

with MedPAR data, DRG weights become eligible for recalibration in order to reflect the appropriate payment within the assigned DRG. Once the weights of a DRG can be evaluated, a technology should no longer be classified as new. Also, the commenter stated that clinical trial results counter the claim of significant improvement, because information presented at the FDA Orthopedics and Rehabilitation Devices Panel public meeting on January 20, 2002, indicated that the InFUSE™ product resulted in an equivalency to that of traditional bone grafting techniques. Although there was a decrease in donor site pain in a small number of subjects in the BMP group, compared with the control group, the commenter questioned whether this factor meets the criteria of substantial clinical improvement. The commenter also questioned the results of a published article on this technology.

Response: One of the criteria for a substantial clinical improvement classification is avoidance of surgery. CMS determined that InFUSE™ should be classified as a substantial improvement if the results of the clinical trials demonstrated outcomes at least equivalent to bone grafting, and the bone harvesting procedure was avoided. CMS clinical staff reviewed the literature and concluded that the current evidence did support grafting equivalence for the FDA approved indications and, therefore, InFUSE™ met the substantial improvement standard. As described above, we did not rely on the applicant's analysis to determine the technology met the high-cost threshold, but conducted direct analysis of available FY 2003 MedPAR data.

b. GLIADEL® Wafer

Glioblastoma Multiforme (GBM) is the most common and most aggressive of the primary brain tumors. Standard care for patients diagnosed with GBM is surgical resection and radiation. According to the manufacturer, the GLIADEL® Wafer is indicated for use as an adjunct to surgery to prolong survival in patients with recurrent GBM. Implanted directly into the cavity that is created when a brain tumor is surgically removed, GLIADEL® delivers chemotherapy directly to the site where tumors are most likely to recur.

The FDA approved GLIADEL® Wafer on September 23, 1996, for use as an adjunct to surgery to prolong survival in patients with recurrent GBM for whom surgical resection is indicated. In announcing its approval, the FDA indicated that GLIADEL® was approved:

“* * * based on the results of a multi-center placebo controlled study in 222 patients who had recurrent malignant glioma after initial treatment with surgery and radiation therapy. Following surgery to remove the tumor, half of the patients were treated with GLIADEL® implants and half with placebo. In patients with glioblastoma multiforme, the 6-month survival rate increased from 36 percent with placebo to 56 percent with GLIADEL®. Median survival increased from 20 weeks with placebo to 28 weeks with GLIADEL®. In patients with pathologic diagnoses other than glioblastoma multiforme, GLIADEL® had no effect on survival.”

Guilford Pharmaceuticals has requested that GLIADEL® still be considered new because, until a new ICD-9-CM code (00.10 Implementation of Chemotherapeutic Agent) was established on October 1, 2002, it was not possible to identify specifically these cases in the MedPAR data. However, as noted previously, technology will no longer be considered new after the costs of the technology are reflected in the DRG weights. Because the costs of GLIADEL® are currently reflected in the DRG weights (despite the absence of a specific code), GLIADEL® does not meet our criterion that a medical service or technology be “new”. That is, FY 2002 MedPAR data used to calculate the DRG weights for FY 2004 in this final rule include cases where GLIADEL® was administered (and the corresponding charges of these cases include charges associated with GLIADEL®). On February 26, 2003, the FDA approved GLIADEL® for use in newly diagnosed patients with high-grade malignant glioma as an adjunct to surgery and radiation. However, our understanding is that many newly diagnosed patients were already receiving this therapy. To the extent this is true, the charges associated with this use of GLIADEL® are also reflected in the DRG relative weights.

According to Guilford's application, the current average wholesale price of GLIADEL® is \$10,985. Guilford submitted charge data for 23 Medicare patients at 7 hospitals from FY 2000. The charges were then standardized and adjusted for inflation using the hospital market basket inflation factor (from 2000 to 2003) in order to determine an inflated average standardized charge of \$33,002. Guilford points out that this charge narrowly misses the DRG 2 threshold published in Table 10 of the August 1, 2002 IPPS final rule of \$34,673. However, we note that, according to the manufacturer, as many as 60 percent of current GLIADEL® cases may be assigned to DRG 1 based

on the presence of CCs. Based on this assumption, the qualifying threshold for GLIADEL® would be \$54,312 (60 percent of the DRG 1 threshold of \$67,404, and 40 percent of the DRG 2 threshold of \$34,673).

As mentioned in section II.B.3.a of the May 19, 2003 proposed rule and above in this final rule, we examined the definitions of DRGs 1 and 2 to determine whether they could be improved. As proposed, we are creating a new DRG for patients with an intracranial vascular procedure and an intracranial hemorrhage and two new DRGs for patients with only a vascular shunt procedure (splitting on the presence or absence of a CC). We also compared the data submitted in the application for add-payments regarding the charges for GLIADEL® cases with the charges of other procedures in DRGs 1 and 2. We found that, although the \$33,002 average standardized charge reported is just below the qualifying threshold in DRG 2, it is actually well below the mean average standardized charge for DRG 1 (\$42,092). As noted previously, as many as 60 percent of current GLIADEL® cases may be assigned to DRG 1 based on the presence of CCs. Therefore, we do not believe that any change to the DRG assignment of cases receiving GLIADEL® is warranted at this time. However, we will continue to monitor our data to determine whether a change is warranted in the future.

Comment: One commenter supported CMS' determination that this technology is currently reflected within the DRG weights and does not meet the criteria of being called “new.” Another commenter commented that CMS' interpretation of whether a technology is “new” is inconsistent with the current statute. The commenter explained that section 1886 (d)(5)(K)(ii)(II) of Act states that CMS should collect data on new technologies “for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued for the technology.” Accordingly, the commenter believed it is inconsistent with the intent of Congress to deny new technology status to a product that has been on the market but for which there is no unique ICD-9 code that allows CMS to track the costs of cases in which it is utilized. The commenter urged CMS to reconsider its interpretation of the statute and approve GLIADEL® as a new technology, making clear that a technology will be considered new for 2 to 3 years from the date that an ICD-9-CM code, specific to the technology, becomes available.