Healthcare Improvement Scotland | SHTG Advice on health technologies

Innovative Medical Technology Overview | September 2025

Optune Gio® tumour treating fields (TTFields) therapy for newly diagnosed glioblastoma, IDH-wildtype

Key messages

- Optune Gio® is a portable, non-invasive device designed to treat glioblastoma, IDH-wildtype*. Optune Gio® generates alternating electrical fields, known as tumour treating fields (TTFields), which are delivered through electrodes (called transducer arrays) attached to the scalp. TTFields work by disrupting cancer cell division and growth. The device received a Conforme Européenne (CE) mark in 2009.
- In 2024, health technology assessments (HTAs) from Canada[1] and Switzerland[2] concluded that TTFields plus temozolomide (TMZ) may be efficacious in terms of survival, based on evidence from the 2017 EF-14 randomised controlled trial (RCT). The RCT showed that in people with newly diagnosed glioblastoma, TTFields plus TMZ significantly improved median overall survival (20.9 versus 16 months) and progression-free survival (6.7 versus 4.0 months) compared with TMZ alone).
- The EF-14 RCT reported no statistically significant difference in the number of severe adverse events between patients treated with TTFields plus TMZ compared with those treated with TMZ alone.
- Both HTAs reported that TTFields generated health gains but at a higher cost, concluding that it is unlikely that TTFields would be cost effective at current willingness-to-pay thresholds. Guidance published by the National Institute for Health and Care Excellence (NICE) in 2018 recommended against offering treatment with TTFields for newly diagnosed glioblastomas, on the basis that the treatment was not cost effective.[3]
- Treatment with the Optune Gio® device means committing to regular head shaving and wearing the device for extended periods of time (at least 18 hours a day). Acceptance of these lifestyle changes will be influenced by a person's values, motivation and support networks. Optune Gio® is normally administered at a patient's home, meaning that living in a remote area does not necessarily pose a barrier to access.

* IDH stands for **isocitrate dehydrogenase,** an enzyme involved in cellular metabolism; mutations in the IDH gene can affect cancer prognosis.

Definitions

Conforme Européenne (CE) mark: A certification mark indicating conformity with health, safety and environmental protection standards for products sold within the European Economic Area.

Isocitrate dehydrogenase (IDH): An enzyme involved in cellular metabolism; mutations in the IDH gene can affect cancer prognosis.

Incremental cost-effectiveness ratio (ICER): A statistic used in cost-effectiveness analysis to compare the relative costs and outcomes of different interventions.

Karnofsky Performance Scale (KPS): A tool to assess a patient's overall functional status.

O^6-methylguanine-DNA methyltransferase (MGMT): An enzyme involved in DNA repair; its status can influence the effectiveness of chemotherapy in glioblastoma.

Quality-adjusted life years (QALYs): A measure of the value of health outcomes, combining quantity and quality of life.

Tumour treating fields (TTFields): Alternating electrical fields used to disrupt cancer cell division and growth.

Temozolomide (TMZ): A chemotherapy drug used to treat glioblastoma.

The technology and its use

Optune Gio® is a novel, portable and non-invasive device designed to prolong survival and slow disease progression in individuals with glioblastoma, IDH-wildtype.[4] It is indicated for treating glioblastoma, IDH-wildtype, the most common type of brain cancer. Optune Gio® is not curative and is typically used in addition to other therapies like radiotherapy and chemotherapy.[1]

The manufacturer states that Optune Gio® is reimbursed in France, Austria, Germany, Israel, Japan, Sweden, Switzerland and the United States.[5] It is only available to patients in NHSScotland in the context of research.

What is innovative about the technology?

Optune Gio® generates alternating electrical fields, known as TTFields, which are delivered through electrodes called transducer arrays attached to a person's shaved scalp. The electrodes emit low-intensity electrical fields directly to the tumour site. TTFields achieve their anticancer effects primarily by disrupting cancer cell division and growth. Patients are advised to wear the device for at least 18 hours per day.[6]

Regulatory information

Optune Gio® TTFields therapy received United States Food and Drug Administration (FDA) approval in 2011 for the treatment of recurrent glioblastoma multiforme (now called glioblastoma, IDH-wildtype) and in 2015 for newly diagnosed glioblastoma multiforme. It received a CE mark in 2009 and EU Medical Device Regulation (MDR) certification in November 2022.

Population, setting and intended user

Optune Gio® is intended for the treatment of adult patients (18 years of age or older) with newly diagnosed World Health Organisation (WHO) grade 4 glioma, following maximal debulking surgery or biopsy, radiation therapy and/or chemotherapy, concomitant with maintenance TMZ with or without Lomustine, and after systemic therapy is stopped (information provided by manufacturer). This IMTO specifically addresses the use of Optune Gio® for individuals with newly diagnosed glioblastomas, excluding those with recurrent glioblastomas.

WHO updated the classification system for brain tumours in 2021. Glioblastoma, IDH-wildtype, was previously known as glioblastoma multiforme. IDH stands for isocitrate dehydrogenase, an enzyme involved in cellular metabolism. Glioblastomas are classified based on the status of the IDH gene: those with normal IDH genes (IDH-wildtype) and those with mutated IDH genes.[7] In this IMTO, we have preserved the terminology used in the reviews and studies we have reported on, and have assumed that glioblastoma multiforme and glioblastoma, IDH-wildtype, refer to the same patient group.

'Brain, other central nervous system and intracranial tumours' is the ninth most common cancer in the UK, accounting for 3% of all new cancer cases (according to figures from 2016 to 2018).[8] In Scotland (2016 to 2018) the average number of cases per year was 563.[8] Glioblastomas are a fast-growing type of brain tumour.[7] They are the most common type of cancerous (malignant) brain tumour in adults. Around 32 out of every 100 primary brain tumours diagnosed in England between 1995 and 2017 were glioblastomas (patients classified using the older WHO classification system).[7]

Equality considerations

Optune Gio® is normally administered at a patient's home, meaning that living in a remote area does not necessarily pose a barrier to access. Support and training on using the device, from appropriately trained professionals, is required.

Patients may find it difficult to manage the technical aspects of the device or may have physical limitations that make it challenging to use without assistance. Patients may need ongoing help from a relative or caregiver to attach the transducer arrays to their scalp.

Users of the Optune Gio® device need to shave their scalp every 3 to 4 days to attach the transducer arrays, which could be particularly distressing and challenging for some people, such as those who avoid cutting their hair for religious reasons.

Optune Gio® cannot be used by some people, including those who are pregnant or trying to become pregnant, those with implanted medical devices (for example, a programmable shunt), or those with a skull irregularity (for example, missing bone with no replacement).

Summary of clinical evidence

Clinical guidelines

Guidance published by NICE in 2018 recommended that TTFields are not offered as part of the management of patients with a newly diagnosed grade IV glioma (glioblastoma).[3]

The manufacturer highlights that Optune Gio® is included in clinical guidelines across multiple health systems. In France, the US, and Spain, guidelines recommend its use based on clinical evidence and expert consensus.[9-11]

Health technology assessments

In 2024, two high-quality HTAs were published: one from Canada[1] and one from Switzerland.[2] The Canadian HTA was based largely on evidence (including an economic model) submitted by the manufacturer, which was thoroughly appraised and validated by the HTA team. The Swiss HTA was based on an independent review of the clinical- and cost-effectiveness evidence. Both HTAs were well reported and, using different methodologies, made logical conclusions based on the available evidence. These HTAs have been used as the main sources of evidence for this IMTO.

Both HTAs included an RCT that evaluated the use of TTFields in people with newly diagnosed glioblastoma multiforme, the EF-14 trial (*Table 1*). The Swiss HTA also included two retrospective cohort studies (*Table 1*). Both HTAs drew almost identical conclusions, stating that there was evidence of low to moderate certainty that in people with newly diagnosed glioblastoma multiforme, treatment with TTFields plus maintenance chemotherapy with TMZ compared with TMZ alone is probably efficacious in terms of survival, may result in little or no difference in severe adverse events, and may have little or no effect on health-related quality of life (HRQoL) except for itchy skin.

The multicentre, phase 3, EF-14 RCT (Stupp *et al*, 2017, n=695) evaluated the efficacy and safety of TTFields in adults with newly diagnosed glioblastoma multiforme following maximal debulking surgery and completion of radiation therapy, together with and after standard-of-care (SOC) maintenance chemotherapy. Patients were randomised 2:1 to TTFields (≥18 hours/day) plus maintenance TMZ or TMZ alone. The trial authors reported that TTFields plus TMZ significantly improved median overall survival (20.9 versus 16 months), and median progression-free survival (6.7 versus 4.0 months) compared with TMZ alone. The hazard ratio

for overall survival was 0.63 (95% confidence interval [CI]: 0.53 to 0.76; *p*<0.001), and for progression-free survival, the hazard ratio was 0.63 (95% CI: 0.52 to 0.76; p<0.001). In the first 3 months, 75% of patients used TTFields for at least 75% of the time. Only two patients (0.4%) in the TTFields plus TMZ group and none in the TMZ group dropped out from the trial.

The HTAs reported on a secondary analysis of the EF-14 trial, published by Taphoorn *et al* (2018), which assessed HRQoL in patients who completed at least one HRQoL scale at baseline. HRQoL was comparable between experimental and control groups, with only itchy skin being significantly worse in the TTFields plus TMZ group compared with TMZ alone.

Both the Canadian and Swiss HTA authors noted concerns about bias in the EF-14 trial. The median time from diagnosis to randomisation was 3.8 months, and 82 patients (8%) were excluded because of progressive disease, potentially causing selection bias and possible overestimation of efficacy findings. Without a placebo control, participants, carers and intervention providers were not blinded. However, overall survival was assessed by an independent neuroradiologist blinded to treatment allocation, reducing outcome measurement bias.

The Swiss HTA also included two retrospective cohort studies (*Table 1*). The first study (Liu *et al*, 2020; n=104) from the USA found no significant difference in overall survival between people treated with TTFields plus TMZ and those treated with TMZ alone (HR for death 0.93, p=0.741; very low certainty evidence). The second study (Chen *et al*, 2022; n=134) from China reported significantly longer overall and progression-free survival in people treated with TTFields plus TMZ, compared with those treated with TMZ alone (HR for death 0.19, p<0.001; HR for progression 0.35, p=0.031; low certainty evidence).

Systematic review

A systematic review with meta-analyses, published in 2023, mirrors the clinical effectiveness findings from the HTAs.[12] The review included seven studies (n=1,430) that compared the impact of TTFields therapy plus SOC chemoradiotherapy on overall survival, compared with SOC. Three of these studies (n=1,066) were included in the Canadian and Swiss HTAs. The remaining four studies were identified by the Swiss HTA but were not eligible for inclusion in the clinical effectiveness results (either they did not meet the inclusion criteria, or there were issues that warranted their exclusion). For this reason, they have not been summarised in *Table 1.* The meta-analysis found a significant improvement in overall survival for patients receiving TTFields plus SOC versus SOC alone (HR 0.63, 95% CI 0.53 to 0.75, p<0.001).

Primary study

One additional primary study, published after the HTAs, was identified.[13] This study assessed survival outcomes, disease progression and treatment patterns in patients with newly diagnosed glioblastoma, treated with or without TTFields in a real-world setting. The study included 208 patients who received standard-of-care therapy at a single centre (USA) between March 2015 and March 2023. Patients were grouped based on whether they received TTFields during maintenance therapy (TTFields: n=109; No TTFields: n=99).

The findings were consistent with those of the EF-14 trial, showing statistically significant improved survival outcomes in the TTFields group compared to the non-TTFields group (median overall survival: 21.7 versus 17.7 months, *p*=0.029; median progression-free survival: 12.4 versus 9.6 months, *p*=0.047).

Ongoing clinical trials

There are ongoing studies which will further develop the evidence base surrounding Optune Gio®. These studies explore, for example, the optimal positioning of TTFields within the treatment pathway, as well as the potential benefits of combining TTFields with other chemotherapy agents or immunotherapy compared to the current standard of care.

- NovoCure Ltd. Phase 3 Study of Optune Concomitant With Temozolomide Plus Pembrolizumab in Newly Diagnosed Glioblastoma (EF-41). Estimated completion date: 2029.
- Stanford University. Study of Tumor Treating Fields With Hypofractionated Chemoradiotherapy in Newly Diagnosed Glioblastoma. Estimated completion date: November 2025
- NovoCure Ltd. Pivotal, Randomized, Open-label Study of Optune® (Tumor Treating Fields) Concomitant with RT & TMZ for the Treatment of Newly Diagnosed GBM (EF-32). Estimated completion date: 2026
- Sidney Kimmel Cancer Center at Thomas Jefferson University. Temozolomide, Radiation Therapy, and Tumor Treating Fields Therapy in Treating Participants With Glioblastoma. Estimated completion date: was due in 2024

Table 1: Studies evaluating TTFields: Detail taken from Swiss and Canadian HTAs[1, 2] and Ballo et al.[12]

Reference	Study Design	Study Population	Results
Stupp *et al* (2017) EF-14	RCT (multicentre, 12 countries) Patients enrolled between July 2009 and December 2014 Median follow up: 40 months Funding: Novocure Ltd.	Patients aged ≥18 years with newly diagnosed glioblastoma multiforme **Intervention**: TTFields plus TMZ (n=466) median age (range): 56 (19 to 83) years 68% male median Karnofsky Performance Scale (KPS) score (range): 90% (60% to 100%) MGMT status methylated: 36% median time from diagnosis to randomisation: 3.8 months **Comparison**: TMZ (n=229) median age (range): 57 (19 to 80) years 69% male median KPS (range): 90% (70% to 100%) MGMT status methylated: 42% median time from diagnosis to randomisation: 3.7 months	**Overall survival** Median (months; 95% CI) TTFields + TMZ: 20.9 (19.3 to 22.7) months TMZ: 16 (14.0 to 18.4) months Hazard ratio (95% CI): 0.63 (0.53 to 0.76, p<0.001) At 6 months, the TTFields group had a 5.5% higher overall survival rate (92.8% versus 87.3%, p=0.015). At 24 months, 12.5% more patients in the TTFields group were alive compared with the TMZ group (43.1% versus 30.7%, p=0.001) **Progression-free survival** Median (months; 95% CI) TTFields + TMZ: 6.7 (6.1 to 8.1) months TMZ: 4 (3.8 to 4.4) months Hazard ratio (95% CI): 0.63 (0.52 to 0.76, p<0.001) At 6 months, 19.1% more patients in the TTFields group were progression free (55.6% versus 36.5%, p<0.001). At 24 months, there was no significant difference in progression-free survival (14.2% versus 9.5%, p=0.064). **Adverse events:** No statistically significant difference in grade 3-4 severe adverse events (RR 1.09 [95% CI 0.91 to 1.30], p=0.58)
Taphoorn *et al* (2018)	as above – secondary analysis of EF-14	as above At 12 months of follow up HRQoL was reported for 139 of the 437 patients (32%) in the TTFields	At 12 months, no statistically significant or clinically relevant differences were found for the HRQoL domains global health scale, cognitive, emotional, physical, role and social functioning, and for the symptom scales pain and weakness of legs.

Reference	Study Design	Study Population	Results
		plus TMZ arm and for 58 of the 202 patients (29%) in the TMZ arm.	
Liu *et al* (2020)	Retrospective cohort study; single centre (United States of America) Patients enrolled between January 2014 and July 2017 Funding not reported	Patients aged ≥18 years with newly diagnosed glioblastoma multiforme **Intervention**: TTFields plus TMZ (n=37) median age (range): 61 (28 to 81) years 62% male median KPS (range): 90% (70% to 100%) MGMT status methylated: 16% **Comparison**: TMZ (n=67) median age (range): 65 (28 to 83) years 57% male median KPS (range): 90% (50% to 100%) MGMT status methylated: 36%	**Overall survival HR (95% CI)** 0.93 (0.58 to 1.47), p=0.741
Chen *et al* (2022)	Retrospective cohort study; single centre (China) Funding from National Natural Science Foundation of China	Patients aged ≥18 years with newly diagnosed glioblastoma multiforme **Intervention**: TTFields plus TMZ (n=47) mean age (standard deviation): 49.4 (13.3) years 45% male mean KPS (standard deviation): 81.8% (11.9%) MGMT status methylated: 24% **Comparison**: TMZ (n=87) mean age (standard deviation): 49.3 (14.6) years 52% male	**Overall survival HR (95% CI)** 0.19 (0.09 to 0.41), p<0.001 **Progression-free survival HR (95% CI)** 0.35 (0.14 to 0.91), p=0.031

Reference	Study Design	Study Population	Results
		mean KPS (standard deviation): 82.2% (15.2%) MGMT status methylated: 37%	
Riegel *et al* (2025)	Retrospective cohort study; single centre (USA) Included consecutive patients treated between March 2015 and March 2023 Not industry funded, but some authors are employees of Novocure Ltd.	Patients aged ≥18 years with newly diagnosed glioblastoma multiforme **Intervention**: Standard of care with concurrent radiotherapy with TMZ followed by maintenance TMZ and TTFields (n=109) mean age (range): 60 (17 to 86) years 57% male **Comparison:** Standard of care with concurrent radiotherapy with TMZ followed by maintenance TMZ (n=99) mean age (range): 64 (28 to 88) years 57% male	**Overall survival** Median (months; 95% CI) TTFields + TMZ: 21.7 (18.7 to 24.8) TMZ: 17.7 (14.6 to 20.6) p=0.029 **Progression-free survival** Median (months; 95% CI) TTFields + TMZ: 12.4 (10.5 to 14.4) TMZ: 9.6 (8.5 to 12.8) p=0.047 The rate of non-local progression was significantly higher for the TTFields group compared with the non-TTFields group (28% versus 14%, p=0.028)
Acronyms: KPS – Karnofsky Performance Scale (a tool used to assess overall functional status); MGMT – O^6-methylguanine-DNA methyltransferase (in glioblastoma, the MGMT gene status can help to determine how effective chemotherapy will be); TMZ – temozolomide (chemotherapy for glioblastoma).			

Summary of safety evidence

According to the manufacturer's website, the most common side effects of Optune Gio® when used together with chemotherapy (TMZ) were low blood platelet count, nausea, constipation, vomiting, tiredness, scalp irritation from the device, headache, seizure and depression. The most common device-related side effects when using Optune Gio® were scalp irritation (redness and itchiness) and headache. Other less common side effects were malaise, muscle twitching, falls and skin ulcers.[4]

A study performed and funded by the manufacturer compiled safety data from routine post-marketing activities for over 25,000 patients across North America, Europe, Israel and Japan (October 2011 to October 2022). The authors stated that 'safety data were collected from routine post-marketing activities and interactions between the device manufacturer, patients, caregivers, and healthcare professionals.' The study concluded that TTFields therapy was well-tolerated in patients with central nervous system (CNS) malignancies. Most therapy-related adverse events were manageable, localised and non-serious skin events. The safety profile of TTFields therapy remained consistent across various subgroups, including age, sex and diagnosis.[14]

The EF-14 trial reported no statistically significant difference in severe grade 3–4 adverse events in patients treated with TTFields plus TMZ, compared with TMZ alone (48% versus 44%, p=0.58).[1, 2]

Summary of economic evidence

Technology costs

The manufacturer advises that the monthly list price for Optune Gio® is £17,500. This cost covers the treatment, necessary hardware, consumables, accessories and technical support from Device Support Specialists (DSSs). Based on the EF-14 study's median treatment duration, patients typically underwent treatment for about 8.2 months. Patients using Optune Gio® are expected to have outpatient visits with their clinician once every 3 months, consistent with standard care protocols. The introduction of Optune Gio® treatment would not be expected to increase the frequency of outpatient visits or incur additional costs from special investigations.

It should be noted that the list price may differ from the actual price paid by the NHS. The manufacturer has stated a commitment to working in partnership with NHSScotland and health boards to agree an arrangement that supports patient access to Optune Gio®.

Published evidence

The Canadian HTA critically appraised a pharmacoeconomic model developed by the manufacturer.[1] The cost-utility model applied safety and efficacy outcomes from the EF-14 trial to illustrate the cost effectiveness of Optune Gio® plus TMZ compared with TMZ alone. The analysis was undertaken using a lifetime time horizon (30 years) from the public payer

perspective. A partitioned survival model (PSM), most commonly used in cost-effectiveness studies of oncology treatments, tracked a cohort of patients across three health states (progression-free, progressed disease and death).

The base case results of the model were that Optune Gio® plus TMZ generated an additional 0.37 quality-adjusted life years (QALYs) at an additional cost of CAN$336,902 (approximately £182,197) compared with TMZ alone. The resulting incremental cost-effectiveness ratio (ICER) was CAN$899,470 (approximately £481,025) per QALY gained.[1]

One of the key limitations of the model was the potential overestimation of efficacy. The treatment effect appeared to be contingent on the frequency and duration of Optune Gio® use. It is uncertain whether treatment adherence is lower in clinical practice compared with trial settings, and ongoing data collection on Optune Gio® will help determine the effectiveness of the treatment in real-world settings.

The Canadian HTA agency noted that Optune Gio® would not be a cost-effective intervention at the proposed price of CAN$27,000 (approximately £14,601) per month. A price reduction in the range of 91% to 97% would be needed for Optune Gio® to be considered cost effective at the local willingness-to-pay threshold of CAN$50K to CAN$100K per QALY.[1]

The Swiss HTA identified three economic evaluations of TTFields for patients with newly diagnosed glioblastoma. All three studies found that TTFields plus TMZ was more effective than TMZ alone, but at higher costs. Even though the studies largely used the same underlying data from the EF-14 trial, the three studies found different effect sizes, because of modelling choices.[2]

Two studies were based on the French healthcare payer perspective but used different model structures (PSM and a Markov model). Both concluded that TTFields were not cost effective at the local threshold. The third study was modelled from a US healthcare payer perspective and concluded that TTFields was cost effective at a threshold of $200,000 per QALY.

Diverging conclusions were mainly driven by different techniques and sources used to model survival. The US-based evaluation used two additional sources to extrapolate survival, but there was concern that their approach overestimated survival gains and underestimated costs, resulting in a lower ICER relative to the French evaluations.

The Swiss HTA agency also developed a PSM cost-effectiveness model using base case assumptions informed by studies identified in the review and applying local unit cost inputs. The model compared TTFields plus TMZ with TMZ alone over a 10-year time horizon. TTFields was associated with an incremental gain of 0.27 QALYs but at an additional cost of CHF151,392 (approximately £132,382). The ICER was CHF 555,465 (approximately £485,715) per QALY gained. The Swiss agency did not, however, conclude whether this ICER represented a cost-effective use of resources[2] (potentially because TTFields are currently reimbursed in Switzerland).

In 2017, the Swedish Dental and Pharmaceutical Benefits Agency (TLV) critically appraised a cost-effectiveness analysis submitted by the manufacturer to the agency.[15] The base case results of the model were that Optune Gio® plus TMZ generated an additional 0.95 QALYs at an additional cost of SEK1,699,830 (approximately £131,053) compared with TMZ alone. The resulting ICER was SEK 1,782,288 (approximately £137,410) per QALY gained.

The TLV had no objections to the structure of the model, acknowledged the maturity of data in the EF-14 trial and opined that the company's assumption of 5-year mortality being equal across both treatment arms was reasonable. TLV clinical experts did however question the validity of a 40-year time horizon and noted the absence of trial-based utility values.[15]

The TLV preferred to apply a 20-year time horizon and felt that the frequency of medical visits and MRI scans should be adjusted upwards to accurately reflect levels of local healthcare resource utilisation. As a result of generic competition, the price of TMZ was also significantly lower than that assumed by the company. Making these adjustments to the model resulted in an increased ICER of SEK 2,100,000 (approximately £161,905) per QALY gained.[15]

Patient and user experience

Both the Canadian and Swiss HTAs outlined the lifestyle adjustments required for Optune Gio® treatment, including patients wearing the device for at least 18 hours daily, regularly shaving their head, and applying the arrays to their scalp, often with caregiver assistance.[1, 2]

The acceptability of the Optune Gio® device to patients will likely depend on their personal values, motivation and their caregiver support network. While some individuals may view Optune Gio® as a source of hope and a chance to regain control over their condition, others might find it burdensome or perceive it as a constant reminder of their illness.[1, 2] The Canadian HTA also highlighted that palliative care services are often delayed beyond the optimal time for benefits, emphasising the importance of managing patient expectations and ensuring the timely provision of palliative care.[1]

Both HTAs referred to a retrospective study by Onken *et al* (2018) on the acceptance of treatment with the Optune Gio® device among patients with high-grade gliomas. Among 58 patients with high-grade glioblastoma multiforme, who were eligible for treatment with the Optune Gio® device, 36% accepted the offer and over 75% adhered to using the device for at least 18 hours per day. The primary reasons patients gave for declining the treatment included the need to shave their heads, the device's visibility, and its interference with daily and social life (50%), while 17% cited a lack of social or family support.[1, 2]

The Swiss HTA referred to another observational study (n=175) by Onken *et al* (2019). The study suggested that the most common challenges with the Optune Gio® device were the therapy duration (74% of patients), the device's size (66%) and its weight (70%). Sixty-six per cent of patients found changing and placing the transducer arrays difficult. Furthermore, 63% experienced difficulties with hobbies and work, 71% with personal care, and 64% with sexuality and relationships. Despite these challenges, around 70% of patients indicated they would use the device again if needed and would recommend it to others.[2]

The Canadian HTA included a submission from the Brain Tumour Foundation of Canada, which gathered information through online surveys and videoconference interviews conducted in 2023. The online surveys received responses from 339 participants (259 caregivers and 80 patients), and 10 interviews were conducted with people who had experience with Optune Gio® (six patients and four caregivers). Most of the participants (94%) were from Canada.[1]

Feedback from the 10 individuals with experience of using Optune Gio® (alongside TMZ) highlighted that Optune Gio® led to clear MRI results, increased survival rates and enabled patients to resume several daily activities. Overall, most of these individuals with experience of using Optune Gio® recommended making the treatment accessible to people living with glioblastoma multiforme.[1]

Conclusions

Optune Gio® is a non-invasive treatment aimed at slowing disease progression and extending survival in patients with newly diagnosed glioblastoma, IDH-wildtype.

The clinical evidence from the EF-14 RCT suggests that TTFields combined with TMZ can improve median overall survival (20.9 versus 16 months) and progression-free survival (6.7 versus 4 months) compared with TMZ alone in people with newly diagnosed glioblastoma. The therapy does not appear to cause a significant increase in severe adverse events. These results are encouraging, but recent HTAs rated this evidence to be of low to moderate certainty because of concerns about bias. For example, participants with more aggressive disease were excluded, which could possibly result in the survival benefits being overestimated.

There is substantial uncertainty regarding the cost effectiveness of Optune Gio®. The high list price of the technology has contributed to ICERs in excess of £100,000 per QALY across economic analyses. The manufacturer states that a number of countries (Austria, Germany, Israel, Japan, Sweden, Switzerland, the United States and France) have opted to reimburse Optune Gio® based on the existing evidence and costs.

Data from ongoing clinical trials are anticipated to help further inform the effectiveness, safety and cost effectiveness of the Optune Gio® device within treatment pathways.

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What is an IMTO?

An IMTO provides a high-level summary of health and care innovations. IMTOs include a description of the technology and its potential use in Scotland, and an overview of the evidence to help gauge the potential impact of the technology on people and health and care services.

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Appendix 1: Abbreviations

DSS	Device Support Specialist
EF-14	RCT that evaluated the efficacy and safety of TTFields in combination with TMZ for the treatment of newly diagnosed glioblastoma
HTA	health technology assessment
HRQoL	health-related quality of life
IMTO	Innovative Medical Technology Overview
KPS	Karnofsky Performance Scale
MGMT	O^6-methylguanine-DNA methyltransferase
RCT	randomised controlled trial
TMZ	Temozolomide
TTFields	tumour treating fields