

FINAL Key Questions and Background

Novocure (Tumor Treating Fields)

Medical Background

Novocure (NovoTTF) is a medical device worn on the head that applies alternating electric fields, also referred to as tumor treating fields (TTF). The only indication for which Novocure is currently FDA-approved is recurrent glioblastoma multiforme (GBM). GBM is the most common and most malignant of the glial tumors. With optimal therapy, the median duration of survival is approximately 1 year. The current treatment of GBM is palliative and includes surgery, radiotherapy, and chemotherapy.

Although several clinical trials are currently underway to evaluate the use of TTF for other indications (e.g., malignant pleural mesothelioma, ovarian carcinoma, pancreatic adenocarcinoma, non-small cell lung cancer), only one trial investigating non-small lung cancer published in a peer-reviewed journal was identified.

Policy Context

Novocure (rebranded as Optune®) is a medical device currently approved for use in adult patients with glioblastoma multiforme that has recurred following chemotherapy. The device is worn on the head and applies alternating electric field therapy also referred to as tumor treating fields (TTF). The mechanism of action for this therapy involves interfering with tumor cell replication through application of electric field therapy. Concerns for this treatment are considered low for safety, and high for efficacy and cost-effectiveness.

Scope of This HTA

Population: Adults diagnosed with recurrent glioblastoma multiforme or other forms of cancer (e.g., non-small lung cancer, ovarian carcinoma, non-recurrent glioblastoma multiforme)

Interventions: Novocure (tumor treating fields)

Comparators: Chemotherapy; Novocure alone vs. Novocure plus adjunctive treatments; placebo; no comparator

Outcomes: Overall survival; tumor response and progression; health outcomes (e.g., quality of life); adverse events; cost and cost-effectiveness

Key Questions

1. What is the clinical effectiveness of Novocure for treatment of the following conditions?
 - a. What is the clinical effectiveness of Novocure for treatment of glioblastoma?
 - b. What is the clinical effectiveness of Novocure for treatment of other cancers?
2. What are the harms associated with Novocure?
3. Does the effectiveness of Novocure or incidence of adverse events vary by clinical history or patient characteristics (e.g., age, gender, prior treatments)?
4. What are the cost implications and cost-effectiveness of Novocure?

Public Comment & Response

See *Draft Key Questions: Public Comment & Response* document published separately.