Washington State Health Care Authority

Health Technology Assessment Program

Proposed technologies 2024

Contents

- ☐ Prospective topic memo
- ☐ Petition materials

Washington State Health Care Authority

Health technology assessment program

Prospective technology topics - 2024

Public comments accepted until **5:00 p.m., April 3, 2024**
Submit all comments to: **shtap@hca.wa.gov**

Summary

The Health Care Authority (HCA) Director selects topics for review through the Health Technology Assessment (HTA) program. Proposed topics are identified by the medical directors from participating agencies - Labor and Industries, Department of Corrections, Health Care Authority (PEBB/SEBB and Medicaid); by HTA staff; or by petition from an interested party.

After selection, the proposed topics are published online for review and comment by the public and health technology stakeholders. This comment period extends for two weeks. Following the public comment period, HTA staff will provide all comments to the Director for consideration before making a final selection of the topics for the review cycle.

At this time, the program proposes the following topics for the 2025 cycle:

- **Continuous glucose monitoring:** Rereview of the determination from 2018.
- **Hyperbaric Oxygen Therapy:** Rereview of the determination from 2013.
- **Endovascular intervention in lower extremity peripheral arterial disease and intermittent claudication**
- **Frenotomy and frenectomy with breastfeeding support**

Background

The HTA program is a legislatively created program that seeks to ensure that health technologies purchased by state agencies are safe and effective, and that coverage decisions of state agencies are consistent. The program relies on scientific, evidence-based information about safety and effectiveness to inform decisions and improve quality. An independent committee of eleven practicing health care clinicians reviews evidence regarding the safety, efficacy, and cost-effectiveness of various medical procedures and/or equipment, and determines if the state should pay for those procedures.

The HCA, in consultation with participating state agencies (Department of Labor and Industries and Department of Corrections), selects technologies for review through the HTA program process. Agency leaders or their designees are liaisons between the HTA program and the participating agencies, and provide consultation on program decisions, clinical committee membership, and to recommend and prioritize technologies.

Interested organization/public recommendations:

Interested individuals may petition the program to review or rereview a technology by using the petition for health technology review form, located on the HTA webpage, at any time.

Prospective topic list

Agency medical directors and policy staff reviewed utilization, emerging technology, activity by other health technology assessment programs, and public requests for a list of prospective technologies for prioritization and recommendation to the HCA director.

New proposed technologies

	Primary criteria ranking		
Technology	**Safety**	**Efficacy**	**Cost**
Endovascular intervention in lower extremity peripheral arterial disease and intermittent claudication	**High**	**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.			

Topics considered, not proposed

	Technology
1	Noninvasive vagus nerve stimulation
2	Left atrium occlusion device (Watchman)
3	Invasive coronary angiography/percutaneous coronary intervention in stable coronary artery disease
4	Peripheral nerve stimulation
5	Functional endoscopic sinus surgery and balloon ostial sinus dilation in chronic rhinosinusitis
6	Bronchial valves

Rereview technologies

Technologies are considered for rereview at least once every eighteen months based on availability of new evidence that may change the decision. All technologies with determinations beyond 18 months since the final determination previously reviewed by the Health Technology Clinical Committee (HTCC) are listed below, along with information on whether they have been selected for rereview.

Petitioners whose topic is not selected for rereview by the Director of HCA may request consideration for selection of the topic by the HTCC.

	Technology	HTCC review history	Rereview?
1	**Continuous Glucose Monitoring (CGM)** New evidence identified that could change previous determination.	HTCC first reviewed in 2011 with a rereview conducted in 2018.	Yes
2	**Hyperbaric Oxygen Therapy (HBOT)** New evidence identified for sensorineural hearing loss that could change previous determination.	HTCC first reviewed in 2013.	Yes
3	**Optune/Tumor Treating Fields (TTF)** Petition for rereview received. Not selected for rereview at this time based on available new evidence.	HTCC first reviewed in 2016 with a rereview 2018. Literature scan in 2018.	No
4	**Femoroacetabular Impingement Syndrome (FAI)** Signal search completed in 2023. New evidence does not appear to support policy changes.	HTCC first reviewed in 2011 with a rereview in 2019. Literature scans in 2014, 2018, and 2023.	No
5	**Artificial Disc Replacement** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2008 with a rereview in 2017. Literature scan in 2016.	Pending
6	**Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA)** Formal literature scan in process to determine if new evidence is available.	HTCC first reviewed in 2013.	Pending
7	**Functional Neuroimaging for Primary Degenerative Dementia and Mild Cognitive Impairment** Formal literature scan in process to determine if new evidence is available.	HTCC first reviewed in 2015	Pending
8	**Gene Expression Profile Testing of Cancer Tissue** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2018	Pending

	Technology	HTCC review history	Rereview?
9	**Intensity Modulated Radiation Therapy (IMRT)** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
10	**Microprocessor-Controlled Lower Limb Prosthetics** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
11	**Robotic Assisted Surgery (RAS)** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
12	**Sleep Apnea Diagnosis and treatment in Adults** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
13	**Upper Endoscopy for GERD and GI Symptoms** Formal literature scan in process to determine if new evidence is available.	HTCC first review in 2012	Pending
14	**Upright/Positional MRI** Formal literature scan in process to determine if new evidence is available.	HTCC first reviewed in 2007. Literature scan conducted in 2012.	Pending

For the current period, the program has not received or identified new evidence to support review of the following:

	HTA Decisions	Latest Review/ Scan
1	Applied Behavioral Analysis (ABA or ABA Therapy) Based Behavioral Interventions for the Treatment of Autism Spectrum Disorder	June 2011
2	Appropriate Imaging for Breast Cancer Screening in Special Populations	January 2015
3	Autologous Blood/Platelet-Rich Plasma Injections	July 2023
4	Bone Growth Stimulation	August 2009
5	Bone Morphogenic Proteins for Use in Lumbar Fusion	March 2012
6	Breast MRI	August 2010
7	Bronchial Thermoplasty for Asthma	May 2016
8	Cardiac Stents	January 2016
9	Carotid Artery Stenting	September 2013

	HTA Decisions	Latest Review/ Scan
10	Cell-Free DNA Prenatal Screening for Chromosomal Aneuploidies (cfDNA)	January 2020
11	Cervical Spinal Fusion for Degenerative Disc Disease	March 2013
12	Chronic Migraine and Chronic Tension-type Headache	March 2022
13	Cochlear Implants: Bilateral Versus Unilateral	May 2013
14	Computed Tomographic Colonography (CTC)	February 2008
15	Coronary Artery Calcium Scoring	May 2020
16	Discography	February 2008
17	Electrical Neural Stimulation (ENS)	October 2009
18	Extracorporeal Membrane Oxygenation Therapy (ECMO)	March 2016
19	Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions	March 2017
20	Facet Neurotomy	June 2020
21	Fecal Microbiota Transplantation	November 2016
22	Genomic Microarray Testing	January 2018
23	Hip Resurfacing	November 2013
24	Hip Surgery for Femoroacetabular Impingement (FAI) Syndrome	December 2023
25	Imaging for Rhinosinusitis	May 2015
26	Implantable Drug Delivery System for Chronic Non-Cancer Pain	August 2008
27	Knee Arthroscopy for Osteoarthritis of the Knee	August 2008
28	Lumbar Fusion for Degenerative Disc Disease	November 2015
19	Negative Pressure Wound Therapy (NPWT) for Home Use	November 2016
30	Nonpharmacologic Treatments for Treatment Resistant Depression	March 2014
31	Osteochondral Allograft/Autograft Transplantation (OAT)	January 2018
32	Peripheral Nerve Ablation for Limb Pain	January 2019
33	Pharmacogenetic Testing for Patients Being Treated with Oral Anticoagulants	May 2018
34	Pharmacogenomic Testing for Selected Conditions	January 2017
35	Positron Emission Tomography (PET) Scans for Lymphoma	November 2018
36	Proton Beam Therapy	May 2019
37	Routine Ultrasound for Pregnancy	November 2010
38	Screening & Monitoring Tests for Osteopenia/Osteoporosis	November 2014
39	Selected Treatments for Varicose Veins	May 2017
40	Spinal Cord Stimulation	November 2023
41	Spinal Injections	March 2016

	HTA Decisions	Latest Review/ Scan
42	Stem Cell Therapy for Musculoskeletal Conditions	June 2020
43	Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy	June 2023
44	Surgery for Lumbar Radiculopathy/Sciatica	May 2018
45	Testosterone Testing	March 2015
46	Tinnitus: Non-Invasive, Non-Pharmacologic Treatments	May 2020
47	Total Knee Arthroplasty	October 2010
48	Transcranial Magnetic Stimulation for Selected Conditions	March 2023
49	Tumor Treating Fields (Optune)	November 2018
50	Tympanostomy Tubes in Children	November 2015
51	Vagal Nerve Stimulation for Epilepsy and Depression	May 2020
52	Vitamin D Screening and Testing	November 2012
53	Whole Exome Sequencing	November 2019

Next steps:

Via this notice, prospective technology topics are posted on the HTA program webpage to gather public comment on the following:

- New topics proposed for review
- Topics selected for rereview
- Consideration of topics eligible for rereview on the basis of evidence available since the original determination

The agency recommendations and public comments will be presented to the HCA director for final selection. Selected topics are posted to the HTA program webpage.

Prioritization criteria:

HTA created a process and tools based on the legislative requirements and criteria that are widely used in technology assessment priority settings. Identification of criteria and use of priority tools makes the process explicit and increases transparency and consistency across decision-makers. The tools are intended to be used by agency liaisons when making recommendations and by the clinical committee when making comments or selections of technologies. The primary criteria are directly linked to the legislative mandates for the program to focus technology reviews where there are concerns about safety, efficacy, or cost effectiveness, especially relative to existing alternatives. See RCW 70.14.100. These criteria are also common to other technology assessment programs. The prioritization criteria tool is available on the website.

Rereview topic criteria:

Rereview criteria are directly linked to the legislative mandate that technologies shall be selected for rereview only where evidence has since become available that could change a previous determination. Technologies are considered for rereviews at least once every 18 months. Rereviews consider only evidence made available since the previous determination. See RCW 70.14.100. The rereview criterion is directed at identifying those situations where a technology requires a rereview to consider new evidence that was not available when the initial review was completed and the likelihood that the new evidence could result in a change to a previous determination.

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:	[redacted] Attention: Katherine E Kokko, MPH
E-mail address:	[redacted]
Telephone number:	[redacted]

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.

novocure®

[redacted]

Washington State Health Care Authority
Attention: Health Technology Clinical Committee
PO Box 42712
Olympia, WA 98504-2712

November 16, 2023

RE: Petition for Technology Review or Re-Review

To the Washington State Health Care Authority,

Enclosed please find Novocure, Inc.'s petition for re-review. In accordance with the petition instructions, we have provided a bibliography of new studies and evidence that demonstrates the efficacy, safety, and cost effectiveness of Tumor Treating Fields (TTFields) on glioblastoma. We have excluded any information that we know was taken into account in 2016 or 2018. **Most notably, since September 2019, CMS now covers Tumor Treatment Field Therapy for patients with newly-diagnosed GBM under Local Coverage Determination (LCD): Tumor Treatment Field Therapy (TTFT) (L34823).**

We encourage the Washington State HCA to join the broad community of commercial, U.S. Governmental, and foreign healthcare payers in covering this therapy. We understand that pursuant to RCS 70.14.110 (3), determinations of the committee *…" shall be consistent with decisions made under the federal Medicare program and in expert treatment guidelines, including those from specialty physician organizations and patient advocacy organizations."*

Washington State Healthcare Authority's non-coverage of Optune creates an inequity of care for its beneficiaries. Those beneficiaries would have coverage for this potentially life-extending therapy if they had were enrolled in Medicare, Tricare, VA or Commercial insurance. Washington State law also requires School and Public Employee Benefit Board plans to refuse Optune to beneficiaries, even when it is a covered benefit under the published policy of carriers, such as Kaiser Permanente, Regence and Premera. This government policy excludes employer-based beneficiaries from receiving Optune and creates an additional barrier for members of those employer groups.

patientforward

New Evidence

Studies

The Health Technology Clinical Committee's (HTCC's) October 17, 2018 "Final Evidence Report" reviewed information on the use of TTFields from 2014 through 2018. Novocure is therefore including all previously un-reviewed relevant studies (GBM only) from 2018 to the present in this "Petition for Re-Review".

Most notable is Ballo et al's systemic review and meta-analysis of TTFields in newly diagnosed glioblastoma, published in the 2023 Journal of Neurooncology. Ballo et al conducted a meta-analysis of 7 comparative studies (N=1430) that evaluated overall survival with Optune + TMZ vs TMZ alone. They concluded that Optune + TMZ provided a long-term survival benefit that increased with more time on treatment, corroborating the results of the EF-14 trial. The analysis showed an increase in median OS of ~5 months with Optune + TMZ in the real-world setting, which was comparable to the 4.9-month data point from the EF-14 trial.

Clinical Guidelines

In addition to being approved by Medicare, since 2018, Optune has been recommended by the National Comprehensive Care Network (NCCN) as a category 1 treatment option for patients with newly diagnosed glioblastoma, (when used together with temozolomide). In March 2023, the NCCN strengthened the Optune recommendation by changing the recommendation from a treatment option to a preferred treatment for certain patients as described below.

Clinical guidelines from other countries should not be used to determine the appropriateness of therapy for the American population, especially by State and Federal programs. The applicable standard of care varies by market and the US Healthcare market is markedly different from the rest of the world.

However, since 2018, the following international clinical guidelines have changed to include Tumor Treating Fields:

- Association des Neuro-oncologues d'Expression Française
- German Society for Hematology and Medical Oncology
- German Society for Neurology
- Regional Cancer Centers in Collaboration (Sweden)
- Spanish Group of Neuro-oncology (GEINO)

Coverage Policies

The following payers, who were used as the basis of comparison in the 2015 and 2018 WSHCA HTCC evaluations, had the following status(es) at the time of each review. **CMS and Oregon Health now cover Optune for newly diagnosed GBM (nGBM).**

	Previous HTCC Review Status	***nGBM Coverage added since 2018***
Aetna*^	X	
CMS*^		X
Oregon Health*		X
Regence*^	X	
Premera^	X	
United^	X	
Humana^	X	
Kaiser^	X	
Cigna^	X	

* = 2016 Review

^ = 2018 Review

In addition, since 2018, these payers with Washington state enrollees have added coverage of Optune to their policies:

- Providence
- Centene

Most notably, TTFields are now covered by Tricare, VA and a Medicare LCD for use in patients with newly diagnosed glioblastoma. The LCD can be found at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34823

Finally, although international guidelines should not be used to determine clinical standards for the US population, Optune has approval and national reimbursement in the following countries:

Austria
France
Germany
Israel
Japan
Switzerland
Sweden

WA State Demand for Optune
Novocure also reviewed WA State claims for the following for 2019-2022. We found that for the following payer types, Novocure has provided millions of dollars in financial assistance and write-offs for WA state residents who were not covered by the following programs due specifically to HCA's negative coverage policy:

- Public/School Employees Benefit Board Plans (Uniform Medical Plan);
- Medicaid Fee-for-Service (FFS)
- Managed Care (MCO) programs

Public and School employees of Washington State are the only employee groups in the country that have TTFields as an exemption to their published policy. Even within these employee groups, there is an inequity. PEBB/SEBB Medicare Advantage plans cover Optune under the existing LCD. This leaves active public and school employees without coverage that retirees are presumably able to access.

Novocure has historically covered these patients in good faith, while we work through this process with the HTCC. While this is not a sustainable business model, Novocure's patient forward mission places the best interest of Washington State GBM patients first.

Weaknesses in the Prior HTCC Evaluations

Reliance on Multiple RCTs
Optune was approved by the Food & Drug Administration based upon the largest randomized controlled trial in newly diagnosed glioblastoma ever conducted. The results of the trial were published in a top-tier journal (*JAMA*) and the therapy has

been adopted in the NCCN Guidelines as a treatment for newly diagnosed (category 1) and recurrent glioblastoma (category 2B). In fact, since March of this year, NCCN CNS Guidelines GLIO-9 includes alternating electric field therapy (Optune) as a *preferred,* category 1 treatment option for patients <70 with KPS>60.

While we recognize that the Health Technology Clinical Committee (HTCC) weights the strength of evidence largely on the number and variety of Randomized Clinical Trials (RCTs), multiple large scale RCTs in rare diseases like Glioblastoma are simply not feasible. The rarity of the disease also makes getting a statistically significant sample that determines whether the clinical effectiveness or safety of TTFields varies by clinical history or patient characteristics impossible.

As a point of comparison, temozolomide is a covered medication under the HCA's preferred drug list (PDL). The efficacy of TEMODAR (generic = temozolomide) was evaluated in MK-7365-051 (NCT00006353), a single randomized (1:1), multicenter, open-label phase 3 trial of 573 patients with newly diagnosed glioblastoma.

This appears to have been sufficient evidence for Washington State's HCA to support coverage. However, despite there being conclusory evidence from a larger, open-label Phase 3 trial (n=695) in the same population, Washington State's HCA declined to cover Optune as it was not found to have sufficient supporting evidence under the HTCC evaluation process.

Indeed, the entire US marketplace, with the exception of Washington State, has determined that the results of the pivotal EF-14 trial and existing evidence provide a sufficient basis upon which to establish a coverage determination. No other payer in the US, including Medicare, has requested additional clinical trials. Blinded randomized controlled trials are the gold standard design for drug trials but are rare among medical device trials. This is because they are generally difficult to blind. And those countries that have done a full, independent health technology assessment (rather than a review of existing literature as done by Washington State) have deemed Optune to be worthy of coverage, including France, Germany and Switzerland.

While we embrace the assurance that multiple RCTs can provide, we feel that the HTCC should put that reliance into context for what is appropriate when it comes to research involving rare diseases.

Overall HTA Evaluation Process Issues
After further global experience with other HTAs, Novocure wishes to point out the following issues with Washington State's HTA evaluation process:

1. As an anti-mitotic therapy, Optune's mechanism of action and benefit is more similar to a pharmacological intervention than most medical devices. Washington's Pharmacy & Therapeutics Committee "evaluates available evidence regarding the relative safety, efficacy and effectiveness of prescription drugs in a class." "Recommendations by the P&T Committee will be solely based on available evidence, not on cost considerations. The cost analysis will be performed after the meeting and does not include the P&T Committee."[1]

   However, per RCW 70.14.100, the HTCC considers cost effectiveness as a determining factor for coverage devices. This creates a significant inconsistency between the evaluation of pharmacological therapies and therapies using alternative delivery methods like a medical device.

   Also, while the HTCC emphasizes cost effectiveness analysis as a key area of evaluation for technologies, Federal policy under Medicare does not allow for cost effectiveness analysis, which essentially sets a threshold value for each year of an individual's life. There is additional discussion at the Federal level about potentially banning the use of QALYs from all Federal programs.

   Only Washington State has cited that beneficiaries have their care determined, in part, by the estimated economic value of life gained, as determined by an arbitrarily set threshold in a single, foreign study (See Bernard-Arnoux (2016) and comments below).

2. While the bulk of the October 17, 2018 "Final Evidence Report" centers around clinical evidence of efficacy, Novocure was in attendance at the HTCC's panel discussion on November 16, 2018. That discussion, which is captured in the transcript of the HTCC meeting, centered largely around QALYs and economic questions which were discussed in broad terms and without specific supporting evidence. None of the related discussion points or assumptions made had been put forth to the public previously, nor was it part of the public hearing dialogue.

[1] https://www.hca.wa.gov/about-hca/programs-and-initiatives/prescription-drug-program/related-laws-and-rules

Consistent with public hearing guidelines, Novocure was not permitted to respond to inaccurate misinformation that circulated during that discussion and upon which the final determination of the committee was based that day. This determination was made despite a 2018 recommendation to ”cover with conditions” by the Medical Director of the HCA.

3. Furthermore, despite Novocure’s request that the public hearing be rescheduled to avoid conflicting with the largest national gathering of the neuro-oncology community, this public hearing was held at the same time as the annual meeting of the Society for NeuroOncology (SNO), the preeminent neuro-oncology medical conference, resulting in the absence of many experts in the field. The notable exception was the expert chosen to inform the HTCC, Dr. Jason Rockhill of the University of Washington. Advocates, patients and others who might have been in attendance were likewise committed to participation at the same annual meeting.

Cost Effectiveness Evaluation

One significant factor in Washington State’s determination of non-coverage was its evaluation of cost effectiveness. Novocure wishes to point out the following issues with Washington State’s cost effectiveness criteria and evaluation of Optune:

1. Novocure’s worldwide experience is that when an HTA is conducted in other markets, the evaluation team either accepts and uses the cost-effectiveness model provided by the manufacturer or provides its own standard for economic assessment. **Washington State does neither.** Instead, per the HTCC’s 2018 response to public comment, the WA State HTCC has relied on one pre-existing economic evaluation from the existing literature, which is based on a foreign standard of care with an arbitrary cost threshold, while acknowledging “…no CEA has been conducted in US populations, using US costs”.

2. The economic evaluation relied upon by the HTCC was *“The cost-effectiveness of tumor-treating fields therapy in patients with newly diagnosed glioblastoma,”* written by Bernard-Arnoux (2016). The evaluation conducted by Bernard-Arnoux et al used *interim* EF-14 data for the survival analysis, which may not capture the full extent of the intervention's effect on survival since the data at a specific point in time may not adequately represent the long-term outcomes. Relying on such incomplete information can lead to biased estimates of life-years gained (LYg).

3. The October 17th 2018 *"Peer review and public comment on draft evidence report"* discards the Novocure-provided 2018 study by Guzaukas, claiming that it is not a true cost-effectiveness analysis (CEA). Please see Guzaukas, 2019, in our attached bibliography which is a cost-effectiveness analysis defined as including "outcomes related to cost or cost effectiveness." This CEA was conducted for the US population. In his article, the author evaluates the costs of both EF-14 arms, and concludes that the ICER of TMZ vs. TTFields+TMZ for the treatment of Newly diagnosed GBM is of 188,637 USD.

The HTCC's response to public comments regarding the 2018 Guzauskas study point out that the ICER is "approximately $198,033 USD…per QALY gained" and further states that "it is still above a threshold that most would not consider cost-effective". However, neither the US, nor the EU has any official threshold for lifetime values. The 100,000 euro willingness-to-pay threshold used in the Bernard-Arnoux analysis was admittedly "arbitrarily chosen" by the authors and has no application to any real world scenario. The French health care system does cover Optune, negating the argument that a higher ICER was not considered cost effective in that market.

We hope that the above information, and that included in our packet, demonstrate the significant progress that Tumor Treating Fields have made for patients with GBM and that the HTCC will add Optune to its list of technologies for "re-review" as soon as possible.

Best Regards,

[redacted]

~Katherine E. Kokko, MPH
Senior Manager, Market Access

novocure®

[redacted]

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

patientforward

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
House of
Representatives

January 23, 2024

Ms. Charissa Fotinos
Medicaid Director
Washington State Health Care Authority
626 8th Avenue SE
Olympia, WA 98501

Dear Ms. Fotinos

We are writing to encourage coverage by the Washington State Healthcare Authority (HCA) of an innovative, FDA-approved and NCCN-recommended device that treats a rare form of aggressive cancer using Tumor Treating Field (TTFields) technology. TTFields utilize alternating electric fields to slow or stop dividing cancer cells without significantly affecting healthy cells. TTFields are FDA-approved to treat an aggressive form of brain cancer called Glioblastoma (GBM).

It has shown promise in extending the lives of those facing what is typically a terminal form of cancer with an average survivor timeline of 12 to 18 months. Although GBM is a rare form of cancer, around 13,000 Americans will receive a GBM diagnosis this year. These patients deserve access to any treatment that may extend their life.

Currently, a significant disparity exists in who has access to the TTFields technology in Washington State. WA State GBM patients who have Commercial, Medicare, TRICARE or VA coverage can access TTFields as an NCCN-recommended treatment; however, the Washington State HCA's denial of coverage for TTFields prevents Washington Medicaid patients, public and school employees, and some clinical trial patients, from accessing this innovative therapy.

The HCA policy negatively impacts the state's Medicaid population and tens of thousands of public and school employees. This includes individuals working in local and state government, higher education, and judicial agencies. TTFields are a safe and effective form of treatment and expanding access should be of the utmost importance to Washington State decision-makers.

We respectfully request the addition of TTFields to the covered treatments available to Washington State HCA beneficiaries.

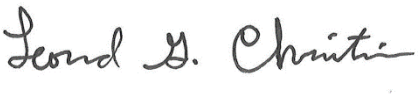
Sincerely,

Amy Walen
State Representative
48th Legislative District

Marcus Riccelli
State Representative
3rd Legislative District

Lisa Callan
State Representative
5th Legislative District

Suzanne Schmidt
State Representative
4th Legislative District



Leonard Christian
State Representative
4th Legislative District

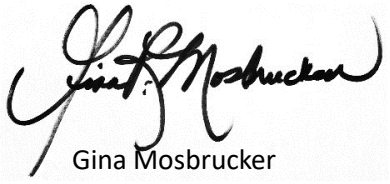
Stephanie Barnard
State Representative
8th Legislative District

Clyde Shavers
State Representative
10th Legislative District

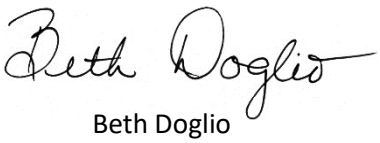
Dave Paul
State Representative
10th Legislative District

Tom Dent
State Representative
13th Legislative District

Stephanie McClintock
State Representative
18th Legislative District



Gina Mosbrucker
State Representative
14th Legislative District

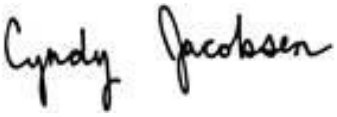


Beth Doglio
State Representative
22nd Legislative District

Jessica Bateman
State Representative
22nd Legislative District

Tarra Simmons
State Representative
23rd Legislative District

Greg Nance
State Representative
23rd Legislative District



Cyndy Jacobson
State Representative
25th Legislative District

Michelle Caldier
State Representative
26th Legislative District

Mari Leavitt
State Representative
28th Legislative District

Dan Bronoske
State Representative
28th Legislative District

Kristine Reeves
State Representative
30th Legislative District

Eric Robertson
State Representative
31st Legislative District

Cindy Ryu
State Representative
32nd Legislative District

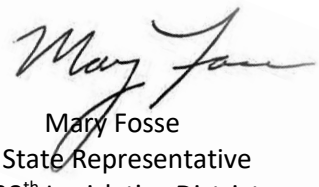
Lauren Davis
State Representative
32nd Legislative District

Tina Orwall
State Representative
33rd Legislative District

Liz Berry
State Representative
36th Legislative District

Sharon Tomiko Santos
State Representative
37th Legislative District

Julio Cortes
State Representative
38th Legislative District



Mary Fosse
State Representative
38th Legislative District

Carolyn Eslick
State Representative
39th Legislative District

Tana Senn
State Representative
41st Legislative District

My-Linh Thai
State Representative
41st Legislative District

Alicia Rule
State Representative
42nd Legislative District

Nicole Macri
State Representative
43rd Legislative District

Brandy Donaghy
State Representative
44th Legislative District

April Berg
State Representative
44th Legislative District

Larry Springer
State Representative
45th Legislative District

Chris Stearns
State Representative
47th Legislative District

Vandana Slatter
State Representative
48th Legislative District

Sharon Wylie
State Representative
49th Legislative District

Monica Jurado Stonier
State Representative
49th Legislative District