CMS Releases Proposed Rules for CY18

On Thursday July 13, the Centers for Medicare & Medicaid Services (CMS) released both the proposed Hospital Outpatient Prospective Payment System (OPPS) and Medicare Physician Fee Schedule (MPFS) rules for calendar year (CY) 2018. Both rules have a 60-day public comment period ending on September 11.

CMS proposes to update OPPS rates by 1.75% for 2018, based on a projected hospital market increase of 2.9% minus both a 0.4% adjustment for multifactor productivity and a 0.75% adjustment required by law. CMS estimated the overall impact as a 2.0% payment increase for hospitals paid under the OPPS in CY 2018. CMS proposed moving a few nuclear medicine Current Procedural Terminology (CPT) services (codes 78018, 78110, 78111, and 78121) into new Ambulatory Payment Classification groups based on hospital cost data from 2016 claims paid. In general, nuclear medicine payments will remain stable, with modest increases proposed. As mandated by statute, CMS proposes to package 1 diagnostic radiopharmaceutical that is on pass-through in 2017: A9586 Florbetapir F18, diagnostic, per study dose, up to 10 mCi. Without additional legislation, SNMMI does not expect to see separate payment (from the procedure payment rate) for this agent in CY 2018. The CMS fact sheet on the OPPS Proposed Rule is available at: www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13.html.

The update to payments under the MPFS based on the proposed CY 2018 rates would be +0.31%. This update reflects the statutory +0.50% update minus 0.19% because net reductions in misvalued codes in 2018 are less than the statutorily set 0.50% target of total fee schedule revenue. After applying these adjustments, the proposed 2018 PFS conversion factor is $35.99 compared to $35.89 for 2017. The overall proposed CY 2018 PFS estimated impact on total allowed charges by specialty are as follows: Nuclear Medicine: (0%); Radiology (–1%); and Cardiology (–2%). Individual impacts may vary, however, with different volumes and types of services. In past MPFS rules, CMS had identified 3 nuclear medicine CPT services (78300, 78305, and 78306 Bone and/or joint imaging) as potentially misvalued. The SNMMI along with the American College of Radiology surveyed these codes and presented recommendations that led CMS to propose maintaining the current work values for 2018. The CMS fact sheet on the MPFS is available at: www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13-2.html.

Centers for Medicare & Medicaid Services
SNMMI

AUC Implementation Delays, CMS Calls for Comments

On July 13, the Centers for Medicare & Medicaid Services (CMS) included a statement in a larger release indicating that the date for implementation of the Medicare Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging as mandated by the 2014 Protecting Access to Medicare Act should be delayed from January 1, 2018, to January 1, 2019. AUC are statements that contain indications describing when and how often an intervention should be performed under the optimal combination of scientific evidence, clinical judgment, and patient values while avoiding unnecessary provisions of services. The CMS announcement also indicates that the first year of the program will be one of "educational and operations testing." The agency noted its intention to allow "practitioners more time to focus on and adjust to the Quality Payment Program." During the first year, CMS proposes paying claims for advanced diagnostic imaging services regardless of whether they contain information on the required AUC consultation in an effort to allow both clinicians and the agency to prepare for this new program. In conjunction with the proposed rule, CMS is posting newly qualified provider-led entities and clinical decision support mechanisms. Qualified provider-led entities are permitted to develop AUC, and qualified clinical decision support mechanisms are the tools through which physicians access AUC. SNMMI, as a qualified provider-led entity under the Medicare AUC program, has been preparing and publishing procedure-specific AUC for the nuclear medicine community.

CMS noted that physicians can begin exploring these mechanisms well in advance of the start of the Medicare AUC program. In addition, by having qualified clinical decision support mechanisms available (some of which are free of charge) clinicians may use 1 of these mechanisms to earn credit under the Merit-Based Incentive Payment System as an improvement activity. This improvement activity was included in the Quality Payment Program proposed rule that was released on June 20, 2017.

CMS is seeking comments "related to whether the program should be delayed beyond the proposed start date of January 1, 2019" and is "interested in comments regarding how long, if longer than 1 year, such a period of educational and operations testing should be available." Comments can be submitted by clicking on the "comments" link at www.federalregister.gov/documents/2017/07/21/2017-14639/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

Centers for Medicare & Medicaid Services

EMA Moves Toward Approval of ^{177}Lu-Oxodotreotide

Advanced Accelerator Applications SA (AAA; Saint-Genis-Pouilly, France) announced on July 21 that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had issued a positive opinion recommending marketing authorization of ^{177}Lu-oxodotreotide (Lutathera) for treatment of unresectable or metastatic, progressive, well-differentiated, somatostatin receptor (SSTR)–positive gastroenteropancreatic neuroendocrine tumors (NETs) in adults. The European Commission, which has the authority to approve medicines for the European Union, Iceland, Norway, and Liechtenstein, will review the CHMP recommendation. Stefano Buono, CEO of AAA, said, "We are proud to achieve this important milestone. We look forward to collaborating with the European health authorities to make ^{177}Lu-oxodotreotide widely available as soon as possible. To date, more than 1,700 NET patients across 10 European countries have already received the treatment under compassionate use and named patient programs."

The CHMP adopted its opinion based on the results of a randomized pivotal phase 3 study (NETTER-1) that compared treatment using ^{177}Lu-oxodotreotide with a double dose of octreotide long-acting release (LAR) in 229 patients with inoperable midgut NETs progressive under standard octreotide LAR treatment and overexpressing SSTRs. Efficacy and safety data also came from an Erasmus University Medical Center phase 1/2 trial conducted in more than 1,200 patients with a wide range of NET involvement. The NETTER-1 study met its primary endpoint by demonstrating that treatment with ^{177}Lu-oxodotreotide was associated with a statistically significant and clinically meaningful risk reduction of 79% in disease progression or death versus treatment with a double dose of octreotide LAR. ^{177}Lu-oxodotreotide, when administered concomitantly with a renal-protective agent, had low rates of grade 3 or 4 hematologic toxicity and no evidence of nephrotoxicity over the median study follow-up of 14 mo.

Advanced Accelerator Applications SA

FROM THE LITERATURE

Each month the editor of Newsline selects articles on diagnostic, therapeutic, research, and practice issues from a range of international publications. Most selections come from outside the standard canon of nuclear medicine and radiology journals. These briefs are offered as a monthly window on the broad arena of medical and scientific endeavor in which nuclear medicine now plays an essential role. The lines between diagnosis and therapy are sometimes blurred, as radiolabels are increasingly used as adjuncts to therapy and/or as active agents in therapeutic regimens, and these shifting lines are reflected in the briefs presented here. We have also added a small section on noteworthy reviews of the literature.

MR vs PET/CT Imaging in Multiple Myeloma

Moreau and colleagues from University Hospital Nantes (France) and a consortium of French and U.S. researchers representing the Imagerie Jeune Myélome study reported on July 7 ahead of print in the *Journal of Clinical Oncology* on a prospective comparison of MR and ^{18}F-FDG PET/CT imaging in initial diagnostic detection of bone lesions and in assessment of prognostic value after chemotherapy but before maintenance therapy in symptomatic patients with multiple myeloma. The study included 134 patients who received a combination of lenalidomide, bortezomib, and dexamethasone (RVD) chemotherapy with or without autologous stem cell transplantation, followed by lenalidomide maintenance. Patients underwent PET and MR imaging at diagnosis, after 3 cycles of RVD, and before maintenance therapy. At diagnosis, MR and PET/CT results were positive in 127 (95%) and 122 (91%) patients, respectively. Normalization of MR at the second and third imaging timepoints was not predictive of progression-free nor overall survival (PFS and OS, respectively). PET/CT normalized after 3 cycles of RVD in 32% of patients with positive PET results at diagnosis, and 30-mo PFS was improved in this group. PET/CT normalized before maintenance in 62% of patients who were positive at diagnosis, and this group had better PFS and OS over the duration of the study. Extramedullary disease at diagnosis was determined to be an independent prognostic factor for both PFS and OS, and PET/CT normalization before maintenance was an independent prognostic factor for PFS. The authors concluded that although no difference between MR and PET/CT was noted in detection of bone lesions at diagnosis, PET/CT "is a powerful tool to evaluate the prognosis of de novo myeloma."

Journal of Clinical Oncology

Biomarkers and Early AD Diagnosis

In an article in the August issue of *The Lancet. Neurology* (2017;16:661–676) Frisoni and colleagues from University Hospitals/University of Geneva (Switzerland) and a consortium of researchers from Switzerland, Italy, Sweden, The Netherlands, the UK, the United States, Spain, and Germany reported on a strategic 5-phase "roadmap" to foster clinical validation of biomarkers in Alzheimer disease (AD), adapted from approaches