Indication	For the treatment of anaplastic astrocytoma or glioblastoma, in patients older than 65 years with a PS 0-2, with MGMT promoter methylated tumours.
Treatment Intent	Palliative
Frequency and number of cycles	Repeat every 28 days Continue until progressive disease, unacceptable toxicity or patient's choice.
Monitoring Parameters pre-treatment	• **Virology screening:** All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • Monitor LFT's, U&E's Glucose and FBC before treatment and on days 1 and 15 of each cycle. • If neuts >/= 1.5 and Plts >/=150 and patient well, proceed with full dose, otherwise see table 3. • Dose reduction should be considered if grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&V and alopecia). Delay until resolution of toxicity to </= grade 1. • **Renal Impairment:** See table 1. • **Hepatic Impairment:** Discuss with Consultant if LFTs deranged pre-cycle 1. If abnormal LFTs at baseline, the benefit/risk should be considered prior to initiating temozolomide, including the potential for fatal hepatic failure. Hepatic injury, including fatal hepatic failure, has been reported in patients treated with temozolomide. ○ For patients who develop significant liver function abnormalities after treatment has started, delay and consider dose reductions according to table 2. Consider the benefit/risk of continuing treatment. Liver toxicity may occur several weeks or more after the last treatment with temozolomide. • **Common drug interactions:** No studies have been conducted to determine the effect of temozolomide on the metabolism or elimination of other medicinal products. • **Missed dose:** if a patient vomits following administration a second dose should not be taken. • For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet.
References	KMCC protocol BRA-002 v6 SPC accessed online 05.04.2024 https://www.thelancet.com/journals/lancet/article/PIIS1470-2045(12)70164-X/fulltext https://clinicaltrials.gov/ct2/show/NCT01502241

NB For funding information, refer to CDF and NICE Drugs Funding List

Table 1 dose modification in renal impairment

Cr clearance (ml/min)	Temozolomide dose
>60	No dose reduction is routinely required
46-60	
30-45	
<30	Not recommended

Table 2 dose modifications in liver impairment after treatment has started

Liver function	Temozolomide dose
ALT >2x ULN -245 units/l and/or Bilirubin 30-62 µmol/l	Delay until LFTs recovered & consultant to assess the benefit / risk of continuing. If decision made to continue, reduce temozolomide in 25% increments If the same toxicity recurs after the second dose reduction, permanently discontinue temozolomide. If prolonged elevation of LFTs, consider liver blood screen and ultrasound.
ALT > 245 units/l and/or Bilirubin >/= 63 µmol/l	Permanently discontinue

Table 3 dose modifications for haematological toxicity

	Temozolomide dose
Neuts >/=1.5 and PLTs >/=150	Proceed with full dose
Neuts 1.0-1.49 and PLTs 100-149	Discuss with consultant, usually delay 1 week and dose reduce following second delay
Neuts <1 and/or PLTs 20-99	Delay until recovery and dose reduce
PLTs <20 and/or bleeding	Platelet transfusion and alert consultant

Repeat every 28 days:

TTO	Drug	Dose	Route	Directions
Day 1 & Day 15	**TEMOZOLOMIDE**	**100mg/m²**	PO	Swallow whole ONCE a day for 7 days followed by 7-day rest. Take this medicine when your stomach is empty. This means an hour before food or 2 hours after food. Swallow this medicine whole. Do not chew or crush. Available as 5mg, 20mg, 100mg,140mg,180mg and 250mg capsules
	Domperidone	10mg	PO	Up to TDS PRN. Maximum 30mg day. Do not take for more than 7 days continuously. Take half an hour before taking temozolomide
	Ondansetron	8mg	PO	BD for 7 days