

STOP DRACONIAN MEDICARE PROTON THERAPY REGULATION

The Center for Medicare and Medicaid Services (CMS) is proposing a regulation that would pay the same for all types of radiation, including proton therapy. Such a drastic cut in reimbursement would drive some proton centers into bankruptcy and deny thousands of cancer patients this life-saving treatment.

I spent weeks researching and responding to the CMS proposal. The result is long, very detailed blog: www.proton-beam-therapy.com/blog.CMS.html. If you would like a free printed version of this 31-page investigative report by mail, contact me: robert@ProtonTherapyBook.com.

These are the predominant factors underlying the proposal.

1. In 2018 the Medicare Payment Advisory Committee (MedPAC) issued a report to congress that included a study of three products that it considered over-priced and thus of low value. Proton therapy was one of those three. Low value is defined as *a technology that provides little or no benefit, in which the potential harm outweighs the potential benefit*. Little or no benefit? Harmful? That's outrageous. Prior to the issuance of that report to Congress, representatives of the National Association of Proton Therapy (NAPT) met with the director of MedPAC to provide updated studies and information to refute that low rating. To no avail. Their data were ignored.

2) In 2014 the Institute for Clinical and Economic Review (ICER) issued a report for Washington State regarding proton therapy that led to the denial of coverage for state employees. The report is based on vastly outdated studies (some as early as 2004) and insufficient data. While admitting it had little evidence to go on, ICER declared that most proton therapy was no better than x-rays and not worth the cost. This report was done before the emergence of pencil beam scanning technology. As a result, it does not represent the true efficacy of proton therapy. Nevertheless, it was quoted as a basis for MedPAC's discriminatory rating of proton therapy in 2018 and the CMS proposed policy. Garbage in, garbage out .

3. The Medicare proposal to pay the same for x-rays and proton therapy was suggested by the American Society for Radiation Oncology (ASTRO) in a report sent to MedPAC in 2017 and reaffirmed in a recent letter to CMS. "The proposed payment model is a step forward in allowing the nation's 4,500 radiation oncologists to participate in the transition to value-based care that improves outcomes for cancer patients," said Paul Harari, MD, Chair of the board of directors of the American Society for Radiation Oncology (ASTRO).

"Value-based care" means x-rays rather than proton therapy. Am I imagining ASTRO's double-dealing? It's letter to CMS also said, *Finally, we support CMS's proposal to include PBT in the model,*" fully knowing the damage it would cause proton therapy. ASTRO uses its influence to disparage proton therapy in other ways, as I detail in my blog.

The CMS policy proposal was strongly influenced by the three reasons I have just outlined:

- The drastic uncalled for conclusion by MedPAC that proton therapy is of low value.
 - The discredited and vastly out-of-date ICER report that is still be quoted by CMS.
 - Actions by ASTRO in promoting the equal-payment model, knowing it would favor x-ray technology.
- Besides these influences, there are other reasons why the CMS proposed rule is a bad idea.

The most egregious aspect of the CMS rule is that is it based on woefully out-dated studies. Suppose a software came out in 1990 and had been upgraded and improved every year since. If you were rating the software in 2019, would depend on reviews written in 2008 or 2010? Hopefully not. But that is exactly what CMS is doing in its rating of proton therapy.

The introduction of pencil beam scanning (PBS) represents a huge advance for proton therapy, increasing the number of cancers it can treat. (Hence my book, *Proton Therapy: Revolutionary Treatment for 80% of ALL Cancers*.) Picture a jar randomly filled with red and white marbles. PBS can target one color and minimally affect the other color, even when the targets aren't contiguous. The older proton technology of passive double scattering can't do that. Nor can x-rays. Yet

CMS has based its proposal on the older technology. Any study that does not take into account PBS does not fairly document the possibilities of proton therapy. In the past four years, I have not seen a single reputable trial between PBS and IMRT that does not show the superiority of proton therapy.

The amount of proof demanded of proton therapy is unreasonable, excessive, and probably unethical. Yes, we all look forward to more high-quality studies, because we know proton therapy will out-perform x-rays. Yet, insistence by proton critics on waiting for more studies before approving proton therapy ignores a large body of data that already exists. Such a strict standard was never imposed upon current widely-accepted x-ray technologies because their benefit was considered obvious. The benefits of proton therapy are equally obvious. As an advocate for the patient side of the proton therapy equation, I say let's get on with it.

The proposed rule would impede the development of proton therapy that promises to be the cancer treatment of the future. If it weren't for the lack of insurance coverage, many more cancer patients would avail themselves of proton therapy. The solution is to increase insurance coverage, not for Medicare to reduce its payments. Fewer treatment fractions plus the promise of arc and flash technologies are likely to lower costs and change the face of radiation oncology. Thwarting proton therapy development to achieve temporary savings would be counterproductive. .

The CMS proposal is based on the mistaken assumption that x-rays and proton therapy are similar and equivalent. It appears some decision makers are not aware of what proton therapy really is, especially since both x-rays and protons are grouped together as radiation.

Electrons used to create x-rays have negligible mass or electrical charge whereas protons have substantial mass and a positive charge. If I were a hydrogen electron (I weigh 175 pounds), my corresponding proton would be sixty tons. Tons! The physical characteristics of x-rays and protons differ hugely. The weight of protons reduces the beam broadening and scatter seen with x-rays. Their positive charge, when reunited with electrons, explains why they can stop at the target. X-rays will never be able to stop, or lay down rows of spots like PBS.

The widely accepted relative biological effect (RBE) for x-rays is 1.0 and for protons 1.1. That means protons have the same effect with ten percent lower dose, or with the same dose, they are ten percent more effective. Proton therapy is more complex and expensive to build and to use than are x-rays. To suggest an equivalency of value and payment shows a lack of knowledge as to the nature of the two modalities. Suggested equality often originates from proponents of x-rays defending their turf.

Thwarting proton therapy will deprive the general public of an effective choice in fighting cancer, thereby reducing the quality of available care. The goal of the proposed CMS rule is to increase efficiency, lowers costs, and maintain the quality of care. Limiting access to proton therapy would have the opposite effect.

I'm not a stakeholder in this situation. I'm a private citizen. As such, I advocate for the general public especially older folks like me who depend on Medicare coverage for our healthcare. It will be devastating if CMS lets us down. In "Three Ways to Make Proton Therapy Affordable," authors Thomas R. Bortfeld and Jay S. Loeffler state:

If cost was not an issue, proton therapy would be the treatment of choice for most patients with localized tumours. Protons can be targeted more precisely than X-rays, so the tissues around the tumour receive two to three times less radiation. This lowers the chance of causing secondary tumours or impairing white blood cells and the immune system. High doses of protons can be delivered safely to hard-to-treat tumours: for instance, those at the base of the skull or in the liver. Such accuracy is crucial when treating cancers in children.

If cost were indeed not an issue, we wouldn't be in this predicament. The proposed regulation was meant to lower costs but this is not the solution. Proton therapy is not like a drug company that has jacked up prices beyond reason, yet that's the comparison MedPAC is making.

A number of studies have shown that in the long run, considering the extra cost of side effects and recurrence, for x-rays, proton therapy isn't out of range. But that misses the point. Even at a higher price, proton therapy is worth the investment for its better results and its promise for the future. Moreover, considering cost over results violates Medicare's own regulations.

CALL TO ACTION

Read my entire blog at www.proton-beam-therapy.com/blog.CMS.html. Please go to the following link to tell your representatives in Washington D.C. you want them to stop this proposed regulation: Alliance for Proton Therapy Access: <https://www.voterveice.net/PROTON/1/campaigns/68657/> respond. Many thanks. Together we hope to make a difference.

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