Three-Year Results of a Prospective Statewide Insurance Coverage Pilot for Proton Therapy: Stakeholder Collaboration Improves Patient Access to Care

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QUESTION ASKED: Prior authorization remains a barrier for patient access to proton beam therapy (PBT); it is associated with frequent denials and treatment delays. Can evidence-based insurance coverage policies facilitate timely patient care with PBT without provider overuse or significantly increased payor costs?

SUMMARY ANSWER: This statewide insurance coverage pilot demonstrates that appropriate access to PBT (1) did not lead to overuse, (2) did not significantly increase comprehensive medical costs, and (3) facilitated timely patient care and research while reducing administrative burden for all stakeholders.

WHAT WE DID: Our large academic cancer center collaborated with a statewide, self-funded employer (responsible for nearly 200,000 plan enrollees) on an insurance coverage pilot for PBT, ensuring preauthorization for prospective clinical trials and evidence-supported anatomic sites while incorporating a value-based analysis of cost and use.

WHAT WE FOUND: Thirty-two patients were approved for the pilot over 3 years (with only 22 actually treated with PBT) versus a predicted use by 120 patients ($P < .01$); the average authorization time decreased from 17 days to < 1 day ($P < .01$), significantly enhancing patient access. In comparison with case-matched patients receiving photon therapy, total medical costs for patients treated with PBT were much lower than anticipated (an increase was expected initially), with no difference in total average medical charges ($P = .82$), in the context of overall ancillary care use.

BIAS, CONFOUNDING FACTORS: Modest sample size within a single academic cancer center.

REAL-LIFE IMPLICATIONS: Objective evidence-based treatment policies can facilitate appropriate patient selection while reducing administrative burden for all stakeholders. Collaboration and transparency among employers, payors, and providers can ensure timely patient access to treatment without significantly increasing total medical costs.

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ASSOCIATED CONTENT Appendix

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abstract

PURPOSE Proton therapy is increasingly prescribed, given its potential to improve outcomes; however, prior authorization remains a barrier to access and is associated with frequent denials and treatment delays. We sought to determine whether appropriate access to proton therapy could ensure timely care without overuse or increased costs.

METHODS Our large academic cancer center collaborated with a statewide self-funded employer (n = 186,000 enrollees) on an insurance coverage pilot, incorporating a value-based analysis and ensuring preauthorization for appropriate indications. Coverage was ensured for prospective trials and five evidence-supported anatomic sites. Enrollment initiated in 2016 and continued for 3 years. Primary end points were use, authorization time, and cost of care, with case-matched comparison of total charges at 1 month pretreatment through 6 months posttreatment.

RESULTS Thirty-two patients were approved over 3 years, with only 22 actually receiving proton therapy, versus a predicted use by 120 patients ($P < .01$). Median follow-up was 20.1 months, and average authorization time decreased from 17 days to < 1 day ($P < .01$), significantly enhancing patient access. During this time, 25 patients who met pilot eligibility were instead treated with photons; and 17 patients with > 6 months of follow-up were case matched by treatment site to 17 patients receiving proton therapy, with no significant differences in sex, age, performance status, stage, histology, indication, prescribed fractions, or chemotherapy. Total medical costs (including radiation therapy [RT] and non-RT charges) for patients treated with PBT were lower than expected (a cost increase initially was expected), with no significant difference in total average charges ($P = .82$), in the context of overall ancillary care use.

CONCLUSION This coverage pilot demonstrated that appropriate access to proton therapy does not necessitate overuse or significantly increase comprehensive medical costs. Objective evidence-based coverage policies ensure appropriate patient selection. Stakeholder collaboration can streamline patient access while reducing administrative burden.

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INTRODUCTION

Advancements in the field of oncology are accompanied by a growing number of long-term survivors¹ and thus a greater number of patients susceptible to late toxicities, particularly after radiation therapy (RT). Proton beam therapy (PBT), in particular, is increasingly being used because of the inherent physical advantages of proton particles, which impart less collateral radiation dose to surrounding normal tissues than do photons.²⁻⁵ The evidence supporting PBT continues to grow, with benefits demonstrated for numerous anatomic sites,⁶⁻¹⁸ support from national

practice guidelines,¹⁹⁻²¹ and ongoing randomized controlled trials (RCTs).^{19,22,23} Approximately 70 proton therapy centers (PTCs) are treating patients around the globe, with nearly half operating in the United States²⁴; however, a significant gap persists between the number of patients who could benefit from and those actually treated with PBT.²⁵

One of the major barriers of patient access is the prior authorization (PA) process, which is associated with high denial rates and treatment delays of several weeks.^{24,26-29} Although intended to facilitate appropriate use,³⁰ PA has been criticized across specialties

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as a resource-intensive, time-consuming burden that inappropriately restricts and adversely affects care.³¹⁻³⁴ These negative effects are particularly grave for patients with cancer, for whom delayed or abandoned treatments result in poor outcomes that would have been entirely preventable if not for coverage issues.

Although traditional Medicare (fee-for-service) coverage generally pays for PBT for appropriate indications,^{26,28,29} managed care plans administered by commercial payors have widely adopted PA for PBT.²⁸ The latter includes administrative-services only plans managed by third-party administrators (TPAs) on behalf of self-funded (self-insured) employers. TPAs cite cost^{24,35,36} and overuse as justifications for these restrictive coverage policies, which vary widely in their definitions of medical necessity.³⁷ Indeed, recent reports have demonstrated that nonclinical factors (eg, payor type) may have a larger impact on coverage determinations than clinically relevant variables.^{26,29}

Recognizing these difficulties, our large, academic PTC engaged in a cooperative strategy to improve patient access while addressing payor concerns. We collaborated with a statewide, self-funded employer of 105,000 workers (responsible for 186,000 covered lives) to implement a PBT coverage pilot, ensuring timely yet appropriate access to care while reducing administrative burden for stakeholders. To address concerns of cost and overuse, the pilot incorporated a value-based assessment of PBT through various end points, including a comprehensive cost analysis (evaluating total medical charges, including non-RT) and use.

The 3-year pilot has been a success with respect to use and value, supporting appropriate access to PBT for all covered lives. Here, we outline the methodology and results of this cooperative achievement as an example for employers, payors, policymakers, and providers. Stakeholder collaboration can facilitate appropriate patient access to evidence-based cancer treatment and decrease administrative burden without significantly increasing costs.

METHODS

The University of Texas System: A State-Governed Self-Insured Employer

The University of Texas System (UTS) is a state government entity that oversees 14 institutions (eight academic and six health care) throughout the state. With an endowment of approximately \$25 billion and an operating budget close to \$20 billion, the self-funded employer has > 100,000 employees throughout the state and is responsible for nearly 200,000 covered lives.

Figure 1A outlines major differences between fully insured (traditional) and self-funded (self-insured) employer-sponsored health plans. Fully insured employers pay a fixed premium per enrollee to an insurance carrier, who, in turn, pays health care claims on the basis of outlined policy coverage benefits. Alternatively, employers (particularly

large entities) can opt to self-insure and thus retain the profit margin an insurance company would add to fully insured plan premiums.

However, self-funding entails additional company risks with respect to volume of health claims. For a self-insured health plan, there are two main costs to account for: fixed and variable (Fig 1A). Fixed costs include administrative fees, stop-loss premiums, and other employee fees; are billed monthly by the TPA or carrier; and are charged on the basis of plan enrollment. On the other hand, variable costs entail the payment for health care claims, which may vary from month to month based on enrollee use. Employers purchase stop-loss or excess-loss insurance to cover the risk of having to reimburse significantly more claims than expected (Fig 1A).

As a self-funded employer, UTS engages in an administrative-services only plan managed by BlueCross BlueShield of Texas (BCBS-Texas); yet BCBS-Texas was limiting PBT access for employees and dependents, similar to other TPAs.²⁸ Ironically, the UTS Board of Regents has recently committed to PBT expansion by approving a second PTC, with plans for two additional centers at other institutions. Furthermore, referring to the insurance plan definition, “medical necessity” should fall within the standard of generally accepted health care practice, considering the following: views of state and national medical communities; guidelines and practices of Medicare, Medicaid, and other government-financed programs; and peer-reviewed literature.³⁷ Thus, the BCBS-Texas policy and definition of medical necessity directly contradicted recommendations with respect to PBT. After presenting these discrepancies to both UTS and BCBS-Texas in May 2015, our PTC leadership collaborated with stakeholders to initiate this coverage pilot.

Coverage Pilot: Design and Structure

The proposed PBT coverage was consistent with evidence-based treatment guidelines,¹⁹⁻²¹ including five literature-supported anatomical treatment sites—head and neck, esophagus, breast, thoracic, and prostate—as well as any of the National Cancer Institute, National Institutes of Health, RCTs being conducted at the time. In lieu of time-intensive PA steps facilitated through BCBS-Texas (Fig 1B), including peer-to-peer, multiple appeals, and/or independent external review (Fig 1C), UTS would provide administrative override to BCBS-Texas for these predefined inclusion criteria, per the schema outlined in Figure 1D, and payment would be coordinated to our PTC at a contracted in-network rate. This pilot study was approved by the institutional review board, and all patients were enrolled in an active institutional review board–approved prospective research study. Confidentiality was maintained per HIPAA.

Understandably, the employer desired minimal impact on policyholders resulting from PBT coverage. As outlined in

FIG 1. Schemas of (A) self-funded versus fully-funded employer plans; (B) pre-pilot prior authorization process; (C) prior authorization appeal process steps; and (D) coverage pilot pre-authorization process. For pre-defined pilot inclusion criteria, the University of Texas System provides override to third-party administrator BlueCross BlueShield of Texas. Average time with authorization dropped from 17 (pre-pilot) to < 1 business day post-pilot (*t*-test; *P* < 0.01). IRO, independent review organization; Pre-Auth, preauthorization; TPA, third-party administrator.

Figure 2, we anticipated treatment of ≤ 40 patients per year, estimated from the total number of covered lives ($n = 186,000$), epidemiologic data (eg, cancer incidence, proportion of patients with cancer requiring RT),^{38,39} proportion of these patients meeting evidence-based PBT indications, and our internal patterns of care. Although we anticipated increased expenses associated with PBT, due to the advanced technology,^{24,35,36} the additional cost to the employer was actually estimated to only represent 0.10% of total medical claims (Fig 2). Costs are presented as relative ratios rather than absolute dollar amounts, because of institutional policies.

End Points

To directly address these potential concerns of the employer and payor, we incorporated a value-based analysis,

specifically looking at (1) patient enrollment and (2) total cost of care with PBT use as our primary end points, as well as time to approval. This comprehensive analysis would include all billed charges (including non-RT claims) from 1 month pretreatment up to 6 months posttreatment. Medical claims of patients receiving PBT with ≥ 6 months' follow-up were compared with patients receiving photon therapy who were treated within the same accrual period and who technically would have been eligible for pilot enrollment. Patients were matched on the basis of the treatment site, and several factors were compared for the following differences between the two groups (Appendix Table A1, online only): sex, age, performance status, follow-up time, cancer stage, histology, indication, fraction number, treatment year, and

FIG 2. Coverage pilot estimated utilization and financial impact to employer. Based on total enrollees, epidemiology, coverage criteria, and care patterns, we anticipated up to 40 eligible patients per year, associated with an expected additional cost of only 0.10% of total medical claims. ^aBased on 0.44% cancer incidence in the United States (NCI 2018).³⁸ ^bBased on 31% radiation therapy rate for cancers (ACR 2018).³⁹ ^cHypothetical full use by all candidates for radiation therapy meeting pilot-eligibility criteria (59%). ^dAdditional employer cost (as a percentage of total medical claims). ^eActual use by pilot-eligible patients (12%)

chemotherapy. Costs are presented as normalized relative cost ratios⁴⁰ rather than absolute dollar amounts, because of institutional policies.

Statistical Analysis

For the comprehensive cost comparison, patient and treatment factors were compared between the patients receiving proton therapy and those receiving photon therapy after case matching by site, to assess for differences between groups. Categorical variables were compared with Pearson χ^2 or Fisher exact test, as appropriate, and continuous variables were compared using the Mood median test. Average billed charges were compared via an independent samples *t* test, as well as average pilot preauthorization time (vs the historical payor-specific PA time). The χ^2 goodness-of-fit test was used to compare observed versus expected pilot enrollment and use, as well as the proportions of RT-related and non-RT charges among the PBT versus photon groups. Costs are presented as normalized relative cost ratios⁴⁰ rather than absolute dollar amounts, because of institutional policies. Statistical analyses were performed with SPSS, version 23

(IBM Corp., Armonk, NY). Analyses were two-tailed, with $P < .05$ as the threshold for statistical significance.

RESULTS

Pilot Enrollment, PBT Use, and Patient Characteristics

All plan-enrolled patients referred for PBT and meeting the specified coverage criteria were successfully approved through the insurance pilot. Despite a 100% approval rate, patient accrual was significantly less than predicted, as demonstrated in Figure 3A. Enrollment initiated with the first patient in April 2016, accruing 32 patients approved for PBT under the pilot coverage indications. Although we expected use by 120 patients over 3 years, only 22 (head and neck, $n = 9$; prostate, $n = 8$; breast, $n = 3$; thoracic, $n = 2$) of these accrued patients were actually treated with PBT (χ^2 test, $P < .01$), with a median follow-up of 20.1 months.

Comprehensive, Case-Matched Medical Charge Comparison

During the pilot, 25 plan-enrolled patients who technically met eligibility were instead treated with photons (x-rays). Of these, 17 were case matched to 17 patients receiving PBT

FIG 3. (A) Insurance Pilot Enrollment and Proton Beam Therapy Utilization. Despite 100% approval, accrual was less than predicted, enrolling 32 patients under pilot indications, with only 22 actually receiving PBT, versus an expected 120 (χ^2 $P < 0.01$); (B) case-matched total cost comparison for proton (n = 17) versus photon (n = 17). Total charges from 1-month pre-treatment up to 6-months post-treatment did not demonstrate a significant difference in total billed medical charges (4.7% lower for proton patients; t -test; $P = 0.82$), in the context of overall ancillary care utilization (shown as a radar plot of normalized relative cost ratios).⁴⁰ Proportion of RT to total charges was 77% v65% for protons versus photons (χ^2 $P < 0.01$).

by site and enrollment period, all with ≥ 6 months of follow-up. Additional factors assessed for differences included sex, age, performance status, follow-up time, cancer stage, histology, indication, fraction number, treatment year, and chemotherapy (Appendix Table A1). The median number of fractions was 30 for both groups ($P = .73$), and there were no significant differences in analyzed variables.

Total medical claims were compared between the two case-matched groups, from 1 month pretreatment through 6 months posttreatment (Fig 3B). On analysis, employer costs with PBT were lower than estimated (an increase for PBT initially was expected). Total average charges (including RT and non-RT expenditures) did not significantly differ between the groups (and were actually 4.7% lower for

PBT; t test, $P = .82$) in the context of overall ancillary care use (eg, internal medicine, pharmacy, laboratory, emergency room, diagnostic imaging). The proportion of RT charges to total charges was 77% versus 65% for PBT and photon therapy (χ^2 test, $P < .01$), respectively. The relative breakdown of ancillary-related costs, including professional versus technical charges, is included in the Data Supplement.

Decreased Administrative Burden and Authorization Time

The average pilot preauthorization time was < 1 business day, versus the historical prepilot PA time of 17 business days (t test, $P < .01$). Resource burden was significantly reduced as a result, leading to high provider and administrative satisfaction.

DISCUSSION

This statewide, self-funded employer success demonstrates that evidence-based access to PBT (1) did not lead to overuse, (2) was not associated with significantly increased overall costs in the context of comprehensive medical care, and (3) facilitated timely patient care and clinical research while reducing administrative burden for stakeholders. Taken together, these 3-year pilot results support appropriate access to PBT for all covered lives, and exemplify the benefits that can result from employer and provider collaboration.

The PA process is panned as resource-intensive barrier to patient care, associated with significant time delays to treatment.^{28,29} The behavior of TPAs is actually quite rational from their market perspective, stemming from apprehension of excessive resource use.^{41,42} Yet, these deep-seated concerns have led to increasingly restrictive payor policies for medical advancements such as PBT.^{28,29} Many commercial payors lack the requisite clinical knowledge to interpret the expansive evidence regarding PBT, resulting in subjective evaluations of its utility and contributing to coverage policies discordant with national practice guidelines¹⁹⁻²¹ and literature-supported indications.^{6,7,28,29,37} Ironically, third-party payors deny coverage because of the lack of level I data supporting PBT, but the ongoing trials attempting to establish such evidence may fail to accrue because of coverage issues.

As demonstrated in this pilot, payors can benefit from the clinical expertise of providers and collaborate up front to design rational, transparent medical policies. In designing this pilot, we sought to limit coverage to evidence-based treatment sites and RCTs, in an attempt to address the question of true overuse.³⁷ Our proposed policy is consistent with expert consensus recommendations published by the American Society for Therapeutic Radiation Oncology²¹ and the National Comprehensive Cancer Network.²⁰ Likewise, the National Institutes of Health and National Cancer Institute¹⁹ strongly advocate for RCT coverage, given the need for quality level I evidence regarding PBT.^{22,27,43,44}

Following these clearly defined, literature-supported coverage guidelines, patient enrollment in the pilot was significantly less than expected, despite a potential pool of 186,000 covered lives. Although we anticipated up to 40 patients per year, for a total enrollment of 120, we accrued 32 patients since initiation, with only 22 actually receiving PBT (Fig 3A). These observed trends remained stable over 3 years of follow-up and thereby convey that appropriate access to PBT does not lead to overuse.

Along with use, cost-related concerns are a common justification by TPAs for restrictive coverage policies. A common narrative is that PBT is more expensive; indeed, PBT is accompanied by higher up-front unit-related costs attributable to higher technologic expenses as compared

with photons (ie, x-rays).^{24,35,36} Yet despite the initial unit-related expenses, emerging data indicate PBT can be cost-effective in the long run, due to fewer toxicities and decreased long-term costs with a full cycle of care.³⁶ Many payors are not incentivized to consider long-term expenses, however, given the high patient turnover among commercially available managed care plans.⁴⁵ On the other hand, employers (particularly large, self-funded entities) can invest in their employees over long-standing relationships. Thus, although direct costs are greater with PBT up front, employers could benefit from fewer medical expenses over the lifetime of an employee. Furthermore, in addition to direct costs (eg, medical and pharmaceutical expenses), there may be long-term indirect benefits with respect to disability and productivity.

Here, we confront these traditionally held notions. Regarding cost concerns, the 3-year results of our coverage pilot did not demonstrate an increase in total medical expenses associated with PBT in the context of full ancillary care use (Fig 3B). Because we had initially accounted for cost increases with PBT, these results came as a pleasant surprise for all stakeholders, demonstrating that appropriate access to PBT did not significantly increase overall medical expenditures when considered from a comprehensive perspective. Longer follow-up will define the full extent of direct and indirect cost benefits associated with appropriate PBT use.

Although both cost and use were favorable for PBT, it is important to consider these findings in the context of a massive, statewide, self-funded employer (responsible for 186,000 covered lives). Even if the pilot fully accrued patients, as expected; and PBT was associated with the cost increases anticipated for all enrollees, the financial impact would have amounted to a 0.10% increase for employer medical costs in the setting of the total annual medical budget (Fig 2). Taking this one step further and assuming full (100%) use of PBT for all patients receiving RT under pilot eligibility, the aggregate impact would have still only resulted in a < 0.50% increase of total expenditures (Fig 2). These hypothetical outcomes reaffirm the minimal impact that appropriate access to PBT would have on total costs.

Finally, the greatest benefits went to the most important stakeholders: our patients. The PA process for PBT is associated with treatment delays of several weeks, attributable to the arduous multistep appeal process (Fig 1C).^{28,29} Patients and providers remain in flux throughout this period, as they balance the benefits of PBT with adverse effects of delaying treatment. Many patients (eg, those with head and neck cancer or thoracic cancer) cannot afford to wait through this time, because of immediate risks of morbidity and death associated with treatment delays.⁴⁶⁻⁴⁹

In contrast, all patients meeting the clearly defined coverage criteria were preauthorized for PBT with the pilot

(Fig 1D). As such, the entire process was streamlined: time to authorization was reduced from 17 days to < 1 day from inquiry, due to circumvention of peer-to-peer, multiple appeal, and/or independent external review process steps (Fig 1C). By ensuring timely treatment, this improvement also increased PBT compliance, eliminating dropouts due to “insurance process fatigue” (and facilitating trial enrollment).²⁹ This new process efficiency benefited all parties, with decreased administrative burden and high satisfaction for patients, providers, and the payor, as well.

To summarize, we have outlined this coverage pilot model in detail as a guideline of successful stakeholder collaboration. The primary limitations of this report are its single-institution nature and modest sample size of the patients receiving PBT and case-matched group receiving photon therapy, with selection restricted by a single employer, specific pilot eligibility criteria, limited treatment time, and stringent follow-up period (≥ 6 months, to comprehensively evaluate total billed medical charges). Although we strove to account for clinically relevant variables within the case-matching criteria (Appendix Table A1), unmeasured characteristics may exist, with the potential to influence outcomes. Finally, despite the methodical application of published^{38,39} and historical institution-specific use figures,

the discordance in actual and estimated pilot enrollment may be attributable to unaccountable differences between the UTS employee demographic and the national population referenced by the literature.^{38,39}

However, to our knowledge, this is the first study with an employer assessing actual expenses instead of hypothetical applications of claims data. As one of the largest and foremost PTCs in the world and a leader in PBT, we have substantial experience with the PA process and its impact on care. Here, we collaborated with a statewide employer responsible for 186,000 covered lives, emphasizing the generalizability and impact of our findings (which remain consistent over 3 years of follow-up since pilot initiation).

In conclusion, this state-wide insurance-coverage pilot demonstrated that appropriate access to PBT did not result in overuse or significantly increased overall employer cost. Objective evidence-based treatment guidelines and policies can ensure appropriate patient selection while reducing administrative burden for all parties. Collaboration and transparency among employers, payors, and providers can ensure timely patient access to cancer treatment while benefiting all stakeholders, without necessitating a significant increase in total medical costs.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**Three-Year Results of a Prospective Statewide Insurance Coverage Pilot for Proton Therapy: Stakeholder Collaboration Improves Patient Access to Care**

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APPENDIX

TABLE A1. Case-Matched Patients Receiving Proton Beam Therapy or Photon Therapy for Cost Comparison

Characteristic	Proton Therapy (n = 17)	Photon Therapy (n = 17)	P ^a
Anatomic location			
Head and neck	7 (41)	7 (41)	.99 ^b
Prostate	6 (35)	6 (41)	
Breast	3 (18)	3 (18)	
Thoracic	1 (6)	1 (6)	
Sex			
Male	11 (65)	11 (65)	.99 ^b
Female	6 (35)	6 (35)	
Age, years			
Median (IQR)	59 (56-62)	66 (60-73)	.09 ^c
ECOG PS			
1-2	3 (18)	4 (24)	.99 ^b
0	14 (72)	13 (76)	
Stage (AJCC VII)			
3-4	5 (29)	7 (41)	.85 ^b
0-2	11 (65)	9 (53)	
Recurrence	1 (6)	1 (6)	
Histology			
Squamous	4 (24)	5 (29)	.99 ^b
Nonsquamous	13 (76)	12 (71)	
Indication			
Definitive	10 (59)	8 (47)	.49 ^b
Adjuvant	7 (41)	9 (53)	
No. of fractions			
Median (IQR)	30 (20-35)	30 (15-35)	.73 ^c
Chemotherapy			
Yes	6 (35)	4 (24)	.45 ^b
No	11 (65)	13 (76)	
Follow-up, months ^d			
Median (IQR)	16 (11-18)	21 (16-26)	.17 ^c
Treatment year			
2018	6 (35)	3 (18)	.31 ^b
2017	8 (47)	7 (41)	
2016	3 (18)	7 (41)	

NOTE. Data reported as No. (%) unless otherwise indicated.

Abbreviations: AJCC, American Joint Committee on Cancer; ECOG, Eastern Cooperative Oncology Group; IQR, interquartile range; PS, performance status.

^aThere were no significant differences among clinical or treatment factors between groups.

^bCategorical variables compared with Pearson χ^2 or Fisher exact test.

^cContinuous variables compared by Mood median test.

^dAll patients had ≥ 6 months of follow-up for comprehensive analysis of medical claims.