

that the per-session costs of delivering image-guided robotic linear accelerator-based SRS are the same, regardless of whether the patient's disease requires one treatment or multiple treatments.

*Response:* Our claims data do not support the assertion that the per-session costs of delivering image-guided robotic linear accelerator-based SRS is equal to the costs of delivering a complete course of image-guided robotic linear accelerator-based SRS treatment. However, we acknowledge the possibility that claims data for G0173 and G0251 may include both image-guided robotic linear accelerator-based SRS treatments as well as other forms of linear accelerator-based SRS treatments and, as a result, the median cost may not accurately reflect the true costs of delivering image-guided robotic linear accelerator-based SRS therapy. As stated in our response to the above comment, we will create two new G codes (G0339 and G0340) to distinguish complete and fractionated image-guided robotic linear accelerator-based SRS treatment from other forms of complete and fractionated linear accelerator-based SRS treatment. We will place HCPCS code G0339 (complete session) in APC 1528 at a payment rate of \$5250. The APC placement of HCPCS code G0340 is discussed below.

While we recognize the costs to provide multi-session image-guided robotic SRS therapy may be greater than the current payment rate for HCPCS code G0251, we received no convincing cost data supporting commenters' claims that the costs of performing each additional session subsequent to the first session of a fractionated treatment is equivalent to the costs of performing a complete session. Rather, we believe that certain economies of scale are realized when performing each additional session subsequent to the first session of a fractionated treatment. That is, based on our understanding of the therapy, we do not believe that the same exact amount of hospital resources would be utilized for each subsequent session.

Statements provided by various interested parties indicate that the costs of providing each session of a fractionated treatment range from \$2700 to \$9000. However, we received no convincing data to substantiate these statements. We have estimated that approximately 75 percent of the costs of a complete session would be required to provide each additional session subsequent to the first session of a fractionated treatment. Therefore, we will place HCPCS code G0340 in new technology APC 1525, which covers procedures ranging from \$3500 to \$4000

in payment and which pays \$3750. This new technology APC range pays approximately seventy-five percent of the payment for HCPCS code G0339. We will modify the descriptor for HCPCS code 0340 to describe additional sessions (second through fifth sessions) subsequent to the first session of a fractionated treatment. In addition, we will expand the descriptor for a complete session (HCPCS code G0339) to include the first session of a multi-session treatment. To further clarify, when providers perform multi-session image-guided robotic SRS therapy, they should bill using HCPCS code G0339 for the first session. For each additional session subsequent to the first session, providers should bill using only HCPCS code G0340 up to a maximum of five sessions.

Although we received no clinical data to substantiate the use of a single session versus multiple fractionations up to five sessions, a few commenters stated that a maximum of five sessions may be utilized to treat certain conditions; therefore, we will continue to pay for the delivery of multi-session therapy (HCPCS code G0340) up to a maximum of five sessions per course of treatment. When additional data is submitted, we may reconsider this payment decision.

As described above, we will create the following new G codes to identify image-guided robotic linear accelerator-based SRS treatment delivery:

HCPCS code G0339—Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment.

HCPCS code G0340—Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment.

#### *SIRTeX Medical (RE: SIR-Spheres Brachytherapy Source)*

*Comment:* The manufacturer of a brachytherapy source to treat liver cancer commented that our proposed payment of \$8,870.88 for APC 2616 was inadequate to pay for its product, which it reported costs \$14,000 per treatment dose. This commenter stated that there are only two products that would fit this APC, which is for Yttrium-90 brachytherapy source. Moreover, this party claimed that there were significant clinical differences between its product and another Yttrium-90 source, and that these differences necessitated the price differential between the two products.

The commenter requested establishment of a separate alpha-numeric HCPCS code for its product, in order to account for the cost differences between the two Yttrium-90 products and to set more equitable payment rates for the two products.

*Response:* We appreciate the concerns of the commenter. We would first note that payment to APC 2616 has increased to \$9,615.50 per dose compared to the 2003 payment of \$6,485.37. The information provided in the comment did not convince us that the payment rate resulting from the 2002 claims data is inadequate to pay hospitals for the Yttrium-90 products. We are uncertain whether or not there are other Yttrium-90 sources in addition to the two discussed in this comment that would need to be considered in any analysis of the relative costs of the products. Therefore, until we have additional data, we believe that code C2616 and APC 2616 adequately describes and pays for Yttrium-90 brachytherapy sources.

#### *Low Osmolar Contrast Media*

*Comment:* A radiology specialty society expressed disappointment because we did not address payment for low osmolar contrast media (LOCM) in the proposed rule. The commenter believes that the variability in usage and Medicare's restricted coverage of LOCM warrant payment in a separate APC in the 2004 final rule. The commenter recommends that we increase the relative weights of APCs that include codes that involve the use of LOCM agents to reflect the additional costs of these agents if we do not establish a separate APC to pay for LOCM.

*Response:* We issued a program memorandum on November 22, 2002 (Transmittal A-02-120, Change Request 2185) in which we removed all requirements differentiating payment between high osmolar contrast material and LOCM as well as restrictions that would limit payment for LOCM only to patients with specific diagnoses. In that program memorandum, we instructed our contractors to discontinue any edits that would prohibit payment for LOCM if specific diagnoses were not reflected on the claim, effective for services furnished on or after January 1, 2003. We further directed contractors to instruct hospitals to include charges for LOCM in the charge for the diagnostic procedure or, if LOCM is billed as a separate charge, to use revenue code 254 or 255 as appropriate. These instructions applied only to hospitals subject to the OPFS.

We disagree with the commenter's recommendation that a separate APC