Strategic Operational Redesign for Successfully Navigating Prior Authorization Barriers at a Large-Volume Proton Therapy Center

Eric D. Brooks, MD, MHS^{1,2}; Matthew S. Ning, MD, MPH¹; Matthew B. Palmer, MBA³; G. Brandon Gunn, MD^{1,4}; Steven J. Frank, MD^{1,4}; and Aashish K. Shah, MD, JD⁵

QUESTION ASKED: Can pragmatic administrative measures be implemented to improve patient access to advanced, cutting-edge oncologic therapies, despite the increasingly restrictive payor landscape?

SUMMARY ANSWER: By implementing a multifaceted payor-focused strategy within our proton therapy center, our payor relations team could more efficiently navigate the prior authorization (PA) process and its associated administrative burdens to improve patient access to evidence-supported cancer treatment. This restructuring was associated with (1) optimized access to timely patient care; (2) improved satisfaction of both patients and providers; and (3) decreased personnel expenses during this time.

WHAT WE DID: Operations were redesigned at our proton therapy center to better reflect the insurance process: (1) certified medical dosimetrists (CMDs), with their unique treatment-related experience, replaced our historical PA team to function as the interface among physicians, patients, and payors; (2) a structured, tiered timeline was implemented to hold payors accountable to PA deadlines; and (3) our PA team provided new leadership with the requisite insurance knowledge to

facilitate strategy and training related to the PA process and payor communication.

WHAT WE FOUND: After implementation of this strategy, time to successful appeal (after coverage denial) decreased from 30 to 18 days ($P < .001$), and the total number of overturned denials increased by 56%, associated with a 37% growth in the center's overall treatment census. During this time, full-time equivalents on the PA team decreased by 44% with the newly hired CMDs (translating into a 34% reduction in personnel expenses).

BIAS, CONFOUNDING FACTORS: Seasonal operational factors, national guideline changes affecting payor coverage policies, and unaccountable biases inherent within a single-institution study at a large, academic practice setting could be confounding factors in this study.

REAL-LIFE IMPLICATIONS: We outline a comprehensive strategy for improving patient access to a technologically advanced and novel cancer therapy, despite the increasingly restrictive current payor landscape. Beyond proton therapy centers, these operational concepts may be adapted for other oncologic practice settings that are also affected by the PA process.

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ASSOCIATED CONTENT

Appendix

Data Supplement

Author affiliations and disclosures are available with the complete article at ascopubs.org/journal/op.

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abstract

PURPOSE Prior authorization (PA) can be a resource-intensive barrier to oncologic care. To improve patient access and reduce delays at our large, academic proton therapy center, we implemented a novel payor-focused strategy to efficiently navigate the PA process while eliminating physician burden and reducing inappropriate denials.

METHODS In 2017, business operations were redesigned to better reflect the insurance process: (1) certified medical dosimetrists (CMDs), with their unique treatment expertise, replaced our historical PA team to function as an effective interface among physicians, patients, and payors; (2) a structured, tiered timeline was implemented to hold payors accountable to PA deadlines; and (3) our PA team provided administrative leadership with requisite insurance knowledge. PA outcomes were compared 6 months before and after the intervention.

RESULTS After implementation of this multifaceted strategy, the median time to successful appeal (after initial denial of coverage) decreased from 30 to 18 days ($P < .001$), and the total number of overturned denials increased by 56%. Because of the efficiency of the CMDs, full-time equivalents on the PA team actually decreased by 44%, translating to a 34% reduction in team personnel expenses. Internal referrals increased by 29%, attributable to optimized communication and diminished administrative burden for providers. New treatment starts also increased, resulting in a 37% larger patient census on treatment.

CONCLUSION Incorporating payor-focused strategies can improve patient access in a cost-effective manner while decreasing time and administrative burden associated with the PA process. These operational concepts can be adapted for other oncologic practice settings facing analogous PA-related obstacles.

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INTRODUCTION

Prior authorization (PA) is a growing national problem affecting timely patient access to care across medicine.¹⁻⁷ Within the field of oncology,⁷ > 90% of surveyed physicians reported delays in their ability to provide therapy because of PA-related impediments, and one-third of providers had to abandon treatment altogether for one or more patients.⁸ These PA-related burdens are particularly onerous for patients awaiting curative oncologic treatments, such as radiation therapy.

Proton beam therapy (PBT), a highly specialized form of radiotherapy with the potential to spare normal tissue and thus minimize toxicity, has been adversely affected by these concerns. The increasing adoption of

PBT has amounted to > 70 proton therapy centers (PTCs) worldwide,⁹⁻¹¹ with nearly half in the United States^{12,13} and anticipation for continued growth of this advanced technology in coming years.¹⁴⁻¹⁶ Yet numerous PTCs have failed operationally¹⁷—and many patients have been denied PBT—because of increasingly restrictive coverage policies that persist in the face of evidence supporting PBT use.¹⁷ Ironically, insurance denials are a major contributor to the lack of level 1 evidence for PBT, because the trials required to generate such data cannot accrue owing to lack of coverage.^{9,18,19}

However, PBT does not stand alone (Data Supplement).^{10,11,20} Restrictive coverage policies can also serve as barriers to patient access for novel systemic therapies, cutting-edge molecular testing, and even

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supportive care services for cancer patients.²¹ Although the PA process is intended to represent a safeguard for inappropriate treatments,²⁰ studies have demonstrated that nonclinical variables—notably, insurance type—may ultimately yield greater influence on insurance outcomes than clinically relevant factors.^{10,11} Such inexplicable findings raise questions about the true impact of the PA process in the current health care climate, other than serving as a barrier to timely treatment.^{5,9,10,20,22,25}

Recognizing these concerns, our PTC successfully implemented an operational strategy aimed at addressing PA-related barriers for our patients. The key concepts underlying our approach can be adapted for other oncologic practice settings to benefit patients and providers in timely, evidence-based treatment delivery.

METHODS

In 2017, our PTC launched a multifaceted initiative to optimize patient access to care (Fig 1). This included (1) restructuring our PA team with uniquely equipped personnel; (2) providing new executive leadership with the requisite insurance knowledge; and (3) deploying a selective tiered system for authorization responses by payors.

PA Team Redesign

We replaced our historical team of registered nurses (RNs) with clinical medical dosimetrists (CMDs) to aid communication among patients, physicians, and payors. Although RNs and advanced practice providers (APPs) certainly benefit from clinical training and direct patient care experience, CMDs have a clear educational advantage with respect to radiotherapy treatment planning, thereby facilitating easy navigation of the PA process specific to PBT.^{27,28} The CMD curriculum, tailored to Radiation

Oncology, encompasses courses in radiobiology, physics, and treatment planning (Appendix Fig A1, online only). This relevant and highly specialized education uniquely positions CMDs in formulating evidence-supported strategies to obtain authorization and successful appeals.

To this end, our center hired 4 experienced CMDs to replace our historical PA team staff and work full time as advanced practice dosimetrists (APDs). In this administrative role, our APDs functioned independently on PA process rebuttals and directly helped patients, payors, and providers navigate through the multilayered PA process, thus reducing the administrative effort burden on clinical teams. The APDs also retain their clinical dosimetric experience, allowing them to generate comparative plans when requested for payors, further supporting their inherent value within this advanced role.

Requisite Payor Knowledge and Experience

To educate and prepare our newly restructured team, our PTC hired and provided a medical executive with extensive firsthand experience in the insurance authorization process to replace the prior PA team manager. Within this new leadership position, our newly appointed chief health care value officer (CHVO) helped with strategy development and implementation, guiding our PTC through the complex modern payor landscape and helping our teams adapt rapidly to payor policy changes as needed.

Notably, the CHVO provided individualized training to our APDs on PA submissions, appeal letters, legalistic rebuttals, document formatting and submission, peer-to-peer scripts, and personalized, evidence-based appeal letters (Appendix Fig A2, online only). Our APDs received a crash course on relevant payor rules and regulations, allowing our staff to hold third parties accountable throughout the PA

FIG 1. Strategic initiative to decrease delays and improve access to proton therapy. APD, advanced practice dosimetrist; IRO, independent review organization; P2P, peer-to-peer; PA, prior authorization.

and appeals timeline. For example, the legally stipulated response time per appeal request generally falls within 15 days from submission,^{29,30} and our APDs vigilantly held payors accountable to deliver within these deadlines and minimize unnecessary treatment delays associated with pending authorization decisions for our patients with cancer.

Selective Tiered Authorization and Appeal Process

To support these strict deadlines, a tiered structure, in the form of an automated electronic system, was implemented to keep track of authorization responses and ensure timely navigation of appeal steps (Fig 1). The basic premise of the tier was built around national and state mandates on maximum response times for payor responses at each authorization step,²⁹⁻³¹ which are not often advertised (Data Supplement). In recent months, several states have proposed legislature that will regulate the turnaround time of payor determinations throughout the PA process.^{32,33} This system was tailored to payor-specific factors, including strategic bypass of late sequential-appeal steps directly toward independent external review, when indicated, and was constantly updated as new legislation was passed. Holding payors accountable to the most up-to-date legislation is critical to minimize treatment delays associated with the PA process.

Analysis

We compared operational metrics 6 months before (October 2016-March 2017) and 6 months after (October 2017-March 2018) implementation of this strategic model, accounting for the expected ramp-up phase between these intervals for orientating and restructuring purposes (Fig 2). Time to insurance approval was computed in calendar days from the date of initial authorization inquiry, through the appeal process, to the date of final determination.

Differences in time to authorization among the pre-intervention and postintervention groups were compared via the Mann-Whitney test. Pearson χ^2 test was used to compare overall approval rates (and proportion of cases appealed) among different disease sites, including pediatric care as a category. For all analyses, the threshold for statistical significance was $P < .05$.

RESULTS

Authorization and Appeals

Over 18 months (October 2016-March 2018), 1,700 patients entered the insurance authorization process for PBT at our PTC. Of these, 1,266 (74%) were ultimately approved for treatment. Of the 633 initially denied coverage, 454 entered the appeal process, and denial was overturned for 199 patients (44%). Approval rates (with proportion appealed) varied significantly ($P < .001$) by disease site and pediatric care: pediatrics, 95% (3%); thoracic, 87% (13%); CNS, 80% (19%); GI, 77% (22%); head and neck, 70% (21%); genitourinary, 66% (16%); and breast, 66% (5%).

Operational Gains

Using this operational strategy, median time to approval decreased from 30 to 18 days after appeal, between the pre- and postintervention time periods ($P < .001$; Fig 3A). Overturned denials increased by 56% (52-81 per 6-month interval; Fig 3B), and internal referrals increased by 29% (342-442), which was attributable to improved communication and decreased administrative burden for providers (with our physicians conducting only 6% of all peer-to-peer communication in this postintervention era). New treatment starts also increased by 22 patients monthly, with a 37% (from 358 to 489) census increase noted (Fig 3C).

FIG 2. Timeline and phase-in of the strategic initiative intervention. Admin., administrative; APD, advanced practice dosimetrist; CMD, clinical medical dosimetrist; d, days; FY, fiscal year; MD, medical doctor; MLP, midlevel provider; PA, prior authorization; RN, registered nurse.

FIG 3. (A) Decrease in delays (time) to approval; (B) improvement in denial overturns; (C) expanded overall patient census after the intervention.

APD Value

Because of the APDs' specialized training and unique skill set, the average APD salary was 19% higher than that of historically used RNs on the PA team, implying greater cost per full-time equivalent (FTE). However, the superior ability of APDs to efficiently navigate the PA process justified this salary discrepancy: each full-time APD could simultaneously coordinate 20-40 PA/appeal requests, approximating the capacity of patients per treatment vault. On the basis of these metrics, our center hired 1 APD per gantry, plus an additional APD (total of 4) to account for volume fluctuations.

Personnel Expenses

Total FTEs on the PA team decreased by 44% after the intervention (from 9 to 5): 4 APDs plus 1 medical executive, who replaced the prior PA team manager. This 44% reduction in FTEs translated into a 34% decrease in personnel expenses associated with the new PA team, despite the increased APD salaries (+19% more than RN salary) and the relatively higher salary of our new medical executive (+21% more than the previous team manager). No losses were documented from an accounting standpoint, and our PTC appreciated significant reductions in administrative-related costs (due to decreased provider burden and treatment delays).

Despite the cost-saving reduction in personnel expenses, there were likely unmeasurable costs with hiring and training during the phase-in period. Yet both appeals and patient census grew during the phase-in period at a slower rate (Fig 2). Considering the average net revenue generated per patient at our PTC, we estimate that 10-13 new starts would justify the PA team expenses (break-even point), versus 15-16 new starts for the prior team structure. With respect to timing, the new PA team would justify its own expense 5-6 months from inception (despite phase-in), which is a conservative estimate based on the significant increase in appeals after inception (Fig 3).

DISCUSSION

To our knowledge, this is the first study to communicate a successful, evidence-based, payor strategy for improving patient access to PBT in the setting of a large-volume academic PTC. Throughout the field of oncology, the PA process can deny patients appropriate access to care.⁷ However, the concepts underlying our operational redesign may be implemented among other oncologic practice settings, for novel systemic therapies or technologically advanced surgical methods, to facilitate efficient navigation through the PA process and promote timely access to evidence-based cancer therapy.

Among our outcomes, the greatest success was the significant decrease in authorization time (and, thus, time to treatment). As numerous studies have demonstrated, minimizing time to curative treatment (eg, radiotherapy, chemotherapy, surgery) is vital for patients with cancer. Through this multifaceted strategic approach, we were able to treat more patients per time interval and to minimize administrative fatigue for patients and providers. Notably, these successes were achieved despite the increasingly restrictive payor policies that have evolved in recent years, particularly for PBT.^{10,34}

This study also supports the high-value proposition of restructuring a payor team to champion patient access to PA-burdened oncologic therapies, a concept that can be easily extrapolated outside of radiation oncology. Reports from other oncologic centers indicate that many practices maintain large PA teams to overcome administrative burden for providers and help facilitate patient access to various cancer therapies^{5,21,35,36}; according to a recent ASCO survey, the average oncologic PA team exceeds 6 FTEs.⁷ However, many of these PA teams likely lack the requisite clinical expertise to articulate a compelling argument for medical necessity and/or the requisite insurance knowledge to efficiently navigate through the multileveled PA process and its complicated timelines.

Regarding the requisite clinical expertise, our success with APDs suggests that PA teams can benefit from the administrative promotion of experienced care-team members with prior training to handle details specific to a given PA process. The nuanced expertise of such care-team members facilitates efficient navigation during payor negotiations. For example, subspecialized APPs may benefit medical or surgical oncology PA teams because these APPs have worked alongside their respective providers and thus understand the evidence, indications, and rationale required for successful peer-to-peer and appeal steps.

As for the requisite insurance knowledge, the same clinical care team members would also benefit from payor-specific education and formal training on appeal steps, imparting the requisite insurance knowledge necessary to efficiently navigate the PA process. As demonstrated by our phase-in period, the orientation process will initially require time and resources but will enable the PA team to operate independently without constant provider input. In turn, such training can lead to reduced administrative burden, decreased treatment delays, increased patient and provider satisfaction, and an overall

high return on investment. At our PTC, the APDs have directly contributed to increased patient volume, along with cost savings from decreased personnel expenses.

Several limitations of this study may limit generalizability for other practice settings. Regardless of the medical specialty, we emphasize that for such a structural intervention to take place, a center's executive leadership must remain cognizant of their limitations and strengths and be willing to invest in the appropriate infrastructure, personnel, and educational measures to successfully do so. Furthermore, although each pillar of this multifaceted strategy may provide some absolute benefit, we believe maximum success relies on synergy of all components working simultaneously within this comprehensive system redesign.

Potential confounders may also limit interpretation of these results. For example, some successes may have resulted from our PTC's marketing activities, although marketing strategy was not altered throughout this intervention and would not affect the noted time reductions. Additional unaccountable factors may include major legislative changes regarding the PA process, leadership changes, and other market forces. In an effort to account for seasonal variations in patient census, our analysis compared data from the same financial quarters (calendar months).

Finally, PBT has also been incorporated as an accepted modality under National Comprehensive Cancer Network guidelines over the course of this study for several sites: thoracic (ie, mesothelioma, thymoma, esophageal, and non-small-cell lung cancer), GI tumors (ie, hepatobiliary cancers), CNS tumors (ie, chordoma, ependymoma, medulloblastoma, meningioma), mucosal melanomas, and various sarcomas and lymphomas³⁷; yet a significant proportion of these patients still required appeal, as outlined by our results. In addition, our center's data from 2014 to 2016,¹⁰ along with other centers' data from 2015 to 2018,⁹ indicate decreasing approval rates throughout the course of this study, supporting the validity of our findings.

In conclusion, this multifaceted strategic approach has optimized navigation through the PA and appeal process at our large academic PTC, improving access to PBT while alleviating administrative burden for patients and providers. The underlying concepts may be adapted for other oncologic practice settings facing analogous PA-related issues to promote timely treatment of patients with cancer.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

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Data analysis and interpretation: Eric D. Brooks, Matthew S. Ning, Matthew B. Palmer, G. Brandon Gunn, Aashish K. Shah, Steven J. Frank

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Final approval of manuscript: All authors

Accountable for all aspects of the work: All authors

REFERENCES

- American Medical Association: 2018 Prior Authorization (PA) Physician Survey. <https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf>
- American Hospital Association, American Health Insurance Plans, American Medical Association, American Pharmacists Association, Blue Cross Blue Shield Association, Medical Group Management Association.: Consensus statement on improving the prior authorization process. <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>
- Casalino LP, Nicholson S, Gans DN, et al: What does it cost physician practices to interact with health insurance plans? *Health Aff (Millwood)* 28:w533-w543, 2009 (suppl 1)
- Vincent GK, Velkoff VA: The Next Four Decades: The Older Population in the United States: 2010 to 2050 (No. 1138). Washington, DC, US Department of Commerce, Economics and Statistics Administration, US Census Bureau, 2010
- Morra D, Nicholson S, Levinson W, et al: US physician practices versus Canadians: Spending nearly four times as much money interacting with payers. *Health Aff (Millwood)* 30:1443-1450, 2011
- National Level Summary Report. Evicore Healthcare. <https://www.evicore.com/-/media/files/evicore/footer-pages/national-level-summary-report-q3-2018.pdf?la=en&hash=135AB0F874C7BFA2D52F16FDFB61FFED>
- Kirkwood MK, Hanley A, Bruinooge SS, et al: The state of oncology practice in America, 2018: Results of the ASCO practice census survey. *J Oncol Pract* 14:e412-e420, 2018
- American Society for Radiation Oncology: Prior authorization and cancer patient care. Executive Summary of a Nationwide Physician Survey, April 2019. <https://www.astro.org/ASTRO/media/ASTRO/News%20and%20Publications/PDFs/ASTROPriorAuthorizationPhysician-SurveyBrief.pdf>
- Gupta A, Khan AJ, Goyal S, et al: Impact of insurance preauthorization requirements on delays in administering proton beam therapy. *Int J Radiat Oncol Biol Phys* 102:e416, 2018
- Ning MS, Gomez DR, Shah AK, et al: The insurance approval process for proton radiation therapy: A significant barrier to patient care. *Int J Radiat Oncol Biol Phys* 104:724-733, 2019
- Alliance for Proton Therapy Access: Cancer care denied: The broken state of patient access to proton therapy. <http://allianceforprotontherapy.org/wp-content/uploads/2018/05/Cancer-Care-Denied-Report.pdf>
- Bortfeld TR, Loeffler JS: Three ways to make proton therapy affordable. *Nature* 549:451-453, 2017
- National Association of Proton Therapy: <https://www.proton.therap-therapy.org/map/>
- Varian Medical Systems Probeam. <https://www.varian.com/products/proton-therapy/treatment-delivery/probeam-360>
- Mevion Medical Systems: MEVION S250I with Hyperscan and Adaptive Aperture. <https://www.mevion.com/products/mevion-s250i-hyperscan-adaptive-aperture>
- IBA Worldwide: Proteus ONE. <https://iba-worldwide.com/proton-therapy/proton-therapy-solutions/proteus-one>
- Hancock J: As proton centers struggle, a sign of a health care bubble? *Kaiser Health News*. <https://khn.org/news/as-proton-centers-struggle-a-sign-of-a-health-care-bubble/>
- Bekelman JE, Denicoff A, Buchsbaum J: Randomized trials of proton therapy: Why they are at risk, proposed solutions, and implications for evaluating advanced technologies to diagnose and treat cancer. *J Clin Oncol* 36:2461-2464, 2018
- Hoppe BS, Henderson R, Pham D, et al: A phase 2 trial of concurrent chemotherapy and proton therapy for stage III non-small cell lung cancer: Results and reflections following early closure of a single-institution study. *Int J Radiat Oncol Biol Phys* 95:517-522, 2016
- Wickizer TM, Lessler D: Utilization management: Issues, effects, and future prospects. *Annu Rev Public Health* 23:233-254, 2002
- Lin NU, Bichkoff H, Hassett MJ: Increasing burden of prior authorizations in the delivery of oncology care in the United States. *J Oncol Pract* 14:525-528, 2018
- Drash W: Judge rips insurance company for 'immoral, barbaric' cancer denials. *CNN*. <https://www.cnn.com/2019/05/16/health/judge-proton-beam-therapy-recusal-unitedhealthcare/index.html>
- Casalino LP, Nicholson S, Gans DN, et al: What does it cost physician practices to interact with health insurance plans? A new way of looking at administrative costs—one key point of comparison in debating public and private health reform approaches. *Health Aff (Millwood)* 28:w533-w543, 2009 (suppl 1)
- Soumerai SB, McLaughlin TJ, Ross-Degnan D, et al: Effects of a limiting Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *N Engl J Med* 331:650-655, 1994
- Ojerholm E, Hill-Kayser CE: Insurance coverage decisions for pediatric proton therapy. *Pediatr Blood Cancer* 65:e26729, 2018
- Thaker NG, Agarwal A, Palmer M, et al: Variations in proton therapy coverage in the state of Texas: Defining medical necessity for a safe and effective treatment. *Int J Part Ther* 2:499-508, 2016
- Medical Dosimetrist Certification Board: CMD credentialing. <https://mdcb.org/cmd-credentialing>
- American Association of Medical Dosimetrists: Medical Dosimetry Education Program. <https://www.medicaldosimetry.org/career-services/education-programs/>
- US Department of Labor: Benefit Claims Procedure Regulations FAQs. <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/benefit-claims-procedure-regulation>

30. Gordon Feinblatt: ERISA Plan Claims and Appeals. <https://www.gfrlaw.com/what-we-do/insights/erisa-plan-claims-and-appeals>.
31. American Medical Association: Advocacy Resources Center: 2018 Prior Authorization State Law Chart. <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/pa-state-chart.pdf>
32. Prior authorization bill may reduce headaches. <https://insiderlouisville.com/health/prior-authorization-bill-may-reduce-insurance-related-headaches/>
33. Frieden J: Prior authorization bill expected in congress this summer. <https://www.medpagetoday.com/practicemanagement/reimbursement/79314>
34. Alliance for Proton Therapy: More than 60 percent of patients seeking proton therapy initially denied coverage. Imaging Technology News. <https://www.itnonline.com/content/more-60-percent-patients-seeking-proton-therapy-initially-denied-coverage>
35. Sakowski JA, Kahn JG, Kronick RG, et al: Peering into the black box: Billing and insurance activities in a medical group: Standardizing benefit plans and billing procedures might help reduce complexity and billing/insurance costs—but only if applied strictly. Health Aff (Millwood) 28:w544-w554, 2009 (suppl 1)
36. Dickens DS, Pollock BH: Medication prior authorization in pediatric hematology and oncology. Pediatr Blood Cancer 64:e26339, 2017
37. National Comprehensive Cancer Network: NCCN Radiation Therapy Compendium. www.nccn.org/professionals/radiation/default.aspx

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**Strategic Operational Redesign for Successfully Navigating Prior Authorization Barriers at a Large-Volume Proton Therapy Center**

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians ([Open Payments](#)).

Matthew B. Palmer

Patents, Royalties, Other Intellectual Property: Patent, Automatic Optimal IMRT/VMAT treatment planning system, a joint patent with Philips Medical Systems and The University of Texas System

Steven J. Frank

Leadership: C4 Imaging, National Comprehensive Cancer Network

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Aashish K. Shah

Employment: Provision Healthcare

No other potential conflicts of interest were reported.

APPENDIX

Courses	RN	CMD	
Human Anatomy	✓	✓	Courses in common
Pathophysiology	✓	✓	
Medical Terminology	✓	✓	
Health Care Ethics	✓	✓	
Research Methods	✓	✓	
Research Design & Statistics	✓	✓	
Clinical Clerkships	✓	✓	Additional radiation therapy training
Anatomy for Radiation Oncology	✗	✓	
Radiation Treatment Planning	✗	✓	
Medical Dosimetry Concepts	✗	✓	
Clinical Radiation Oncology	✗	✓	
Medical Physics	✗	✓	
Current Trends in Healthcare Mgmt.	✗	✓	
Medical Law	✗	✓	

FIG A1. Educational advantage of advanced practice dosimetrists (APDs). CMD, certified medical dosimetrist; RN, registered nurse; Mgmt, management.

A

Dear [Insurance Company]:

This letter is in response to [Insurance Company]'s adverse determination on use of the prescribed Proton Beam Radiation therapy for your insured member, Mr. John Doe. Due to the serious and urgent nature of Mr. Doe's condition, we hereby appeal that adverse decision on an expedited basis.

Mr. Doe has Right Parietal WHO Grade 3 Astrocytoma. He needs immediate Proton Beam Therapy (PBT) in order to improve long-term survival while preserving neurocognitive function with minimized side effects. In support of our request for reconsideration of [Insurance Company]'s initial adverse determination, we herein offer a detailed showing of Mr. Doe's medical condition and why PBT is needed. We request that [Insurance Company] approve utilization of PBT for Mr. Doe's Right Parietal WHO Grade 3 Astrocytoma urgently.

A. CLINICAL SUMMARY

Mr. Doe is a 38-year-old male Pediatrician diagnosed with a WHO Grade 3 diffuse Astrocytoma, without definite features of GBM. Staining of p53 was > 95% favoring IDH mutant tumor. His oncology story began in early January 2019, when he presented with headaches described as posterior head to the left retro-orbital area. These symptoms were initially managed empirically for sinusitis with steroids. However, upon a steroid taper, his symptoms worsened, prompting evaluation at a local ER on 03/19/19, where an MRI of the brain revealed a 3.0 X 1.8 X 2.4 cm mass in his right parietal lobe. Mr. Doe then underwent a craniotomy on 03/22/19, with postoperative MRI on 03/23/19 revealing a gross total resection.

As demonstrated further below, Mr. Doe's tumor is in a highly complex location, abutting his brainstem. He now needs radiation therapy, but utilizing the modality of choice is crucial in order to spare his healthy brain tissue. PBT is the superior modality of choice because it lowers excessive radiation dose to his brainstem, unlike traditional radiation therapy such as IMRT or VMAT, which can NOT treat his tumor while safely sparing his critical brain structures. Specifically, Mr. Doe's prescription dose is a total of 57 cobalt gray equivalent to his gross tumor volume, but his gross tumor volume abuts his brainstem, which has a dose threshold tolerance of 54 cobalt gray equivalent. PBT is the only modality that can treat his tumor to full dose, and still spare his brainstem.

B

Above is a sagittal view of Mr. Doe's disease. As shown, his disease is abutting the superior-posterior aspect of his brainstem **

**Total prescription dose= 57 Gy. Max dose allowed to brainstem =54 Gy. **

B. SUMMARY OF TIMELINE FOR AUTHORIZATION REQUEST

We submitted an urgent request for authorization for treatment on April 25, 2019. After making repeated, unanswered requests for a status update, we finally received an answer from [Insurance Company] on May 30, 2019. To our surprise and dismay, [Insurance Company]'s response was that Mr. Doe's urgent request for PBT had been denied. Even more surprising and egregious was the fact we had NOT been provided an option for a Peer-to-Peer discussion with a Medical Director at [Insurance Company].

In light of the urgency of Mr. Doe's medical need to receive PBT, we immediately requested that [Insurance Company] provide an impromptu Peer-to-Peer discussion. [Insurance Company] agreed to such a discussion, which was held on May 30, 2019, but the Medical Director that [Insurance Company] provided for that discussion is a retired Urologist, not a physician specialist in brain/central nervous system. Thus, that Medical Director Urologist lacked the specialized training and experience essential to fully evaluate and make an appropriate, informed decision on the very complex facts of this brain tumor case. Accordingly, we now make this urgent, written appeal of that adverse decision, and request that our appeal be considered by a Specialty Match Reviewer who is a board-certified radiation oncologist with proton beam clinical experience.

FIG A2. (A) Appeal letter. (B) Sagittal view of patient's disease. As shown, the disease is abutting the superior-posterior aspect of the patient's brainstem. (C). Proton therapy is the standard of care to treat the patient's astrocytoma; letter continued. (D) [Insurance company]'s medical policy is outdated and not consistent with the current state of the evidence and national guidelines; letter continued.

C**C. PROTON THERAPY IS THE STANDARD OF CARE TO TREAT MR. DOE'S ASTROCYTOMA**

Mr. Doe's treatment site is in a sensitive anatomical location: within his Right Parietal Lobe. This region, which controls both speech and eyesight, is particularly sensitive to integral radiation. Furthermore, this region of the brain is just proximal and abutting critical areas such as hippocampi, brain stem, optic chiasm, optic nerve, and neurocognitive centers. Sparing this region from radiation as much as possible is both medically necessary and the prudent choice given Mr. Doe's young age of 38, his long life expectancy, and his employment status as a Pediatrician.

With utilization of PBT, a contralateral dose toward the contralateral hippocampus will be near zero, effectively sparing the right hippocampus completely. The importance of sparing the hippocampus has been well documented, including in a recent study in the Red Journal (V.Gondi) that found 40% of the bilateral hippocampi should be lower than 730cGy in order to mitigate long-term memory impairment. A conventional IMRT plan for Mr. Doe would deliver an average (mean) dose to the entire left hippocampus to 1000cGy, well above the benchmark advocated by the V. Gondi study. In contrast, the proton plan we advocate for Mr. Doe will spare the left hippocampus completely.

Mr. Doe is young, active, and has a long, productive life expectancy. If treated with the suboptimal, conventional IMRT plan, he will suffer unnecessarily from acute and late effect neurological complications risks. His ability to maintain a normal lifestyle and continue working as a Pediatrician will be at higher risk for impact, since he would potentially require several years of additional procedures and maintenance, and require assistance simply to manage basic daily tasks if such structures are affected. All of these effects – effects directly caused by using suboptimal IMRT rather than the optimal PBT – would be detrimental to Mr. Doe and his family from both a financial and emotional standpoint. Utilizing the optimal PBT will not only help Mr. Doe to resume an active, productive life, but also benefit the [Insurance Company] financially by eliminating the need for Mr. Doe to receive potentially years of future ancillary care necessitated by use of suboptimal IMRT.

D**D. [INSURANCE COMPANY]'S MEDICAL POLICY IS OUTDATED AND NOT CONSISTENT WITH THE CURRENT STATE OF THE EVIDENCE AND NATIONAL GUIDELINES**

We reviewed [Insurance Company]'s medical policy 8.01.10 regarding Proton Beam Therapy, which was last updated more than two years ago, in September, 2016. That policy cites 40 articles that pertain to PBT for various disease sites, but not one of them pertains to Astrocytoma, or, for that matter, provides any clear indications for the treatment of such brain tumors. In fact, the updated, 2018 National Comprehensive Cancer Network (NCCN) Guidelines on current Radiation Therapy Criteria for determining appropriate PBT use conclude that PBT is appropriate for Central Nervous System (CNS) tumors.

Unfortunately, because [Insurance Company]'s guidelines have not been updated since 2016, they fail to include consideration of those current, industry-recognized, national Guidelines, which were updated three times by NCCN in 2018 to conclude that Proton Therapy is the Standard of Care for medical conditions such as Mr. Doe's, based on his tumor's location within the CNS. The failure to include consideration of these Guidelines in [Insurance Company]'s medical policy regarding PBT is a glaring, highly significant omission that is leading to inappropriate, medically unsupported decisions on PBT authorization such as that made regarding Mr. Doe.

Moreover, our thorough evaluation of the [Insurance Company] policy found no explicit statement that PBT for Astrocytoma as "not medically necessary." In fact, the four indications specified in its policy as "not medically necessary" are prostate cancer, non-small-cell lung cancer, pediatric non-CNS tumors, and tumors of the head and neck. Mr. Doe's tumor does not fit within any of those prohibited categories. As is medically well-known, a brain tumor is a tumor of the Primary CNS. Thus, since it is not specifically identified as "not medically necessary," PBT for a brain tumor should be considered as medically necessary, a conclusion fully supported by the 2018 NCCN Guidelines on Current Radiation Therapy Criteria discussed above.

[Insurance Company]'s continued use of an outdated medical policy that runs contrary to recognized National Guidelines has resulted in an authorization denial that is medically unsupportable and appears contrary to [Insurance Company]'s own definition of when PBT therapy is "not medically necessary." This egregious, untenable approach leaves us and other providers having to defend the treatment of rare, medically urgent indications such as Mr. Doe's.

In light of the above, we hereby formally appeal and request reconsideration of the May 30, 2019 denial of PBT authorization for Mr. Doe, and request that, in light of Mr. Doe's serious, complex, and urgent medical condition, our appeal be expedited and reviewed by a Specialty Match Reviewer who is a board-certified radiation oncologist with proton beam clinical experience.

FIG A2. (Continued).