NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

RPP decision paper

Review of TA23; Temozolomide for the treatment of recurrent malignant glioma, and TA121; Carmustine implants and temozolomide for the treatment of newly diagnosed high grade glioma

Final recommendation post consultation
TA23 Recommendation 1.1 of TA23 should be changed to reflect current conventions and the guidance should be transferred to the 'static guidance list'. The existing recommendations 1.2 and 1.3 should be withdrawn. The updated wording for TA23 will read as follows: 1.1 Temozolomide is recommended as an option for treating malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy only if the patient has a Karnofsky performance status score greater than or equal to 70 and a projected life expectancy of 12 weeks or more. 1.2 When using the Karnofsky performance status score, clinicians should be mindful aware of the need to secure equality of access to treatment for patients with disabilities. Clinicians should bear in mind that people with disabilities may have difficulties with activities of daily living that are unrelated to their prognosis with respect for malignant glioma. In such cases For such people clinicians should make appropriate judgements of about performance status, taking into account the person's usual functional capacity and requirement need for assistance with activities of daily living. 1.3 This recommendation has been updated by recommendation 1.1 in the NICE technology appraisal guidance on carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma. 1.4 People whose treatment with temozolomide is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

TA121

TA121 should be placed on the static list.

1. Background

TA23 was published in April 2001, and TA121 was published in June 2007.

At the GE meeting of 15 December 2015 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

TA23

Recommendation 1.1 of TA23 should be changed to reflect current conventions and the guidance should be transferred to the 'static guidance list'. The existing recommendations 1.2 and 1.3 should be withdrawn because they were superseded by TA121, which considered the use of temozolomide in newly-diagnosed malignant glioma.

The updated wording for TA23 will read as follows:

1.1 Temozolomide is recommended as an option for treating malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy only if the patient has Karnofsky performance status greater than or equal to 70 and a projected life expectancy of 12 weeks or more.

1.2 When using Karnofsky performance-status score, clinicians should be mindful of the need to secure equality of access to treatment for patients with disabilities. Clinicians should bear in mind that people with disabilities may have difficulties with activities of daily living that are unrelated to their prognosis with respect malignant glioma. In such cases clinicians should make appropriate judgements of performance status taking into account the person's usual functional capacity and requirement for assistance with activities of daily living.

TA121

TA121 should be placed on the static list.

That we consult on these proposals.

3. Rationale for selecting this proposal

TA23

It is expected that, since temozolomide is recommended as a first line treatment in TA121, only a small number of patients would have treatment with temozolomide for recurrent disease as recommended in TA23. Therefore, although there is new evidence available, it is expected that the number of people having temozolomide at recurrence would be too small to warrant a review of the guidance.

The wording of recommendation 1.1 should be changed to reflect current conventions.

Recommendations 1.2 and 1.3 were outside the scope of the original appraisal and have been superseded by TA121 and should be withdrawn.

TA121

There is no new evidence to change the recommendations in TA121. TA121 should be moved to the static list.

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: Eisai Ltd **Response to proposal:** No comment	**Comment from Technology Appraisals** No response required.

Respondent: Royal College of Nursing **Response to proposal:** No comment	**Comment from Technology Appraisals** No response required.

Respondent: Association of British Neurologists **Response to proposal:** Agree, with caveat <u>Proposed change is to TA23</u> - deletion of 1.2 and 1.3 - agree that this is sensible <u>Re rewording of TA23 1.1</u> I agree that the new indication is appropriate. The wording is slightly ambiguous. The proposed indication states *Temodal is indicated for the treatment of: children from the age of 3 years, adolescents and adult patients with malignant glioma, such as gliobastoma or anaplastic astrocytoma, showing recurrence or progression after standard therapy.* Does this mean it is for *all* malignant glioma showing recurrence or progression after standard therapy? In this case I do not agree with the statement as Temodal is current standard initial treatment for glioblastoma. Temodal treatment does however follow standard therapy for grade III glioma (eg anaplastic astrocytoma, anaplastic oligodendroglioma) on recurrence or progression. Or does this mean it is indicated for malignant glioma such as gliobastoma (therefore first line standard treatment) *AND* it is also indicated, for example for anaplastic astrocytoma that is grade III glioma) showing recurrence or progression after standard therapy? I would agree with this. The statement can be read in two ways and therefore rewording to make clearer would be indicated.	**Comment from Technology Appraisals** Comment noted. The update of the wording for TA23 has been proposed to reflect current conventions, with no intention to change the recommendations in the original guidance. Section 1.1 of TA23 relates to treatment of recurrent malignant glioma **when first-line chemotherapy treatment has failed**. Current conventions word the recommendations as closely as possible to the marketing authorisation, and where relevant, this is followed by the characteristics of the subpopulation for which the technology is recommended. Applying this to TA23 would update the wording of section 1.1 as proposed. The recommendations still, however, cover malignant glioma after standard first-line treatment. The proposal paper acknowledges that, because temozolomide is recommended as a first-line treatment in TA121, only a small

Finally in the pending studies section there does not appear to be the mention of the BR14 (EORTC 26053-22054). A phase III trial on concurrent adjuvant temozolamide chemotherapy in 1p/19q intact anaplastic glioma. The results of which may have an impact on the proposed guideline.	number of patients would have treatment with temozolomide for recurrent disease as recommended in TA23. Because TA121 recommends temolozomide for some patients with newly diagnosed glioblastoma multiforme, the BR14 (EORTC-26053-22054) trial is unlikely to have a material impact on the guidance.

Paper signed off by: Janet Robertson, 22 February 2016

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