BC Cancer Protocol Summary for Palliative Therapy of Glioblastoma using Tumour Treating Fields (OPTUNE GIO™)

Protocol Code	*UCNTTF*
Tumour Group	*Neuro-Oncology*
Contact Physician	*Dr. Rebecca Harrison*

ELIGIBILITY:
Patients must have:
- Newly diagnosed supratentorial grade 4 astrocytoma (IDH wildtype glioblastoma or IDH mutant grade 4 astrocytoma),
- Undergone maximal debulking surgery and radiation therapy concomitant with temozolomide,
- Treatment initiation after at least 4 weeks, but no more than 7 weeks, of chemoradiotherapy,
- Treatment ordered and supervised by a provider certified by Novocure Canada Inc.,
- Planned for adjuvant temozolomide therapy,
- BC Cancer Compassionate Access Program (CAP) approval prior to treatment initiation. Initial CAP approval is for 13 weeks. To continue treatment, apply to CAP for re-approval. Subsequent approval is valid until clinical disease deterioration (symptomatic progression).

Patients should have:
- KPS greater than or equal to 70,
- Adequate caregiver support system in place to support the use of Tumour Treating Fields (OPTUNE GIO™)

Note: Forward all referrals and healthcare provider inquiries to ProvincialTxCoordination@bccancer.bc.ca

EXCLUSIONS:
Patients must not have:
- Infratentorial tumour location
- Currently implanted programmable device
- Clinically significant arrhythmias

TESTS:
- No routine laboratory testing requirements

FOLLOW UP:
- Nursing symptom assessments as per concurrent adjuvant temozolomide protocol (monthly, in person when appropriate)
- Physician follow up assessments to align with concurrent adjuvant temozolomide protocol (at minimum every 8 weeks for 6 months then every 3 months)
- Positioning, logistics and troubleshooting are handled by the manufacturer support team

TREATMENT:

- Tumour Treating Fields (TTF) OPTUNE GIO™ 200 kHz for at least 18 hours daily, starting during the adjuvant temozolomide treatment phase
- Continue treatment until clinical disease deterioration, unacceptable device-related toxicity, or 24 months of treatment, whichever occurs first
- See OPTUNE GIO™ Instructions for Use and Patient Information and Operation Manual

DOSE MODIFICATIONS:

- No specific dose modifications
- Management of TTF-associated skin reactions may include antiperspirants, antibiotics, skin barrier films, moisturizers, and topical steroids
- Treatment interruption may be required for intolerable Grade 2 or worsening Grade 3 dermatologic adverse effects. Consider referral to dermatology in patients with challenging skin conditions.

PRECAUTIONS:

1. **Skin Adverse Reactions:** TTF is associated with localized skin toxicity, including mild to moderate skin irritation, contact dermatitis, hyperhidrosis, pruritus, skin erosions/ulcers and infections. Severe Grade 3 skin toxicity has been reported in 2% of patients.
2. **Petroleum-based ointments** are not recommended for use with TTF due to the effect on electrical impedance. Water-based formulations are preferred.
3. Significant systemic adverse events are not associated with Tumour Treating Fields (OPTUNE GIO™).

Call Dr. Rebecca Harrison or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

OPTUNE GIO™ Patient Support Program for questions, troubleshooting, and supplies.
1-866-320-2006 (24/7, toll-free) or supportcanada@novacure.com

References:

1. Stupp, R., et al., Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma: A Randomized Clinical Trial. JAMA, 2017. 318(23): p. 2306-2316.
2. Optune (NovoTTF-200A) CADTH Health.Technology Review Recommendation.Canadian Journal of Health Technologies. March 2024; 4(3): 1-18.
3. Lacouture ME at al. Prevention and Management of Dermatologic Adverse Events Associated With Tumor Treating Fields in Patients With Glioblastoma. Front. Oncol. 2020;10:1045.