

Operations Memo No. 9 (Revised)



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: August 25, 1999

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Subj: **Partial Reimbursement For Baseline gated Tc-99 m Sestimibi (Cardiolite®) Stress Test In COURAGE**

To: Study Personnel

Thru: Trial Leadership

For patients to be considered for enrollment in the COURAGE trial, it is possible to document myocardial ischemia in COURAGE patients in a variety of ways. These are outlined in the protocol and the Operations Manual. The preferred method, however, is a gated Tc-99m sestamibi SPECT study with exercise stress, or in patients who cannot exercise adequately, adenosine stress. This protocol can be done as a one-day protocol or a two-day protocol according to individual site preference.

Participating sites are encouraged to follow a protocol listed below in an effort to standardize the kind of testing performed to document ischemia (more uniform testing allows for more consistent risk assessment); although, it is recognized that it may not be possible to obtain this kind of test on all patients. As an incentive to perform these tests, Dupont and Fujisawa have kindly committed to provide the Tc-99m sestamibi (Cardiolite) and adenosine for the performance of the COURAGE recommended protocol. Also, a partial reimbursement of \$300 (US) will be provided for each patient undergoing gated Tc-99m sestamibi SPECT at baseline (prior to treatment initiation) for COURAGE patients.

In order to be eligible for the partial reimbursement of \$300, the protocol must be performed **before the patient receives treatment** AND include a **gated stress study using Tc-99m sestamibi**, such as the following nuclear protocols:

- 1) One-day rest Tc-99m sestamibi / gated stress Tc-99m sestamibi protocol
- 2) One-day rest Tl-201* / gated stress Tc-99m sestamibi protocol ("dual-isotope protocol")
- 3) Two-day rest Tc-99m sestamibi / gated stress Tc-99m sestamibi protocol

* Please note that if you choose to use Tl-201 or tetrofosmin, the costs for these isotopes will be the responsibility of your site. Tl-201 and tetrofosmin will not be provided for you. Also, SPECT studies using Tl-201 or tetrofosmin will not be used for analysis in the COURAGE trial.

How Do You (Or Your Nuclear Department) Get Reimbursed For This Test

For Tc-99m sestamibi (Cardiolite®):

The Tc-99m sestamibi will be provided by DuPont for all pre-randomized and post-randomized nuclear studies performed throughout the course of the trial. It should be ordered in the usual way and if used for a COURAGE patient, the Tc-99m sestamibi will be provided at no charge. Please consult your DuPont Clinical Specialist if you have questions about ordering Tc-99m sestamibi.

For Adenosine:

Adenosine (donated by Fujisawa for the COURAGE Trial) will also be available on site for use if the patient cannot exercise adequately. If adenosine is used, the Albuquerque Coordinating Center will replenish your supply.

For the \$300 partial reimbursement:

For the enrollment period of the trial, a \$300 partial reimbursement for each baseline gated Tc-99m sestamibi test performed on an enrolled patient who was screened and later randomized will be provided. In addition to this, for a trial period of three months, a \$300 partial reimbursement for each baseline gated Tc-99m sestamibi test performed on a patient who was screened for the COURAGE Trial, but not ultimately randomized will also be provided. Therefore, during the trial period, you will receive a \$300 partial reimbursement for each baseline gated Tc-99m sestamibi test performed for the COURAGE Trial, whether or not the patient is ultimately randomized. To document the gated Tc-99m sestamibi tests that qualify for the partial reimbursement, we ask that you keep a log of these tests. To apply for your reimbursements, send this log to Lisa Miranda at Cedars-Sinai each month. West Haven CSPCC will disperse the money to your site on a quarterly basis.