

APC 9118 with a payment amount of \$2,084.55 and HCPCS A9523 in APC 9117 with a payment amount of \$18,066.09. We note that payment rates for radiopharmaceuticals are not subject to wage index adjustments because no portion of the payment is attributed to labor-related costs.

Because we proposed that payment for G0273 and G0274 no longer include payment for Zevalin, we also proposed to place G0273 into newly created APC 0406 and G0274 into newly created APC 0408. These APCs include procedures that are similar clinically and in terms of resource consumption to G0274 and G0273, respectively.

Zevalin (ibritumomab tiuxetan) is a radioimmunotherapy that is used to treat patients with certain forms of non-Hodgkin's lymphoma (NHL). Medicare began payment under the OPPS for Zevalin services furnished on or after October 1, 2002.

On June 27, 2003, the FDA approved the manufacture and sale of Bexxar (tositumomab and Iodine I 131 tositumomab), which is another radioimmunotherapy used to treat patients with certain forms of non-Hodgkin's lymphoma. Both Zevalin and Bexxar are therapeutic regimens administered in two separate steps: The first step is diagnostic to determine radiopharmaceutical biodistribution of radiolabeled antibodies; the second step is the therapeutic administration of targeted radiolabeled antibodies.

On September 8, 2003, we issued a One Time Notification (Transmittal 1, Change Request 2914) to implement payment for Bexxar effective for services furnished on or after July 1, 2003. We instructed hospitals to bill for Bexxar using HCPCS codes G0273 (Pretx planning, non-Hodgkins), G0274 (Radiopharm tx, non-Hodgkins), and G3001 (Administration and supply of tositumomab, 450mg). Publication deadlines precluded our being able to address payment for Bexxar in the August 12, 2003 proposed rule.

Comment: A major hospital association, a nuclear medicine specialty organization, several providers that treat cancer patients, and two radiopharmaceutical manufacturers submitted comments regarding the changes we proposed to the coding and payment for Zevalin (ibritumomab tiuxetan) under the 2004 OPPS. The commenters agree with our proposal to separate payment for Zevalin from the payment for the procedure and to pay for Zevalin using HCPCS codes A9522 and A9523, which would not be subject to a wage index adjustment. One commenter noted that the HCPCS descriptors for A9522 and A9523 define

the unit of service as "per millicurie," but that the payment we proposed for these two codes appeared to be a total payment amount rather than a per millicurie rate. Several commenters recommended that the code descriptors for A9522 and A9523 be revised to read "per dose" rather than "per millicurie."

Response: We appreciate the commenters' support of our proposal to pay for Zevalin separately from its administration. We also agree with the commenter who suggested that the payment rate proposed for A9522 and A9523 was incorrectly shown as a total payment amount rather than a per millicurie rate, and we have made certain that the final payment amounts implemented in the 2004 update are consistent with the code descriptor for the service. We further agree with the recommendation of commenters that the HCPCS descriptors for Indium 111 ibritumomab tiuxetan and Yttrium 90 ibritumomab tiuxetan would be less confusing if expressed in terms of dose rather than millicuries. However, the descriptors for A9522 and A9523 were established by the HCPCS National Panel through the process described on our Web site at <http://www.cms.hhs.gov/medicare/hcpcs/>, and such a descriptor change could not be applied for in time for January 1, 2004 implementation of the OPPS. Therefore, we are establishing two temporary C-codes for hospitals to use to bill under the OPPS for Indium 111 ibritumomab tiuxetan and Yttrium 90 ibritumomab tiuxetan, for services furnished beginning January 1, 2004, as follows:

C1082, Supply of radiopharmaceutical diagnostic imaging agent, indium-111 ibritumomab tiuxetan, per dose

C1083, Supply of radiopharmaceutical therapeutic imaging agent, Yttrium 90 ibritumomab tiuxetan, per dose

Comment: One commenter recommended that we create separate codes that parallel A9522 and A9523 to bill for Bexxar (tositumomab and I-131 tositumomab).

Response: We are establishing two temporary C-codes for hospitals to use to bill under the OPPS for I-131 tositumomab for services furnished beginning January 1, 2004, as follows:

C1080, Supply of radiopharmaceutical diagnostic imaging agent, I-131 tositumomab, per dose

C1081, Supply of radiopharmaceutical therapeutic imaging agent, I-131 tositumomab, per dose

Comment: Several commenters recommended that we discontinue use of HCPCS codes G0273 and G0274 to

describe the administration of Zevalin and that, instead, we instruct hospitals to report new CPT code 78804, Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging, and new CPT code 79403, Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion. One commenter expressed concern about our proposal to assign G0273 for pre-treatment planning and administration of the diagnostic dose to APC 0406, Tumor/Infection Imaging because the payment rate proposed for APC 0406 (\$258.10) is inadequate to pay for the cost of the scans required to measure the distribution of the radiopharmaceutical agent. The same commenter agreed with our proposal to assign G0274 for administration of the therapeutic dose to APC 0408, with a proposed payment rate of \$217.16.

Response: We agree with the commenters' recommendations that we replace HCPCS codes G0273 and G0274 with CPT codes 78804 and 79403, respectively. We will direct our contractors to instruct hospitals to use CPT code 78804 to report administration of the diagnostic dose of ibritumomab tiuxetan and I-131 tositumomab and to report CPT code 79403 to report administration of the therapeutic dose of ibritumomab tiuxetan and I-131 tositumomab. We also agree with the concern of commenters that the payment amount for APC 0406 in the final rule is insufficient for administration of the diagnostic radiolabeled antibodies plus the imaging required to determine radiopharmaceutical localization of tumor(s) and distribution of the radiopharmaceutical agent. Therefore, we are assigning CPT code 78804 to New Technology APC 1508, which has a payment rate of \$650. After we have had an opportunity to collect claims data that indicate hospital costs for this procedure, we will re-evaluate its APC assignment. Further, there are several additional expenses associated with these innovative radioimmunotherapies used to treat patients with certain forms of non-Hodgkin's lymphoma, which we discuss below. We are therefore assigning CPT code 70403 to New Technology APC 1507, until we have collected sufficient data to confirm the appropriate clinical APC for this service.

Comment: Several commenters expressed concern that our proposed payment for Zevalin (\$2,084.55 for the diagnostic dose of indium and \$18,066.09 for the therapeutic dose of