

ISSUED 27 JUNE 2007

PRESS RELEASE

NICE issues guidance on the use of carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma

NICE has issued guidance today (27 June 2007) on the use of carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma, a type of cancerous brain tumour.

Brain tumours account for fewer than 2% of all primary cancers. Approximately 1860 new cases of malignant glioma are diagnosed in England and Wales each year.

Symptoms vary but can include seizures, visual disturbance, speech and language problems and changes in the ability to carry out normal daily activities, which can be assessed using a performance scale, such as the WHO performance status classification.

Approximately 30% of adults with high-grade gliomas survive for at least 1 year, and 13% survive for 5 years. Treatment usually consists of surgery where possible, followed by radiotherapy (which has been demonstrated to prolong survival).

NICE recommends the following:

- Temozolomide, within its licensed indications, is recommended as an option for the treatment of newly diagnosed glioblastoma multiforme (GBM) in patients with a World Health Organization (WHO) performance status of 0 or 1.
- Carmustine implants, within their licensed indications, are recommended as an option for the treatment of newly diagnosed high-grade glioma only for patients in whom 90% or more of the tumour has been surgically removed.

- Carmustine implants are not recommended for the treatment of newly diagnosed high-grade glioma for patients in whom less than 90% of the tumour has been surgically removed.

Andrea Sutcliffe, Deputy Chief Executive at NICE and Executive Lead for this appraisal, said: “We have recommended temozolomide and carmustine implants for the patient groups who will benefit the most. This is a good use of NHS resources and it will ensure that patients who suffer from this rarer form of cancer are entitled to the same standard of care, regardless of where they live.”

Ends

Notes for editors

About glioma

1. Brain tumours account for less than 2% of all primary cancers. Approximately 1860 new cases of malignant glioma are diagnosed in England and Wales each year.
2. Approximately 30% of adults with high-grade gliomas survive for at least 1 year, and 13% survive for 5 years.
3. Diagnosis of high-grade glioma is provisionally made through a computed tomography (CT) scan or MRI. The diagnosis is then confirmed and the tumour classified histologically, either at the time of surgical resection or by a single-event biopsy if surgery is not possible.
4. In the UK, treatment usually consists of surgical resection where possible, followed by radiotherapy. Surgery may achieve either complete resection or partial resection of the tumour. Radiotherapy has been demonstrated to prolong survival and is usually recommended after surgery.

About this appraisal

5. Treatment with carmustine implants should be provided only within specialist centres that in general conform to guidance in ‘Improving outcomes for people with brain and other central nervous system tumours’ ([NICE cancer service guidance 2006](#)), and should be supervised by specialist neurosurgeons who spend at least 50% of their clinical programmed activities in neuro-oncological surgery. The specialists should also have access to:
 - multidisciplinary teams to enable preoperative identification of patients in whom maximal resection is likely to be achievable
 - magnetic resonance imaging (MRI) to enable preoperative identification of patients in whom maximal resection is likely to be possible, and
 - image-directed technology, such as neuronavigation, for use intraoperatively to assist the achievement of maximal resection.
6. Carmustine implants (Gliadel) are biodegradable copolymer discs impregnated with an alkylating agent called carmustine. They are about the size of a 5p coin and are implanted into the resection cavity at the time of surgery. Carmustine implants have a UK marketing authorisation for the treatment of newly diagnosed high-grade malignant glioma as an adjunct to surgery and radiation, and for the treatment of recurrent GBM as an adjunct to surgery.

7. Temozolomide (Temodal) undergoes hydrolysis in the body to produce monomethyl triazenoimidazole carboxamide (MTIC). MTIC is thought to act by methylation of DNA in a way that prevents cell division. Temozolomide has a UK marketing authorisation for the treatment of newly diagnosed GBM concomitantly with radiotherapy and subsequently as monotherapy treatment. It also has a UK marketing authorisation for the treatment of malignant glioma showing recurrence or progression after standard therapy.
8. The WHO performance status classification categorises patients as:
 - 0:** able to carry out all normal activity without restriction
 - 1:** restricted in strenuous activity but ambulatory and able to carry out light work
 - 2:** ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
 - 3:** symptomatic and in bed for greater than 50% of the day but not bedridden
 - 4:** completely disabled; cannot carry out any self-care; totally confined to bed or chair.
8. Improving outcomes for people with brain and other central nervous system tumours. NICE cancer service guidance (2006). Available from: <http://guidance.nice.org.uk/csgbraincns>.

About NICE

9. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
10. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.