan. *J Nucl Med* 42:71-76, 2001.
3. Larson S, and Robbins R. Positron Emission Tomography in Thyroid Cancer Management. *Seminars in Roentgen* 37(2):169-174, 2002.
4. Wang W, Larson SM, Fazzari M, et al. Prognostic value of [18F]fluorodeoxyglucose positron emission tomographic scanning in patients with thyroid cancer. *J Clin Endocrinol Metab.* 2000;85(3):1107-13.