



**National Institute for
Health and Clinical Excellence**

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PRESS RELEASE

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

NICE has issued a new draft version of its guidance on the clinical and cost-effectiveness of carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma. NICE has not yet issued final guidance to the NHS on the use of carmustine implants and temozolomide for this indication. Consultees, healthcare professionals and members of the public now have the opportunity to comment on the provisional recommendations contained in the draft document. All comments must be received by 31 January 2007. Final guidance is expected in June 2007.

The draft recommendations are as follows:

- Temozolomide, within its licensed indications, is recommended for the treatment of newly diagnosed glioma in patients with a World Health Organization (WHO) performance status of 0 or 1.
- Carmustine implants are not recommended for the treatment of newly diagnosed high-grade glioma.

Andrea Sutcliffe, Deputy Chief Executive at NICE and Executive Lead for this appraisal, said: "Our review of the evidence indicates that carmustine implants have a small benefit in overall survival in newly diagnosed high-grade glioma, but there

was insufficient evidence to demonstrate its benefit as a cost-effective use of NHS resources.

“Our review of the evidence on temozolomide demonstrated a small improvement in overall survival for all patients with high grade glioma. However, the survival benefits were greatest for those patients who are able to carry out normal activities without restriction and patients who are restricted in strenuous activity but are able to walk and carry out light work – defined as a WHO status of 0 and 1 – and so we have recommended temozolomide for these patients. There was insufficient evidence to recommend temozolomide for other patient groups.

“NICE follows an open and transparent process which includes consultation and changes in draft recommendations are a result of this robust process.”

Ends

Further information: NICE press office, 020 7067 5900.

Notes for editors

About this appraisal

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. 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.
3. 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.
4. 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.

About NICE

5. On 1 April 2005 the National Institute for Clinical Excellence took on the functions of the Health Development Agency to form the National Institute for Health and Clinical Excellence (NICE). NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
6. 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.