

Indication	Treatment of high-grade glioma (WHO grade 4), given after neurosurgery to patients with performance status 1 or 0, and followed by temozolomide monotherapy (part 2 STUPP regime).
Treatment Intent	Concurrent
Frequency and number of cycles	Repeat every 7 days for 3- 6 cycles
Monitoring Parameters pre-treatment	<ul style="list-style-type: none"> • Monitor LFTs, U&Es, glucose and FBC before treatment at each cycle. • LFTs should be repeated 28 days after completion of treatment. • Abnormal LFT should be discussed with consultant. • If neuts ≥ 1.5 and Plts ≥ 150 and patient well, proceed with full dose. If neuts ≥ 1.5 and Plts 100-149 discuss with consultant. • If neuts ≤ 1.4 and/or Plts ≤ 99 omit treatment for 1 week then continue full dose when blood count has recovered. • Renal Impairment: No dose reduction is routinely required in patients with renal impairment but, if severe impairment, confirm dosage requirements with Consultant. • Hepatic Impairment: • No dose reduction is routinely required in patients with hepatic impairment but discuss with Consultant and consider the following: <ul style="list-style-type: none"> ○ Hepatic injury, including fatal hepatic failure, has been reported in patients treated with temozolomide. If abnormal LFTs at baseline, the benefit/risk should be considered prior to initiating temozolomide, including the potential for fatal hepatic failure. ○ For patients who develop significant liver function abnormalities after treatment has started, discuss the benefit/risk of continuing treatment with the Consultant. Liver toxicity may occur several weeks or more after the last treatment with temozolomide. • If grade 3 or 4 non-haematological toxicity occurs, consider omitting treatment for 1 week.
References	KMCC proforma BRA-001 v5 part 1 ARIA regimen BRA-001 part 1 LCA protocol temozolomide and radiotherapy v4 SPC accessed online 05/11/2019

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

Protocol No	BRA-001 (part 1)	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V6	Written by	M.Archer
Supersedes version	V5	Checked by	C.Waters E.Parry
Date	05/12/2019	Authorising consultant (usually NOG Chair)	J.Glendenning

Repeat every 7 days.

Day	Drug	Dose	Route	Administration
1	TEMOZOLOMIDE	75mg/m²	PO	Swallow whole ONCE a day 7 days a week during period of radiotherapy treatment. 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. SUPPLY 7 DAYS UNLESS SPECIFIED BY THE CONSULTANT. Available as 5mg, 20mg, 100mg, 140mg 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
	Co-trimoxazole	480mg	PO	BD Monday, Wednesday and Friday, whilst on concomitant chemoradiation.
	Ondansetron	8mg	PO	Take one tablet half an hour before temozolomide, once a day 7 days a week. SUPPLY 7 DAYS UNLESS SPECIFIED BY THE CONSULTANT

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