

Submitted by:

Al Musella, DPM

President, Musella Foundation For Brain Tumor Research & Information, Inc

1100 Peninsula Blvd

Hewlett, NY 11557

888-295-4740

Musella@virtualtrials.com

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NCCN Guidelines Panel: Central Nervous System Cancers

I respectfully request the NCCN Central Nervous System Panel to reconsider the recommendation made in the Version 1.2014 guidelines for “Alternating electric field therapy for glioblastoma”, where they changed from a category 2B to a category 3 recommendation for recurrent Glioblastoma. **I would like this changed to a category 1 for both Newly Diagnosed and Recurrent Glioblastoma for the following reasons:**

1. This treatment is FDA approved for recurrent Glioblastoma and is in use at over 100 brain tumor centers. It is not yet approved for newly diagnosed Glioblastoma.
2. New data from the EF-14 trial was presented at the Society Of Neuro-Oncology’s annual meeting on Nov. 15, 2014 which showed that in this large (315 patients), well designed trial for newly diagnosed Glioblastoma, overall survival was increased by 3 month over the control group which was the standard of care. Progression free survival also increased by over 3 months, and the 2 year survival increased by almost 50% from 29% to 43%. This data will soon be published.
3. The Patient Registry Dataset was recently published in “Seminars in Oncology” [http://www.seminoncol.org/article/S0093-7754\(14\)00203-6/abstract](http://www.seminoncol.org/article/S0093-7754(14)00203-6/abstract) this reported on the post marketing registry of all 457 Recurrent Glioblastoma patients who used the NovoTTF therapy from 2011 to 2013. They reported no adverse effects except minor skin irritation. Median overall survival was 9.6 months (from the time this treatment started, not from time of diagnosis) and 2 year survival was 30%. Prior trials reported Overall survival at 2 years of about 7-9%.
4. The current NCCN guidelines include “Radiation, concurrent and adjuvant temozolomide” as a category 1 recommendation for newly diagnosed Glioblastoma. This was based on a 2.5 month improvement over the previous standard of care. As noted above, Optune, when added to the current standard treatment, improved survival by 3 months and added no significant side effects. Furthermore, many of the recommended treatments listed in your guidelines are off label– therefore Optune deserves the same category 1 recommendation for newly diagnosed even though it is not yet FDA approved for newly diagnosed.
5. The current NCCN guideline for recurrent Glioblastoma includes a long list of treatments, most of which are category 2B. None of these have performed as well as the results of Optune, and most have had significantly more side effects.

6. I feel Optune deserves a category 1 recommendation because there have been 2 large randomized phase 3 trials, the large registry dataset, and many published articles. I feel that fulfills the requirement for Level 1 “high level” quality of evidence as required for you to consider it as a category 1 recommendation.

Furthermore, I would like you to use the name of the treatment “Optune” instead of “Alternating Electric Field Therapy”, as there are old, unproven (not FDA approved) alternative treatments that can be classified as “alternating electric fields”. Those alternative treatments were not tested in the lab and in large human clinical trials, and should not be grouped in with Optune. Optune is the new name for the Novo TTF 100-A System.