Variations in Proton Therapy Coverage in the State of Texas: Defining Medical Necessity for a Safe and Effective Treatment

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Abstract

Purpose: The definition of medical necessity and indications for coverage of proton beam therapy (PBT) for the treatment of cancer can vary greatly among different professional societies (PSs) and payors. Variations in policies introduce substantial inefficiencies and limit access for patients who may clinically benefit from PBT. The purpose of this study was to analyze differences in medical necessity and coverage policies among payors and a PS.

Materials and Methods: Peer-reviewed references and coverage decisions were abstracted from the coverage policies of each of the major payors in the state of Texas (Aetna-TX, UnitedHealthcare-TX, Blue Cross Blue Shield-TX) as well as from a representative PS, the Particle Therapy Cooperative Group. Differences in number and quality of references as well as coverage decisions were analyzed with descriptive statistics.

Results: Proton beam therapy coverage in the state of Texas varied among payors and the PS for several disease sites, including the central nervous system, eyes, and prostate. The PS cited more references and higher levels of evidence than payor policies ($P < .01$). Levels of evidence were inconsistent between policies. Interestingly, only 18% to 29% of cited references overlapped between policies.

Conclusions: Payors and PSs have independent and nonstandardized processes for determining PBT coverage, which result in variations in both coverage and evidence cited. These differences can lead to clinical inefficiencies and may reduce access to PBT based on payor status rather than clinical utility. A collaborative approach among all stakeholders would help create a more consistent, equitable, and patient-centered PBT policy that could identify areas for further evidence development.

Keywords: insurance policy; coverage; proton therapy; radiation oncology
Introduction

Medical necessity is an elusively defined concept that is used to describe health care that is reasonable, necessary, appropriate, and based on evidence-based clinical standards of care. The concept of medical necessity serves as a "gatekeeper" for health care service utilization, because services that are considered medically necessary are often covered by payors [1]. The process of defining medical necessity has been decentralized, nonstandardized, and typically ceded to payors for local coverage determination [2, 3]. In effect, payors and providers have had different working definitions of medical necessity, with some definitions incorporating cost and cost effectiveness rather than quality or clinical effectiveness. A particular area of controversy centers on coverage of advanced medical technologies. Although innovations in medical technology have, in part, contributed to superior outcomes in several areas, including cancer care [3–5], coverage decisions and definitions of medical necessity for advanced technologies have remained inconsistent across payors and professional societies.

Radiation oncology, in particular, has relied on innovations in technology to improve outcomes for patients with cancer by more effectively delivering radiation therapy (RT) dose to tumor cells and sparing normal healthy tissues [6–8]. Radiation therapy technology has evolved from 2-dimensional to 3-dimensional and, more recently, to intensity-modulated RT (IMRT). Each successive generation of new technology has held promise for improved outcomes but has also become increasingly expensive for providers, given the progressively complex machinery and skilled personnel required.

Proton beam therapy (PBT) is an evolution in RT delivery technology that is considered both safe and effective [9, 10]. Proton beam therapy has superior ability to spare surrounding normal healthy tissues owing to its unique physical properties as compared with traditional photon RT, such as IMRT [11]. Studies have shown that extraneous irradiation can have long-term detrimental effects, including secondary cancers [12]. Given the greater expense of delivering PBT, reimbursements have often been higher than for traditional photon RT. Although the potential advantage of PBT over photon therapy is strong, the data on the clinical utility of PBT continue to develop by disease site.

Despite a significant body of published evidence regarding PBT, coverage policies vary significantly between different payors and professional societies, and payors are becoming transparent about the incorporation of costs into coverage decisions. Using PBT as a case example of the controversy surrounding coverage and costs of advanced technologies, we examined the sources of coverage variations among PBT policies in the state of Texas and have proposed solutions toward a more uniform and collaborative approach to determining medical necessity.

Methods and Materials

Proton beam therapy policies that cover a large proportion of patients in the state of Texas, where our institution resides, were chosen for this analysis. These policies included Aetna-TX (policy last updated in August 2014) [13], Blue Cross Blue Shield of Texas (BCBS, policy last updated in May 2011), and UnitedHealthcare-TX (UHC, policy last updated in September 2014) [14]. All policies were last reviewed by the study authors in January 2015. The recently proposed Health Care Services Corporation (HCSC)-TX policy may be adopted by BCBS-TX in 2015 as replacement of the 2011 policy and was included for comparisons between successive BCBS policies. The current Medicare policy [15], which allows the treating radiation oncologist to make a determination of what is reasonable and medically necessary, was also used for comparison. Between 2006 and 2014, 75% of patients from the state of Texas treated with PBT at our institution were covered under 1 of these 4 plans. The model policy of the large professional medical society Particle Therapy Cooperative Group – North America (PTCOG, current policy last reviewed in March 2014) [16] was also included as a representative professional society policy.

Indications for medical necessity by disease site were abstracted from each reviewed version of the PBT policies. All literature references that were cited by each policy to justify their coverage decisions were individually abstracted. References were stratified by year of publication, disease site (ie, breast cancer, pediatric cancer), whether the reference was PubMed-indexed, whether the reference pertained to PBT, and level of evidence (LOE). PubMed indexing of citations implies that the references were from higher quality primary or peer-reviewed literature. The LOE schema (Table 1) was adapted by internal consensus at this institution from an existing stratification algorithm of the Oxford Centre for Evidence-Based Medicine [17]. Higher level numbers (ie, levels 6 to 8) were considered weaker LOE. Systematic reviews and meta-analyses were ranked on the basis of the underlying LOE of the reviewed studies.

The cumulative numbers of PubMed-indexed citations were graphed by year of publication from 1990 to 2014 and compared across all policies. The number of PubMed-indexed references by disease site was also compared across policies.
with descriptive statistics. The LOEs of PubMed-indexed references were compared across policies by using the Kruskal-Wallis test. All tests were 2-sided and $P$ values less than .05 were deemed statistically significant.

**Results**

Indications of PBT medical necessity per disease type varied among the reviewed state of Texas PBT policies (Table 2). For instance, PBT is considered medically necessary for cancers of the central nervous system and for localized prostate cancers under the BCBS-TX, Medicare, and PTCOG policies, but not under the Aetna-TX or UHC-TX policies.

The total number of cited references and PubMed-indexed references also varied among policies. Of PTCOG’s 346 total references, 340 (98%) were also indexed in the PubMed database, a significantly higher percentage ($X^2, P < .01$) than Aetna (80 of 109, 73%), BCBS (20 of 28, 71%), or UHC (64 of 91, 70%). Most PubMed-indexed references were PBT-specific (rather than pertaining to general radiation oncology or oncology), ranging from 90% of BCBS references to 99% of PTCOG references.

### Table 1. Levels of evidence for the cited literature.

| Level of evidence | Type of study |
|-------------------|---------------|
| Level 1           | Large multi-institutional prospective randomized clinical trials |
| Level 2           | Single-institution randomized controlled studies |
| Level 3           | Well-conducted single-arm studies |
| Level 4           | Prospective registries |
| Level 5           | Well-structured retrospective studies and systematic review of lower-level evidence |
| Level 6           | Population or claims-based studies, and smaller case series |
| Level 7           | Anecdotal patient case reports, dosimetric studies, mechanism based |
| Level 8           | Clinical reviews |

The levels of evidence schema was adapted from an existing stratification algorithm created by the Oxford Centre for Evidence-Based Medicine and modified for proton beam therapy by internal consensus at our institution.

### Table 2. State of Texas medical necessity determinations for PBT for various disease sites.

| Disease site                              | Aetna | BCBS | Proposed HCSC policy | UHC | PTCOG-NA |
|-------------------------------------------|-------|------|----------------------|-----|----------|
| Chordomas and chondrosarcomas of the skull/cervical spine | X     | X    | X                    | X   | X        |
| Uveal melanomas (confined to globe)      | X     | X    | X                    | X   | X        |
| Ocular tumors (other)                    |       | X    |                      | X   | X        |
| HCCs (liver)                             |       | X    |                      | X   | X        |
| GI tract cancers (non-HCC)               |       |      |                      |     | X        |
| Intracranial arteriovenous malformations | X     | X    | X                    | X   | X        |
| Pediatric solid tumors                   | $X^a$ | $X^c$| $X^c$                | $X^c$| $X^b$   |
| Breast cancers                           |       | X    |                      | X   | X        |
| CNS cancers                              |       | X    |                      | X   | X        |
| Head and neck cancers                    |       | X    |                      | X   | X        |
| Lung cancers                             |       | X    |                      | X   | X        |
| Hematologic cancers                      |       | X    |                      | X   | X        |
| Prostate cancer (localized)              |       | X    |                      |     | X        |
| Urinary tract cancers                    |       | X    |                      |     | X        |
| Gynecologic cancers                      |       | X    |                      |     | X        |
| Unresectable retroperitoneal sarcoma     |       | X    |                      |     | X        |

**Abbreviations:** PBT, proton beam therapy; BCBS, Blue Cross Blue Shield; HCSC, Healthcare Services Corporation; UHC, UnitedHealthcare; PTCOG-NA, Particle Therapy Cooperative Group – North America; X, considered medically necessary; HCC, hepatocellular carcinoma; GI, gastrointestinal; CNS, central nervous system.

**Note:** This list is not all-inclusive, but illustrative of the heterogeneity between policies with regard to definitions of medical necessity for PBT.

$^a$Age $\leq$ 21 years for Aetna policy.

$^b$Age up to 18 years for PTCOG policy.

$^c$Age $< 19$ years for UnitedHealthcare and BCBS policies.
Interestingly, 30%, 29%, and 27% of references in the UHC, BCBS, and Aetna policies, respectively, were not PubMed-indexed. Many of these references pertained to consensus statements or general reviews, such as those of the National Comprehensive Cancer Network (13 references), Blue Cross Blue Shield Technology Evaluation Center (10), the Agency for Healthcare Research and Quality (8), UpToDate (8), the ECRI Institute (6), the American College of Radiology Appropriateness Criteria (2), American Society for Radiation Oncology position statements, and others.

Overall, the PTCOG policy cited more references and included a greater number of PBT-specific PubMed-indexed references published from 2012 to 2014 than any other policy (Figure 1A), whereas Aetna, BCBS, and UHC had fewer total references and fewer citations from the more recent 2012 to 2014 period. Because the reviewed BCBS policy was updated last in 2011, no references were published from the more recent 2012 to 2014 period.

Across all policies, the most number of references pertained to prostate cancer (85 references), followed by central nervous system (55), ocular melanoma (53), and pediatrics (53). The number of references per disease site varied across policies, with PTCOG citing more PBT-specific PubMed-indexed literature for each disease site than other policies (Figure 1B).

The LOE of the cited references also varied between policies. PTCOG cited more level 2 through 8 evidence than any other policy (Figure 2A). The mean LOE was 5.3 for PTCOG, 6.0 for Aetna, 5.1 for UHC, and 5.4 for BCBS. These differences were statistically significant (analysis of variance, \( P < .01 \)). Similar variations were observed for each disease site, such as for prostate cancer (Figure 2B). Interestingly, overlap of PubMed references between policies was limited. PTCOG’s policy had 62 references (18.3%) that had any overlap with the other 3 policies. Twenty-five percent of references from the BCBS policy overlapped with Aetna; 20% of BCBS overlapped with UHC; and 29% of UHC overlapped with Aetna.
There were several key differences between the 2011 BCBS-TX policy and the proposed 2015 policy update. The proposed 2015 policy cites more references (Figure 3A) that pertain to more disease sites than the current 2011 policy (Figure 3B). Interestingly, the proposed policy cites fewer references for prostate cancer (11 in 2011 versus 4 in 2015) (Figure 4).

Additionally, the proposed policy provides a different number of cited references and LOE for several disease sites. The 2015 proposed policy would now cover PBT for certain lung, liver, and ocular tumors but would no longer cover PBT for localized prostate cancer treatment.
Discussion

Despite the existence of a finite body of medical literature, we observed significant variations in the definitions of medical necessity for PBT among several major payors and a large professional society. In particular, the number and quality of references used in each policy to justify coverage decisions varied significantly, which implies underlying variation, inconsistency, and nonstandardization of the process for drafting coverage policies. Rather than decentralizing coverage decisions to individual payors and creating variable working definitions of medical necessity, we recommend a more collaborative and integrated approach, which will better unite the interests of all stakeholders. Our analysis exposes several problems with the current process of defining medical necessity and identifies several solutions with direct health policy implications.

Problems

Policymakers tend to focus on access to care, the scope of care coverage, the delivery of care, and the cost of care [18]. Although in theory the scope of care coverage should be driven by the best available medical evidence, combinations of political, economic, and social pressures are real influences that ultimately shape coverage [19, 20]. The current payor-centric approach to defining medical necessity has introduced variations and differences in standards of care, which are readily evident by the high degree of heterogeneity among PBT coverage policies observed in this study. The American Medical Association defines medical necessity as health care services or products that a prudent physician would provide to a patient in a manner that is in accordance with generally accepted standards of medical practice, that is clinically appropriate in terms of type, frequency, extent, site, and duration, and that is not primarily for the economic benefit of the health plans and purchasers or convenience of any stakeholder [21]. Although both Aetna and BCBS have adopted the American Medical Association definition, UHC formally incorporates cost into the process for determining benefit coverage and/or provider payment for services, tests, or procedures [22]. The Stanford Center for Health Policy has concluded that some payor policies were willing to apply the criterion of cost-effectiveness in practice but do not include the clause in the contract owing to fear of litigation [23]. For instance, in a study that analyzed payor use of clinical evidence and cost information in coverage and medical necessity decision-making, 88% to 92% of payors were willing to consider cost in medical decision-making [24].

In the current system, the payor can be incentivized to create processes that reduce employer or subscriber premiums, whereas providers can be incentivized to maximize billing in a perceived zero-sum fee-for-service reimbursement system, which can lead to some inappropriate billing practices and resultant coverage limitations by payors. By relegating coverage decisions to any single stakeholder, coverage decisions are potentially shifted away from shared patient-provider decision making regarding quality, safety, and best evidence-based clinical practices. Because the insurance subscription process occurs annually, payor-defined coverage policies are also more aligned with short-term rather than long-term gains, which is where PBT may be more beneficial owing to fewer long-term effects [12, 25].
Given the rapidly evolving advances in medicine [26], medical policies are often outdated. Reliance on these outdated policies in the name of quality could, paradoxically, lead to lower quality care and a slower diffusion of best practices. We observed that currently active PBT policies contained several outdated references that did not account for the latest published evidence. For instance, several payors cited outdated consensus statements rather than modern and updated evidence-based guidelines to inform coverage decisions. In addition, we observed that updated policies, such as the proposed BCBS 2015 update, were inconsistent in the exclusion of old references and inclusion of new references, resulting in significant changes to coverage decisions. Such policies introduce dissonance among patients/providers and payors and detract from the delivery of patient-centered care.

An additional problem caused by nonstandardized coverage policies is the introduction of clinical workflow inefficiencies. Given the laborious, inconsistent, and often contentious process of payor-specific benefits authorization, providers may require full-time employees solely for the PBT authorization process [20]. Physician treatment decisions may also need to be modified depending on the patient’s payor, rather than the patient’s specific case. A recent analysis found that patient insurance status was the best predictor of PBT utilization, rather than primary clinical considerations [27]. Proton beam therapy is a costly investment [28, 29], and without standardized coverage indications, most treatment centers are faced with pressures to treat a high proportion of “simple” cases, often to the detriment of patients with higher prioritization scores [30]. Comparative dosimetric treatment plans for IMRT and PBT, which may be requested by payers and treating physicians, can further exacerbate departmental workflow inefficiencies, increase wait times, increase the overall cost of care, and have implications for equitable access. Although several groups have emphasized the value of clinical standardization and the dissemination of best practices through clinical pathways [31, 32], variations among coverage policies may limit the ability of providers to uniformly implement best practices.

Solutions

Open collaboration, rather than competition, between expert providers, payors, employers, patients, and policy makers is a first step toward a unifying definition of medical necessity across all disease sites. Collaboration would reduce the substantial redundancy of multiple payor and professional society policies, complement the operational strengths of each stakeholder, and align coverage decisions with patient-centered prioritization of care. Such collaborations could better address how evidence should be used in decision-making, with an emphasis on LOE and if/how cost-effectiveness should contribute to the process [23]. The US Department of Health and Human Services has been tasked to oversee the processes of defining medical necessity under the Affordable Care Act, and such oversight should be designed with the input of all stakeholders involved in delivering health care. A possible shortcoming of a more centralized definition of medical necessity is perceived intrusion on the physician-patient relationship. However, this intrusion can be obviated by ensuring that policy decisions include providers from professional medical societies, such as PTCOG, the American Society for Radiation Oncology, the Institute of Medicine, or others, to help in determining medical necessity [33].

Open collaboration in oncology has recently led to innovative solutions, including clinical care pathways, IMRT guidelines, and episode-based payment models [34–36]. By creating clinical pathways that emphasize the use of treatment regimens that offer the greatest survival benefit at the lowest toxicity, pathways may result in improved outcomes and lower costs. Several early results from pathway collaborations have suggested that lower costs with good outcomes are achievable [35, 36]. For instance, in Massachusetts, collaboration between BCBS and providers resulted in consensus agreement to cover IMRT for many cancer types and ultimately reduced insurance delays for patients requiring IMRT [34]. These collaborations had appeals processes by which physicians could make treatment decisions outside of the specified guidelines if deemed medically necessary.

A pitfall of these collaborations, however, is the lack of a formal policy for coverage under evidence development [37]. Despite ongoing evidence development at the professional medical society level [16, 37], uniformly high LOE is not available for PBT for all disease sites. Indeed, it is expected that not all types of cancers may benefit from the current delivery methods of PBT, but the lack of clinical trials across many disease sites creates a challenge to identifying the sites that would benefit most. Strategic prioritization of resources to specific disease sites could close gaps in current knowledge. Currently, many payors’ contractual language specifies noncoverage of “unproven” or “experimental” treatments. Rather than a blanket policy, providers and payors could enter a dialogue regarding which indications have highest priority (ie, through prioritization schema) for coverage under evidence development. Payors could partner with centers of excellence, such as those of the Alliance of Dedicated Cancer Centers, to allow high-performing practice units the opportunity to develop evidence in a controlled and robust way. Limitations of this collaborative approach could include the higher administrative cost and significant time investment required from all
stakeholders in order to implement these solutions. Although such a collaborative approach has the potential to raise some costs in the short term, such an approach would enable a more rational and transparent process to defining medical necessity, coverage decisions, and ultimately, the reimbursement of proton therapy services.

Providers and payors will ultimately need to focus on enhancing the value of care delivery [18, 26]. By evaluating treatment decisions through the lens of value, which can be broadly defined as outcomes divided by costs, payors and providers can identify treatments and clinical pathways that enhance the outcomes that truly matter to patients while reducing costs over the full care cycle rather than over a single intervention [18, 38]. Bundled payment for all cancer-related treatments and related complications over a specified period holds significant promise for improving value. Payors and providers would also be required to publicly report their risk-adjusted outcomes (and costs) for each patient, which would further incentivize competition on value and patient engagement. In such a system, a formal definition of medical necessity would be unnecessary, because only those treatments that maximize value would be delivered. Although value-based health care delivery may seem like a significant departure from the current system, collaboration among all stakeholders can galvanize rapid movement in this direction.

Newcomer (from UHC) and colleagues [39] recently reported the results of a pilot episode-based payment for chemotherapy. Although spending on chemotherapy actually increased under this arrangement, the total full cycle cost of care for pilot participants was 34% lower owing to lower rates of hospitalizations and complications [39]. Similar pilots are being conducted with advanced technologies and with multidisciplinary, rather than single-modality, care. If a costly technology raises the overall cost of care, competition on value would ensure that the increased cost is worth the improved quality of outcomes [18]. This work by Newcomer et al [39] is a good example of the benefits of a collaborative rather than adversarial relationship between payors and providers.

Conclusion

We observed significant variations in PBT coverage decisions and definitions of medical necessity among several major payors and a large professional society. A unified and collaborative approach among providers, patients, payors, and policymakers would serve to create a consistent, equitable, and patient-centered PBT policy and help to identify strategic focus areas for further evidence development. The ultimate goal of such collaboration is to deliver medical care that enhances value for all patients over the full cycle of care, regardless of payor, rather than restricting access to best practices.

ADDITIONAL INFORMATION AND DECLARATIONS

Conflicts of Interest: The authors have no conflicts of interest to disclose.

Acknowledgments: Oral presentation at the 54th Annual Conference of the Particle Therapy Cooperative Group, San Diego, California, May 18–23, 2015.

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