ASTRO
TARGETING CANCER CARE

251 18th St. South, 8th Floor
Arlington, VA 22202

Main: 703.502.1550 · Fax: 703.502.7852
www.astro.org · www.rtanswers.org

Inpatient Prospective Payment System (IPPS) 2020 Proposed Rule
Summary of Issues Impacting Radiation Oncology

On Tuesday, April 24, the Centers for Medicare and Medicaid Services (CMS) issued the Hospital Inpatient Prospective Payment System (IPPS) proposed rule. The rule contains several issues of interest to the field of radiation oncology, including proposed New Technology Add-On Payments (NTAP) for three technologies involving radiation treatment delivery; proposed changes to the criterion and payment for evaluating NTAPs, that will also be applied to Outpatient Prospective Payment System (OPPS) transitional pass-through payments for devices; and proposed modifications to the Medicare wage index. Comments in response to the rule are due June 24. The final rule will be implemented on October 1, 2019 (FY 2020).

Proposed New Technology Add-On Payments (NTAP) for New Services and Technologies for FY2020

A new medical service or technology may be considered for NTAP if the DRG prospective payment rate is inadequate based on the estimated costs incurred with respect to discharges involving a new medical service or technology. In order to secure a new technology add-on payment, the new medical service or technology must demonstrate that it is 1) new; 2) costly such that the applicable DRG rate is inadequate; and 3) a substantial clinical improvement over existing services or technologies. The following applications were received for services related to the delivery of radiation therapy in the inpatient setting:

AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution
Progenics Pharmaceuticals submitted an application for AZEDRA®, which is a drug solution formulated for intravenous use in the treatment of patients with iobenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma. These are rare tumors with an incidence of approximately 2 to 8 people per million per year.

AZEDRA® was approved by the FDA on July 30, 2018 and according to Progenics, it is the first and only drug indicated for the treatment of adult and pediatric patients 12 years and older who have been diagnosed with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. CMS invites public comment as to whether or not AZEDRA® is substantially similar to other currently available therapies and/or technologies and meets the "newness" criteria.

Currently, there are no specific MS-DRGs for the assignment of cases involving the treatment of patients who have been diagnosed with pheochromocytoma or paraganglioma. In order to demonstrate that AZEDRA® is more costly than a potential MS-DRG rate, Progenics identified potential patient cases across a series of MS-DRGs and determined that the average charge per case ranged from $21,958 to $152,238. Progenics then determined that an average case-weighted standardized charge per case of $1,078,631 for AZEDRA®. CMS has expressed concern regarding the limited number of cases that were analyzed as part of this process, while also acknowledging the difficulty in obtaining cost data for such a rare condition. The Agency seeks comments on whether AZEDRA® meets the cost criterion.

Finally, with regard to meeting the substantial clinical improvement standard, Progenics asserts that based on two clinical studies AZEDRA® has been shown to reduce the incidence of hypertensive episodes and use of antihypertensive medications, reduce tumor size, improve blood pressure control, and reduce secretion of tumor biomarkers. CMS expresses concern regarding the assertion found in the IB12 study that AZEDRA® provides a safe alternative therapy for those patients who have failed other available treatment therapies. The Agency seeks comments regarding this assertion.

CivaSheet®

CivaTech Oncology, Inc. submitted an application for CivaSheet®, which is intended for use as a brachytherapy for placement into a body cavity or tissue as a source for the delivery of radiation therapy. CivaSheet® may be used either for primary treatment or for the treatment of residual disease after excision of the primary tumor. It can also be used concurrently, or sequentially, with other treatment modalities such as external beam radiation therapy or chemotherapy. CivaTech asserts that CivaSheet® is the first low dose rate brachytherapy device designed specifically for the delivery of intraoperative radiation therapy.

CivaSheet® received FDA 510(k) clearance by the FDA in 2014. It was also approved as a "sealed source" by the Nuclear Regulatory Commission and added to the Registry of Radioactive Sealed Sources and Devices on October 24, 2014. On May 9, 2018, CivaSheet® was registered by the American Association of Physicists in Medicine (AAPM) on the "Joint AAPM/IROC Houston Registry of Brachytherapy Sources Complying with AAPM Dosimetric Prerequisites." CivaSheet® was not commercially distributed among IPPS hospitals until May 2018. According to CivaTech, the "newness" period for CivaSheet® should begin on May 9, 2018. CMS is in agreement but seeks public comment on whether inclusion of the AAPM criteria is an appropriate indicator of the first availability of CivaSheet® for meeting the "newness" criteria.

Additionally, CivaTech asserts that CivaSheet® is not substantially similar to any existing technology because it uses a unique mechanism for delivering radiation treatment when compared to existing LDR brachytherapy. CMS seeks comment on whether CivaSheet® meets the "newness" criteria.

With regard to whether a product is assigned to the same or similar MS-DRG, CivaTech asserts that patients who may be eligible for treatment using CivaSheet® include those patients with pancreatic, colon and anus, pelvic area, head and neck, soft tissue sarcomas, non-small cell lung cancer, ocular melanoma, atypical meningioma and retroperitoneum cancers, which map to a variety of MS-DRGs. According to CivaTech's analysis, the average case-weighted charge per case was determined to be $188,897. The charge per case for CivaSheet exceeded the average case-weighted threshold amount of $87,447 by $101,451. CMS invites comments regarding whether CivaSheet® meets the cost criterion.

CivaTech asserts that CivaSheet® meets the substantial clinical improvement criterion because it improves local control of different cancers; reduces the rate of device-related complications; reduces the rate of radiation toxicity; decreases future hospitalizations; decreases the rate of

subsequent therapeutic interventions; improves back pain and appetite in pancreatic patients; and improves local control for pancreatic cancer patients. CMS expresses concern that the supporting data appear to be feasibility studies substantiating the use of CivaSheet® in different cancers and different anatomic locations. According to the Agency, there do not appear to be any comparisons to other current treatments, nor any long-term follow-up with comparisons to currently available therapies. CMS seeks comments regarding whether CivaSheet® meets the substantial clinical improvement criterion.

GammaTile™

GT Medical Technologies, Inc. submitted an application for GammaTile™, which is a brachytherapy technology for use in the treatment of patients who have been diagnosed with brain tumors. The technology uses cesium-131 radioactive sources embedded in a collagen matrix that are designed to provide adjuvant radiation therapy to eliminate remaining tumor cells in patients who required surgical resection of brain tumors. The GammaTile™ is biocompatible and is left in the body permanently without need for future surgical removal.

The GammaTile™ technology received FDA clearance under section 510(k) as a Class II medical device on July 6, 2018. ICD-10-PCS procedure code 00H004z (Insertion of radioactive element, cesium-131 collagen implant into brain, open approach) was approved for use on October 1, 2017. According to GT Medical Technologies, Inc. when compared to treatment using external beam radiation therapy, GammaTile™ is fundamentally different in structure, function and safety. It delivers treatment through a form of internal radiation termed brachytherapy. CMS expressed concern that GammaTile may be similar to current forms of radiation therapy or brachytherapy. Specifically, the Agency is concerned that GammaTile™ is an improvement in brachytherapy treatment delivery and points out that placement of cesium-131 source in a collagen matrix offset may constitute a new delivery vehicle. CMS invites public comment regarding whether GammaTile™ is substantially similar to existing technologies and whether the technology meets the "newness" criteria.

With regard to the cost criterion, GT Medical Technologies conducted an analysis using MS-DRGs 025 through 027 (Craniotomy and Endovascular Intracranial Procedures). According to the analysis, GammaTile™ meets the cost criterion because the average case-weighted standardized charge per case of $253,876 exceeds the average case-weighted threshold amount of $143,749. CMS expressed concern that the analysis does not include a reduction in costs due to reduced operating room times related to the time associated with the freehand placement of seeds in other brain brachytherapy procedures. CMS invites public comment regarding whether GammaTile™ meets the cost criterion.

GT Medical Technologies, Inc. asserts that GammaTile™ meets the substantial clinical improvement standard because it offers a treatment option for a patient population that is unresponsive too, or ineligible for, currently available treatments for recurrent CNS malignancies and significantly improves clinical outcomes when compared to currently available treatment options. CMS expresses concern regarding the clinical efficacy and safety data provides by GT Medical Technologies, Inc. Additionally, the Agency asserts that the findings supporting improved clinical standards appear to be derived from relatively small case studies and not data

from FDA clinical trials. CMS invites public comment regarding whether GammaTile™ meets the substantial clinical improvement criterion.

Evaluation of Substantial Clinical Improvement Criterion for IPPS NTAP and OPPS Transition Pass-Through Payments for Devices

CMS is seeking comment on the "substantial clinical improvement" criterion for evaluating applications for both the IPPS (NTAP and the OPPS transitional pass-through payment for devices. Existing regulations provide that a new technology is an appropriate candidate for additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available.

The Agency recognizes that additional clarity regarding the requirements associated with the "substantial clinical improvement" criterion will help the public better understand how CMS evaluates new technology applications for add-on payments and will provide greater predictability about which applications will meet the criterion. The request for comments is intended to inform future rule making but may result in changes applied to the 2020 final IPPS and OPPS rules.

New NTAP Pathway for Transformative New Devices

CMS is also proposing a new NTAP pathway for transformative new devices. This new approach would recognize devices that are part of the Federal Drug Administration's (FDA) Breakthrough Devices Program and receive FDA marketing authorization. These devices would be considered new and would not be required to meet the requirement that it substantially improves, relative to the existing technologies, the diagnosis or treatment of Medicare beneficiaries. This new approach would apply to applications for FY 2021.

Additionally, the Agency is proposing to modify the NTAP payment methodology. Currently, if the costs of care exceed the Diagnosis Related Grouper (DRG) payment, then Medicare will make an add-on payment equal to the lessor of: 1) 50 percent of the costs of the new medical service or technology; or 2) 50 percent of the amount by which the cost of the case exceeded the DRG payment. CMS has received concerns that the existing 50 percent cap does not provide sufficient incentive for the use of new technology and is proposing to increase the cap to 65 percent beginning October 1, 2019.

Medicare Wage Index Disparities

In the 2020 IPPS proposed rule, CMS recognizes concerns regarding disparities between high and low wage index hospitals as a result of the application of the current Medicare Wage Index system. To address these concerns, the Agency is proposing to increase the wage index values

for hospitals with a wage index below the 25th percentile and decrease the wage index values for hospitals with index values above the 75th percentile.

CMS is proposing to increase the wage index value for hospitals below the 25th percentile by half of the difference between each individual hospital's wage index value and the 25th percentile wage index value. A similar methodology would be used to reduce the wage index value for hospitals above the 75th percentile wage index value, thus keeping the proposal budget neutral.

CMS is also proposing to modify the "rural floor" policy which dictated that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that same state. The Agency is proposing to remove the wage data of urban hospitals that have reclassified as rural from the rural floor methodology. CMS believes that the inclusion of these hospitals in the past has exasperated Medicare wage index disparities between low and high wage hospitals.

This policy would be effective for at least four years, beginning in FY2020, and includes a transition period for those hospitals that experience a significant decrease in their wage index values due to this proposed change. The Agency is proposing a 5 percent cap on any decrease in a hospital's wage index for FY2020 in comparison to the hospital's final wage index in FY2019. This policy will be in effect for two years.

More information regarding the 2020 IPPS can be found at the following link:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Proposed-Rule-Home-Page.html