Washington State Health Care Authority

June 14, 2024 Meeting Materials
Health Technology Clinical Committee

Petition materials: Tumor Treating Fields (TTF)

Contents

Washington State Health Care Authority

Submit competed petition to: shtap@hca.wa.gov; **or**
Atten: Health Technology Assessment
PO Box 42712**,** Olympia, Washington 98504-2712; **or**
FAX (360) 586-8827

Petition for technology review or re-review

Your name:	Novocure, Inc.
Mailing address:	195 Commerce Way, Portsmouth NH 03801 Attention: Katherine E Kokko, MPH
E-mail address:	kkokko@novocure.com
Telephone number:	603-973-1739

Note: Not all questions will apply to all technologies. For assistance email the HTA program at the address above, or phone (360) 725-5126 (TTY 711).

Technology topic Optune

If this topic has been reviewed by the health technology assessment program in the past, skip to question 7, below. See technologies HTCC has previously reviewed.

1. Background information

- Does this technology have FDA approval? ☐ Yes ☐ No
- When was this technology approved?
- For what indications has FDA approved this technology?
- Why do you believe this technology merits consideration for assessment?
- Proposed research questions.

Click here to enter text.

2. Potential patient harm(s) or safety concerns

- What is the potential for patient harm, related to use of this technology?
- What are the likelihood and severity of the potential harms or adverse outcomes that may result from recommended use of this technology?
- Are there significant potential harms associated with this technology compared to alternatives?

Click here to enter text.

3. Therapeutic efficacy, effectiveness or diagnostic accuracy

- What is the potential effectiveness of this technology on the indicated clinical condition? (e.g., prevent/reduce mortality; increase quality of life)
- How are indicated conditions diagnosed? Is there a consensus on diagnosis?

- For diagnostic technologies: Is this technology compared to a "gold standard" technology?
- What is the diagnostic accuracy or utility?
- What published, peer-reviewed literature documents the efficacy of this technology or the science that underlies it? Please enclose publications or bibliography.

Click here to enter text.

4. Estimated total cost per year

- What are the direct health care costs of this technology (annual or lifetime)?
- What is the potential cost-effectiveness of this new technology compared with other alternatives?
- Which private insurers reimburse for use of this technology? Please provide contact information and phone numbers.

Click here to enter text.

5. Secondary considerations

- **Number of persons affected** - What are the numbers of people affected by this technology in the State of Washington?
- **Severity of condition(s)** - What is the severity of the condition treated by this technology? Does it result in premature death; short or long term disability? How would this technology increase the quality of care for the State of Washington?
- **Policy-related urgency -** Is there a particular urgency related to this technology? Is it new and rapidly diffusing? How long has this technology been in use? Is there a standard of care? Is this technology or proposed use(s) controversial?
- **Potential or observed variation** - What is the observed or potential for under, or overuse of this technology? Are there any variations in use or outcomes by region or other characteristics?
- **Special populations and ethical concerns** - Is use limited to small populations; what characteristics are present (e.g., race, ethnicity, religion, rare condition, socioeconomic status) that may impact policy decision?

Click here to enter text.

6. References

- List other organizations that have completed technology assessments on this topic (please provide date of technology assessments and links).
- Cite any Center for Medicare and Medicaid Services (CMS) national coverage decision on this topic and the date issued.
- Provide list of key references used in preparing this petition.

- Have any relevant medical organizations (e.g., American Medical Association) expressed an opinion on this technology? If so, please provide verification documents and contact names, numbers and links.
- Bibliography or reference list of requestor attached: ☐ Yes ☐ No

Click here to enter text.

7. For re-review petitions only

Re-review of a technology requires new evidence that could change a previous decision. What new evidence should be considered? Please provide specific publication information and/ or references.

Please see attached letter and reference list. The reference list contains new publications not considered during previous HTCC reviews of Optune.

195 Commerce Way
Portsmouth, NH 03801

603.436.2809
novocure.com

LITERATURE LIST

Novocure is providing this updated list of GBM-specific, peer-reviewed literature that was not considered as part of past WA State Health Technology Assessments (HTAs) for Optune™

ECONOMIC

Burton, E, Ugiliweneza et al. (2015) A Surveillance, Epidemiology and End Results-Medicare data analysis of elderly patients with glioblastoma multiforme: Treatment patterns, outcomes and cost. Mol Clin Oncol.

Guzauskas, Gregory F, Pollom et al. (2019) Tumor treating fields and maintenance temozolomide for newly-diagnosed glioblastoma: a cost-effectiveness study. Journal of Medical Economics.Journal of Medical Economics. 22 (10) :1006-1013.

Messali, A, Hay et al. (2013) The cost-effectiveness of temozolomide in the adjuvant treatment of newly diagnosed glioblastoma in the United States. Neuro Oncol. Neuro Oncol. 15 (11) :1532-1542.

Norden, A D, Korytowsky et al. (2019) A Real-World Claims Analysis of Costs and Patterns of Care in Treated Patients with Glioblastoma Multiforme in the United States. J Manag Care Spec Pharm.J Manag Care Spec Pharm. 25 (4) :428-436.

Palmer, J., Chavez et al. (2021) Health-Related Quality of Life for Patients Receiving Tumor Treating Fields for Glioblastoma.Frontiers in oncology. 11 :772261-772261.

GUIDELINES

Association des Neuro-oncologues d'Expression Francaise (ANOCEF). (2018)Référentiel Glioblastome (grade IV OMS).

Centers for Medicare & Medicaid Services. (2019) Local Coverage Determination (LCD) Tumor Treatment Field Therapy (TTFT). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34823

National Comprehensive Cancer Network. (2022) NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Central nervous system cancers. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Regional Cancer Centers in Collaboration (Sweden). Tumours of the brain and spinal cord National care programme 2020-01-14 Version 3. https://kunskapsbanken.cancercentrum.se/globalassets/cancerdiagnoser/hjarna-cns/vardprogram/nationellt-vardprogram-tumorer-hjarna-ryggmarg.pdf

Segura, P.P., Quintela, N.V., García, M.M. et al. SEOM-GEINO clinical guidelines for high-grade gliomas of adulthood (2022). Clin Transl Oncol 25, 2634–2646 (2023). https://doi.org/10.1007/s12094-023-03245-y

Wick W. *Gliome – Leitlinien für Diagnostik und Therapie in der Neurologie*. 2021. https://www.awmf.org/uploads/tx_szleitlinien/030-099l_S2k_Gliome_2021-07.pdf

PRECLINICAL

Chen D, Le SB, Hutchinson TE et al. (2022) Tumor Treating Fields dually activate STING and AIM2 inflammasomes to induce adjuvant immunity in glioblastoma. J Clin Invest. e149258. https://www.doi.org/10.1172/JCI149258

RETROSPECTIVE

Aly, A, Singh et al. (2020) Survival, costs, and health care resource use by line of therapy in US Medicare patients with newly diagnosed glioblastoma: a retrospective observational study. Neurooncol Pract.Neurooncol Pract. 7 (2) :164-175.

Shi W, Blumenthal DT, Oberheim Bush NA, et al. (2020) Global post-marketing safety surveillance of Tumor Treating Fields (TTFields) in patients with high-grade glioma in clinical practice. *J Neurooncol*. 148(3):489-500.

Oberheim-Bush NA, Shi W, McDermott MW, Grote A, Stindl J, Lustgarten L. The safety profile of Tumor Treating Fields (TTFields) therapy in glioblastoma patients with ventriculoperitoneal shunts. J Neurooncol. 2022 Jul;158(3):453-461. doi: 10.1007/s11060-022-04033-4. Epub 2022 May 31. PMID: 35639236; PMCID: PMC9256561.

Vymazal J, Kazda T, Novak T, Slanina P, Sroubek J, Klener J, Hrbac T, Syrucek M, Rulseh AM. Eighteen years' experience with tumor treating fields in the treatment of newly diagnosed glioblastoma. Front Oncol. 2023 Jan 19;12:1014455. doi: 10.3389/fonc.2022.1014455. PMID: 36741707; PMCID: PMC9892904.

REVIEW

Ballo MT, Conlon P, Lavy-Shahaf G, Kinzel A, Vymazal J, Rulseh AM. Association of tumor treating fields (TTFields) therapy with survival in newly diagnosed glioblastoma: a systematic review and meta-analysis. J Neurooncol. 2023;164(1):1-9. doi:10.1007/s11060-023-04348-w

Mehta, M, Wen, P et al. (2017) Critical review of the addition of tumor treating fields (TTFields) to the existing standard of care for newly diagnosed glioblastoma patients. Critical Reviews in Oncology/Hematology, Volume 111, Pages 60-65, ISSN 1040-8428, https://doi.org/10.1016/j.critrevonc.2017.01.005

Regev, Ohad, Merkin et al. (2021)Tumor-Treating Fields for the treatment of glioblastoma: a systematic review and meta-analysis. Neuro-Oncology Practice.Neuro-Oncology Practice. 8 (4) :426-440.

Burri SH, Gondi V, Brown PD, Mehta MP. The Evolving Role of Tumor Treating Fields in Managing Glioblastoma: Guide for Oncologists. Am J Clin Oncol. 2018 Feb;41(2):191-196. doi: 10.1097/COC.0000000000000395. PMID: 28832384; PMCID: PMC5779316.

Ghiaseddin AP, Shin D, Melnick K, Tran DD. Tumor Treating Fields in the Management of Patients with Malignant Gliomas. Curr Treat Options Oncol. 2020 Jul 30;21(9):76. doi: 10.1007/s11864-020-00773-5. PMID: 32734509; PMCID: PMC7391234.

SUB-GROUP

Ballo, M, Urman et al. (2019) Correlation of Tumor Treating Fields Dosimetry to Survival Outcomes in Newly Diagnosed Glioblastoma: A Large-Scale Numerical Simulation-Based Analysis of Data from the Phase 3 EF-14 Randomized Trial. Int J Radiat Oncol Biol Phys. Int J Radiat Oncol Biol Phys. 104 (5) https://www.doi.org/10.1016/j.ijrobp.2019.04.008

Ballo MT, Qualls KW, Michael LM et al. (2022) Determinants of tumor treating field usage in patients with primary glioblastoma: A single institutional experience. *Neuro-Onc Adv*. 15;4(1):vdac150.

Glas, Martin et al. (2022) The Impact of Tumor Treating Fields on Glioblastoma Progression Patterns. International journal of radiation oncology, biology, physics vol 112,5 (2022):1269-1278. https://www.doi.1016/j.ijrobp.2021.12.152

Toms, S.A., Kim, C.Y., Nicholas, G. et al. Increased compliance with tumor treating fields therapy is prognostic for improved survival in the treatment of glioblastoma: a subgroup analysis of the EF-14 phase III trial. J Neurooncol. 2019 Jan;141(2):467-473. doi: 10.1007/s11060-018-03057-z.

Ram Z, Kim CY, Hottinger AF, Idbaih A, Nicholas G, Zhu JJ. Efficacy and Safety of Tumor Treating Fields (TTFields) in Elderly Patients with Newly Diagnosed Glioblastoma: Subgroup Analysis of the Phase 3 EF-14 Clinical Trial. Front Oncol. 2021 Sep 27;11:671972. doi: 10.3389/fonc.2021.671972.

Vymazal J, Wong ET (2014). Response patterns of recurrent glioblastomas treated with tumor-treating fields. *Semin Oncol*. 41 Suppl 6:S14-24.

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

April 17, 2024

To whom it may concern:

SUBJECT: Health Technology Assessment Topic Selection, 2024

As the Director of the Health Care Authority, I select technologies for review by Health Technology Clinical Committee in consultation with other agencies and the Committee itself (70.14 RCW). Technologies are selected when there are concerns about safety, efficacy or value (cost-effectiveness), when state expenditures are or could be high, and when there is adequate evidence to conduct a review. Technologies are selected for rereview when new evidence is available that could change a previous determination.

For the current selection cycle, I reviewed the proposed topics and the comments received from interested individuals and groups who responded in the public comment period (March 20 to April 3, 2024). Based on this review I have selected the following technologies for assessment:

Technology	Primary Criteria Ranking		
	Safety	Efficacy	Cost
Endovascular intervention in lower extremity peripheral arterial disease and intermittent claudication	**Medium**	**Medium**	**High**

Endovascular intervention, including procedures such as angioplasty and stent placement, is commonly used in the management of lower extremity peripheral arterial disease (PAD).

Frenotomy and frenectomy with breastfeeding support	**Medium**	**High**	**Medium**

Procedures to cut the frenulum, a band of tissue in the mouth, often performed to address issues related to tongue-tie or lip-tie, which can affect breastfeeding.

Continuous Glucose Monitoring	**Medium**	**High**	**High**

New evidence identified that could change previous determination.

Hyperbaric Oxygen Therapy (HBOT)	**Medium**	**High**	**High**

New evidence identified for sensorineural hearing loss that could change previous determination.

At this time, **Optune/tumor treating fields (TTF)**, which was first reviewed in 2016 with a formal updated literature scan in 2017 and rereview in 2018, is not selected for rereview after public petition was reviewed. The information provided does not support that there is new evidence likely to change the previous determination. At this time, **hip surgery for femoroacetabular impingement syndrome (FAI)**, is not selected for rereview. The HTA program monitors the literature on this topic with detailed literature

searches including a recently concluded search (December 2023). Based on these searches and consideration by the participating agencies and the Health Technology Clinical Committee, new evidence is not likely to change the previous determination.

Upon publication of the selected list of technologies, a 30-day comment period will begin whereby any interested person or group may provide information to be considered in the review of the selected topic(s).

Should you have any questions or concerns, please contact the HTA Program at shtap@hca.wa.gov.

Sincerely,

Susan E. Birch MBA, BSN, RN
Director

Enclosure(s)

By email

cc: Josh Morse, HTA Director, CQCT, HCA
Valerie Hamann, HTA Program Specialist, CQCT, HCA
Melanie Golob, HTA Program & FFS Operations Manager, CQCT, HCA

Washington State Health Care Authority

Health Technology Clinical Committee
Findings and Decision

Topic: Tumor treating fields, (TTF) – re-review
Meeting date: November 16, 2018
Final adoption: January 18, 2019

Meeting materials and transcript are available on the HTA website.

Number and coverage topic:

20181116A - Tumor treating fields, (TTF) – re-review

HTCC coverage determination:

Tumor treating fields is **not a covered benefit**.

HTCC reimbursement determination:

Limitations of coverage:

N/A

Non-covered indicators:

N/A

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on tumor treating fields, (TTF) is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of TTF for: 1) newly diagnosed glioblastoma multiforme; 2) recurrent glioblastoma multiforme; and 3) treatment of other cancers. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover tumor treating fields for treatment of newly diagnosed glioblastoma multiforme, recurrent glioblastoma multiforme, and for treatment of other cancers.

	Not covered	Covered under certain conditions	Covered unconditionally
Tumor treating fields – newly diagnosed	9	0	0
Tumor treating fields - recurrence	9	0	0
Tumor treating fields – other cancers	9	0	0

Discussion

The committee reviewed and discussed the available studies for use of TTF. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of TTF was equivalent for safety unproven for efficacy and less cost-effective than comparators.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no NCD for tumor treating fields.

The committee discussed clinical guidelines identified for tumor treating fields from the following organizations:

- National Comprehensive Cancer Network (NCCN) – 2018
  NCCN Clinical Practice Guidelines in Oncology. Central Nervous System Cancers
  Version 1.2018
- U.K. National Institute for Health and Care Excellence (NICE) – 2018
  Brain tumours (primary) and brain metastases in adults (2018)

- Medical Oncology Spanish Society (SEOM) – 2017
  SEOM clinical guidelines for diagnosis and treatment of glioblastoma (2017)
- European Association for Neuro-Oncology (EANO) – 2017
  EANO guideline on the diagnosis and treatment of adult astrocytic and oligodendroglial gliomas (2017)
- America Association of Neuroscience Nurses (AANN) 2016
  Care of the Adult Patient with a Brain Tumor (2014)39 (Revised 2016)
- European Society of Medical Oncology (ESMO) 2014

  High-grade glioma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow up (2014)

The committee determined the guidelines do not have concordant recommendations. The HTCC determination is consistent with some and differs from some of the reviewed guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of tumor treating fields for public comment; followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.