



Louis Jacques, MD
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

JAN 6 2014

Dear Dr. Jacques,

The Agency for Healthcare Research and Quality (AHRQ) understands that the Centers for Medicare & Medicaid Services (CMS) will cover the use of Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) only for beneficiaries with LSS who are enrolled in an approved clinical study.

A clinical study seeking Medicare payment for PILD for LSS must address one or more aspects of the following questions in a prospective, randomized, controlled design using current validated and reliable measurement instruments and clinically appropriate comparator treatments, including appropriate medical or surgical interventions or a sham controlled arm, for patients randomized to the non-PILD group.

The study protocol must specify a statistical analysis and a minimum length of patient follow up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of benefit.

- i. Does PILD provide a clinically meaningful improvement of function and/or quality of life in Medicare beneficiaries with LSS compared to other treatments?
- ii. Does PILD provide clinically meaningful reduction in pain in Medicare beneficiaries with LSS compared to other treatments?
- iii. Does PILD affect the overall clinical management of LSS and decision making, including use of other medical treatments or services, compared to other treatments?

These studies must be designed so that the contribution of treatments in addition to the procedure under study are either controlled for or analyzed in such a way as to determine their impact.

- a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The research study does not unjustifiably duplicate existing studies.

- d. The research study design is appropriate to answer the research question being asked in the study.
- e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.
- g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>).
- l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Jean Slutsky". The signature is fluid and cursive, with the first name "Jean" written in a larger, more prominent script than the last name "Slutsky".

Jean Slutsky
Director, Center for Outcomes and Evidence