



NATIONAL ASSOCIATION FOR PROTON THERAPY ADDRESSES RECENT NEW YORK TIMES, WASHINGTON POST, AND SIMILAR ARTICLES

As a community of major academic, comprehensive cancer, and regional healthcare institutions that provide proton therapy, among a number of other cancer therapies, it was with great dismay that we recently read the articles published by the New York Times, the Washington Post, and several other major newspapers. Unfortunately, the evidence-based value of proton therapy was omitted as was a critical on-going access issue – inappropriate insurance denials.

At the outset, the peer-reviewed published evidence from leading oncologists around the world continues to support the significant value proton therapy offers certain patients fighting cancer. As of 2018, there are over 800 clinical studies published on proton therapy including 285 just over the last three years, the overwhelming majority of which support the value of the therapy.¹ Below are a few illustrative examples of the research demonstrating the significant clinical benefits of proton therapy when compared to standard radiation therapy.

- Esophageal Cancer²
 - 41% decrease in lung complications
 - 20% decrease in hospitalization rate
- Head & Neck Cancer³
 - 44% increase in 5-year disease free survival for nasal & paranasal sinus cancers
 - 60% decrease in the need for feeding tube placement for nasopharynx cancers
- Liver Cancer⁴
 - 58% increase in 2-year overall survival in hepatocellular cancer
 - 54% increase in 4-year overall survival in intrahepatic cholangiocarcinoma

Because of these (and other) evidence-based benefits, patients and physicians around the world are seeking proton therapy and, therefore, our cancer care community is incorporating this therapy into their cancer service

¹ National Association for Proton Therapy (NAPT) Model Policy, “Coverage of Proton Beam Therapy”. Endorsed by Alliance Dedicated Cancer Centers and Particle Therapy Cooperative Group – North America.

² Lin SH, Komaki R, Liao Z, et al. Proton beam therapy and concurrent chemotherapy for esophageal cancer. *Int J Radiat Oncol Biol Phys* 2012;83:e345-351. Wang J, Wei C, Tucker SL, et al. Predictors of postoperative complications after trimodality therapy for esophageal cancer. *Int J Radiat Oncol Biol Phys* 2013;86:885-891. Lin SH, Merrell KW, Shen J, et al. Multi-institutional analysis of radiation modality use and postoperative outcomes of neoadjuvant chemoradiation for esophageal cancer. *Radiother Oncol* 2017;123:376-381. Takada A, Nakamura T, Takayama K, et al. Preliminary treatment results of proton beam therapy with chemoradiotherapy for stage I-III esophageal cancer. *Cancer Med* 2016;5:506-515.

³ Tokuyue K, Akine Y, et al. Proton therapy for head and neck malignancies at Tsukuba. *Strahlenther Onkol.* 2004;180(2):96-101. Holliday E, Garden AS, Fuller CD, et al. Proton therapy reduces treatment-related toxicities for patients with nasopharyngeal cancer: A case-match control study of intensity-modulated proton therapy and intensity modulated photon therapy. *Int J Particle Ther* 2015;2(1):19-28. Lewis GD, Holliday E, Kocak-Uzel E, et al. Intensity-modulated proton therapy for nasopharyngeal carcinoma: Decreased radiation dose to normal structures and encouraging clinical outcomes. *Head Neck* 2016;38:E1886-E1895.

⁴ Hong TS, Wo JY, Beow YY, et al. A multi-institutional phase II study of high dose hypofractionated proton beam therapy in patients with localized unresectable hepatocellular carcinoma and intrahepatic cholangiocarcinoma. *J Clin Oncol* 2016;34(5):460-468. Fukuda K, Okumura T, Abei M, et al. Long-term outcomes of proton beam therapy in patients with previously untreated hepatocellular carcinoma. *Cancer Sci* 2017;108:497-503. Bush DA, Kayali Z, Grove R, Slater JD. The safety and efficacy of high-dose proton beam radiotherapy for hepatocellular carcinoma: a phase 2 prospective trial. *Cancer* 2011;117:3053-3059. Kawashima M, Furuse J, Nishio T, et al. Phase II study of radiotherapy employing proton beam for hepatocellular carcinoma. *J Clin Oncol* 2005;23:1839-1846.



lines. There are currently 28 proton therapy centers operational in the United States. Since 2001, 26 of those centers have opened which equates to 1.5 proton therapy centers per year. In comparison, there are over 2,500 standard radiation therapy centers in the U.S. Based on these statistics, we believe that the proton therapy field has experienced tempered growth over this time period while we have responsibly developed the needed evidence.

Insurers are inappropriately denying proton beam therapy. While we don't disagree that some proton therapy centers have struggled, like any other healthcare business, there are a number of factors that impact the financial stability including, for example, the complexity of emerging technologies, varying market expectations, and limited payer coverage. We believe that one of the most significant factors is inappropriate insurance denials. In order to challenge these denials, cancer patients, their families and caregivers, and our community must devote very significant resources, which unduly taxes our health care system. This has become a broader trend in health care and is particularly troubling when these denials are ultimately overturned, but only after care delays and significant expense. For example, with our most fragile patient population – pediatrics, our colleagues at the University of Pennsylvania recently published that 97% of insurance denials were overturned upon appeal.⁵

Our colleague, Dr. Anthony Dritschilo, chair of the Georgetown University Radiation Oncology department, was quoted as saying that “Every major cancer center, that has a full-service radiation oncology department should consider having protons.” We believe that Dr. Dritschilo is correct. Harvard's Andres Soriano Professor Radiation Oncology, Emeritus, Dr. Herman Suit, once provided that: “There is NO advantage to ANY patient for ANY irradiation of ANY normal tissue ... Direct radiation complications NEVER occur in unirradiated tissues.”

Our community continues to support the responsible adoption of proton therapy and development of evidence to support its appropriate use. We also believe that insurance companies need to actively reassess the body of published evidence, regularly adjust their coverage policies, and ensure that the entire value proposition for a patient is considered as the utmost priority.

⁵ Ojerholm E, Hill-Kayser CE. Insurance Coverage Decisions for Pediatric Proton Therapy. *Pediatr Blood Cancer* 2018 Jan; 65(1). doi: 10.1002/pbc.26729.