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Critical Review

The Burden of Insurance Prior Authorization on Cancer Care: A Review of Evidence From Radiation Oncology

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Purpose: Despite its high cost-effectiveness, radiation oncology faces the greatest prior authorization (PA) burden of any medical specialty. Insurance denials and resulting treatment delays have been documented across several treatment modalities, including stereotactic body radiation, intensity modulated radiation, and proton therapy. Although insurance companies suggest that PA is intended to control health care spending and ensure the implementation of evidence-based practice, the number of radiation treatment plans reviewed by the PA process that result in changes is quite low. Yet, the cost to patients, providers, and the health care system is rising.

The increased administrative work required to address the appeal process, including the development of radiation plan comparisons, results in lost productivity of radiation staff and increased clinic costs that are not currently reimbursed. Treatment delays from PA may elevate patient anxiety and affect their ability to enroll in clinical trials, resulting in decreased quality of care. As a result of possible harm to patients, the Centers for Medicare and Medicaid Services developed a ruling that mandates increased transparency of insurers' requirements, decreased allowable time for arriving at PA decisions, and a more efficient electronic communication system to address the time and resource burden of PA.

Methods and Materials: This article summarizes key discussions from the literature and provides recommendations to help mitigate insurance PA strain.

Results: These recommendations broadly address the following key areas: (1) omission of PA for routine care and clinical trials, (2) implementation of efficient, streamlined electronic peer-to-peer communication, (3) increased transparency of insurance requirements and rationale for denials, and (4) decreased time allowances for PA decisions.

Conclusions: Policy reform focused on evidence-driven treatment coverage, reduction of the proportion of cases requiring PA, and a simplified, timely insurance appeal process is necessary to ensure optimal cancer care for patients requiring radiation therapy as part of their cancer journey.

Introduction

Radiation therapy (RT), used in more than half of all cancer cases, accounts for only 3% to 4% of the total yearly cancer care spending per patient under active

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treatment in the United States.[1-3] This statistic is in stark contrast to the 18% to 20% for chemotherapeutics/biologics and 11% to 13% for surgeries.[3] Despite its high cost-effectiveness, radiation oncology faces the greatest prior authorization (PA) burden of any medical specialty.[4] Before treatment initiation, PA determines which treatments will or will not be covered based on factors including treatment necessity, evidence backing for a given indication, and alignment with insurance company policies. Steps typically include physician request for certain treatments; case-by-case review by insurance companies with a decision to approve, deny, or ask physicians for further information; and any appeals including peer-to-peer (P2P) meetings with insurance company representatives after a denial.[5] When a treatment gets denied, a physician may appeal for desired treatment, or patients may proceed with a nonpreferred therapy, pay out-of-pocket, or choose not to get radiation.

Although insurance companies claim to implement PA to control health care spending and ensure implementation of evidence-based practice, the American Society for Radiation Oncology (ASTRO) surveys have consistently named PA as the top challenge for clinics.[6] Ninety-three percent of radiation oncologists in a nearly 700 participant survey stated this process has delayed their patients from receiving life-sustaining treatments, with 31% of participants reporting an average treatment delay of >5 days.[6] Insurance PA can lead to decreased quality of care by creating treatment delays, elevating patient anxiety, and compromising productivity of radiation oncology practices. Moreover, PA delays and insurance denials lead to the use of less-conformal treatments and affect clinical trials.

Although the 2001-2005 Medical Expenditure Panel Survey indicated the average annual number of patients with cancer with Medicare at 5.5 million versus with private insurance at 7.3 million, private insurers are responsible for the majority of insurance denials and insurance-related delays for radiation treatments.[7-12] Although Medicare sets some predefined coverage limits based on patient disease, Medicare does not require PA for RT.[13] Meanwhile, Medicare Advantage, which is required to provide at least the services Medicare covers, often gatekeeps treatments through a PA process similar to private insurance.[14]

This article outlines the impact of PA and insurance denials on patients, clinics, treatment planning, and patient enrollment on clinical trials. It also provides recommendations for easing the burden of PA as summarized in Table 1.

Delays and effects on patient experience

Delivery of radiation is a time-sensitive process with delays impacting critical outcomes. For example, each week of delay in treatment initiation for curative-intent treatments for early-stage cancers is associated with an increased absolute mortality risk of 1.2% to 3.2%, according to an observational study of 3,672,561 patients.[15] In a study of 697 cases requiring PA, the mean delay for initiation of radiation treatments was 12.1 days, and even among plans approved without image guided radiation therapy (IGRT), there was a mean delay of 9.8 days.[16] In 15 cases, the delay was >20 days.[16] In a study of 196 patients whose treatments were initially denied, treatment was delayed in 36.7% with a mean delay of 7.8 days and a range of 1 to 49 days.[8]

In an anonymous patient survey regarding PA for any oncologic care, despite the majority of respondents reporting being personally involved in fixing PA issues, most responders noted delays in recommended services.[17] A total of 73% of delayed services were delayed >2 weeks, and 22% of survey participants were unable to receive recommended care because of denials.[17] The PA experience, including PA delays and patient time spent involved in the PA process, was described as "bad" or "horrible" by most patient responders and caused increased anxiety and decreased trust in their health care systems and insurance companies.[17] The pervasive stress that patients experience is demonstrated by the fact that almost three-fourths of 2019 ASTRO physician survey respondents reported that their patients regularly express concerns about PA delays.[6]

To combat these delays and associated detrimental effects on patients, some legislative changes are being implemented such as the Centers for Medicare and Medicaid Services (CMS) Interoperability and Prior Authorization Final Rule (Patient Access Final Rule) effective in 2026, which requires federally regulated insurance plans such as Medicare Advantage and Medicaid to respond to urgent PA requests with approval or denial within 72 hours and nonurgent plans within 7 calendar days.[18,19] For affected insurance plans, this ruling should significantly expedite the time involved in waiting for a PA decision. Starting 2027, CMS will also require payers to establish an application programming interface including an online PA progress tracker portal for patients, which will further ameliorate patient anxiety while awaiting PA decisions.[20]

Impact on clinics

Participants in a physician-directed survey of 300 oncologic providers indicated that if the time and resources devoted to PA were to be redirected, most providers believe that their health care system would focus on increasing the number of patients treated, advancing research, and building up palliative care, outpatient, and supportive care services.[21] According to the ASTRO 2019

Table 1 Summary of proposed prior authorization (PA) changes

Change	Description	Potential positive ramifications	Downsides of proposed solution
Elimination of PA for routine care and clinical trials	For standard of care cases and for patients enrolling on clinical trials, establishing an insurance autoapproval system	Decreased administrative burden and delays from PA for most cases, reduced PA cost, increased ability of clinical trials to recruit sufficient patients for primary endpoints	Debates over what qualifies as routine care, fewer double checks for safety of a clinical trial for a given patient
GOLD CARD Act	Autoapproval of treatments for physicians meeting specific PA approval metrics	Decreased administrative burden and delays from PA, decreased friction between physicians and insurers, reduced cost of PA	May unduly influence physicians' treatment decisions
Streamlined electronic communication systems	Electronic systems for PA that use standardized forms, as discussed in acts such as the Patient Access Final Rule and the Improving Seniors' Timely Access to Care Act. Additionally, allowing for electronic communication platforms for P2P instead of the traditional phone call	Decreased administrative burden and delays from PA and P2P, long-term decreased cost to health care system	Initial costs to insurers of implementing these changes, potential miscommunication through electronic platforms for P2P
Increasing insurer requirement transparency	Requirements of the Patient Access Final Rule that insurers provide transparent rationales for treatment denials	Decreased futile PA requests, increased provider awareness of acceptable indications for a given treatment	May encourage cookie-cutter denial practices that do not take into account specifics of a given case
Decreasing allowable time for PA decisions	Requirements of the Patient Access Final Rule that insurers decrease time to PA decision to 72 hours for urgent plans and to 7 calendar days for routine care	Decreased PA delays	Challenging without increasing automation of PA process
Standardization of PA for private insurance plans	Extending the CMS Final Rule to private insurers	Decreased delays in PA, increased efficiency in the processing of PA requests by clinics, increased equity of care across insurers	Initial costs to insurers of implementing changes, need for strict policy enforcement because of lack of positive incentives for insurance companies

Abbreviations: CMS = Centers for Medicare and Medicaid Services; P2P = peer-to-peer.

physician survey, 17% of radiation oncologists divert >10% of their patient care time to responding to PA concerns, over a third spend 5% to 10% of their workday on PA, and almost two-thirds had to hire additional staff in the prior year to keep up with the demands of the PA process.[6]

This time devoted to PA process is a hefty expense burden on clinics. Through time-driven activity-based costing at a singular academic medical center, PA annual department costs were estimated at $491,989 with subsequently approved treatments accounting for 94% of these estimated costs.[22] Because a mere 6% of costs associated with PA were for plans that insurance companies ultimately denied coverage, the vast majority of cases are likely appropriate treatments for which a PA process is unnecessary. The time and cost burden for all events ranged from 51 to 95 minutes and $28 to $101, whereas P2P discussion ranged from 92 to 95 minutes and $75 to $101, respectively.[22] For each case, Financial Clearance Specialist requirements ranged from 48 to 54 minutes and $21 to $23, whereas Attending Physician requirements ranged from 2 to 28 minutes and $6 to $71, respectively.[22] Although this analysis does not take into account the additional time and cost burden of comparison plan generation by dosimetrists and medical physics, conservative extrapolation from this single institution would suggest annual national PA treatment costs to be $40,125,848 for all academic practices with subsequently approved PAs making up 86% of that at $34,632,620.[22]

Some additional frustrating challenges to clinics posed by the PA process include interruptions to clinic flow, unfruitful P2P discussions, and lack of transparency over what companies are willing to cover or their reasons for denial. Moving back patient treatment start dates because of PA delays creates extra logistical challenges with the overall radiation treatment schedule and with aspects such as coordination of patients' systemic therapies, lodging, and transportation. Physicians are often interrupted during other obligations to participate in P2P discussions because of insurance companies or their associated Radiation Oncology Benefits Managers (ROBMs) only offering broad time ranges or inconvenient and inflexible times during clinic hours during which they will call for the P2P discussions. Additional options for communication by e-mail or an electronic portal as part of P2P conversations instead of reliance on the traditional phone call would decrease the time physicians spend away from patient-facing care. Moreover, although the expectation for a P2P is to meet with a radiation oncologist peer knowledgeable in the literature pertaining to the proposed treatment, 44% of physicians who responded to the ASTRO 2019 survey said they are typically scheduled to meet with non-specialist peers.[6] A similar concern that arises is speaking with peers who are incapable of reversing denials because of company policy, regardless of evidence backing a treatment. In providing an option for P2P review, insurance companies and ROBMs need to commit to hiring appropriate specialty-matched peers and to making any hidden regulations such as those that prohibit approval of certain treatments for certain indications publicly available. Any denial, whether initial or after P2P, should be clearly explained.

To improve costs, efficiency, and experiences for patients and medical personnel, electronic communication for the PA process is showing promise, but the adoption of the automative PA process is low, with only 21% of PAs being fully electronic across medical specialties.[23] Through reducing administrative costs, increasing net promoter scores, and allowing patients to receive care with fewer delays and denials, nationwide implementation of transparent electronic communication methods is expected by the 2021 Council for Affordable Quality Healthcare Index to save the United States $437 million a year.[23]

The CMS Patient Access Final Rule, in addition to decreasing the time to PA decision, proposes standardized PA forms across insurers and an electronic PA process versus relying on faxing or mailing forms.[19] These measures should help decrease clinics' time on the PA process. This ruling also aims to increase transparency of the PA process for federally regulated insurance plans by requiring insurance companies to make their PA requirements publicly available, to provide specific rationales for denials, and to report PA metrics.[19]

Similarly, the Improving Seniors' Timely Access to Care Act, which initially passed the House on September 14, 2022, but was rejected by the Senate, is now being reintroduced to the House of Representatives for consideration after passing the House Ways and Means Committee.[24] This act that applies to seniors with Medicare Advantage plans would require insurers to report PA utilization, denials, and approvals to CMS to encourage the adoption of evidence-based guidelines.[24] The act also seeks to increase insurance coverage transparency, decrease care delays, and facilitate communication by implementing an electronic PA process.[24] Although guidelines developed using federally regulated insurer PA metric data could also serve as a benchmark for private insurer PA practices, without an extension of a mandate such as the Patient Access Final Rule to private insurance plans, private insurers are unlikely to change their PA practices to reduce patient delays and clinical burden.

PA concerns by treatment modality

The PA process is most cumbersome for complex treatment modalities such as intensity modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT), and proton therapy. These therapies, which are often more expensive, are most susceptible to being flagged during PA for denial or requiring further

information from physicians prior to a decision. Therefore, delays during the PA process are more likely for plans using these modalities. Treatment delays because of PA are correlated with commercial insurance programs for IMRT, SBRT, and proton therapy.[9,11,25]

Because of the increased use of more expensive radiation modalities in recent years, private insurance companies have started contracting ROBMs, which conduct PA reviews for radiation services to help control costs while screening for medical necessity and appropriateness according to evidence-based guidelines.[26] In addition to creating more layers of administrative complexity to the PA process, the main downside of ROBMs is that radiation oncologists typically weigh in several factors that ROBMs may not account for, such as a patient's goals, comorbidities, prior response to cancer-directed therapies, anatomy, and tumor characteristics when choosing a preferred treatment. Therefore, although ASTRO supports the development of transparent, professional guidelines with peer review, ASTRO opposes restrictive guidelines of ROBMs that oversimplify medical decision-making for individual patients and discredit the professional judgments garnered through patient-doctor relationships.[26]

Because treating physicians pick up on denial trends for insurers or receive certain pushback from ROBMs, even if not explicitly stated as an indication for denial per company policy, physicians may stop trying for approval of their preferred modality for a given indication. Although the link between radiation oncology treatment prescribing patterns and insurance barriers is currently underexplored in the literature, in the broader health care landscape, a 2020 cross-sectional online survey showed that clinical practices were affected by the perceived likelihood of PA being required, insurers' clinical documentation requirements, and difficulties communicating with insurance companies.[27] In this report, a fourth of physician respondents admitted to modifying diagnoses, and three-fourths relayed that they often avoid evidence-based newer medications to circumvent PA process roadblocks.[27] Moreover, more than a third of respondents reported that they altered medications to prevent treatment delays because of insurance PA.[27] Given the high PA burden inflicted on radiation oncology clinics especially for IMRT, SBRT, and proton therapy, it is likely that clinical practice is being unduly influenced by PA. Physicians shaping treatment decisions to conform to insurance coverage trends against their own medical judgment may result in unequitable patient care and lead to an underrepresentation of treatment denials.[27]

IMRT

The presumed overuse of IMRT poses a financial concern for insurers, so to allay fears of overpayment, companies often require a comparison of a three-dimensional (3D) plan to an IMRT plan prior to authorizing IMRT. These comparison plans, which are not intended for use on patients but are solely designed to prove the superiority of the desired IMRT plan, require considerable time to develop on the part of physicians, dosimetrists, and medical physicists, leading to further delays in care and disruptions to clinical workflow. To discourage reliance on comparison plan generation and other time-consuming processes, current procedural terminology billing codes could be developed to account for the time radiation oncology clinics spent on PA including the generation of treatment comparison plans.

In a study evaluating potential delays in care of 91 patients receiving 3D-conformal radiation therapy (3D-CRT) and IMRT, the average time of computed tomography simulation scan to treatment start was 9 days if no plan comparisons were needed and 11 days for those requiring comparisons.[28] Other studies have also investigated treatment delays related to PA for IMRT. Treatment delays because of P2P reviews in 270 patients with lung cancer treated with curative-intent RT yielded a median delay in treatment at 7 days compared with 0 day for patients where P2P was not required.[25] Another study analyzed the effects of insurance authorization requirements on 21 IMRT cases with 5 different insurance carriers.[29] IMRT was approved in 19 of the cases with a median time for authorization of 21 days and median time from request to treatment initiation of 26 days.[29] During the delays, 21% showed measurable tumor progression, 5% were restaged, and 5% developed a threatened bronchial obstruction.[29]

SBRT

SBRT techniques also use several time-sensitive steps with delays, such as obtaining insurance PA, impacting clinical outcome. In a study of 1,534 patients, factors that influenced time to patient simulation included treatment site, fractionation request, and insurance type.[9] SBRT cases involving the brain (mean, 3.8 days), lung (3.4 days), and spine (4.0 days) were approved faster than those involving the prostate (12.0 days).[9] This long delay for prostrate SBRT is unusual given that in cases of prostate radiation the alternatives to SBRT, including moderately hypofractionated and conventionally fractionated regimens, are significantly more costly to insurers than SBRT.[30] Single fraction (mean, 3.8 days) was approved faster than cases with 2 to 5 or >5 fraction sizes (10.2 days).[9] Overall, stereotactic radiosurgery/SBRT (mean, 2.0 days) took slightly longer for insurance authorization than 2D plans/3D-CRT (1.9 days), but less time than IMRT/IGRT (2.9 days).[9] Of these patients, 36.1% had commercial insurance (mean time to authorization, scheduling and confirming simulation, 2.2 days), 24.4%

had Medicare (simulation, 0.9 days), and 1.4% had Medicaid (simulation, 2.0 days).[9]

Perhaps the delays to PA decisions for SBRT stem from insurance payers being conflicted concerning the necessity of SBRT for different indications. After the update of ASTRO's SBRT model policy, 77 payers with SBRT policies were identified, and the proportion of payers deeming SBRT a medical necessity was 97% for primary lung cancer, 91% for spine reirradiation, 68% for prostate cancer (68%), 66% for radioresistant spinal metastases, and 66% for primary liver cancer.[31] Current policies are beginning to align with ASTRO's model policies, but national benefits managers and national payers are still covering more indications than regional payers, signaling needed improvements at the regional level.[31]

Proton therapy

Proton therapy is used in 44 active United States centers with an additional 7 under development.[32] A growing body of clinical trials supports proton therapy's adoption for various disease sites, and numerous additional trials are under active accrual.[32] Although proton therapy can offer improved sparing of adjacent healthy tissue with preserved target coverage compared with SBRT or IMRT,[33] its indications are still less defined, and there is a substantial increase in cost transitioning from photon to proton plans.[34] Consequently, higher appeal and denial rates for proton therapy would be expected. However, the differences in denial rates between private insurers and public insurers observed in multiple studies are unexpected.[10-12,35,36]

Some studies in specific disease sites illuminate the differences in insurance denials between public and private insurers. A study of patients with esophageal cancer noted patients with private insurance experienced more denials, even post-appeal.[11] Meanwhile, a study of patients with thoracic malignancies revealed that Medicare insurance and secondary insurance were associated with increased initial approval for proton therapy, with no other factors examined—including disease site, inquiry year, diagnosis, or fraction number—being correlated with upfront approval.[36] The final approval rates in this thoracic population were not significantly linked to specific insurance carriers but were positively correlated with curative intent and reirradiation cases.[36] Of the 623 patients with thoracic malignancies, 513 were approved for protons with 433 upfront approvals, and 126 entered appeal with 80 approved (63.5%).[36] The median approval time was 5 days without appeal versus 13 days for denial and 19 days with appeal.[36]

Appeal outcomes in a patient cohort with thoracic or head and neck cancers found that Medicare was again a strong predictor of initial approval with 91% of Medicare patients' treatments being approved on initial request (median, 3 days), compared with 30% of privately insured patients' treatments (median, 14 days).[12] A total of 306 cases were denied with 276 appeals and 189 ultimately overturned (median, 21 days).[12] Submission of comparison plans of proton versus photon was unexpectedly associated with increased denials as was prescribed dose ≥66 Gy.[12]

One study examining a broader cohort of 612 patients (554 adults, 58 pediatrics aged ≤21 years) with multiple cancer types from April 2016 to June 2017 oddly did not see differences in overall insurance approval rate based on patient age, disease site, or type of insurance and had an exceptionally high overall approval rate of 94%.[37] However, median decision time was 39 days for those with denials versus 6 days for approvals, and 49 patients experienced delays of >60 days.[37] Moreover, a separate analysis found that 64% of adult patients faced initial denials for proton therapy, and 32% remained denied following appeal.[38] Reirradiation cases had a 57% initial denial rate, and those considered for randomized phase 3 trial enrollment had an even higher 64% initial denial rate.[38] From 2015 to 2018, initial denials rose from 55% to 74% signifying growing barriers to proton therapy approval.[38] The average treatment delay was 3 weeks for those requiring appeal with 19% of those denied abandoning radiation treatment altogether.[38] As the number of proton therapy centers worldwide continues to expand, it is imperative that insurance coverage policies be updated to minimize these extensive delays from proton therapy insurance denials, which are significant predictors of worse outcome.[39]

A couple of studies have tried to promote ethical allocation of proton therapy through developing scoring systems to quantify the utility of proton therapy on a case-by-case basis, and ASTRO has a frequently updated proton therapy model policy that can help inform coverage decisions.[40] Such systems, if employed by insurers and ROBMs as screening tools, may cut down on long delays and minimize unwarranted denials. One point-based triage system was used to predict initial approval for proton therapy, stratified cases by the anticipated benefit of protons.[35] Scoring >15 points on the triage scale—which assigned points for clinical advantage, strength of evidence, survival expectancy, performance status, and research protocol enrollment—correlated with higher initial insurance approval.[36] The patient median age of 54 years and having Medicaid and no third-party insurance were linked to a higher overall approval likelihood.[35] Another study reported that their expert panel-derived scoring system is also predictive of increased insurance approval.[10] For patients with ultimately approved proton plans, 93% were on Medicaid, 88% had Medicare, and 78% had private insurance.[10] The median response time for denials was 12 days, with private insurance or third-party coverage significantly increasing the likelihood of final denials.[10]

The higher incidence of proton therapy denials by private insurers, as opposed to Medicare, highlights the need for legislative intervention to incentivize private insurers to reconsider overly restrictive coverage policies. Because private insurance predominantly serves a younger demographic than Medicare, this disparity in access to proton therapy disproportionately impacts young and middle-aged patients. At least as many proton therapy approvals for privately insured patients as Medicare patients would be expected, especially because these individuals typically have a longer expected remaining lifetime to be burdened by toxicities inflicted by less-conformal treatments.

This age rationale for proton therapy has classically been applied to pediatric malignancies, with adolescent cancers yielding more initial denials and fewer final approvals for toxicity-sparing modalities on and off trial than for young children. For example, only 9% of the pediatric patients in one analysis were initially denied proton therapy but were all subsequently approved after appeal, and PA did not delay treatment start.[38] Meanwhile, an analysis of 157 combined pediatric plus adolescent patients found that pediatric requests for proton therapy were approved day one 100% of the time without appeal (median 3 days) whereas adolescents were significantly less likely to be approved upfront without appeal (median 10 days without appeal versus 12 days with appeal). [41]

Insurance denials' impact on treatment planning

Although many radiation oncology treatment denials by insurance are overturned through appeal, for some cases there is no option for appeal and others require changes to modality, dose prescription, or daily setup imaging. For example, although insurance approvals for intensity modulated proton therapy (IMPT) in patients with thoracic malignancies in one study yielded a nearly 90% insurance approval rate with 80% avoiding P2P and appeal processes, P2P was available in less than half the patients denied with <30% success rate after the appeals.[42] Another analysis examining deidentified billing record cases of 1,620 patients over a 7-month period revealed that 43% of cases required PA, and 17.6% were denied and sent for P2P review.[16] A total of 69.1% of denials were overturned during P2P review without altering prescriptions, 4.1% were overturned without requested IGRT, 4.1% were approved for downgraded modality, 4.1% were denied and RT abandoned, and 1.6% of the results were unavailable.[16]

In 206 cases of initially denied radiation requests, commercial insurance payers made up 96.6%, with only 3.4% of denials being from Medicare/Medicare Advantage.[8] A total of 61.1% of denials were approved without change after P2P review, insurance change, external appeal, and/or employer request, whereas 9.2% proceeded with treatment without authorization by departmental administrative clearance.[8] Moreover, 27.2% were approved only after insurer-requested modifications were made to RT technique and/or prescription dose.[8] In 21 cases with a decrease in prescription dose, a median decrease in biologically effective dose was 24 Gy.[8] In 58 cases with RT technique change, 34.5% changed from IMRT to 3D-CRT, 27.6% SBRT to 3D, 25.9% SBRT to IMRT, 10.3% SBRT to 2D, and 1.7% 3D to 2D.[8] Therefore, in this analysis, denials led to the utilization of less-conformal treatment techniques and decreased prescription doses.

Although many PA cases are approved without change, time and resources are still lost; therefore, policy change is needed to bypass the PA process for physicians deemed as using medical resources judiciously as part of evidence-based clinical practice. If radiation oncology services were included in the "Getting Over Lengthy Delays in Care as Required by Doctors Act of 2022," dubbed the "GOLD CARD Act," radiation oncologists would be able to bypass the Medicare Advantage PA requirements if at least 90% of their prior requests during the previous 12 months were approved.[43] The GOLD CARD Act would free physicians of the PA process and allow them to use the time to meet the needs of their patients without delays. Although average insurance approvals for radiation are close to this cutoff of 90%, a theoretical risk of the GOLD CARD Act is that physicians may consciously or subconsciously curb their practice patterns to qualify for the exemption or in response to receiving the exemption, which is likely why policies such as this have not been widely adopted.

Insurance denials' impact on clinical trials

In addition to PA's impact on routine care, insurance denials present barriers for patients on clinical trials that hinder advancements in radiation oncology. The Secretary of Human Health and Services in 2000 authorized Medicare coverage for medical complications and routine care for patients taking part in clinical trials.[44] Moreover, Section 2709 of the Patient Protection and Affordable Care Act prevented denial of coverage for routine care during approved clinical trial participation across insurers but did not apply to Medicaid plans or any grandfathered health insurance plans or to investigational RT treatments.[45] Starting January 2022, as part of an amendment to the Social Security Act, Medicaid is required to cover routine care for patients enrolled in qualifying clinical trials.[46] However, some insurers still use investigational treatment exemption to justify lack of coverage during therapies such as SBRT or proton therapy despite their long-term use and often favorable side effect profiles. Although insurance companies attribute treatment

denials to lack of evidence for given treatment modalities in certain disease sites, 18% of National Clinical Trials Network (NCTN) trials between 2000 and 2011 had inadequate patient accrual to be able to answer trial questions and oncologic clinical trial enrollment has typically included only 2% to 4% of adult patients with cancer.[47,48] Denials pose extra patient accrual challenges, thus extending the completion time and costs of trials seeking to address the degree of benefit from these therapies.

Although data are limited on the impact of SBRT denials on clinical trial accrual, in a study of 15 eligible patients for the Spine Patient Optimal Radiosurgery Treatment for Symptomatic Metastatic Neoplasms phase 2 trials comparing SBRT regimens with 1 fraction external beam radiation, 3 patients experienced insurance denials with P2P assessment resulting in reversal of all 3, allowing all to remain in the trial.[49]

In the case of clinical trials involving proton therapy, the decreased approval rate for younger patients compared with older patients because of insurance coverage has meaningful implications for the fidelity of clinical trial results. In a simulated randomized clinical trial comparing proton therapy with IMRT in which insurance denial rates were higher for the proton group, the researchers assumed insurance denial was possible in patients aged <65 years and hypothesized that the denials lead to bias and loss of statistical power when using intent-to-treat analyses.[50] In their study of 300 patients, the researchers found that insurance denials lead not only to misclassification bias in intent-to-treat analysis but also to missing data problem in per-protocol analysis and covariate imbalance between treatment arms in as-treated analysis.[50] Denials force critical appraisal of features such as age, which influences clinical success.

Conclusions

PA, designed to lower health care cost by deterring the use of treatments that do not represent evidence-based practice, has become a counterproductive strategy, leading to treatment delays and increased administrative workload. The negligible impact on the majority of treatment plans, coupled with significant costs and burdens, calls for the elimination of PAs for routine care as well as other burden-reduction strategies such as the GOLD CARD Act and an automated PA system with fewer administrative hurdles and tighter authorization decision deadlines.

Private insurance companies are responsible for the majority of PA concerns, and in a given hospital network, there are typically multiple commercial insurance providers with widely differing PA requirements.[51] Efforts to standardize the PA process for private insurance plans are needed to decrease administrative burden devoted to interacting with various insurance companies and to insure equitable access to care for patients.[43] One way to streamline the process is to extend to the private insurance sector the PA policy changes that are proposed for federally regulated plans such as the GOLD CARD Act. When physicians requesting complex treatments do not qualify for PA exemption under the GOLD CARD Act, a second way to reduce delays and alleviate the administrative load of PA would be to implement the streamlined electronic system as envisioned in the Improving Seniors' Timely Access to Care Act or per the Patient Access Final Rule in 2026. Moreover, insurers must support clinical trial participation and provide transparent, evidence-based rationales for treatment denials as well as shift to electronic communication for peer-to-peer reviews to further reduce disruptions. Comprehensive policy focused on evidence-driven treatment coverage, reduction of the proportion of cases requiring PA, and a timely insurance appeal process is necessary to ensure optimal cancer care for patients requiring RT as part of their cancer journeys.

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References

1. Atun R, Jaffray D, Barton M, et al. Expanding global access to radiotherapy. *Lancet Oncol*. 2015;16:1153-1186.
2. Perez C, Brady L, eds. *Principles and Practice of Radiation Oncology*. 3rd ed Lippincott-Raven; 1998.
3. Fitch K, Pelizzari PM, Pyenson B. Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Milliman; April 2016. Accessed June 21, 2024. https://www.siteneutral.org/wp-content/uploads/2016/06/1_COA-Study.-Cost-Drivers-of-Cancer-Care.pdf.
4. Schwartz A, Brennan T, Verbrugge D, Newhouse J. Measuring the scope of prior authorization policies: applying private insurer rules to medicare part b. *JAMA Netw*. 2021;2: e210859.
5. O'Reilly K. 7 Prior authorization terms that drive every doctor to distraction. JAMA Netw Am Med Assoc. November 13, 2023. Accessed June 23, 2024. https://www.ama-assn.org/practice-management/prior-authorization/7-prior-authorization-terms-drive-every-doctor-distraction.
6. ASTRO Targeting Cancer Care. *Prior Authorization Obstacles Unnecessarily Delay Patient Access to Cancer Treatments, Physician Survey Finds*. Arlington, VA; April 25, 2019.
7. Tangka F, Trogdon J, Richardson L, et al. Cancer treatment cost in the United States: has the burden shifted over time? *Cancer*. 2010;116:3477-3484. https://doi.org/10.1002/cncr.25150.
8. Shin J, McBride S, Cuaron J, Gomez D. Clinical sequelae of initial insurance denials in a large academic radiation oncology center. *Int J Radiat Oncol*. 2023;117:S90.

9. Blacksburg SR, Ghafar R, Green S, Sheu R. Operations management in radiation oncology: Identifying workflow parameters that portend for simulation delay. *Int J Radiat Oncol Biol Phys*. 2014;80:S747-S748.
10. Grzywacz V, Quinn T, Wilson T, et al. Ethical allocation of proton therapy and the insurance review process. *Pract Radiat Oncol*. 2021;11:E449-E458.
11. Chiang JS, Voss M, Yu N, et al. Insurance request and approval process for proton beam therapy in patients with esophageal cancer. *Int J Radiat Oncol Biol Phys*. 2023;117:e571-e572.
12. Ning M, Gomez D, Shah A, et al. The insurance approval process for proton radiation therapy: A significant barrier to patient care. *Int J Radiat Oncol Biol Phys*. 2019;104:724-733.
13. Radiation therapy. Medicare.gov. 2024. Accessed June 22, 2024. https://www.medicare.gov/coverage/radiation-therapy.
14. United Healthcare. Prior authorization for radiation therapy services. Uhcprovider.com. 2024. Accessed June 20, 2024. https://www.uhcprovider.com/en/prior-auth-advance-notification/oncology-prior-auth/oncology-comm-radiation-prior-auth.html.
15. Khorana A, Tullio K, Elson P, et al. Time to initial cancer treatment in the United States and association with survival over time: An observational study. *PLOS ONE*. 2019;14: e0215108.
16. Koffler D, Chitti B, Hwant L, et al. Futility of the third-party peer-to-peer review process and entailed delays to cancer-directed therapy. *Int J Radiat Oncol*. 2022;114(3S):S93.
17. Chino F, Baez A, Elkins I, et al. The patient experience of prior authorization for cancer care. *JAMA Netw Open*. 2023;6: e2338182.
18. Centers for Medicare & Medicaid Services. CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F). CMS.gov. 2024. Accessed June 20, 2024. https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f.
19. American Society for Radiation Oncology. CMS final rule establishes prior authorization requirements, reducing burden and increasing interoperability. astro.org. January 17, 2024. Accessed June 26, 2024. https://www.astro.org/news-and-publications/what-is-happening-in-washington/2024/cms-final-rule-establishes-prior-authorization-requirements.
20. Green EB. Advancing interoperability and improving prior authorization: No one said it would be easy! Ebglaw.com. April 1, 2024. Accessed June 25, 2024. https://www.ebglaw.com/insights/publications/advancing-interoperability-and-improving-prior-authorization-no-one-said-it-would-be-easy.
21. Cancer Health: American Society of Clinical Oncology. Prior authorization has a negative impact on cancer care. January 9, 2023. Accessed June 22, 2024. https://www.cancerhealth.com/article/prior-authorization-negative-impact-cancer-care-asco.
22. Bingham BS, Chennupati S, Osmundson EC. Time driven activity based costing as a method for estimating the practice-level and national cost burden of treatment-related prior authorization for academic radiation oncology practices. *Int J Radiat Oncol*. 2021;11:S70-S71.
23. Bhaumik K, Sarkar S, Fernandes G, Dillon L. How electronic prior authorizations can benefit stakeholders. EY Building a better working world. March 23, 2023. Accessed June 24, 2024. https://www.ey.com/en_us/insights/health/how-electronic-prior-authorization-can-help-health-care.
24. H.R.3173 — Improving Seniors' Timely Access to Care Act of 2021. (2021-2022). CONGRESS.GOV. 117th Congress. Accessed June 25, 2024. https://www.congress.gov/bill/117th-congress/house-bill/3173.
25. Salgado L, Smith W, Sheu R, et al. Delays in radiation therapy as a result of peer to peer review process. *Radiat Oncol Biol Phys*. 2019;105:E615.
26. American Society for Radiation Oncology. Benefit managers. astro.org. 2024. Accessed June 23, 2024. https://www.astro.org/practice-support/reimbursement/private-payers/benefit-managers.
27. Salzbrenner S, Lydiatt M, Helding B, et al. Influence of prior authorization requirements on provider clinical decision-making. *Am J Manag Care*. 2023;29:331-337.
28. Novak J, Germino E, Ivanov Y, et al. Prior authorization for three-dimensional versus intensity-modulated radiotherapy comparison plans may delay treatment. *Int J Radiat Oncol Biol Phys*. 2020;108: E420-E421.
29. Durkee B, Cruz A, Rodriguez D, Kenyon M, Gibbs I. Do new insurance policies requiring DVH comparison address IMRT overuse or simply harm patients? *Int J Radiat Oncol Biol Phys*. 2014;90:S64-S65.
30. Hodges J, Lotan Y, Boike T, et al. Cost-effectiveness analysis of stereotactic body radiation therapy versus intensity-modulated radiation therapy: An emerging initial radiation treatment option for organ-confined prostate cancer. *J Oncol Pract*. 2012;8:3S.
31. Roach M, Thomas T, Paravati A, Mahajan A. Differences in United States insurance payer policies and American Society for Radiation Oncology's (ASTRO) model policy on stereotactic body radiation therapy (SBRT). *Int J Radiat Oncol Biol Phys*. 2019;104:740-744.
32. The National Association of Proton Therapy. Proton-therapy.org. 2023. Accessed June 26, 2024. https://www.proton-therapy.org.
33. Zaki P, Chuong M, Schaub S, et al. Proton beam therapy and photon-based magnetic resonance image-guided radiation therapy: The next frontiers of radiation therapy for hepatocellular carcinoma. *Technol Cancer Res Treat*. 2023;22: 15330338231206335.
34. Smith W, Richard P, Zeng J, et al. Decision analytic modeling for the economic analysis of proton radiotherapy for non-small cell lung cancer. *Transl Lung Cancer Res*. 2018;7:122-133.
35. Grzywacz V, Quinn T, Reitemeier P, et al. Third-party insurance providers and initial rejection of proton therapy. *Int J Radiat Oncol Biol Phys*. 2020;108:E420.
36. Ning M, Gunn G, Palmer M, et al. The proton insurance approved process for thoracic patients: Metrics and access. *Int J Radiat Oncol Biol Phys*. 2017;99:E407-E408.
37. Sethi R, Horick N, Yeap B, et al. Insurance coverage approval delay among patients receiving proton radiation therapy. *Int J Radiat Oncol Biol Phys*. 2018;102:E429-E430.
38. Gupta A, Khan A, Goyal S, et al. Insurance approval for proton beam therapy and its impact on delays in treatment. *Int J Radiat Oncol Biol Phys*. 2019;104:714-723.
39. Yu N, Sio T, Mohindra P, et al. The insurance approval process for proton beam therapy must change: Prior authorization is crippling access to appropriate health care. *Int J Radiat Oncol Biol Phys*. 2019;104:P737-P739.
40. American Society for Radiation Oncology. Model policies. Accessed June 26, 2024. https://www.astro.org/practice-support/reimbursement/model-policies.
41. Bishop A, Livingston J, Wages C, et al. Adolescent and young adult populations face yet another barrier to care with insurers. *Int J Radiat Oncol Biol Phys*. 2020:108.
42. Mohindra P, Scull A, Molitoris JK, et al. Insurance approval for proton therapy in patients with thoracic malignancies: An experience from a cost-neutral payor environment. *Int J Radiat Oncol Biol Phys*. 2021;111:E353-E354.
43. O'Reilly K. Prior authorization: "Gold card" approach to prior authorization introduced in Congress. JAMA Network. July 26, 2022. Accessed June 24, 2024. https://www.ama-assn.org/practice-management/prior-authorization/gold-card-approach-prior-authorization-introduced-congress.
44. American Society of Clinical Oncology. Medical Coverage Database (MCD) National Coverage Determination (NCD): routine costs in clinical trials. CMS.gov. 2024. Accessed June 27, 2024. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&fromdb=true.
45. American Society of Clinical Oncology. Affordable care act provision requiring insurance coverage of clinical trials. society.asco.org. 2014. Accessed June 27, 2024. https://society.asco.org/sites/new-www.asco.org/files/content-files/research-and-progress/documents/affordable-care-act-clinical-trials-coverage-provision.pdf.

46. Department of Health & Human Services. Updated: Mandatory Medicaid coverage of routine patient costs furnished in connection with participation in qualifying clinical trials. medicaid.gov. April 13, 2022. Accessed June 22, 2023. https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf.
47. Bennette C, Ramsey S, McDermott C, et al. Predicting low accrual in the National Cancer Institute's Cooperative Group Clinical Trials. *J Natl Cancer Inst*. 2016;108:djv324.
48. Lara P, Higdon R, Lim N, et al. Prospective evaluation of cancer clinical trial accrual patterns: Identifying potential barriers to enrollment. *J Clin Oncol*. 2001;19:1728-1733.
49. McClelland S, Brately M, Zuhour R, Sun Y, Spratt D. Insurance denial of care for randomized controlled trial-eligible patients. Incidence and success rate of peer-to-peer authorization in allowing patients to remain trial-eligible. *Am J Clin Oncol*. 2024;47:56-57. https://doi.org/10.1097/COC.0000000000001054.
50. Hernandez M, Lee J, Yeap B, et al. The reality of randomized controlled trials for assessing the benefit of proton therapy: Critically examining the intent-to-treat principle in the presence of insurance denial. *Adv Radiat Oncol*. 2021;6: 100635.
51. Shen X, Spratt D, Dusetzina S, Chen R. Variations in medical necessity determinations across commercial insurance carriers for prostate cancer procedures. *Int J Radiat Oncol Biol Phys*. 2023;115:34-38.