AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

September 1, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1786-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Proposed Rule; CMS-1786-P

Dear Ms. Brooks-LaSure,

The American Association of Physicists in Medicine (AAPM)[1] is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 31, 2023 *Federal Register* notice regarding proposed changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems.

Packaging Policy

CMS packages several categories of non pass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged with the payment for the related procedure or service. CMS did not propose any changes to the overall packaging policies for 2024, however, CMS is seeking comment on potential modifications to the packaging policy for diagnostic radiopharmaceuticals.

AAPM is concerned that packaging payment for diagnostic radiopharmaceuticals in the hospital outpatient setting creates barriers to beneficiary access, particularly when hospitals have a high proportion of Medicare beneficiaries or are serving underserved communities. While pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market, CMS's current packaging policy for diagnostic radiopharmaceuticals impedes access to new and innovative diagnostic tools for Medicare beneficiaries. We agree with the Agency that Medicare is committed to ensuring beneficiary access to diagnostic radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries.

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 9,000 medical physicists.

The AAPM recommends that CMS pay separately for diagnostic radiopharmaceuticals with per-day costs above the HOPPS drug packaging threshold of $140 effective January 1, 2024. AAPM encourages CMS to adopt an average sales price (ASP) + 6% payment policy for diagnostic radiopharmaceuticals.

Our recommendation mirrors the existing payment policy for therapeutic radiopharmaceuticals and other separately-payable drugs and biologicals. We believe separate payments for diagnostic radiopharmaceuticals is the best policy approach to ensure beneficiary access to diagnostic radiopharmaceuticals and equitable payment for innovative and effective technologies.

Comprehensive APC Methodologies for Surgical Insertion Codes for Brachytherapy

CMS continues to utilize Comprehensive Ambulatory Payment Classifications (C-APC) in CY 2024. Under the C-APC policy, CMS provides a single payment for all services on the claim regardless of the span of the date(s) of service. Conceptually, the C-APC is designed so there is a single primary service on the claim, identified by the status indicator (SI) of "J1". All adjunctive services provided to support the delivery of the primary service are included on the claim.

Since the inception of the Comprehensive APC methodology, the AAPM has commented on concerns around the claims data used for rate setting due to significant variations in clinical practice and billing patterns across the hospitals that submit these claims. We met with CMS staff in February 2018 and in our 2019, 2020, 2021 and 2022 HOPPS proposed rule comment letters, the AAPM proposed a modified C-APC methodology for the surgical codes related to brachytherapy that mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes. For CY 2024, CMS proposes to continue the flawed C-APC payment methodology for the surgical insertion codes for brachytherapy treatment. To date, the Agency has not addressed these concerns and the impact on Medicare beneficiary access to brachytherapy in the hospital outpatient setting is evident.

While AAPM supports policies that promote efficiency and the provision of high-quality care, we have long expressed concern that the C-APC methodology lacks the appropriate charge capture mechanisms to accurately reflect the services associated with the C-APC.

The AAPM remains concerned that the rates associated with C-APCs do not accurately or fully reflect the services and costs associated with the primary procedure. The current C-APC methodology is of particular concern as CMS continues to expand the number of packaged and bundled services. Given the complexity of coding, serial billing for cancer care, and potentially different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services, the AAPM continues to oppose the current comprehensive APC payment methodology for cancer care. **We urge the Agency to explore alternatives to the C-APC methodology so that it appropriately values this life saving service.**

The current Comprehensive APC payment methodology for brachytherapy does not accurately reflect the true cost of providing the procedures.

The AAPM recommends that CMS discontinue the Comprehensive APC payment policy in 2024 for all brachytherapy insertion codes. CMS should revert to status indicator "T" for CPT codes 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55874 55875, 55920, 57155 and 58346.

Alternatively, CMS could continue to pay for "J1" brachytherapy insertion codes under the C-APC payment methodology but exclude and make separate payment for designated preparation and planning services in addition to the C-APC payment (see Attachment A).

Low Volume APC Policy

Beginning in 2022, CMS established a Low Volume APC policy that designates clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims that can be used for rate setting purposes in the claims year used for rate setting for the prospective year (the CY 2022 claims year for this CY 2024 proposed rule) as Low Volume APCs. We agree with CMS that low utilization of services can lead to wide variation in payment rates from year to year, especially as it relates to brachytherapy sources and new procedures and services. Under the proposed Low Volume APC policy, the payment rates for these APCs would be set at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data.

The AAPM supports continuation of the Low Volume APC policy.

We thank you for this opportunity to submit our comments and request that CMS carefully consider these issues for the final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (561) 631-0677.

Sincerely,

Ehsan Samei, PhD, DABR, FAAPM, FSPIE, FAIMBE, FIOMP, FACR
President, American Association of Physicists in Medicine

Michele S. Ferenci, PhD
Chair, Professional Economics Committee

ATTACHMENT A

The AAPM identified a list of twenty-eight (28) codes proposed for separate payment in addition to the C-APC payment for the brachytherapy insertion codes (CPT 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55874, 55875, 55920, 57155, 58346) effective January 1, 2022 (see below). Not all planning and preparation codes would be utilized for each brachytherapy insertion procedure code listed above. This C-APC modified policy mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes.

- 10035 Placement of soft tissue localization device (egg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including image guidance; first lesion
- 32553 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple
- 49411 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvis (except prostate), and/or retroperitoneum, single or multiple
- 55874 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance
- 55876 Placement of interstitial device(s) for radiation therapy guidance, prostate, single or multiple
- 76000 Fluoroscopy, up to 1 hour physician or other qualified health care professional time
- 76872 Ultrasound, transrectal
- 76873 Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning
- 77280 Therapeutic radiology simulation-aided field setting; simple
- 77285 Therapeutic radiology simulation-aided field setting; intermediate
- 77290 Therapeutic radiology simulation-aided field setting; complex
- 77295 3-dimensional radiotherapy plan, including dose-volume histograms
- 77300 Basic radiation dosimetry calculation
- 77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
- 77306 Teletherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77307 Teletherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77316 Brachytherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77317 Brachytherapy isodose plan; intermediate, include basic dosimetry calculation(s)
- 77318 Brachytherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77321 Special teletherapy port plan
- 77331 Special dosimetry, only when prescribed by treating physician
- 77332 Treatment devices; simple
- 77333 Treatment devices; intermediate
- 77334 Treatment devices; complex
- 77336 Continuing medical physics consultation
- 77338 Multi-leaf collimator devices for IMRT
- 77370 Special medical radiation physics consultation
- C9728 Placement of interstitial devices for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach); abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple