Effective Health Care Program

Proton beam radiotherapy in the U.S. Medicare population: growth in use between 2006 and 2009

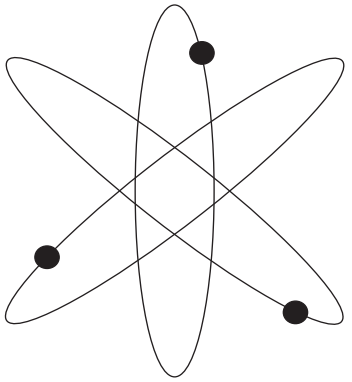
Proton Beam Radiotherapy

Data Points # 10

Proton beam radiotherapy is a form of external beam radiation that offers better precision for localized dosage than other types of external beam radiotherapy. Because proton beams deposit most of their energy during the final portion of their trajectory, they diminish the risk of damage to tissue surrounding the tumor and thus allow for higher treatment doses with fewer side effects. Proton beam radiotherapy has been used in research applications since the 1950s and entered clinical practice in the United States in 1990.[1]

No randomized controlled trials and only a few well-conducted cohort studies have compared proton beam radiation to other treatments.[2,3] In the absence of evidence of clinical superiority, proton beam radiotherapy has gained acceptance based on a theoretical advantage for the treatment of specific cancers. Agreement is strongest for the use of proton radiotherapy for (1) tumors surrounded by critical structures such as the eye, brain, and spinal cord that preclude or complicate resection or other radiation techniques, or (2) tumors for which other treatments are not very effective. For example, proton beam radiotherapy is preferred for solid tumors in children because it minimizes detrimental effects of radiation on developing structures surrounding the tumor and reduces the risk of long-term side effects.[3]

In January 2001, three proton beam treatment centers were operating in the United States (Loma Linda, California; Massachusetts General Hospital in Boston; and the University of California, San Francisco). By 2006, three additional centers had opened at Indiana University in Bloomington, M.D. Anderson Cancer Center in Houston, and the University of Florida in Gainesville, followed in 2009 by another in Oklahoma City. By June 2011, the United States was home to 10 proton beam treatment centers, with many more proposed or under construction (**Figure 1**).



From 2001 to June 2011, the number of centers providing proton beam therapy grew from 3 to 10. From 2006 to 2009, the number of Medicare beneficiaries receiving proton beam therapy nearly doubled.

The near doubling of Medicare beneficiaries receiving proton beam therapy from 2006 to 2009 was due to a 68 percent increase in use for "conditions of possible benefit," mostly prostate cancer, with no increase in use for commonly accepted indications.

Prostate cancer is the most common condition for which a Medicare beneficiary recieves proton beam therapy.

CMS has yet to issue a national coverage rule for proton beam therapy or its specific indications.

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The number of proton beam centers also increased worldwide, from 17 centers operating outside of the United States in 2001 to 29 in 2011.[4]

The Centers for Medicare & Medicaid Services (CMS) has yet to release a national coverage or noncoverage determination for proton beam radiotherapy, so local Medicare administrative contractors (previously known as fiscal intermediaries or carriers) have the authority to develop local coverage decisions (LCDs). Local advisory committees (with membership primarily comprising physicians[5]) provide input for developing LCDs, which specify conditions for payment of claims, including acceptable procedure and diagnosis codes. The first LCDs for proton beam radiotherapy went into effect in 2009,[6,7] prior to which LCDs included proton beam radiotherapy along with external beam radiotherapy in general but without identifying specific indications.[8]

Currently, LCDs vary by contractor regarding their indications for coverage of proton beam radiotherapy, but most LCDs include one or more of the following:

1. A list of conditions for which proton beam radiotherapy is medically reasonable (e.g., eye, brain, and spinal cord) and a second list of conditions for which proton beam radiotherapy *may* be medically reasonable if specified requirements are met and documentation is adequate (e.g., lung, prostate).
2. A requirement that the medical record include evidence of benefit for proton beam radiotherapy over other treatment modalities.
3. A requirement (for some indications) that the patient be treated as part of a clinical trial.
4. Special documentation requirements for prostate cancer.
5. A statement that proton beam radiotherapy will be evaluated on a case-by-case basis. Providers must contact the contractor to discuss indications and payment.

Despite the rarity of commonly accepted indications such as tumors of the eye, skull base, and spinal cord, use of proton beam radiotherapy has accelerated in the last decade. Proponents argue that the theoretical advantages of the proton beam's precision apply to more common conditions such as prostate cancer and non-small cell lung cancer; however, no evidence exists for the comparative effectiveness or harms of this therapy.[2] Financial factors may in part be driving this trend of including more common conditions among the indications for proton beam therapy, since expanding its use allows for faster recovery of the substantial investment needed to construct a proton beam center.[9] A major concern among detractors of proton therapy is cost; one report cited costs of providing proton therapy that were more than double those of other radiation therapies.[9] The difference in Medicare payment rates for proton beam radiotherapy versus other radiation therapies is not trivial (**Table 1**).

Figure 1: Locations of current and proposed proton beam treatment facilities in the United States

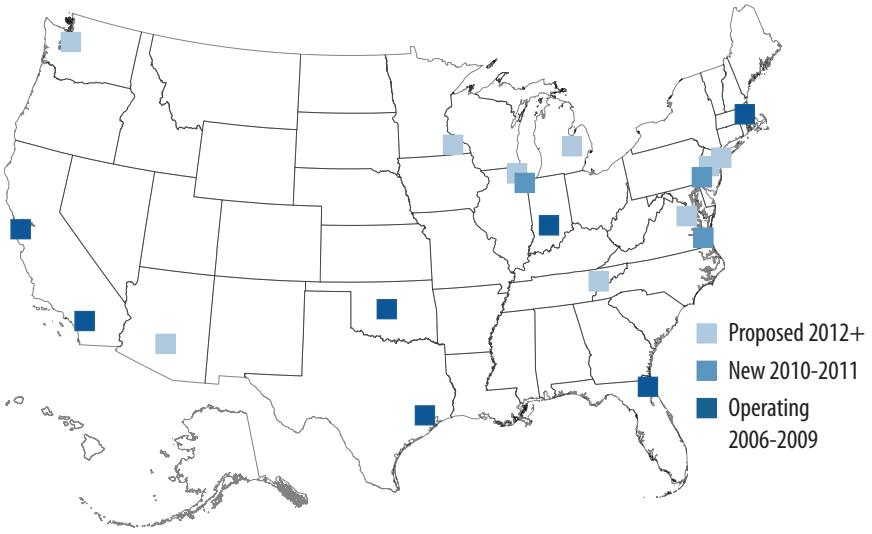


Table 1: Medicare payment rates for three-dimensional conformal radiation therapy (3D CRT), intensity-modulated radiation therapy (IMRT), and proton beam radiotherapy in 2007

Type of external beam radiation	Outpatient		Freestanding center	
	APC	Payment ($)*†	HCPCS	Payment ($)**†
3D CRT	301	137	77412-77416	149-158
IMRT	412	336	77418	568
Proton beam radiotherapy	664 & 667	1,161-1,389	77520-77525	516-1,098

*Payment rate per treatment. Rate from the Federal Register, not adjusted for regional variation (42 CFR Parts 410, 416).
**Payment rate per treatment. National payment rate, except in the case of proton beam radiotherapy, which is priced by the Medicare administrative contractor.
†Number of treatments varies by cancer and type of radiation used.
APC = ambulatory payment classification; HCPCS = Healthcare Common Procedure Coding System.

Payment rates (which include both Medicare trust fund reimbursement and patient cost sharing) for proton beam radiotherapy vary by the type of facility providing the services and its location. Hospital-based treatment centers receive payments based on the Hospital Outpatient Prospective Payment System (HOPPS) ambulatory payment classifications (APCs), which are wage adjusted according to provider location.[10] Rates for payments to freestanding centers are set by local Medicare administrative contractors based on Healthcare Common Procedure Coding System (HCPCS) codes. APC codes 664 and 667 and HCPCS codes 77520, 77522, 77523, and 77525 are used to bill for proton beam radiotherapy. Changes in payment for proton beam therapy between 2006 and 2009 varied across providers. Hospital outpatient-based facilities experienced a rate decrease from 2007 to 2009 followed by a return to 2007 levels in 2010 and 2011. Freestanding centers experienced variable changes. Some contractors reduced payment rates approximately 5 percent from 2008 to 2009, while others granted small increases (1 percent) in rates during the same period.[11]

Table 2: "Medically reasonable" conditions [6,7,12]

Commonly accepted indications (Group 1)	Conditions of possible benefit (Group 2)
Intraocular melanomas	Prostate
Benign or malignant primary and secondary tumors of the brain and spinal cord	Non-small cell lung cancer†*
Benign or malignant tumors of the base of the skull or axial skeleton	Esophageal
Solid tumors in children up to 18‡	Other:
Other:	Ovarian
Pituitary and pineal gland tumors	Vaginal
Soft tissue sarcoma	Bladder
Metastases to the brain	Bony pelvis
	Cervical
	Uterine**
	Rectal and anal
	Heart
	Mediastinal
	Breast
	Gastric
	Liver
	Thyroid and parathyroid metastatic tumors (other than brain)
	Malignant lesions of the head and neck*
	Skin**
	Unresectable retroperitoneal sarcoma*
	Lymphoma**
	Multiple myeloma***
	Benign skull tumor***
	Lymph node metastases***

* These indications are under the category of "may be considered medically reasonable and necessary" in two LCDs that specify conditions but are considered "medically reasonable and necessary" in another.
** These indications are not covered in one of the LCDs.
*** These indications appear in the claims but are not covered in the LCDs listing specific indications.
† Constitute separate categories in our analysis due to their size.
‡ Not found in our dataset.

This report details the increased use of proton beam radiotherapy among Medicare beneficiaries from 2006 to 2009 in terms of both recipients and indications.

METHODS

This analysis included all Medicare beneficiaries with claims indicating a diagnosis in the malignant or benign neoplasms range of the ICD-9 codes (140-239) and receipt of proton beam therapy (HCPCS 77520-77525) between January 1, 2006, and December 31, 2009.

Measures

For each year, we calculated the number of unique beneficiaries, diagnoses, and reimbursements. We counted each beneficiary only once, in the year treatment started, regardless of whether treatment duration spanned two calendar years. We grouped diagnoses by the degree of consistency in LCD policy regarding proton beam therapy (**Table 2**). Group 1 diagnoses include cancers for which proton beam is considered medically reasonable in *all* of the LCDs; we termed these "commonly accepted indications." Group 2 contains diagnoses for which proton beam may be reasonable; we termed these "conditions of possible benefit." This category also includes some diagnoses (such as multiple myeloma) that are not included in any LCD but do appear in the claims. In cases where multiple diagnosis codes are associated with proton beam radiotherapy for a single patient, we choose the most common diagnosis code within the neoplasm range of ICD-9 codes (140-239). Fewer than 11 cases offered no diagnosis code for proton beam claims other than a radiation therapy diagnosis code (V58.0), and these were classified as "other."

When possible, we report use by specific diagnosis, and we uniformly report prostate and non-small cell lung cancers separately due to their high frequency among proton beam recipients. We assigned proton beam recipients to their provider by matching ZIP Codes for service providers to those of the proton beam centers operational at the time of the service. Fewer than 11 apparent users could not be matched to an existing center, and Medicare reimbursed none of the claims they submitted. Patients who received State assistance with Medicare premiums or cost sharing when proton beam radiotherapy treatment was initiated are identified by Dual Status codes 01 to 09.

Throughout this report, "reimbursement" will refer to the amount paid by the Medicare program, and "payments" will refer to total payments (Medicare reimbursement and patient cost sharing). For hospital-based facilities, we obtained it from the line payment amount. These estimates include only payments related to the use of the facility, equipment, and technician fees (the technical components of the service). Our estimates do not include payments to physicians for treatment planning and management, because these cannot be differentiated from payments for standard external beam radiation therapy.

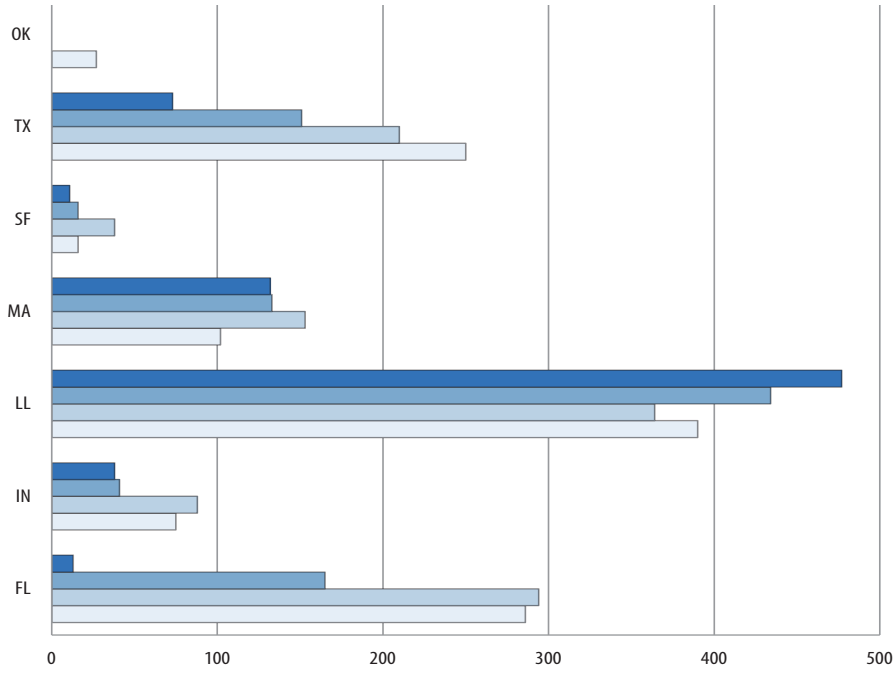
We calculated mean payment per beneficiary and treatment course (several weeks for some tumors) as the sum of all paid claims. In cases where treatment took place in two years (e.g., December to January), we considered the total amount to have taken place in the year treatment began. Patients beginning treatment in December 2009 were not included in the calculation of mean, median, and total payments because it is not possible to determine whether the treatment was completed or continued into 2010. Denied claims were excluded from the analysis. We separately analyzed the number and proportion of denied claims by year, provider, and indication to assess whether usage differed importantly from an analysis of paid claims.

RESULTS

Providers

The number of centers operating in the United States remained constant at six from 2006 to 2008. One center was added in 2009. However, from 2006 to 2009, the number of beneficiaries treated increased from about 740 to almost 1,200. Centers varied considerably in treatment volume over the study period. Three centers maintained stable or decreased caseloads (SF, MA, LL) and two others doubled theirs. Florida's caseload rose dramatically, from 13 in 2006 to 286 in 2009 (**Figure 2**).

Figure 2: Growth in number of beneficiaries treated with proton beam radiotherapy by facility, 2006-2009



Number of Cases	FL	IN	LL	MA	SF	TX	OK
2006	13	38	477	132	11	73	
2007	165	41	434	133	16	151	
2008	294	88	364	153	38	210	
2009	286	75	390	102	16	250	27

OK=Oklahoma City, OK; TX=Houston, TX; SF=San Francisco, CA; MA=Boston, MA; LL=Loma Linda, CA; IN=Indianapolis, IN; FL=Gainesville, FL.

Patients

Patients receiving proton beam therapy were more likely to be younger than age 75 and white (**Table 3**). Approximately 5 percent of recipients were under age 65 and received Medicare benefits due to disability. The high percentage of males (85 percent) is consistent with the large number who received proton therapy for prostate cancer. A small percentage of patients (5.8 percent) received assistance with their Medicare premiums and/or full Medicaid benefits. Prostate cancer is the most common diagnosis on Medicare claims for proton beam radiotherapy (69.9%). Other diagnoses that appeared frequently included lung (7.1%), eye (6.6%), malignant and benign brain tumors (4.1%), bone tumors (2.2%), and metastatic tumors in the brain and bones (1.0%; **Table 3**).

Between 2006 and 2009, we observed a small decrease in the proportion of patients receiving treatment for Group 1/commonly accepted indications (18.7 percent in 2006 to 10.6 percent in 2009; **Figure 3** and **Table 4**).

Table 3: Characteristics of proton beam radiotherapy users in Medicare, by demography and indication, 2006-2009

Demographic characteristic	N	%	Demographic characteristic	N	%
Total	3,977	100.0	Year initiated treatment		
Sex			2006	744	18.7
Male	3,397	85.4	2007	940	23.6
Female	580	14.6	2008	1,147	28.8
Age (years)			2009	1,146	28.8
<65	208	5.2	State buy-in	232	5.8
65-69	1,356	34.1			
70-74	1,178	29.6	Commonly accepted indications (Group 1)	591	14.9
75-79	777	19.5	Eye	262	6.6
80+	458	11.5	Malignant brain and nervous system	79	2.0
Race			Benign brain tumors	83	2.1
White	3,526	88.7	Bone (axial skeleton)	87	2.2
Black	143	3.6	Other	80	2.0
Hispanic	139	3.5			
Asian	79	2.0	Conditions of possible benefit (Group 2)	3,386	85.1
American Indian	13	0.3	Prostate	2,778	69.9
Other/unknown	77	1.9	Lung	284	7.1
Region			Metastatic tumors	38	1.0
Northeast	509	12.8	Esophageal	28	0.7
Midwest	402	10.1	Other/unknown*	258	6.5
South	1,583	39.8			
West	1,483	37.3			

* Other or unknown includes leukemia, lymphoma, skin, and unspecified sites.

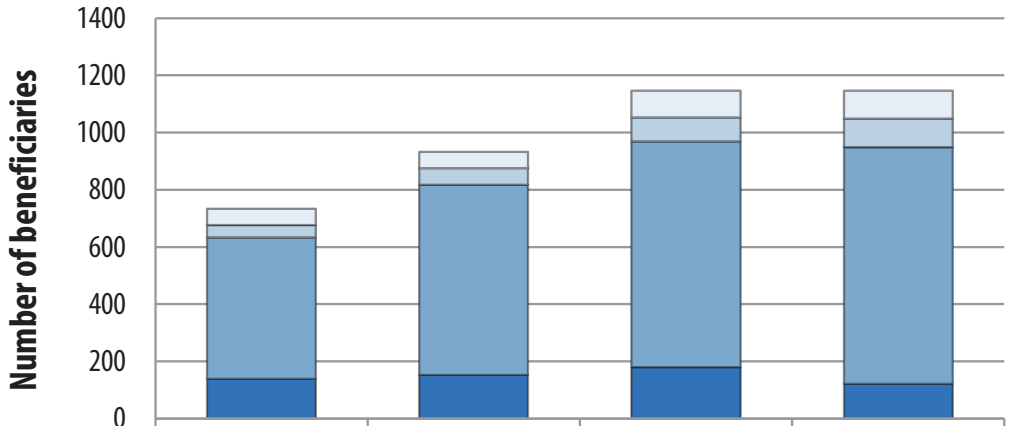
Over this same period, the number of beneficiaries treated for conditions of possible benefit (Group 2) nearly doubled, from 595 to 1,025.

A similar increase was observed for prostate and lung cancers. Across the four study years, the bulk of the proton beam beneficiaries covered by Medicare were individuals with prostate cancer (66% to 72%).

Reimbursement Associated With Proton Beam Radiotherapy

Medicare reimbursements for proton beam therapy peaked at $28 million in 2007 and dropped to $27 million in 2009 (**Table 5**), with the drop owing partly to payment decreases and the shift toward treating the majority of patients in freestanding centers instead of hospital outpatient settings (see **Table 6**). Payments per treatment day averaged $897 for Medicare and $197 for the patient (or the patient's payer). This amount includes no physician management or planning fees. Reimbursement per patient varies by treatment indication. An analysis of claims suggests that ocular tumors typically receive a relatively short course of therapy (one week), whereas other cancers, such as prostate, receive daily doses for six to eight weeks. Average total treatment reimbursements range from about $5,000 for ocular tumors to $25,000 for prostate cancers (**Table 7**). In 2009, prostate cancer comprised 73 percent of the cases and 79 percent of the amount paid by Medicare.

Figure 3: Growth in proton beam radiotherapy by diagnosis, 2006-2009



	2006	2007	2008	2009
Group 2--Other	58	58	94	97
Group 2--Lung	43	57	84	100
Group 2--Prostate	494	666	790	828
Group 1	139	152	179	121

Table 4: Distribution of diagnoses associated with proton radiotherapy claims over time, 2006-2009

	2006		2007		2008		2009	
	n	%	n	%	n	%	n	%
Commonly accepted indications (Group 1)	139	18.7	152	16.2	179	15.6	121	10.6
Eye	62	8.3	58	6.2	87	7.6	55	4.8
Malignant brain and nervous system	27	3.6	19	2.0	17	1.5	16	1.4
Benign brain tumors	22	3.0	26	2.8	21	1.8	14	1.2
Bone (axial skeleton)	15	2.0	28	3.0	24	2.1	20	1.7
Other	13	1.7	21	2.2	30	2.6	16	1.4
Conditions of possible benefit (Group 2)	595	80.0	781	83.1	968	84.4	1,025	89.4
Prostate	494	66.4	666	70.9	790	68.9	828	72.3
Lung	43	5.8	57	6.1	84	7.3	100	8.7
Metastatic tumors	*	*	*	*	11	1.0	11	1.0
Esophageal	*	*	*	*	12	1.0	15	1.3
Other/unknown	58	7.8	58	6.2	71	6.2	71	6.2

*One or more cell sizes <11, suppressed to comply with Medicare reporting requirements.

Table 5: Annual total reimbursement by Medicare to proton beam treatment centers by claim year, 2006-2009*

	2006	2007	2008	2009
Total reimbursement (in million $)**	17.2	28.3	27.3	27.2

*Number excludes reimbursement for physician management.
**Reimbursement is calculated for all claims in each year.

Table 6: Annual range of payments for proton radiotherapy claims, by type of center, 2006-2009*

	2006	2007	2008	2009
Outpatient				
Average payment ($)	1,072	1,303	936	816
Range of payment ($)	992 - 1,249	1,267 - 1,536	863 - 1,085	752 - 941
Freestanding				
Average payment ($)	909	947	931	919
Range of payment ($)	516 - 983	516 - 1,098	519 - 1,087	524 - 1,098
% of cases using freestanding centers	18.2%	39.7%	55.0%	57.1%

*The number of daily treatments varies by tumor type. Typically a prostate cancer case will have this daily charge 30 times, and ocular tumor 5 times. Reimbursement per case and total reimbursement are calculated based on the year in which the treatment cycle began.

Table 7: Annual mean, median, and total reimbursement for proton beam radiotherapy, by diagnosis and year, 2006-2009**

	2006			2007			2008			2009		
	Median ($)	Mean ($)	Total ($)	Median ($)	Mean ($)	Total ($)	Median ($)	Mean ($)	Total ($)	Median ($)	Mean ($)	Total ($)
Commonly accepted indications (Group 1)												
Eye	4,145	5,375	333,300	5,137	6,943	402,716	3,079	3,455	300,607	3,143	4,561	228,035
Malignant brain and nervous system	25,341	22,248	600,701	24,092	24,207	459,949	21,726	22,286	378,865	20,844	15,688	219,638
Benign brain tumors	15,328	14,849	326,667	1,229	13,582	353,138	22,572	16,460	345,654	20,742	20,354	264,596
Bone	24,630	22,277	334,151	32,021	29,367	822,273	26,525	28,212	677,082	24,795	24,645	492,902
Other	13,884	17,195	223,544	1,229	6,942	145,774	1,497	7,210	216,314	18,778	15,081	226,217
Conditions of possible benefit (Group 2)												
Prostate	35,074	29,706	14,674,540	33,053	34,954	23,314,013	29,526	27,922	22,086,508	27,984	25,444	19,515,378
Lung	27,371	22,627	972,963	27,544	23,898	1,313,790	27,259	21,702	1,822,934	25,458	21,871	1,990,240
Esophageal	*	*	*	*	*	*	21,807	20,957	230,231	20,367	18,589	167,297
Metastatic tumors	*	*	*	*	*	*	6,291	10,963	131,557	9,285	12,713	177,975
Other/unknown	15,844	18,419	1,068,383	18,438	22,318	1,316,790	16,985	18,569	1,318,364	13,314	19,241	1,289,174

*One or more underlying cell sizes <11, suppressed to comply with Medicare reporting requirements.
** Numbers exclude reimbursement for physician management.

Impact of Denied Claims on Assessment of Proton Beam Therapy Use

As always, analysis of denied claims proved difficult. Most commonly, claims were denied for being submitted multiple times. Denied claims accounted for 5 percent of the claims submitted in each year. Eight to 19 percent of patients had at least one claim denied between 2006 and 2009 (**Table 8**). In very few cases were all claims for proton beam radiotherapy denied, and a small portion of these came from ZIP Codes with no proton beam radiotherapy providers. Thus, it is likely that these fully denied claims represent billing errors rather than actual receipt of proton beam radiotherapy. In general, providers whose programs were established prior to 2002 were less likely to have any claim rejected than newer providers, with the exception of San Francisco (established in 1994), with 51 percent of beneficiaries having some or all claims denied. The frequency of any claim denial did not vary between indicated (Group 1) and potentially indicated (Group 2) conditions. Of note, most denied claims for indicated conditions were for ocular tumors where the exact location in the eye was initially unspecified.

DISCUSSION

As a highly specific form of advanced radiotherapy, proton beam therapy may play an important role in treating tumors surrounded by critical structures such as the eye, brain, and spinal cord. All of these are commonly accepted indications for this precise therapy that allows dose escalation to the tumor site while minimizing the unintended consequences in adjacent tissue. However, many are being treated for tumors for which there is far less consensus about this therapy's use and for which no clinical trial data yet suggest superiority of proton beam therapy over other modalities such as intensity modulated radiotherapy and brachytherapy. The specific tumors for which precise targeting of dose offers overwhelming potential benefits (commonly accepted indications) are rare, and few facilities would likely treat enough such patients to support a proton beam center.

The major growth in proton beam therapy from 2006 to 2009 was due to a 68 percent growth in utilization in "conditions of possible benefit," mostly prostate cancer. Several factors likely explain the trend toward using proton beam therapy for prostate cancer. First, concerns about impotence, incontinence, and procitis caused by radiation damage to adjacent tissue may be driving patients and physicians to seek more specific forms of radiotherapy. Second, evidence of improved disease-free survival with higher doses of conventional prostate radiation has led some physicians to seek safer ways to escalate dose.[13] Third, prostate cancer is more common than the other conditions of possible benefit.

Table 8: Distribution of diagnoses associated with proton radiotherapy claims over time, by year, location, and diagnosis

	Total cases (n)	% of total cases with any claims denied	% of total cases with all claims denied**
Year			
2006	754	8.0	*
2007	953	14.1	1.4
2008	1,159	19.2	1.0
2009	1,162	13.5	1.4
Provider			
FL	766	45.6	*
IN	243	8.6	*
LL	1,656	<0.7	0.0
MA	526	2.1	*
OK	27	0.0	0.0
SF	104	51.0	22.1
TX	687	17.8	*
Diagnosis			
Group 1	695	14.8	4.2
Group 2			
Lung	285	13.0	*
Prostate	2,786	14.3	*
Other	262	13.7	5.0

*One or more cell sizes <11, suppressed to comply with Medicare reporting requirements.
** This column is a subset of the "Any claims denied" column.

With 217,730 new cases diagnosed in 2010,[14] even a small percentage of prostate cancer patients seeking to use proton beam therapy will lead to a large increase in use of the technology. While less than one-half a percent of incident prostate cancer patients received proton beam radiation therapy in 2009, those cases accounted for almost 75 percent of all proton therapy use. The potential for treating a greater percentage of prostate cancer cases with proton beam therapy likely explains the planned opening of several new treatment facilities in the United States in the coming years. The cost of such an expansion will be further multiplied by the fact that with 6 to 8 weeks of therapy (compared to one week for ocular neoplasms), prostate tumors are by far the most expensive to treat with proton beams. Even a minimal trend toward proton therapy in prostate cancer treatment is likely to be widely felt by proton beam centers and have economic implications for the Medicare program.

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