ACCC Efforts Pay Off—Drug Reimbursement in HOPD Set to Increase in 2011

The proposed 2011 Hospital Outpatient Prospective Payment System (HOPPS) rule was released July 2, 2010, by the Centers for Medicare & Medicaid Services (CMS). In the proposed rule, reimbursement for drugs and pharmacy services will increase to ASP+6 percent from the current ASP+4 percent. ACCC has advocated for this change for the past three years, ever since reimbursement began to decrease in 2007.

In meetings with CMS staff and in testimony before the APC Panel, ACCC has stated that hospitals should be reimbursed at least ASP+6 percent, if not higher, for drugs and their associated pharmacy costs. ACCC data have shown that pharmacy overhead costs are higher than CMS allows for, and, therefore, the ASP+ number should be higher. Each year, CMS listened, but continued to decrease the reimbursement. ACCC continued to push for its position, and it appears that all of that effort has finally paid off.

Highlights of the Proposed 2011 HOPPS

The proposed payment rates for 2011 reflect a 2.15 percent increase in the hospital operating market basket. Hospitals that fail to meet the quality data reporting requirements will receive an update that is reduced by 2.0 percentage points.

While CMS proposes a payment rate of average sales price (ASP)+6 percent for separately payable drugs, biologicals, and radiopharmaceuticals with or without pass-through status, the agency cautions stakeholders that the final payment rate could be lower than ASP+6 percent after CMS finalizes its calculations with updated data later this year.

CMS also proposes:

- To increase the packaging threshold for drugs and biologicals from $65 per day to $70 per day.
- To continue to use the full set of CPT codes for reporting drug administration services and to continue to pay separately for the same set of drug administration codes under the 2011 HOPPS as were paid separately in the 2010 HOPPS.
- For the CY 2012 payment determination, CMS proposes to retain the existing 11 Hospital Outpatient Quality Data Reporting Program (HOP QDRP) measures. The agency proposes to add one structural measure for the CY 2012 payment determination: "Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data." CMS also proposes to add four new claims-based imaging efficiency measures to the HOP QDRP measurement set, all of which were listed as under consideration for CY 2012 and subsequent years in the CY 2010 HOPPS final rule.

A full analysis of the proposed 2011 HOPPS rule is available on the members-only section of ACCC's website: *www.accc-cancer.org.*

Highlights of the Proposed 2011 PFS

CMS released the proposed 2011 Medicare Physician Fee Schedule (PFS) on June 25, 2010. In brief, the 2011 proposed PFS rule would:

- Reduce physician payment rates in 2011 by an additional projected 6.1 percent under the sustainable growth rate (SGR) formula. The 6.1 percent payment cut would be in addition to the impending 21.2 percent cut that has been thus far delayed by Congress, for a net cut of nearly 28 percent, unless Congress enacts further changes to physician payment rates.
- Continue the second year of a four-year transition to practice expense (PE) relative value units (RVUs) calculated using Physician Practice Information Survey (PPIS) data.
- Change the utilization rate for determining PE RVUs for diagnostic imaging equipment priced over $1 million and expand the list of services to which the higher equipment utilization rate assumption applies.
- Identify and revise potentially misvalued services under the PFS.
- Expand the imaging multiple procedure payment reduction (MPPR) policy by increasing the reduction from 25 percent to 50 percent and extending it to multiple imaging services provided not only within the same family of codes, but across such families, as well as add four additional CPT codes to the policy.
- CMS is proposing to rebase the Medicare Economic Index (MEI), updating the PE and malpractice RVUs using 2006 data instead of 2000 data. This rebasing would have an overall positive effect on medical and radiation oncology services. After the rebasing, and taking into account the second year of a four-year transition put into place last year, medical oncology will see a roughly 1 percent decrease overall, instead of a 2 percent decrease, and radiation oncology will see a 2 percent increase, instead of a nearly 2 percent decrease in 2011. These figures assume Congress will halt the 21 percent and 6 percent reductions to the SGR.

A full analysis of the proposed 2011 PFS is available on the members-only section of ACCC's website: *www.accc-cancer.org.*

ACCC Comments on NCA for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer

On July 27, 2010, ACCC submitted comments to CMS about the opening of a national coverage analysis (NCA) for autologous cellular immunotherapy treatment of metastatic prostate cancer. ACCC is deeply concerned that CMS has opened this NCA

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regarding an autologous cellular immunotherapeutic agent for its Food and Drug Administration (FDA)-approved indication to treat certain forms of prostate cancer. In its comments, ACCC wrote: "Not only is CMS's action contrary to Congress' intent to ensure beneficiary access to drugs and biologicals used in an anticancer chemotherapeutic regimen, but it threatens to stifle future innovation and cancer research for years to come."

Accordingly, ACCC urged CMS to withdraw this NCA immediately.

ACCC also is concerned that CMS's decision to initiate this NCA will be "detrimental to cancer research for years to come. Cancer is a deadly disease, and patients often require treatment with the most innovative and cutting-edge therapies to win their battles against it. Bringing new therapies to market is costly, however, and investors will be more hesitant to fund new research if CMS threatens to restrict coverage for medically accepted indications of cancer drugs."

The full comments are posted on ACCC's website at: *www.accc-cancer.org.*

Expanded Enrollment for 340B Opens

On Aug. 2, 2010, expanded enrollment in the 340B discount drug program opened for thousands of providers who are newly eligible to participate under the health reform law. The expansion of the 340B Drug Pricing Program included in the Patient Protection and Affordable Care Act makes discounted drugs available to freestanding cancer centers, as well as children's hospitals, critical access hospitals, rural referral centers, and sole community hospitals. The newly eligible facilities will save an average of 20 percent to 50 percent on covered outpatient medications, according to the Health Resources and Services Administration, the division of the Health and Human Services Department that administers the program.

As reported in the August 3 *BNA Health Care Daily Report*, under the expansion the number of facilities participating in the 340B program is expected to increase from 14,000 to nearly 20,000, including 1,500 newly eligible hospitals. Enrollment under the expansion will take place using a rolling, online admissions process that ends Sept. 30, 2010. All forms must be submitted by Sept. 27, 2010.

New! Online and In Print: ACCC's *Part B – Drug Information Guide*

ACCC will soon launch its *Part B - Drug Information Guide* to help oncologists and pharmacists, as well as oncology support and administrative staff, navigate the increasingly complex policies of off-label drug coverage. ACCC's *Part B - Drug Information Guide* is a compilation of oncology drugs from the nationally recognized drug compendia, as well as the indications that the compendia list for these drugs.

"ACCC's *Part B - Drug Information Guide* requires users to actively participate in the coverage process," said ACCC Executive Director Christian Downs, JD, MPH. "It is not a stand-alone document. It is the first step in determining whether there is evidence on the appropriateness of use of an oncology drug for a specific oncology-related indication."

Where such evidence exists users must obtain more information by 1) reading through the relevant sections of each compendium themselves or 2) contacting the manufacturer(s) and asking for evidence of appropriateness. This evidence may then be submitted to carriers to support coverage.

The following information is included with the *Part B - Drug Information Guide*:

- Any drug with a J-code in the oncology range of J8500-J9600. These are the drugs that are covered under Part B of the Medicare Program.
- Newly approved drugs that may not yet have had a code assigned to them.
- Oral anti-cancer drugs that have an injectable counterpart that are reimbursed under Part B.
- Drugs that have been approved by the FDA for oncology use that have a designated J-code outside J8500 to J9600. However, drugs that are labeled for supportive care indications or only as adjuncts to therapeutic regimens are not included.
- For each drug, HCPCS codes.
- Indication with the associated ICD-9 diagnosis code.
- Manufacturer and contact information for the manufacturer.

ACCC's *Part B - Drug Information Guide* will be printed once each year and mailed to ACCC members. Listings in this first edition are current through July 15, 2010. The online version, available at *www.accc-cancer.org/druginfo*, will be updated on the first day of each month.

CMS Amends NCD on PET Scans for Tumors and Myeloma

On Aug. 4, 2010, CMS amended section 220.6.17 of the National Coverage Determinations Manual to:

1. Remove the current absolute restriction of coverage to 'only one' FDG PET scan to determine the location and/or extent of the tumor for the therapeutic purposes related to the initial treatment strategy as described above
2. Ensure that CMS continues to nationally cover one FDG PET scan to determine the location and/or extent of the tumor for the therapeutic purposes related to the initial treatment strategy as described above
3. Allow local Medicare administrative contractors (MACs) the discretion to cover (or not cover) within their jurisdictions any additional FDG PET scan for the therapeutic purposes related to the initial treatment strategy as described above.