

Medicare Payment & Coverage for Proton Beam Radiation Therapy: Winter 2010/2011 Update

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Proton beam radiation therapy has significantly developed over the last few years with treatment centers coming online in Illinois, Virginia, Oklahoma and Pennsylvania. In addition, intentions to build new centers have been announced in locations throughout the country, including Arizona, California, Maryland, Minnesota, New York, Ohio and Tennessee.² This article is a summary of recent developments in the Medicare payment and coverage for proton beam radiation therapy (“**Proton Therapy**”) and builds from a Fall 2009 American Health Lawyer’s Association, Regulation Payment & Accreditation Article by Jason B. Caron and titled “Ensuring Appropriate Incentives for Proton Beam Therapy: A Review of the Medicare Reimbursement Landscape” (the “**2009 AHLA Article**”)(**Attachment 1**).

Payment Update

As discussed in more detail in the 2009 AHLA Article, Proton Therapy centers are generally enrolled in Medicare as either (i) hospital provider-based centers, or (ii) free-standing centers. With respect to hospital provider-based centers, the payments rates are set nationally through the Medicare Hospital Outpatient Prospective Payment System based on cost data reported by hospitals (“**HOPPS**”). The following chart summarizes the HOPPS recent payments rates for Proton Therapy.

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² The following is a sample of articles and media releases related to recently announced Proton Therapy centers:

<http://minnesota.publicradio.org/display/web/2010/11/16/proton-beam-cancer-mayo/>
<http://www.sdbj.com/news/2011/jan/10/200m-proton-therapy-centers-deliver-cancer-fightin/>
http://articles.baltimoresun.com/2010-10-14/health/bs-hs-proton-cancer-20101013_1_proton-therapy-cancer-treatment-radiation-therapy
<http://www.dotmed.com/news/story/14231/>
<http://www.medicitynews.com/2010/09/does-dayton-really-need-two-proton-therapy-centers/>
<http://www.knoxnews.com/news/2010/may/27/proton-therapy-center-okd-for-development/>

**National Medicare Proton Therapy Rates For Hospital Outpatient
Departments**

	2006	2007	2008	2009	2010	2011
APC 664	\$947.93	\$1161.29	\$816.59	\$703.38	\$942.31	\$1,031.71
APC 667	\$1134.08	\$1389.37	\$977.09	\$840.56	\$1232.67	\$1,349.61

With respect to Proton Therapy provided in freestanding centers, the various Medicare Administrative Contractors (“MACs”) establish the payment rates. Given the relatively small number of freestanding centers currently operating in the US, only a small number of MACs have set payment rates for Proton Therapy (First Coast Options Services, National Government Services and Trailblazer Health Enterprises). The following chart summarizes the payment rates for the MACs with freestanding centers in the relevant MAC’s jurisdiction(s):

MAC Proton Therapy Rates for Freestanding Proton Therapy Centers					
MAC	Year	CPT®			
		77520	77522	77523	77525
Trailblazer Health Enterprises (Houston)	2008	\$905.34	\$936.96	\$973.52	\$1086.64
	2009	\$845.56	\$875.08	\$909.22	\$1014.84
	2010* (1/1 - 5/31)	\$852.67	\$882.43	\$916.86	\$1023.37
	2010* (6/1 - 12/31)	\$881.43	\$901.85	\$937.03	\$1045.89
	2011	\$800.42	\$828.40	\$860.76	\$960.86
Trailblazer Health Enterprises (Oklahoma)	2008	\$769.21	\$796.18	\$827.37	\$923.86
	2009	\$726.44	\$751.88	\$781.31	\$872.36
	2010* (1/1 - 5/31)	\$790.37	\$818.08	\$850.12	\$949.21
	2010* (6/1 - 12/31)	\$807.94	\$836.25	\$868.99	\$970.29
	2011	\$746.27	\$772.41	\$802.65	\$896.19
Trailblazer Health Enterprises (Virginia) (Targeted to transition to Palmetto GBA in Mid-March 2011)	2010	\$849.15	\$878.90	\$913.31	\$1019.75
	2011	\$787.26	\$814.84	\$846.74	\$945.43
First Coast Service Options, Inc. (“ First Coast ”)(Florida)	2008	\$905.25	\$936.93	\$973.14	\$1086.30
	2009	\$915.21	\$947.24	\$983.84	\$1098.25
	2010	\$915.21	\$947.24	\$983.84	\$1098.25
	2011 ³	\$935.34	\$968.08	\$1,005.48	\$1,122.41

³ We were informed by First Coast that they will be re-evaluating the Proton Therapy codes and may be implementing new pricing later in 2011.

National Government Services, Inc. (Indiana)	2008	\$518.94	\$518.94	\$786.34	\$786.34
	2009	\$524.65	\$524.65	\$794.99	\$794.99
	2010	\$524.65	\$524.65	\$794.99	\$794.99
	2011	\$536.19	\$536.19	\$812.48	\$812.48
Palmetto GBA (Virginia)(Targeted to transition from Trailblazer in Mid-March 2011)	2011	As of 1/11/2011, Palmetto GBA had not established payment rates for proton beam therapy.			
Wisconsin Physicians Service Insurance Corporation (“WPS”) (Illinois)	2010	As of 1/6/2011, WPS had not established payment rates for proton beam therapy.			
	2011				

Coverage Update

To date, the Centers for Medicare and Medicaid Services has not adopted a National Coverage Determination for Proton Therapy. However, a number of Medicare contractors have adopted or proposed Local Coverage Determinations (“LCDs”). Most recently (December 2010), Wisconsin Physicians Service Insurance Corporation issued a proposed LCD – a series of meeting are scheduled for this winter and comments are due on the proposed LCD by March 27, 2011. The following chart summarizes the current landscape of LCDs:

Summary of Proton Therapy LCDs		
<p>(Note: The Medicare program has been and continues to consolidate the Medicare program contractors, e.g., from fiscal intermediaries and carriers to Medicare Parts A & B MACs. Due to a number of factors, including contractor appeals, the Medicare contractors for a number of jurisdictions are still in flux. In the chart below, we have identified those jurisdictions that are currently in flux. However, we note that the contractor consolidation is an evolving dynamic.)</p>		
Contractor	Jurisdiction	Summary of LCD
First Coast Services Options, Inc. (Medicare Parts A & B MAC)	Florida, Puerto Rico, and Virgin Islands	<ul style="list-style-type: none"> Provides a short list of conditions for which proton therapy will be considered medically reasonable and necessary. Provides a second list of conditions that “may be” considered medically reasonable and necessary. However, for the second list of conditions, a rigorous medical necessity standard must be met and the patient must be treated as part of

		<p>a clinical trial.</p> <ul style="list-style-type: none"> • All other indications are not considered reasonable and necessary. • Includes a number of documentation requirements. • First Coast also issued a draft LCD for “Radiation Therapy for Basal Cell and Squamous Cell Carcinomas” in October of 2010 which indicates that proton beam therapy is not covered for Stage T1 basal cell carcinoma or squamous cell carcinoma. (The comment period for this draft LCD ended on 11/29/2010).
Trailblazer Health Enterprises (Medicare Parts A & B MAC)	Colorado, New Mexico, Oklahoma, Texas & Virginia (until 3/19/2011)	<ul style="list-style-type: none"> • “Because proton beam therapy is relatively new and available in only a few locations, the provider/physician will need to contact Medicare <i>to discuss indications</i> and payment. Each claim will be individually reviewed.” • Trailblazer also issued a draft Proton Beam Radiotherapy LCD for Virginia, where it is a Carrier, on February 23, 2006 (Draft Trailblazer LCD). In summary, the Draft Trailblazer LCD was a least-costly alternative type policy and included a list of conditions for which proton therapy was medically necessary. In addition, the Draft Trailblazer LCD included a list of conditions for which proton therapy would be priced the same as IMRT. Under the Draft Trailblazer LCD, proton therapy for all other conditions would be priced the same as conventional radiotherapy. The Draft Trailblazer LCD has not been finalized, and Trailblazer has indicated that reimbursement policy would be handled on a case-by-case basis.
National Government Services	Indiana (Carrier), Connecticut	<ul style="list-style-type: none"> • In a recently retired LCD, the following language appeared: “Because proton treatment delivery is relatively new and

<p>(NGS) (Medicare Parts A & B MAC & legacy carrier / fiscal intermediary) (Part of NGS' jurisdiction is under CMS contractor rebidding "corrective action" and may be subject to rebid and assignment to a different contractor.)</p>	<p>(A/B MAC), Kentucky (Carrier) and New York (A/B MAC)(Note: National Government Services appears to have jurisdiction in several states where the provider has selected National Government Services as the provider's Medicare Part A fiscal intermediary and has not been transitioned to a Medicare Parts A & B MAC)</p>	<p>available in only a few locations, the carrier in which one of these is located will need to contact that provider <i>to discuss indications</i> and payment."</p>
<p>Noridian Administrative Services LLC (Medicare Parts A & B MAC)</p>	<p>Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming</p>	<ul style="list-style-type: none"> • The medical record must clearly evidence the medical necessity of proton radiotherapy in lieu of other modalities of treatment.
<p>Palmetto GBA (Medicare Parts A & B MAC)</p>	<p>American Samoa, California (Northern and Southern), Nevada, Guam, Hawaii, North Carolina, Northern Mariana Islands, South</p>	<ul style="list-style-type: none"> • The medical record must clearly evidence the medical necessity of proton radiotherapy in lieu of other modalities of treatment.

	<p>Carolina, Virginia (Targeted to start in Mid-March, 2011) and West Virginia</p>	
<p>Highmark Medicare Services (Medicare Parts A & B MAC)</p>	<p>Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania</p>	<ul style="list-style-type: none"> • Highmark has issued a new Proton Therapy LCD, effective October 28, 2009, that, in brief: <ul style="list-style-type: none"> ○ Provides a list of conditions for which proton therapy is considered medically reasonable and necessary. ○ Provides that proton therapy is indicated when: (1) The dose volume histogram illustrates at least three critical structures or organs protected by the use of proton therapy; (2) the dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissues; (3) there is documented clinical rationale that doses are generally thought to be above the level otherwise attainable with other radiation methods might improve control rates; or (4) there is documented clinical rational that higher levels of precision associated with proton therapy compared to other radiation treatments are clinically necessary. ○ With respect to prostate cancer, requires: (1) physician documentation of patient selection criteria (stage and other factors); (2) documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits; and (3) documentation of the specific

		<p>reasons why proton therapy was the treatment of choice for the specific patient. Other factors considered favorable for coverage include enrollment of the patient in an appropriate clinical registry for planned assessment and publication.</p> <ul style="list-style-type: none"> • Includes a number of specific documentation requirements.
<p>Wisconsin Physicians Service Insurance Corporation (“WPS”) (Medicare Parts A & B MAC & legacy carrier / fiscal intermediary) (Part of WPS’ jurisdiction is under CMS contractor rebidding “corrective action” and may be subject to rebid and assignment to a different contractor.)</p>	<p>Nebraska (A/B MAC), Minnesota (Carrier), Missouri (A/B MAC), Kansas (A/B MAC), Illinois (Carrier) Iowa (A/B MAC) and Wisconsin (Carrier) (Note: Wisconsin Physicians Service Insurance Corporation appears to have jurisdiction in all states where the provider has selected Wisconsin Physicians Service Insurance Corporation as the provider’s Medicare Part A fiscal intermediary and has not been transitioned to</p>	<ul style="list-style-type: none"> • WPS has a historical LCD that states, “Clinical use of proton beam therapy is relatively new and there are no facilities available within our jurisdiction at the present time.” • On December 1st of 2010, WPS issued a proposed LCD for proton therapy. • The proposed LCD provides a short list of conditions for which proton therapy will be considered medically reasonable and necessary. • The WPS proposed LCD then provides a second list of conditions that “may be” considered medically reasonable and necessary. However, for the second list of conditions, a rigorous medical necessity standard must be met and the patient must be treated as part of a clinical trial. • With respect to prostate cancer, the draft LCD includes prostate cancer on the second list of conditions for which proton therapy “may” considered medically reasonable and necessary. Furthermore, the draft LCD provides as follows: “There is as yet no good comparative data to determine whether or not Proton Beam Therapy for prostate cancer is superior, inferior, or equivalent to external beam radiation, IMRT, or brachytherapy

	<p>a Medicare Parts A & B MAC)</p>	<p>in terms of safety or efficacy. The prostate cancer should be locally advanced prostate cancer (i.e., Stages C or D1 [without distant metastases], also classified as T3 or T4) (the tumor has spread through the capsule on one or both sides but has not invaded seminal vesicles or other structures) and any N disease (either no spread to lymph nodes or there has been spread to the regional lymph nodes Note: Spread beyond local lymph nodes is considered metastatic disease. Coverage and payments of Proton Beam Therapy for prostate cancer will require: a. Physician documentation of patient selection criteria (stage and other factors); b. Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits; and c. Documentation of the specific reasons why Proton Beam was the treatment of choice for the specific patient.</p> <p>Other factors considered favorable for coverage include enrollment of the patient in an appropriate clinical registry for planned assessment and publication.”</p> <ul style="list-style-type: none"> • Lastly, the proposed LCD provides that: “If a patient cannot clearly meet the criteria for coverage but desires proton beam radiotherapy based on a marketed theoretical advantage, the claim should be billed with the appropriate modifier appended to the treatment delivery code.” • The proposed LCD also includes a number of documentation requirements. • WPS will be facilitating a number of advisory committee meetings which are currently scheduled to begin on 1/28/2011 and end on 2/10/2011. • Comments on the proposed LCD are due
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National Heritage Insurance Company, Corp. (Medicare Parts A & B MAC)	Maine, Massachusetts, New Hampshire, Rhode Island and Vermont	<ul style="list-style-type: none"> National Heritage Insurance Company, Corp. has not issued a LCD that addresses Proton Therapy.

What's On The Horizon

Looking beyond the above snapshot of Proton Therapy payment and coverage, the Proton Therapy reimbursement landscape is likely to continue to evolve in the coming years as new centers come online and additional MACs address this newer technology for their Medicare beneficiaries. In addition, research efforts are underway to study Proton Therapy, including comparative effectiveness research designed to compare Proton Therapy to numerous other treatment modalities. This research is highly likely to be relied upon by payors in establishing Proton Therapy reimbursement. For example, the recently proposed Wisconsin Physician Services LCD cited two Agency for Health Care Research & Quality reports: “Particle Beam Radiation Therapies for Cancer, Revised November 2009” and “Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer, February 2008.” In addition, the National Institutes of Health convened a conference in December to discuss comparative effectiveness research and a number of presenters, including payor representatives, addressed Proton Therapy and the need for additional research.

Ultimately, Proton Therapy is still a relatively new technology and the Medicare reimbursement landscape continues to evolve. As such, Proton Therapy stakeholders will want to (i) actively engage in Proton Therapy research efforts, and (ii) continue to monitor and engage in the Medicare reimbursement dialogue from the policy, payment and coverage perspectives so as to ensure that this promising technology is a cancer treatment option for Medicare beneficiaries.