



August 26, 2020

Dear Insurer,

It has come to our attention that some patients with cancer are being denied insurance coverage for proton beam radiation therapy within clinical trials supported by the National Cancer Institute (NCI).

We are urging that insurance providers that have denied coverage reconsider their position for patients participating in these nationally recognized, federally supported clinical trials and approve coverage for both modes of external-beam radiation therapy – proton beam as well as photon therapy – used in these important randomized clinical trials.

Proton beam therapy and photon therapy have been used for years and are FDA-approved, non-experimental, efficacious treatments for cancer. Investigators have hypothesized that proton beam therapy may offer the benefit of sparing organs and normal tissue from the effects of radiation, thereby reducing side effects and risks to patients. Proton therapy has also been shown to allow increased radiation dose to the targeted tumor, which may result in better control of the cancer.

Data from prospective, randomized trials, however, are lacking and are critical to determining the comparative effectiveness of proton beam vs. photon therapy. These trials are necessary, and timely completion is critical as more and more cancer centers around the country are beginning to offer proton beam therapy to patients.

The NCI strongly believes that randomized studies are necessary to determine whether proton therapy significantly improves clinically important patient outcomes (and, if so, what the magnitude of that benefit is). The NCI is supporting the following multi-center randomized clinical trials comparing proton beam therapy against photon therapy:

Trial # NRG-BN001 (Active): “Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma”

ClinicalTrials.gov link: <https://clinicaltrials.gov/ct2/show/NCT02179086>

Trial # NRG-BN005 (Active): “A Phase II Randomized Trial of Proton Vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas”

ClinicalTrials.gov link: <https://clinicaltrials.gov/ct2/show/NCT03180502>

Trial # NRG-GI003 (Active): “A Phase III Randomized Trial of Protons Versus Photons for Hepatocellular Carcinoma”

ClinicalTrials.gov link: <https://clinicaltrials.gov/ct2/show/NCT03186898>



Trial # NRG-GI006 (Active): “Phase III Randomized Trial of Proton Beam Therapy (PBT) Versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer”

ClinicalTrials.gov link: <https://clinicaltrials.gov/ct2/show/NCT03801876>

Trial # RTOG-1308 (Active): “Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy for Inoperable Stage II-IIIb NSCLC”

ClinicalTrials.gov link: <https://clinicaltrials.gov/ct2/show/NCT01993810>

Trial # NCT01617161 (DFCI #11-497) (Active): “PARTIQoL (Prostate Advanced Radiation Technologies Investigating Quality of Life): Phase III Randomized Clinical Trial of Proton Therapy vs. IMRT for Low or Intermediate Risk Prostate Cancer”

ClinicalTrials.gov link: <http://clinicaltrials.gov/show/NCT01617161>

For the above reasons, we request that insurers provide coverage for patients participating in federally supported, randomized studies studying proton beam therapy. It is critical that participation in such randomized clinical studies is supported, to provide the much-needed data on which patients and insurers can make scientifically informed decisions regarding the use and advancement of medical practices to treat cancer.

We thank you for your attention to this matter.

Bhadrasain Vikram, MD

Chief, Clinical Radiation Oncology Branch
National Cancer Institute, RRP/DCTD
Tel: 240-276-5690 or 5726
vikramb@mail.nih.gov

Andrea M. Denicoff, MS, RN

Head, NCTN Clinical Trials Operations
Scientific Liaison, Patient Reported Outcomes
National Cancer Institute, CTEP/DCTD
Tel: 240-276-6094
denicofa@mail.nih.gov