Washington State Health Care Authority

FINAL Key Questions and Background

Tumor treating fields

Background

In 2018, an estimated 1,735,350 new cancer cases and 609,640 cancer deaths will occur in the United States.[1] Cancer is typically treated by surgery, radiation therapy, or systemic therapy (e.g., chemotherapy). Targeted cancer therapies such as hormone therapy (e.g., tamoxifen for breast cancer) or immunotherapy (e.g., rituximab for non-Hodgkin lymphoma) are systemic therapies that are used to interfere with specific molecules involved in cancer cell growth. Targeted drugs can (a) block or turn off molecular signals that control cell division and proliferation, (b) change proteins within the cancer cells so they are no longer viable, (c) stop making new blood vessels that feed cancer cells, (d) trigger the immune system to kill the cancer cells, or (e) carry toxins to cancer cells to kill them. Radiation therapy is a physical method that uses high-energy beams to kill cancer cells; although it is typically administered from a source outside of the body, it can also be delivered internally (e.g., brachytherapy).

Another physical treatment is a form of electromagnetic field therapy that uses alternating electrical fields to disrupt mitosis (i.e., cell division); cellular proteins are prevented from moving to their correct locations, resulting in cancer cell death. This therapy, also known as tumor treating fields (TTFs), externally delivers alternating electric fields that are very-low intensity and of intermediate frequency (i.e., 100-300 kHz) to an area of proliferating cancer cells. The specific frequency used in treatment is inversely related to the size of the specific cancer cells. Normal cells, which are affected at -50 kHz, remain unaffected by the frequencies used to treat cancer cells. TTFs have been shown to arrest cell proliferation and destroy cancer cells during division in animal models and human cancer cell lines.[2-6]

Policy context

Optune® (formerly the NovoTTF-100A System), a delivery system for TTFs, was approved by the U.S. Food and Drug Administration (FDA) in 2011 for the treatment of recurrent glioblastoma multiforme (GBM) and in 2015 for the treatment of newly diagnosed GBM in combination with temozolomide, an oral chemotherapy drug. The State of Washington's Health Technology Clinical Committee (HTCC) voted in January 2016 to decline to cover Optune®. This health technology assessment (HTA) will review the efficacy, safety, and cost-effectiveness of TTFs for treating GBM and other cancers to assist the HTCC in reviewing its existing policy and determining coverage for this medical device.

Scope of this HTA

The research questions, analytic framework, and key study selection criteria are listed in this section.

Efficacy question 1 (EQ 1). What is the clinical effectiveness of tumor treating fields for the treatment of newly diagnosed glioblastoma multiforme, recurrent glioblastoma multiforme, and other cancers?

Efficacy question 1a (EQ 1a). Does the clinical effectiveness of tumor treating fields vary by clinical history or patient characteristics (e.g., age, sex, Karnofsky performance score, surgical resection)?

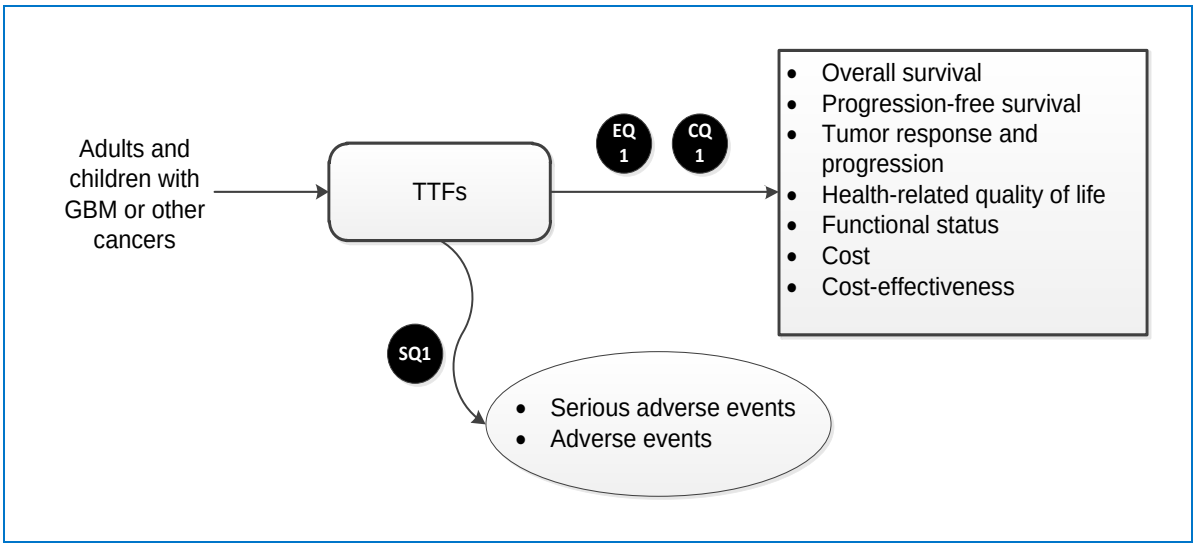
Safety question 1 (SQ 1). What are the harms associated with tumor treating fields for the treatment of newly diagnosed glioblastoma multiforme, recurrent glioblastoma multiforme, and other cancers?

Safety question 1a (SQ 1a). Do the harms associated with tumor treating fields vary by clinical history or patient characteristics (e.g., age, sex, Karnofsky performance score, surgical resection)?

Cost question 1 (CQ 1). What are the costs and cost-effectiveness of tumor treating fields?

Figure 1 depicts the framework of the HTA.

Figure 1. Analytic framework depicting scope of this health technology assessment



Population: Adults or children with a histologically confirmed diagnosis of incident or recurrent GBM or other cancer (e.g., non-small cell lung cancer, ovarian cancer, pancreatic cancer)

Intervention: TTFs

Comparator: Chemotherapy; TTFs plus chemotherapy or other adjunctive treatments; placebo; no comparator

Outcomes:

Efficacy: Overall survival; progression-free survival; tumor response and progression; health-related quality of life; functional status (e.g., cognitive function measured by the Karnofsky Performance Scale)

Safety: Serious adverse events; adverse events (e.g., dermatitis, insomnia, headaches)

Final

Cost/Cost-Effectiveness: Cost; cost-effectiveness

Time period: No time restriction

Setting: Countries categorized as "very high human development" according to the United Nations Development Programme's 2016 Human Development Report[7]

Other criteria: English-language publications

Public comment and response

No public comments were received.

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