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2007

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Kerry N. Weems
Acting Administrator
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Department of Health and Human Services
Attention: CMS 1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS 1392-P, Proposed Changes to the Hospital Prospective Payment System
and CY 2008 Rates

Dear Mr. Weems:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the proposed changes to the hospital outpatient prospective payment system for 2008. ASH represents approximately 11,000 hematologists in the United States who are committed to the treatment of patients with blood-related disorders. ASH members include hematologists and hematologist/oncologists who provide expert care to Medicare beneficiaries and whose services are frequently covered by the Hospital Outpatient Prospective Payment System (HOPPS). ASH would like to offer specific comments on issues that affect hematologists.

Bone Marrow and Stem Cell Processing Services

ASH is concerned about the APC assignment and the proposed payment level for the bone marrow and stem cell processing procedures, Codes 38207-38215. These services involve the expert processing of bone marrow and stem cells prior to transplantation and include such critical procedures as the therapeutic removal from the graft of certain undesirable cells. Since the inception of the HOPPS program, and until the present time, CMS has failed to recognize and appropriately fund these important CPT codes.

CMS established three "G" codes with which to report these services. Two of the codes were erroneously classified as clinical diagnostic laboratory tests and excluded from HOPPS: G0265 (cryopreservation, freezing and storage of cells for therapeutic use) and G0266 (thawing and expansion of frozen cells for therapeutic use). The third code, G0267 [bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (e.g., T-cells, metastatic carcinoma)], was covered under HOPPS.

ASH appreciates the fact that, after several years of discussion, codes 38207-38215 will now be recognized under HOPPS according to the proposed rule, but we are concerned about their proposed APC assignment. Codes 38207-38209 were assigned to APC 0344, Level IV Pathology, with a proposed payment rate of \$54.69. This APC consists primarily of anatomic pathology services, including Codes 88307 and 88309, that involve the handling and preparation of tissue specimens for microscopic evaluation. Clearly, the effort, processes and, therefore, the costs involved in cryopreserving,

thawing and washing bone marrow/stem cells for a potentially life-saving transplant are very different from the costs involved in preparing tissue for diagnostic studies.

ASH, working with AABB, ASBMT and other interested societies, conducted a survey of hospital centers that perform bone marrow transplantation services including some where these highly specialized processing services are performed. We requested data from the centers on direct costs: clinical labor, supplies and reagents. Based on the data we received from seven institutions, the mean and median direct costs of performing these services are as follows:

Code 38207, Cryopreservation and storage – mean \$809 and median \$500
Code 38208, Thawing without washing – mean \$206 and median \$144
Code 38209, Thawing with washing – mean \$325 and median \$206

Assuming direct costs are about 50 percent of total costs; this would indicate that total costs approximate twice the direct cost estimates. This would raise the estimate of total costs to:

Code 38207, Cryopreservation and storage – mean \$1,618 and median \$1,000
Code 38208, Thawing without washing – mean \$412 and median \$288
Code 38209, Thawing with washing – mean \$650 and median \$412

ASH recognizes that eventual reporting under this series of codes will ultimately provide CMS with charge and cost data for these codes. However, at a minimum, these data will not be available until the payment rates are established for CY 2010 based on CY 2008 claims. In the interim, ASH urges CMS to place these codes in an APC that pays substantially more than the \$54 amount which will cover only a small fraction of the real costs. ASH suggests that APC 0111, Blood Product Exchange (paying \$776) would be an appropriate initial payment level. It would pay substantially less than the costs of freezing and storing the product and somewhat more than the cost of thawing the same material. On average, this APC would be a reasonable interim APC until better data are available in two years.

G0267, currently paid for under HOPPS, is assigned to APC 0110. This is the blood transfusion APC which has a payment rate of \$222.44. The data in this APC is dominated by transfusion procedures particularly Code 36430. The median cost data for G0267 indicate only 194 single claims were billed (438 total claims) with a median cost of \$405.84. ASH is confident that most of the billings within G0267 are for the lower cost services such as red blood cell removal (Code 38212). On the other hand, codes 38210 (T-cell depletion) and 38211 (tumor cell depletion) are extremely costly services that are performed by only a limited number of facilities and very rarely in the Medicare age group. We have data for five facilities that indicate that the reagent kits alone for codes 38210 and 38211 cost from \$5,913 to \$7,968 per patient and clinical staff costs range from \$270 to \$1,344. Thus, the \$222 payment rate would cover only a miniscule portion of the costs. ASH, therefore, would like two options for pricing Codes 38210 and 38211:

Option 1—Place Code 38210 and Code 38211 into a higher paying APC. ASH suggests APC 0112, Apheresis and Stem Cell Procedures, with a payment rate of \$2,035.93. We think this would be a reasonable interim rate until adequate cost data is collected.

Option 2—Reimburse Code 38210 and Code 38211 on a cost-based method based on a hospital's charges reduced to cost using the cost to charge (CCR) methodology. This would be analogous to the method used for pricing pass-through devices and would also be an appropriate interim measure until data is available for these processing services.

Regarding the other cell depletion codes, 38212-38215, the Society notes that survey data for seven hospitals indicated the following direct costs (clinical labor and supplies) for these codes:

Code 38212, Red Blood Cell Removal—Mean \$591 and Median \$239
Code 38213, Platelet Depletion—Mean \$272 and Median \$272
Code 38214, Plasma (Volume) Depletion—Mean \$269 and Median \$124
Code 38215, Cell Concentration in Plasma—Mean \$265 and Median \$265

Assuming direct costs are approximately half of total costs, this would result in the following estimates of total costs:

Code 38212, Red Blood Cell Removal—Mean \$1,082 and Median \$478
Code 38213, Platelet Depletion—Mean \$544 and Median \$544
Code 38214, Plasma (Volume) Depletion—Mean \$538 and Median \$248
Code 38215, Cell Concentration in Plasma—Mean \$530 and Median \$530

In lieu of APC 110, we would recommend that Codes 38212-38215 be placed in a separate APC using the actual median cost data for G0267. This would raise the payment level to the \$400 level from the proposed \$220 rate of APC 0110. This change is clearly supported by the survey data. When CMS has adequate claims data for the individual codes it might be appropriate to adjust the APC grouping further. However, it is an appropriate and reasonable interim step.

Payment for Radioimmunotherapy Agents

ASH is extremely concerned about the proposed payment rate for Bexxar (I131 Tositumomab), which is a radioimmunotherapy (RIT) agent. Similar issues apply to Zevalin (Ibritumomab Tiuxetan), which is also a RIT. The principle use of a RIT is for the treatment of non-Hodgkin's Lymphoma for patients who have not responded well to a prior course of chemotherapy treatment. There are two major problems with the proposed payment for I131-Tositumomab. First, the initial treatment is considered as a diagnostic procedure. Under the proposed rule, the cost of radiopharmaceuticals for diagnostic as opposed to therapeutic purposes will be “packaged” and not separately paid. Second, the proposed payment level for I131-Tositumomab grossly underestimates the cost of this product.

The complete I131-Tositumomab treatment regimen is provided over 7 to 14 days. After an initial treatment, the patient is evaluated through whole body dosimetry to determine if the biodistribution of the agent is acceptable. If it is not, no further I131-Tositumomab treatment is provided. In the proposed rule, CMS indicates its intention to discontinue separate payment for diagnostic radiopharmaceuticals and to package the cost of the agent in the cost of the nuclear medicine procedure. CMS classified the initial dose of I131 Tositumomab as a “diagnostic” so that it would be classified as packaged and given “N” status under HOPPS. This decision is erroneous. All the doses of I131-Tositumomab are intended to be therapeutic and part of a multi-day treatment regimen and thus paid separately. This is the case even if the decision is made not to furnish any further doses because the biodistribution of the initial dose of the agent was not considered acceptable.

It is also our understanding that the proposed payment rate for the therapeutic use of I131-Tositumomab would cover less than half of the \$30,000 cost to hospitals. It is clear that the CMS' estimate of costs grossly undervalues actual costs of I131-Tositumomab. Whether this is because of a defect in the cost to charge method (CCR) due to the unwillingness of hospitals to adequately mark up the charges for very costly services (i.e., the phenomenon of charge compression) or for other reasons, unless corrected, this could prove devastating to this important therapy. It may severely limit patient access to this invaluable treatment since hospitals will not be able to absorb a loss exceeding \$16,000 per patient. If this occurs it will eliminate one of the few treatment options and perhaps the only treatment option for some patients with non-Hodgkin's Lymphoma who have failed chemotherapy treatment. And, finally, it could have a chilling effect on the development of future drugs and radiopharmaceuticals for treating other forms of cancer and other diseases.

For purposes of the proposed packaging rule, ASH strongly urges CMS to reconsider the classification of I131-Tositumomab as a diagnostic radiopharmaceutical and to treat all doses of I131 Tositumomab as therapeutic. With respect to the level of payment, ASH is not presenting specific recommendations as to how CMS can best fix this problem. The Society understands that this issue was presented at the meeting of the APC Advisory Committee on September 6, 2007 and that several options were proposed. This included paying for the agent as a drug and not as a radiopharmaceutical so that it would be paid at the rate of 106 percent of average sales price (ASP). ASH further understands that the manufacturer has indicated a willingness to submit quarterly ASP prices. Also, the APC Advisory Committee and the manufacturer urged CMS to consider establishing a "composite" APC reflecting the full costs for the entire course of therapy including all the procedural services, radiopharmaceuticals, drugs and supplies. All of these methods would seem promising. However, what is critical is that CMS find ways to substantially improve the payment so that patients are not deprived access to this valuable cancer treatment.

Thank you again for the opportunity to offer these comments. If ASH can provide any further assistance including furnishing the actual survey instrument and survey data, please contact Carol Schwartz, ASH Senior Manager of Policy and Practice, at 202-292-0258 or at cschwartz@hematology.org.

Sincerely,



Andrew I. Schafer
President