

Temozolomide

for the treatment of malignant glioma

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Temozolomide 20mg and 100mg capsules in line with their registered indications for the treatment of:
 - Newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and subsequently as monotherapy treatment, and
 - Malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

Subsidy status

Generic temozolomide 20mg and 100mg capsules are recommended for inclusion on the Standard Drug List (SDL).

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Factors considered to inform the recommendations for subsidy

Technology evaluation

- 1.1 The MOH Drug Advisory Committee (“the Committee”) considered the evidence presented for the technology evaluation of temozolomide for the treatment of malignant glioma. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from public healthcare institutions and the MOH Oncology Drug Subcommittee (ODS). Published clinical and economic evidence for temozolomide was considered in line with its registered indications.
- 1.2 The evidence was used to inform the Committee’s deliberations around four core decision-making criteria:
 - Clinical need of patients and nature of the condition
 - Clinical effectiveness and safety of the technology
 - Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives
 - Estimated annual technology cost and the number of patients likely to benefit from the technology.
- 1.3 Additional factors, including social and value judgments, may also inform the Committee’s subsidy considerations.

Clinical need

- 2.1 In Singapore, temozolomide plus radiotherapy is the current standard of care after surgical resection for paediatric and adult patients with newly diagnosed glioblastoma multiforme in line with local and international clinical guidelines. Temozolomide is also used to treat patients with recurrent malignant glioma.

Clinical effectiveness and safety

- 3.1 The Committee noted that published clinical evidence demonstrates a statistically significant survival benefit for temozolomide plus radiotherapy compared to radiotherapy alone in adults with newly diagnosed glioblastoma multiforme.
- 3.2 The Committee acknowledged that clinical data supporting the use of temozolomide for recurrent malignant glioma was limited, with no overall survival benefit demonstrated, compared with standard chemotherapy. Progression free survival was improved in a selected subgroup of patients with grade IV tumours, but statistical significance was not achieved in all patients with high grade glioma.
- 3.3 No relevant trials were identified which studied the use of temozolomide in paediatric patients. However, the Committee acknowledged expert testimony from local clinicians who considered that temozolomide was well-tolerated in children and that the benefits seen in adults were likely to be similar to those in the paediatric population.

Cost effectiveness

- 4.1 The Committee considered the cost-effectiveness of temozolomide and noted that there were no local economic evaluations available. It acknowledged that published economic evidence from the UK showed that the incremental cost-effectiveness ratio (ICER) of proprietary temozolomide for the treatment of newly diagnosed glioblastoma multiforme and recurrent glioma lay at the upper end of the range which would normally be considered cost-effective in the UK. However, given the severity of the condition and the limited effective treatment options available, the Committee considered that temozolomide is likely to represent an acceptable use of healthcare resources in Singapore, especially with the recent availability of a generic formulation which was considerably cheaper than the proprietary brand.

Estimated annual technology cost

- 5.1 The Committee acknowledged that approximately 100-150 patients were expected to benefit from subsidy of temozolomide each year. At the price proposed by the generic manufacturer, the annual cost impact of temozolomide was estimated to be less than \$500,000 in the first year of listing on SDL.

Recommendation

- 6.1 On the basis of the available evidence, the Committee recommended listing generic temozolomide 20mg and 100mg capsules on SDL for the treatment of malignant glioma, due to acceptable clinical effectiveness and safety compared to other treatment options, and its lower cost compared to proprietary temozolomide. This recommendation allows use of generic temozolomide in line with its registered indications for patients with newly diagnosed or recurrent malignant glioma.

About the Agency

The Agency for Care Effectiveness (ACE) is the national health technology assessment agency in Singapore residing within the Ministry of Health. It conducts evaluations to inform the subsidy of treatments, and produces guidance on the appropriate use of treatments for public hospitals and institutions in Singapore. When using the guidance, the responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at www.ace-hta.gov.sg/about

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