

yttrium) would be approximately \$2,000 less than what it costs a hospital to purchase Zevalin from a nuclear pharmacy, thereby jeopardizing beneficiary access to this therapy. One commenter submitted information from a nuclear pharmacy attesting that it has dispensed 2,068 patient-specific doses of Zevalin nationwide (1,071 Indium doses and 997 Yttrium doses) and that its current charges are \$2,260 per dose of Indium-111 Zevalin and \$19,565 per dose of Yttrium-90 Zevalin. The commenter stated that this represents nearly 80 percent of all Zevalin doses dispensed between product launch in April 2002 through June 30, 2003.

Another commenter expressed concern about the adverse impact that the proposed reduction in payments for Zevalin could have on payment for Bexxar in 2004. The commenter urged us not to base payment for Bexxar on what we proposed for Zevalin but, rather, on hospital acquisition costs for Bexxar, which approximate the wholesale acquisition cost (WAC) of \$2,250 for the diagnostic dose and \$19,500 for the therapeutic dose.

Response: Although we established a code to enable hospitals to bill for and receive separate payment for Zevalin effective October 1, 2002, hospitals could only report this code through December 31, 2002. (Effective January 1, 2003, we combined payment for Zevalin with its administration, using HCPCS codes G0273 and G0274.) Our 2002 claims data are insufficient to allow us to calculate a median cost for Zevalin. Because Bexxar was approved by the FDA in June 2003, it was not billed at all in 2002. Therefore, we cannot determine payment rates for either radiopharmaceutical based on the standard methodology that we use to calculate the other APC relative payment weights and rates. In instances where we lack adequate data upon which to base a payment rate, we have relied wholly or in part on external data as the basis for rate setting. For example, in the absence of claims data, we use data submitted in applications for new technology status to enable us to assign a service to an appropriate new technology APC. Elsewhere in this final rule, we discuss how we are using external data to set 2004 payment rates for certain other services and procedures.

We received information consistent with our request for verifiable data (68 FR 47998) that indicates the payment amounts we proposed for A9522 and A9523 in the proposed rule do not reflect the price for Zevalin that is widely available to the hospital market.

Therefore, we are making final the following payments, effective for services furnished on or after January 1, 2004:

For HCPCS code C1080 (APC 1080) the payment is \$2,260;

For HCPCS code C1081 (APC 1081) the payment is \$19,565; For HCPCS code C1082 (APC 9118) the payment is \$2,260;

For HCPCS code C1083 (APC 9117) the payment is \$19,565.

Comment: One commenter expressed concern about the inadequacy of the 2003 payment rate (\$2,159) that we established for HCPCS code G3001, Administration and supply of tositumomab, 450mg. The commenter noted that the WAC for unlabeled tositumomab is \$2,125, and that a payment amount of \$2,159 is not sufficient to pay hospitals for both the acquisition of unlabeled tositumomab and its administration. The commenter was also concerned that packaging the unlabeled antibody tositumomab with its administration and assigning it to an APC that is subject to wage adjustment would result in large payment differences across the country. The commenter noted that the unlabeled antibody rituximab, which is used with Zevalin therapy, is a separately payable drug and therefore not subject to wage index adjustments. The commenter recommended that we either increase the payment rate for G3001 and exempt it from wage adjustment or that we create a new code for unlabeled tositumomab, assign a payment rate that reflects its acquisition cost, and pay separately for its administration using HCPCS code Q0084.

Response: After carefully reviewing the commenter's concerns, we have assigned HCPCS code G3001 to New Technology APC 1522, which has a payment rate of \$2,250. Unlabeled tositumomab is not approved as either a drug or a radiopharmaceutical, but is a supply that is required as part of the Bexxar treatment regimen. Therefore, we do not agree with the commenter's recommendation that we assign a separate new code to unlabeled tositumomab. Moreover, administration of unlabeled tositumomab is a complete service that qualifies it for assignment to a New Technology APC. We believe that the increased payment resulting from assignment of G3001 to New Technology APC 1522 will be sufficient to enable hospitals to acquire and administer unlabeled tositumomab, notwithstanding application of a wage adjustment.

Comment: One commenter recommended that we modify the payment amounts for the existing codes

used to bill for Bexxar or that we establish new codes to recognize the costs of patient evaluation, education, and clearance for radiation safety purposes as well as the costs of compounding Bexxar by radiopharmacies. The same commenter suggested that, as an alternative to establishing a new code for the costs associated with the procedures required for patient safety and education when Bexxar is used, we allow hospitals to report an appropriate Evaluation and Management code for patient evaluation, education, and clearance when receiving diagnostic or therapeutic services involving radioisotopes.

Response: We disagree with the commenter's recommendation that an additional code is needed to pay for radiopharmacy compounding costs or that an allowance of \$1,000 should be added to the payment for the both diagnostic and therapeutic doses of Bexxar to offset these costs. We believe that the rates we are implementing in this final rule, as discussed above, provide sufficient payment for radiopharmacy compounding or delivery costs that hospitals may incur when using Bexxar or Zevalin. We have carefully considered the commenter's recommendation that hospitals be allowed to bill an appropriate evaluation and management code for patient evaluation, education, and clearance following procedures involving radioisotopes. We recognize that special requirements may have to be met before releasing a patient following exposure to a high dose of radiation. We would expect the patient's physician to provide, and bill for separately with appropriate documentation, a significant portion of the preparation and education needed by a patient being treated with Zevalin or Bexxar. However, to the extent that qualified hospital staff are required to provide additional face-to-face patient education and instructions before the patient's release following radioimmunotherapy, the hospital may bill an appropriate evaluation and management code as long as the medical record documents that the services are medically necessary and that they constitute a distinct, separately identifiable evaluation and management service that is consistent with the hospital's criteria for that service.

Drugs and Biologicals for Which Pass-Through Status Will Expire in 2004

Section 1833(t)(6)(C)(i) of the Act specifies that the duration of transitional pass-through payments for drugs and biologicals must be no less