



Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma

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ST. HELIER, Jersey–(BUSINESS WIRE)–Novocure (NASDAQ: NVCR) today announced the Medicare durable medical equipment (DME) Medicare Administrative Contractors (MACs) have released a final local coverage determination (LCD) providing coverage of Optune for Medicare beneficiaries with newly diagnosed glioblastoma (GBM) effective September 1, 2019. The [final LCD](#) and a [summary response to comments](#) are available in the U.S. Centers for Medicare & Medicaid Services (CMS) coverage database.

“We are extremely pleased that CMS has established coverage of Optune for patients with newly diagnosed GBM and that many of the restrictions originally proposed were removed in response to public comment,” said Bill Doyle, Novocure’s Executive Chairman. “The FDA approved Optune for patients with newly diagnosed GBM following a large phase 3 clinical trial that demonstrated adding Optune to temozolomide extends survival while maintaining quality of life. Novocure is committed to providing access to Optune for all patients who may benefit, consistent with the FDA-approved label.”

The coverage criteria finalized by the DME MACs is generally similar to Optune’s commercial coverage criteria for newly diagnosed GBM. According to the LCD, Optune will be covered initially by Medicare when the following criteria are met:

- The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
- The beneficiary has received initial treatment with maximal debulking surgery (when feasible), followed by chemotherapy and radiotherapy; and,
- Optune is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy, whichever is later; and,
- The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
- The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
- The beneficiary will use Optune for an average of 18 hours per day. (*Adherence to therapy is defined as the use of Optune for an average of 18 hours per day excluding days the treating practitioner has documented a medical need to limit or interrupt treatment.*)

For beneficiaries who are undergoing treatment with Optune for newly diagnosed GBM prior to enrollment in Fee-For-Service (FFS) Medicare and are seeking Medicare coverage for Optune, the LCD states that Optune will be covered by Medicare when the following criteria are met:

- The beneficiary has been receiving Optune following initial maximal debulking surgery (if feasible) followed by chemotherapy/radiotherapy for histologically confirmed newly diagnosed GBM; and,
- Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating practitioner who documents in the beneficiary’s medical record that the beneficiary is adherent with Optune for an average of 18 hours per day and the beneficiary is deriving benefit from the therapy.

Approved Indications

Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

The NovoTTF-100L System is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Important Safety Information

Contraindications

Do not use Optune in patients with GBM with an implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render

Optune ineffective. Do not use the NovoTTF-100L System in patients with MPM with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc.

Use of Optune for GBM or the NovoTTF-100L System for MPM together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune for GBM or the NovoTTF-100L System for MPM in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune and the NovoTTF-100L System may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

Optune and the NovoTTF-100L System can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving Optune in combination with chemotherapy in patients with GBM were thrombocytopenia, nausea, constipation, vomiting, fatigue, convulsions, and depression.

The most common (≥10%) adverse events related to Optune treatment alone in patients with GBM were medical device site reaction and headache. Other less common adverse reactions were malaise, muscle twitching, and falls related to carrying the device.

The most common (≥10%) adverse events involving the NovoTTF-100L System in combination with chemotherapy in patients with MPM were anemia, constipation, nausea, asthenia, chest pain, fatigue, device skin reaction, pruritus, and cough.

Other potential adverse effects associated with the use of the NovoTTF-100L System include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical site reaction and skin breakdown/skin ulcer.

If the patient has an underlying serious skin condition on the treated area, evaluate whether this may prevent or temporarily interfere with Optune and the NovoTTF-100L System treatment.

Do not prescribe Optune or the NovoTTF-100L System for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune and the NovoTTF-100L System in these populations have not been established.

Forward-Looking Statements

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Novocure's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs, clinical trial progress, development of potential products, interpretation of clinical results, prospects for regulatory submission and approval, manufacturing development and capabilities, market prospects for its products, coverage, collections from third-party payers and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Novocure's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, regulatory and political conditions as well as more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 28, 2019, with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Novocure does not intend to update publicly any forward-looking statement, except as required by law. Any forward-looking statements herein speak only as of the date hereof. The Private Securities Litigation Reform Act of 1995 permits this discussion.



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