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Hospital Outpatient Prospective Payment System Payment Policies for Calendar Year 2009: Overview of Final Rule Provisions Affecting Reimbursement for Oncology

Background:

The Centers for Medicare and Medicaid Services (CMS) on October 30, 2008 put on display its final rule with comment period setting payment policies under Hospital Outpatient Prospective Payment System (HOPPS) for calendar year (CY) 2009. The rule will be published in the November 18, 2008 Federal Register. Comments on a limited number of subjects will be accepted until December 29, 2008.

The rule contains a number of provisions of importance to oncology. Perhaps most notably, CMS adopts a policy that could have led to reimbursement for separately paid drugs and biologicals at Average Sales Price (ASP) plus 2%. However, the agency elected to continue to use a transition mechanism for 2009, meaning that these therapies will be reimbursed at ASP plus 4%. This is down one percentage point from 2008 and equal to the benchmark in the proposed rule.

CMS once again rejected comments from ASCO and others calling for separate reimbursement for all antineoplastic drugs and other products used in chemotherapy. While the agency will continue to pay separately for all anti-emetics—even those that do not exceed the \$60 packaging threshold that has been established for 2009—it reserves the right to package chemotherapy and supportive care products (including anti-emetics) in the future.

The agency also finalized changes to its policies affecting reimbursement for drug administration Ambulatory Payment Classifications (APCs) and made a number of policy choices affecting payments for imaging, radiation oncology and radiopharmaceuticals.

The balance of this document provides more details about these and other policies.

Reimbursement for Separately Paid Drugs and Biologicals

CMS will continue to use its current methodology to establish payments for the acquisition and handling of separately paid drugs and biologicals that do not qualify for pass through status. This methodology compares mean cost information from hospital claims data with ASP data to establish a percentage markup over ASP that each product will be paid. For 2008, CMS used a transition mechanism to set payments at ASP plus 5%. For 2009, CMS uses a similar transition mechanism to move to ASP plus 4% – noting that its final rule calculations would have resulted in a payment rate of ASP plus 2%. The agency says that payment at ASP plus 4% is similar to a 50/50 blend of ASP plus 5% and ASP plus 2%. CMS notes that “another transitional payment year appropriately allows for a gradual change...to a refined claims-based payment methodology.”

CMS will continue to pay for pass through drugs and biologicals at ASP plus 6% or the CAP payment rate if such a rate is again applicable, whichever is lower. These rates will be updated quarterly to reflect ASP changes or the reinstatement of the CAP program, if applicable.

CMS notes that a majority of comments expressed support for a pharmacy stakeholder proposal that would have attempted to redistribute pharmacy overhead costs toward higher cost drugs and biologicals. CMS does not believe it is appropriate to adopt this approach for 2009. However, the agency notes that it is “particularly interested in further exploring this approach.”

In response to “overwhelming” negative comments, CMS did not finalize its proposal to split the drugs charged to patients cost center into two separate cost centers for high overhead and low overhead drugs. The agency states that it remains interested in further refinements to its payment methodology.

340B Hospital Issues

In response to various conversations it has had with stakeholder groups, CMS is requesting comment on payment to 340B hospitals for separately paid drugs and biologicals, specifically “whether hospitals participating in the 340B program should be paid for drugs under the OPPS at adjusted rates because they have different average acquisition costs.” CMS raises the possibility of using its equitable adjustment authority so that payments to 340B and non-340B hospitals reflect the costs specific to each class of hospital.

Packaging Policies

CMS finalizes its proposal to continue to update the packaging threshold for separately paid drugs and biologicals using the Producer Price Index (PPI), resulting in the packaging threshold remaining at \$60 for CY 2009.

CMS will also continue its policy of exempting 5H3T anti-emetics from packaging, noting a continued desire for each beneficiary receiving chemotherapy to have access to the anti-emetic that is most effective for that beneficiary. However, CMS specifically rejects comments

requesting separate payment for antineoplastic agents and other anti-cancer products—and reserves the right to package anti-emetics in the future.

The agency will also continue to use the same policy of maintaining separate payment for products that were separately paid in 2008 and proposed for separate payment in 2009, even for products that fell below the packaging threshold based on updated data.

The agency dismisses a variety of proposed alternatives to the current packaging threshold and update process, noting, “We continue to believe that unpackaging payment for all drugs, biologicals and radiopharmaceuticals is inconsistent with the concept of a prospective payment system.” The agency also dismisses concerns about payment differentials between HOPPS and the Physician Fee Schedule, noting that the payment systems are quite different and that physician payment for drugs is set by statute.

Radiopharmaceuticals and Contrast Agents

CMS finalizes its proposal to continue to package diagnostic radiopharmaceuticals and contrast agents, reiterating its desire to continue to expand the use of packaging and describing these products as effectively supplies. The agency also restates its contention that it has discretion to treat different classes of products in different ways in light of the expiration of the MMA’s packaging threshold. CMS clarifies that diagnostic radiopharmaceuticals and contrast agents are drugs and can continue to be eligible for pass through payments where appropriate. However, the agency also finalizes its proposal to create an offset to pass through payments for future diagnostic radiopharmaceuticals to reflect the costs of existing radiopharmaceuticals packaged with nuclear medicine Ambulatory Payment Classifications (APCs).

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) preempted the CMS proposal to pay for therapeutic radiopharmaceuticals based on ASP. All such products will be paid based on hospital charges reduced to cost.

Drug Administration Payments

CY 2009 represents the first rate setting process for which CMS can see the full set of Drug Administration CPT codes in claims data. CMS finalizes its proposal to use the full set of CPT codes for drug administration and its proposal to use a five APC structure for drug administration payments in 2009.

CMS made no changes in the five drug administration APCs described in the 2009 proposed rule, except to recalculate medians and payment rates based on the more complete set of claims released with the final rule. A comparison of rates by code for 2008 final, 2009 proposed, and 2009 final rules accompanies this summary.

RTI Report Recommendations on Possible Changes to Cost Report Data Processing

CMS commissioned RTI to study charge compression issues in the outpatient hospital prospective payment system, following a report that looked at the inpatient payment system. One of RTI's findings suggested that administrative changes in the use of cost report data to create cost-to-charge ratios (CCRs) would be likely to result in increases for the CCRs used to set rates for drug administration codes. CMS solicited comments on RTI's recommendations, and indicates in the final rule that it will not be pursuing the RTI recommendations that are associated with increasing these CCRs because it is not confident that RTI's assumptions underlying these recommendations "are correct".

Radiation Oncology

The APC panel recommended in September that CMS unpackage image guided radiation therapy codes (IGRT) when presenters showed that IGRT was being packaged with inappropriate services. Presenters described data analysis showing that radiation oncology procedures with bypass code status were leading to few IGRT costs being packaged into radiation oncology procedures in the single claims used for rate setting. CMS did not accept the APC panel recommendation and finalized packaging for radiation oncology guidance as a matter of principle, because all other guidance procedures are packaged.

At the same time, CMS removed the radiation oncology bypass codes from the bypass list indicating that they did not conform to its criteria for bypass policy (not addressing the exceptions to bypass policy). This action resulted in a large decrease in claims used in rate setting for radiation oncology procedures. This change affected the rates for a number of radiation oncology codes, increasing a few and decreasing brachytherapy procedure payment rates in particular. CMS will accept comments on this action for future rate setting.

Imaging

CMS finalized its policy in the proposed rule to use composite APCs to set rates for multiple CT/CTA, MR/MRA, and ultrasound procedures on the same date of service. Numerous comments were submitted suggesting delays and other considerations to further shape this policy. CMS provided reasons for rejecting all suggestions and finalized this policy without modification.

CMS rejected suggestions in comments to require an edit for imaging procedures "with contrast" to have a contrast media code on the claim for payment, similar to the edit implemented in 2008 for nuclear medicine procedures and radiopharmaceuticals. The reason given was that it would be administratively complex and wasn't seen as necessary.

IVIG

CMS finalizes its proposal to package payment for pre-administration services, noting that the transient market conditions for IVIG that led CMS to create this additional payment seem to have improved.

Hospital Quality Reporting Requirements

The final rule also continues the implementation of the provision of the Medicare Improvement and Extension Act requiring hospitals to comply with quality reporting requirements or risk a 2 percentage point reduction in their annual update factor. CMS finalizes a number of reporting requirements, including a requirement to report mammography follow-up rates as an imaging efficiency measure. The agency notes the specific endorsement of this measure by some commenters and, in response to concerns from other commenters, clarifies that it does not intend to set a particular rate of follow-up as appropriate at this time.

In addition, CMS reviews the comments it received on potential future expansions of these reporting requirements, including four cancer specific measures that it is considering for inclusion in 2011 or later years.

These measures include:

- “Radiation Therapy is Administered within 1 Year of Diagnosis for Women Under Age 70 Receiving Breast Conserving Surgery for Breast Cancer;”
- “Adjuvant Chemotherapy is Considered or Administered within 4 Months of Surgery to Patients Under Age 80 with AJCC III Colon Cancer;”
- “Adjuvant Hormonal Therapy for Patients with Breast Cancer;” and
- Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection”

These measures were also under consideration in the proposed rule for Calendar Year 2008.

CMS finalized its decision not to apply the payment reduction for hospitals that fail to report the approved measures to separately paid drugs and biologicals or items paid under new technology APCs.

The agency will implement public reporting of these quality measures in 2010, but has not determined the details of reporting at this time.

Healthcare-Associated Conditions (HACs)

As CMS continues to implement a prohibition on payment for Hospital-Acquired Conditions in the inpatient hospital setting, it has begun to discuss ways to extend the principles of that payment provision to the OPPS in the form of “Healthcare-Associated Conditions.” The agency did not make specific proposals to implement such a policy in the OPPS, but rather solicited

“comments on options and considerations, including statutory authority, related to extending the IPPS hospital acquired conditions payment provision for hospitals to the OPPS.” In the proposed rule, the agency discussed the criteria for the inclusion of particular events as HACs, the collaboration process that could be used to select them and potential specific OPPS HACs. They solicited comments on these specific items:

- Object left in during surgery;
- Air embolism;
- Blood incompatibility; and
- Falls and trauma fractures, dislocations, intracranial injuries, crushing injuries, and burns.

However, CMS also indicated that it expected that ultimately OPPS payment policy should address a broad range of HACs and the agency requested input on other items that should be included and “that may be associated with significant harm, such as adverse drug events related to medication errors...”

The agency acknowledged a number of difficulties in attempting to extend the HAC provision to the OPPS, but stated its intent to continue moving forward in future years to implement OPPS payment reductions where HACs are present.

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Comparison of 2009 Final, 2009 Proposed, and 2008 Final Data

Data Source: Hospital Outpatient Prospective Payment System (HOPPS) 2009 Final, 2009 Proposed, 2008 Final Data

Prepared For: ASCO

Date: November, 2008

HCPCS	Long Descriptor	APC			Payment Rate		
		08 Final	09 Proposed	09 Final	08 Final	09 Proposed	09 Final
90779	Unlisted therapeutic, prophylactic or diagnostic intravenous or intra-arterial injection or infusion	0436	0436		\$ 16.21	\$ 25.03	
96549	Unlisted chemotherapy procedure	0436	0436	0436	\$ 16.21	\$ 25.03	\$ 24.89
90761	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)	0437	0436		\$ 25.13	\$ 25.03	
90761	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)	0437	0436		\$ 25.13	\$ 25.03	
90766	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	0437	0436		\$ 25.13	\$ 25.03	
90767	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (List separately in addition to code for primary procedure)	0437	0437		\$ 25.13	\$ 36.66	
90772	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	0437	0436		\$ 25.13	\$ 25.03	
90773	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intra-arterial	0438	0437		\$ 51.22	\$ 36.66	
90774	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	0438	0437		\$ 51.22	\$ 36.66	
90775	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)	0438	0437		\$ 51.22	\$ 36.66	
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	0438	0437	0437	\$ 51.22	\$ 36.66	\$ 36.13
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic	0438	0437	0437	\$ 51.22	\$ 36.66	\$ 36.13
96405	Chemotherapy administration; intralesional, up to and including 7 lesions	0438	0437	0437	\$ 51.22	\$ 36.66	\$ 36.13
96406	Chemotherapy administration; intralesional, more than 7 lesions	0438	0438	0438	\$ 51.22	\$ 74.32	\$ 73.67
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)	0438	0437	0437	\$ 51.22	\$ 36.66	\$ 36.13
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)	0438	0438	0438	\$ 51.22	\$ 74.32	\$ 73.67
96423	Chemotherapy administration, intra-arterial; infusion technique, each additional hour (List separately in addition to code for primary procedure)	0438	0438	0438	\$ 51.22	\$ 74.32	\$ 73.67
96542	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents	0438	0439	0439	\$ 51.22	\$ 126.80	\$ 128.62
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	0439	0439	0439	\$ 105.38	\$ 126.80	\$ 128.62
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)	0439	0438	0438	\$ 105.38	\$ 74.32	\$ 73.67
96420	Chemotherapy administration, intra-arterial; push technique	0439	0439	0439	\$ 105.38	\$ 126.80	\$ 128.62
90760	Intravenous infusion, hydration; initial, up to 1 hour	0440	0438		\$ 114.64	\$ 74.32	
90765	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	0440	0439		\$ 114.64	\$ 126.80	
96521	Refilling and maintenance of portable pump	0440	0440	0440	\$ 114.64	\$ 191.06	\$ 187.96
96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (eg, intravenous, intra-arterial)	0440	0439	0439	\$ 114.64	\$ 126.80	\$ 128.62
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96
96422	Chemotherapy administration, intra-arterial; infusion technique, up to one hour	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96
96425	Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96
96440	Chemotherapy administration into pleural cavity, requiring and including thoracentesis	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96
96445	Chemotherapy administration into peritoneal cavity, requiring and including peritoneocentesis	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96

96450	Chemotherapy administration into cns (eg intrathecal) requiring and including spinal puncture	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96
C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump	0441	0440	0440	\$ 149.34	\$ 191.06	\$ 187.96
96523	Irrigation of implanted venous access device for drug delivery systems	0624	0624	0624	\$ 36.24	\$ 39.41	\$ 39.92
90768	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)						
C8950	Intravenous infusion for therapy/diagnosis; up to 1 hour						
C8951	Intravenous infusion for therapy/diagnosis; each additional hour (List separately in addition to C8950)						
C8952	Therapeutic, prophylactic or diagnostic injection; intravenous push of each new substance/drug						
C8953	Chemotherapy administration, intravenous; push technique						
C8954	Chemotherapy administration, intravenous; infusion technique, up to one hour						
C8955	Chemotherapy administration, intravenous; infusion technique, each additional hour (List separately in addition to C8954)						

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