

more effective in its use than autogenous iliac crest bone graft, when either is placed in the LT-Cage™ Lumbar Tapered Fusion Device for anterior lumbar interbody fusion. Use of InFUSE™ Bone Graft instead of autogenous iliac crest bone graft:

- Obviates iliac crest bone graft donor site morbidity.
- Reduces operative time, blood loss and hospitalization.
- Results in greater fusion success.
- We found that the Oswestry Low Back Pain Disability score and SF-36 Physical Component and Pain Index score were consistently 10 percent better in the InFUSE™ Bone Graft group than the autogenous iliac bone graft group.

- Enables earlier return to work.”

As indicated in the May 19, 2003 proposed rule, among the issues we planned to consider were: does avoiding the complications associated with the iliac crest bone harvesting procedure constitute a substantial clinical improvement; and, with the increased rate of osteoarthritis and osteoporosis in the Medicare population, is there evidence that the technology represents a substantial clinical improvement in spinal fusions among this population? In the May 19, 2003 proposed rule, we indicated we were particularly interested in data on the results of aged Medicare patients who have been treated with BMP, and any basic biology bench data on the results of using BMP in osteoporotic bones.

Since the May 19, 2003 proposed rule, we received from the sponsor of this application an analysis, prepared by an orthopedic surgeon, that showed limited evidence of results in a series of patients older than 65, all with good or better fusion results than the younger age group. That analysis presented evidence that older patients typically have better results than younger patients in the standard iliac crest bone harvesting fusion procedure. Finally, it included the results of bench testing of mesenchymal and osteoblastic cells that demonstrated response to rhBMP-2, including cells from elderly patients.

The sum of this evidence does not preclude generalizing the results of InFUSE™ trials to Medicare aged beneficiaries. In addition, the small series of Medicare-aged patients treated with InFUSE™ technology, as well as the bench science on the response of elderly mesenchymal cells to rhBMP-2, do provide some positive, though limited, evidence for generalizability. These results, combined with the benefits of the elimination of the need to harvest bone from the iliac crest (and the associated complications), lead us to

conclude that InFUSE™ does meet the substantial improvement criteria. Therefore, we are approving InFUSE™ for add-on payments under § 412.88, to be effective for FY 2004.

This approval is on the basis of using InFUSE™ for a single-level, lumbar spinal fusions, consistent with the FDA's approval and the data presented to us by the applicant. Therefore, we intend to limit the add-on payment to cases using this technology for anterior lumbar fusions in DRGs 497 and 498. Cases involving InFUSE™ that are eligible for the new technology add-on payment will be identified by assignment to DRGs 497 or 498 as a lumbar spinal fusion, with the combination of ICD-9-CM procedure codes 84.51 and 84.52.

As explained above, we are limiting our approval of this technology to uses consistent with our substantial clinical improvement decision. Therefore, add-on payments are only available for use of the technology at a single-level. The average cost of the InFUSE™ is reported to be \$8,900, and a single level fusion requires two of the products. Therefore, the total cost for the InFUSE™ for a single-level fusion is expected to be \$17,800. Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the DRG payment for the case. As a result, the maximum add-on payment for a case involving the InFUSE™ is \$8,900.

For purposes of budget neutrality, it is necessary to estimate the additional payments that would be made under this provision during FY 2004. We identified 205 cases in DRGs 497 and 498 in the March 2003 update of the FY 2003 MedPAR data. For our FY 2004 budget neutrality estimate, we are projecting this number will grow to 500. Given this estimate and the maximum add-on payment of \$8,900, we estimate the total amount of the add-on payments for the InFUSE™ for FY 2004 will be \$4.4 million dollars.

*Comment:* One commenter asked that CMS reconsider the decision to exclude multilevel fusions with InFUSE™ from the cost threshold calculation. The commenter noted that excluding multilevel fusions with InFUSE™ is inconsistent with FDA guidance, clinical practice and other CMS payment decisions for new technologies (notably the creation of DRGs for drug-eluting stents based on the presence of a condition not indicated on the product label, that is, acute myocardial infarction).

*Response:* As stated previously, because the FDA has not approved this

technology for multilevel fusions and the applicant has not submitted data to demonstrate this technology is a substantial clinical improvement for multilevel fusions, we cannot issue a substantial clinical improvement for multilevel fusions. In the September 7, 2001 final rule implementing this provision (66 FR 46913), we stated our position that the special payments under this provision should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries. Where such an improvement is not demonstrated, we continue to believe the incentives of the DRG system provide a useful balance to the introduction of new technologies, and no new technology add-on payment is necessary.

*Comment:* In the proposed rule, we stated that, if InFUSE™ meet the cost threshold, we would evaluate whether it qualifies as a substantial clinical improvement. One commenter noted that, assuming InFUSE™ does meet the cost threshold, CMS would make a determination on whether the technology meets the substantial clinical improvement criterion without public input or the opportunity to address concerns that CMS may have. The commenter noted that these actions are inconsistent with the Administrative Procedure Act and CMS's pledge to be more open in its policy making.

*Response:* Because of the many questions that remained at the time of the proposed rule, we were unable to determine if InFUSE™ qualified as a substantial clinical improvement. However, in order to receive comments on this determination, we indicated certain issues we would consider when determining if InFUSE™ qualifies as a substantial clinical improvement. As noted above, we received additional information that enabled us to approve this technology as a substantial clinical improvement. Therefore, we believe interested parties had sufficient information to provide informed comments.

*Comment:* One commenter, a designer, manufacturer, and supplier of orthopedic devices and supplies, explained that the applicant's analysis probably includes cases for both posterior approaches or posterior instrumentation, or both, which are considered off-label uses from the indications approved by the FDA. Therefore, the commenter requested that cases that do not meet FDA approved indications, once identified, be eliminated from the analysis.

The commenter also noted that once claims of InFUSE™ can be identified