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National Comprehensive Cancer Network  
Central Nervous System Cancers Committee  
275 Commerce Dr. Suite 300  
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**VIA E-Mail: [submissions@nccn.org](mailto:submissions@nccn.org)**

Date of request: 11/06/2015

NCCN Guidelines Panel: Central Nervous System Cancers

On behalf of Novocure Inc., I respectfully request the NCCN Central Nervous System Cancers committee to review and discuss the enclosed data for a uniform consensus recommendation of Tumor Treating Fields (TTFields) delivered by Optune™ in combination with temozolomide for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma.

Specific Changes: Recommend the inclusion of TTFields delivered by the Optune in the Central Nervous System Cancer guidelines as an FDA approved treatment for adult patients (21 years or older) with histologically-confirmed newly diagnosed glioblastoma (GBM) in combination with temozolomide (TMZ) following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

Rationale: A phase III randomized controlled trial (EF-14) in newly diagnosed GBM showed that Optune in combination with TMZ extends progression free and overall survival significantly compared to patients receiving TMZ alone. Optune received PMA approval by the United States Food and Drug Administration on 10/5/2015 for the treatment of newly diagnosed glioblastoma GBM in combination with TMZ; following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

We would like to thank the following NCCN Member Institutions for their participation in the EF-14 pivotal trial;

- University of Alabama at Birmingham, Birmingham, AL
- City of Hope, Duarte, CA
- University of California San Diego Moores Cancer Center, La Jolla, CA
- University of Colorado Denver, Aurora, CO
- H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL
- The Johns Hopkins Hospital, Baltimore, MD
- Washington University School of Medicine, St. Louis, MO
- Ohio State University Arthur G. James Cancer Hospital, Columbus, OH
- University of Washington/Seattle Cancer Care Alliance, Seattle, WA

The following supporting materials are submitted in support of this proposed change. The EF-14 publication has been submitted to a top-tier journal and is currently under peer review.

Novocure Inc. Optune instructions for use. Retrieved November 4, 2015, from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf10/P100034S013d.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013d.pdf)

U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Optune P10034/S013 Summary of safety and effectiveness, October 5, 2015. Retrieved November 4, 2015, from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf10/p100034s013b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034s013b.pdf)

We appreciate the consideration of the attached information by the Central Nervous System Cancer Committee in its review of the NCCN Guidelines for Central Nervous System Cancers. Should you require additional information or have any questions, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jai Grewal', with a stylized flourish at the end.

Jai Grewal, MD  
US Medical Director