

With respect to the comment that we should add APC 0656 to the list of APCs for which a device was required to be on the claim for weight setting, we believe it would be inappropriate to do so for the 2004 OPPS. This is because the drug-eluting stent was not approved by the FDA until 2003, and, therefore, it did not appear in the 2002 data. Moreover, since there are no device codes for coronary stents for use on claims in 2003, the 2003 data will not contain the device codes that would be needed to create a subset of stent device claims to use for the 2005 OPPS. However, in view of the reinstitution of device coding for 2004, we will consider this comment in our work to develop the 2006 OPPS. Moreover, as we indicated above, we based the payment for APC 0656 on the median for APC 0104, which was calculated from claims that contained C codes for stents.

Cardioverter Defibrillator (APC 0107)

Comment: Commenters indicated that the proposed payment for this APC was too low to pay for the device, much less the cost of the services to implant it. They indicated that the cost of the device in 2002 varied between \$19,160 and \$21,410 among major group purchasers, considerably more than the proposed payment of \$15,773.28. They asked that we use the external data to set the device portion of the hospital cost.

Response: We reviewed the data for this APC and considered the comments of the APC Panel at its August 2003 meeting on the August 12, 2003 proposed rule. We were convinced that the median for this device is too low to be appropriate relative to other median costs. We used external data that had been presented to the APC Panel to calculate a mean external acquisition cost and used one part external cost to one part median cost from our claims data to acquire an adjusted cost for the device. We then added the nondevice median from our claims data to the adjusted device acquisition cost to acquire an adjusted median that we used to set the relative weight for this APC. Effective for October 1, 2003, we established codes to be used for reporting the services assigned to APCs 107 and 108. Specifically, CPT code 33240 (Insertion of cardioverter defibrillator) is no longer recognized as a valid code for OPPS. Instead, hospitals now report either G0297 (Insertion of single chamber pacing cardioverter defibrillator pulse generator) or G0298 (Insertion of dual chamber pacing cardioverter defibrillator pulse generator). Also effective for October 1, 2003, CPT code 33249 (Insertion/

replacement/repair of cardioverter defibrillator and insertion of pulse generator) is no longer recognized as a valid code for OPPS. Instead, hospitals will report either G0299 (Insertion or repositioning of electrode lead for single chamber pacing cardioverter defibrillator and insertion of pulse generator) or G0300 (Insertion or repositioning of electrode lead for dual chamber pacing cardioverter defibrillator and insertion of pulse generator). These codes were created to capture differential costs related to single and dual chamber cardioverter defibrillators. Claims containing the CPT codes we no longer recognize for OPPS (CPT codes 33240 and 33249) are being returned to providers to be coded correctly and resubmitted.

Insertion of Pacemaker Dual Chamber (APC 0655) and Insertion of Pacemaker Single Chamber (APC 0089)

Comment: A commenter indicated that the proposed payment rates for these APCs are only slightly more than the lowest median hospital acquisition cost of the device leaving a hospital little or no payment for the services to implant it. They asked that we re-evaluate and price these APCs at a level that pays the full cost of the device and services.

Response: We carefully reviewed the data for these APCs. We were not convinced that there was a need to adjust the median for either of these APCs. The median cost for APC 0655 is about 12 percent higher than the adjusted median on which the 2003 payment weights were based (2003 adjusted median of \$7,298.52 versus the final rule median of \$8,225.23). The median cost for APC 0089 is slightly higher than the adjusted median on which the 2003 weights were based (2003 adjusted median of \$6,686.16 versus the final rule median of \$6,754.63). The comment was not convincing that these median costs were inappropriate in relation to the other median costs that will be used to set the relative weights. Moreover, since median costs for both APCs rose above the amounts achieved by upward adjustments for these APCs in 2003, we believe that the medians are appropriately relative to the costs for other services that will be used to set the relative weights.

Insertion of Pacemaker, Dual Chamber Generator Only (APC 0654)

Comment: A commenter indicated that the proposed payment rate is about 95 percent of the hospital acquisition cost of the device, leaving the hospital at an immediate loss if it implants this

device. They asked that we re-evaluate and price these APCs at a level that pays the full cost of the device and services.

Response: The median cost for this APC is about 19 percent higher than the adjusted median on which the 2003 payment weight was based (2003 adjusted median of \$5,456.63 versus the final rule median of \$6,495.61). We saw no reason to further adjust the median on which the relative weights for 2004 are based. The comment was not convincing that these median costs were inappropriate in relation to the other median costs that will be used to set the relative weights. Moreover, since the median cost for the APC rose above the amounts achieved by upward adjustments for the APC in 2003, we believe that the median is appropriately relative to the costs for other services that will be used to set the relative weights.

INTEGRA Wound Products and Other Wound Products

Comment: We received a comment concerning INTEGRA Dermal Regeneration Template and INTEGRA Bilayer Wound Matrix in which the commenter stated that there is a payment disparity between the INTEGRA products and APLIGRAF, DERMAGRAFT and TRANSCYTE, which are eligible for separate payment as biologicals. The commenter noted that hospitals that use APLIGRAF, DERMAGRAFT, and TRANSCYTE receive an extra payment in the form of a pass-through or other separately paid APC payment in addition to the APC payment for the skin repair procedures (APC 0025), while users of the aforementioned INTEGRA products receive only the regular payment associated with skin repair CPT codes. The commenter stated that this payment differentiation provides a financial incentive to hospitals to use the other skin replacement products, and places INTEGRA at a competitive disadvantage. The commenter recommended that we create a product-specific APC for INTEGRA to provide comparable payment for "this class of products." Alternatively, the commenter recommended that we establish a single APC that includes the cost of all or most skin replacement technologies. The manufacturer noted that hospitals using INTEGRA would receive only \$340.41 under our proposed rate for APC 0025, while total payments for APC 0025 plus the product-specific codes for APLIGRAF, DERMAGRAFT, and TRANSCYTE would be between \$770.86 and \$1,072.86.

Response: TRANSCYTE was approved for transitional pass-through