

**Guidance on
the use of
temozolomide
for the
treatment of
recurrent
malignant
glioma (brain
cancer)**

1. Guidance

- 1.1 Patients with recurrent malignant glioma (brain cancer) who have failed first-line chemotherapy treatment with other agents (either because of lack of efficacy or because of side effects) may be considered for treatment with temozolomide. Such patients must have a histologically proven malignant glioma (WHO grades III and IV, or transformed grade II) at first relapse, recurrence or progression (as assessed by imaging), Karnofsky performance status greater than or equal to 70 and a projected life expectancy of 12 weeks or more, at initiation of temozolomide treatment. (See Appendix D for definition of Karnofsky status and Appendix E for definition of WHO tumour grading).
- 1.2 Temozolomide is not recommended for first-line chemotherapy treatment for patients with malignant glioma who have failed primary therapy (surgery and/or radiotherapy), except in the context of a randomised controlled trial against a standard-treatment comparator.
- 1.3 As temozolomide is not currently licensed for adjuvant chemotherapy treatment of malignant glioma, its use in this indication has not been considered in this appraisal.

This section (Section 1) constitutes the Institute's Guidance on the use of temozolomide for the treatment of recurrent malignant glioma (brain cancer). The remainder of the document is structured in the following way:

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|----------------------------|---|
| 2 Clinical Need | 8 Review of Guidance |
| 3 The Technology | Appendix A: Appraisal Committee |
| 4 Evidence | Appendix B: Sources of Evidence |
| 5 Implications for the NHS | Appendix C: Information for Patients. |
| 6 Further Research | Appendix D: Karnofsky Performance Score |
| 7 Implementation | Appendix E: WHO Classification |

The full document and a Summary of Evidence are available from our website at www.nice.org.uk or by telephoning 0870 1555 455 and quoting the reference number 23698.

**Arweiniad ar y
defnydd o
temozolomide
ar gyfer y
driniaeth o
glioma
dychweliadol
malaen (canser
yr ymennydd)**

1 Arweiniad

- 1.1 Efallai yr ystyrir Cleifion gyda glioma dychweliadol malaen (canser yr ymennydd) sydd wedi methu â thriniaeth cemotherapi cyntaf gyda chyfryngau eraill (naill ai oherwydd diffyg effeithlonrwydd neu oherwydd sgil effeithiau) ar gyfer triniaeth gyda temozolomide. Rhaid bod gan y fath gleifion glioma malaen wedi ei brofi yn histolegol (Graddfeydd WHO III a IV, neu raddfa drawsnewidiol II) ar yr ailwaeledd cyntaf, dychweliad neu ddatblygiad (fel y'i hasesir gan ddelweddu), statws perfformiad Karnofsky sy'n fwy na 70 neu'n hafal iddo ac yr amcangyfrifir y byddant yn byw am 12 wythnos neu fwy, wrth ddechrau'r driniaeth o temozolomide. (Gwelir Atodiad D am ddiffiniad o statws Karnofsky ac Atodiad E am ddiffiniad o raddio tiwmor WHO).
- 1.2 Nid argymhellir Temozolomide ar gyfer triniaeth gyntaf i gleifion cemotherapi gyda glioma malaen sydd wedi methu therapi cychwynnol (llawfeddygaeth a/neu radiotherapi), heblaw yng nghyd-destun treial ar hap wedi ei reoli yn erbyn cymharydd triniaeth safonol.
- 1.3 Gan nad yw temozolomide wedi ei drwyddedu ar hyn o bryd ar gyfer trin glioma malaen drwy gemotherapi gynorthwyol o, nid yw ei ddefnydd yn cyd-destun hwn wedi ei ystyried yn y gwerthusiad hwn.

**Dyddiad
Cyhoeddi** Ebrill 2001

**Dyddiad
Arolygu** Mawrth 2004

**Arweiniad Gwerthuso
Technoleg Rhif 23**

Mae'r adran hon (Adran 1) yn ymgorffori Arweiniad y Sefydliad ar ddefnyddio temozolomide ar gyfer trin glioma dychweliadol malaen (canser yr ymennydd). Strwythurir gweddill y ddogfen fel a ganlyn:

- | | |
|-----------------------|---------------------------------------|
| 2 Angen Clinigol | 8 Arolwg o'r Arweiniad |
| 3 Y Dechnoleg | Atodiad A: Pwyllgor Gwerthuso |
| 4 Tystiolaeth | Atodiad B: Ffynonellau Gwybodaeth |
| 5 Goblygiadau i'r NHS | Atodiad C: Gwybodaeth i Gleifion |
| 6 Ymchwil Bellach | Atodiad D: Sgôr Perfformiad Karnofsky |
| 7 Gweithredu | Atodiad E: Dosbarthiad WHO |

Mae'r ddogfen lawn a Chrynodeb o Dystiolaeth ar gael ar ein gwefan yn www.nice.org.uk neu drwy ffonio 0870 1555 455 a dyfynnu cyfeirnod 23698.
