ASTRO
TARGETING CANCER CARE

AMERICAN SOCIETY
FOR RADIATION ONCOLOGY
251 18th St. South, 8th Floor
Arlington, VA 22202

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

August 1, 2024

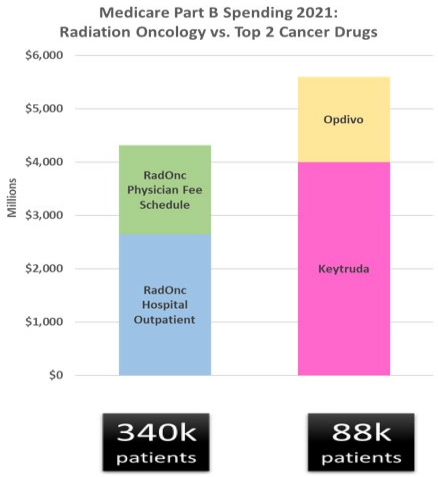
Rep. Diana DeGette
US House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 20515-4329

Rep. Larry Bucshon, MD
US House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Dear Rep. DeGette and Dr. Bucshon:

The American Society for Radiation Oncology[1] (ASTRO) appreciates the opportunity to provide input in response to the 21st Century Cures initiative request for information. We applaud Congress' continued commitment to spurring the next generation of life-changing treatments and ensuring that patients can access them. ASTRO's priority is to protect patient access to the most appropriate treatments at the right time. Stable payments for physicians, increased funding for critical cancer research, curbing prior authorization abuse, access to new and innovative technologies, and standardized data are key elements required to achieve that goal.

Stable physician payment for radiation therapy
Radiation therapy is a highly cost-effective cancer treatment, often used as an alternative to surgery to preserve organ function. In fact, Medicare spends less on radiation oncology than it does on just two cancer drugs, yet more than four times as many beneficiaries receive radiation therapy as part of their cancer treatment than receive those two drugs. More than half of the people diagnosed with cancer this year will receive radiation therapy.



[1] ASTRO members are medical professionals, who practice at hospitals and cancer treatment centers in the United States and around the globe and make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

Despite this high value, Medicare has cut radiation oncology payments more than nearly all other physician specialties, threatening patient access to state-of-the-art cancer care. The current Medicare payment system is broken and fails to support the higher quality care patients deserve.

Radiation oncology has experienced 23% in cuts under the physician fee schedule since 2013, leading to challenges accessing care. Practice costs are rising, as cutting-edge technology and skilled staff get more expensive. At the same time, more Medicare beneficiaries and cancer survivors need access to lifesaving radiation therapy close to home to complete treatment regimens successfully.

Without stable payments, patients' access to quality care will suffer. Radiation therapy is primed to make incredible gains for people with cancer, but the current Medicare payment system is prohibiting the investments necessary to further reduce cancer mortality. Radiation oncologists are committed to payment reform that achieves better outcomes and lower costs for patients, as well as creating savings for Medicare.

The new Radiation Oncology Case Rate (ROCR) Value-Based Payment Program Act (S.4330/HR.8404), sponsored by Senators Thom Tillis (NC), Gary Peters (MI), Congressmen Brian Fitzpatrick (PA), Jimmy Panetta (CA), John Joyce, MD (PA), and Paul Tonko (NY), will increase patient access to care, enhance the quality of cancer treatments, reduce disparities for rural and underserved patients, and lower Medicare and patient spending.

ROCR will:

- Increase value-based care by changing radiation oncology payment from per treatment to per patient, similar to other payment reform models.
- End the decades-long declines in Medicare payments for radiation therapy services, protecting the viability of radiation oncology clinics across freestanding and hospital-based settings.
- Build off payment reforms for other capital-intensive health care services, such as End Stage Renal Disease.
- Unify payments across different care settings, and
- Save Medicare more than $200 million over 10 years.

ROCR enhances patient care by:

- Supporting shorter courses of treatment for certain cancers, when appropriate, allowing patients to get back to their lives faster and have more time for work and spend time with family and loved ones.
- Ensuring access to technologically advanced cancer treatments close to where patients live.
- Using a systematic approach to improve quality and protect patient safety.
- Reducing disparities that limit underserved and rural patients from accessing and completing treatments.

ROCR:

1. Sets case rates derived from values published by Medicare for 15 cancer types commonly treated with radiation therapy.
2. Applies an annual inflationary update and savings adjustment.
3. Adds funds to cover transportation services for eligible rural and underserved patients to reduce disparities.
4. Adjusts payment based on practice accreditation status, which ensures comprehensive quality assurance, improvement and patient safety.

Increased funding for cancer research

ASTRO remains committed to advocating for sustained increases in cancer research funding at the NIH, NCI, and ARPA-H despite the setbacks faced over the last year. Outright cuts and even flat funding for these institutions will have detrimental effects on the research community and America's cancer patients. Research funding contributes to:

- A 33% decrease in the cancer death rate since 1991; that's 3.8 million lives saved.
- In FY 2022, NIH research funding supported nearly 570,000 jobs and produced more than $96 billion in economic output nationwide.
- Radiation oncology is responsible for 40% of all cancer cures and is received by more than half of patients diagnosed with cancer.
- Investments in radiation therapy research and innovation could improve cure rates for 3.5 million people and provide palliative relief for 3.5 million others.

Because of the incredible promise of cancer research, and the impact of cancer on patient lives, NCI receives more research grant applications than any other Institute or Center at NIH, by far. But the scientific demand has far outpaced NCI's budget, meaning that five out of every six proposals go unfunded every year. The only way to meet this demand is by boosting funding for NCI.

ASTRO requests $51.303 billion in funding for the NIH, an increase of $3.803 billion over FY2024 appropriations. $7.934 billion for NCI, an increase of $614 million over FY2024 appropriations. And at least $1.5 billion for ARPA-H that does not displace or reduce funding, particularly from NCI. We also request that Congress ensure initiatives like the Cancer Moonshot support efforts to enhance access to radiation therapy, address disparities in care and treatment outcomes, and reduce obstacles to care like treatment delays.

Beyond this general request for increased funding, NIH should enhance its prioritization of radiation oncology funding given the value of the therapy and that more than half of patients with cancer receive at some point during their treatment course. Despite the large role radiation therapy plays in cancer care, only about 5% of recent cancer clinical trials investigated radiation therapy as an experimental intervention (Liu et al., 2018). The lack of proportionate research funding potentially hampers the progress and development of innovative techniques and technologies that could further optimize and personalize radiation therapy, thus limiting the ability to maximize its therapeutic benefits. According to our analysis, from 2011 through 2021, less than 0.5% of the total NIH budget and less than 2% of the NCI budget supported research related to radiation oncology.

Curb prior authorization abuse

Prior authorization is a cumbersome process that requires physicians to obtain pre-approval for medical treatments or tests before rendering care to their patients. The process for obtaining this approval is lengthy and typically requires physicians or their staff to spend time negotiating with insurance companies — time that would be better spent taking care of patients. On average, for every one hour of clinic time, physicians spend nearly two more hours on administrative support and prior authorization.

Radiation oncologists, more than any other clinical specialty, face the greatest likelihood of encountering prior authorization obstacles, according to a 2021 article in JAMA Health Forum. Prior authorization is consistently ranked by radiation oncologists as the biggest challenge facing their clinics. In nationwide surveys by ASTRO, more than 90% of radiation oncologists reported patient treatment delays caused by prior authorization, with the average delay lasting longer than a week. Delays in the start of radiation

therapy are associated with worse outcomes for people with cancer, including increased risk of death. Furthermore, Radiation Oncology Benefit Managers (ROBMs) oversimplify the process of individual patient care management and abrogate the professional and personal judgments of physicians and patients.

Prior authorization is important, but inconsistent, overused and presents significant administrative and clinical concerns. Building off House-passed prior authorization reform legislation, and CMS implementation through the rule-making progress, major changes have been proposed for Medicare Advantage plans and commercial payers also are considering new processes. With the overwhelming majority of the House and Senate supporting prior authorization reforms, ASTRO joins more than 500 other groups urging Congress to finish the job by passing the Improving Seniors Timely Access to Care Act of 2024 (S4352./HR.8702). To prevent unnecessary delays and patient anxiety in cancer care, it is vital these reforms include radiation therapy services. This legislation would ensure patients and their physicians make care decisions instead of insurance companies and would allow radiation oncologists to spend less time managing redundant paperwork and return to treating people with cancer. To further streamline the prior authorization queue and give physicians much-delayed relief from hours of time with insurers, Congress introduced the GOLD Card Act in 2023 (HR.4968). The Getting Over Lengthy Delays in Care As Required by Doctors Act would exempt physicians from MA plan prior authorization requirements as long as 90% of prior authorization requests (excluding drugs) in the preceding year are approved.

For cancer patients who receive radiation therapy, prior authorization restrictions can delay care for days or weeks, increasing cancer mortality. Prior authorization restrictions are unproductive, impractical and harmful to patients. In addition, Medicare Advantage (MA) prior authorization requirements and reimbursement setup make it difficult for many patients to enroll or participate in clinical trials. MA plans require prior authorization for clinical trials that are sponsored by the plan, as well as for any trials that are not sponsored by the MA plan. Practices are often not being paid directly, leaving the responsibility of payment to the patient, who then must seek reimbursement for billed services. Routine costs for services that are provided as part of a clinical trial should be paid for just as the MA plan would have been required to do so had the patient not been enrolled in a trial. Another barrier to participation in trials is the fact that MA plans do not pay for the initial consult that is required before a patient can enroll in a clinical trial. All of this acts as barriers to clinical research and advancement of treatments as patient enrollment is needed to determine the effectiveness of a clinical trial treatment. Yet another reason for prior authorization to be overhauled in the Medicare Advantage market.

Access to New Technologies

In 2016, when the 21st Century Cures Act was signed into law, the FDA received the authority to expedite the review of "breakthrough" medical devices to diagnose or treat life-threatening or irreversibly debilitating conditions. Unfortunately, CMS has done too little to ensure the 21st Century Cures Act delivers for Medicare beneficiaries.

In late 2021, CMS repealed the Medicare Coverage of Innovative Technology (MCIT) policy, which had bipartisan Congressional support explaining that it would propose a revised version of MCIT. In 2022, again in April 2023, and again later that spring, CMS promised to release this revision. Finally, and only after significant pressure from multiple stakeholders across the health care spectrum, including patient groups and Congress itself, CMS released a Transitional Coverage for Emerging Technologies (TCET) notice on June 22, 2023. Despite significant stakeholder input, a final rule has yet to be released.

Patients deserve access to new and innovative technologies to treat their cancer. Providing a predictable pathway to national Medicare coverage for new medical devices and diagnostics provides such access. ASTRO supports policies that improve patient care and support innovation by providing a clear, transparent, and consistent coverage process while maintaining robust safeguards for the Medicare program. We urge CMS to issue a final rule as soon as possible.

In addition to its use for the treatment of cancer, there has been significant growth in the use of radiation therapy for the treatment of nonmalignant disease. Patients with conditions such as osteoarthritis, plantar fasciitis and Parkinson's Disease are able to benefit from the use of radiation therapy delivered using new technology. For these conditions, radiation therapy provides pain relief, improves function or mitigates the need for surgery or costly medications. We urge Congress to support the use of novel applications of radiation therapy for nonmalignant disease.

Standardized Data

Standardized data is critical to improve healthcare initiatives included in the 21st Century Cures Act and discussed above. For example, currently the Food and Drug Administration (FDA) is only capturing binary yes/no information regarding radiation therapy as part of drug trials rather than the detail needed to impact future patient care, research and discovery. Collecting a core set of radiation therapy elements as part of drug trials would be valued and embraced by many stakeholders seeking to utilize oncology data to ease patient burden and increase innovation.

The availability and use of data standards is key to interoperability, data transparency and liquidity. Since 2019, ASTRO has been actively working in the Common Oncology Data Elements eXtension (CodeX) FHIR Accelerator and has completed work to standardize data elements necessary for many different outcomes and data priorities. Prior to this initiative, limited standards existed, outside of Digital Imaging and Communications in Medicine (DICOM), that could transfer data between non-radiation oncology systems. To date, CodeX has created four radiation therapy FHIR profiles, six extensions, and nine value sets, resulting in 322 new radiation oncology-specific data elements. These concepts have not only been added into the Minimal Coding Oncology Data Elements (mCODE) standard, but also have been approved for new Systemized Nomenclature of Medicine-Clinical Terms (SNOMED CT) codes and tested by information system vendors. We urge Congress to fund the important work currently being undertaken by CodeX and mCODE to standardize data.

We appreciate the opportunity to provide feedback on these important issues and look forward to working with you in the future. For more information, please contact Cindy Tomlinson, Senior Manager for Patient Safety and Regulatory Affairs at cindy.tomlinson@astro.org.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer