

Indication	<p>For the treatment of Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation or isocitrate dehydrogenase-2 (IDH2) mutation in adult patients following surgical intervention who are not in need of immediate chemotherapy or radiotherapy and not currently exhibiting any high-risk features.</p> <p>NB The patient must have had at least one prior surgery, but no other prior anticancer treatments (chemotherapy or radiation).</p>
Treatment Intent	Palliative
Frequency and number of cycles	<p>Repeat every 28 days</p> <p>Continue until disease progression, unacceptable toxicity or withdrawal of patient consent whichever occurs first.</p>
Monitoring Parameters	<ul style="list-style-type: none"> • 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. • Haematological monitoring and parameters: • FBC, U&Es, LFT's and random glucose should be taken prior to the start of treatment, every 2 weeks for the first 2 cycles and then at each cycle for the first 2 years, then continue monthly or as clinically indicated. More frequent monitoring may be required in certain patients. • If neuts <1.0 or PLT <100 d/w consultant. • Hepatic impairment: No starting dose adjustment is recommended for patients with mild or moderate (Child-Pugh class A or B) impairment. Vorasicidenib should not be used in patients with pre-existing severe hepatic impairment. • Renal impairment: No starting dose adjustment is recommended if CrCl > 40 mL/min, if CrCl ≤40mL/min or patient receiving dialysis use with caution no data available. • Management of adverse reactions and dose adjustments: • Dose interruption or reduction may be required based on individual safety and tolerability. If a dose reduction is required, the first dose reduction should be 20mg OD and the second dose reduction 10mg OD, if 10mg OD is not tolerated treatment should be permanently discontinued. See table 1 for recommended dose modification and management of adverse reactions. • If patient weighs <40kg discuss dose with consultant. • Common drug interactions (for comprehensive list refer to BNF/SPC): <ul style="list-style-type: none"> ○ Concomitant use of strong or moderate CYP1A2 inhibitors (e.g. fluvoxamine and ciprofloxacin) should be avoided. Co-administration of vorasicidenib with moderate CYP1A2 inducers (e.g. phenytoin and rifampicin) may decrease vorasicidenib plasma concentration, consider alternative therapy. ○ Co-administration of vorasicidenib with CYP2B6, CYP2C8, CYP2C9, CYP2C19, or CYP3A4 substrates should be avoided, especially those with narrow therapeutic range (e.g. carbamazepine, ciclosporin, phenytoin, tacrolimus valproic acid, and warfarin), as the plasma concentration of the concomitant medicinal product may be decreased ○ Smoking tobacco may decrease vorasicidenib plasma concentrations, patients should be advised to avoid smoking during treatment. • Vorasicidenib contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. • Missed dose: If a dose is missed, take the missed dose as soon as possible within 6 hours. If a dose is missed by more than 6 hours, skip the missed dose and take the next dose at the scheduled time.

Protocol No	BRA-011	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
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	<p>If vomiting occurs after taking a dose, do not take a replacement dose, and take the next dose at the scheduled time on the following day.</p> <ul style="list-style-type: none"> • Pregnancy and contraception: Women of childbearing potential and males with female partners of childbearing potential should use effective contraception during treatment and for at least 3 months after the last dose of vorasidenib. Vorasidenib may decrease concentrations of hormonal contraceptives, barrier methods should be applied as a second form of contraception to avoid pregnancy. • For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet.
References	<p>SPC accessed online 01.04.2026 ARIA regimen Off protocol vorasidenib https://www.nice.org.uk/guidance/gid-ta11498/documents/674-2 CDF list V1.392 accessed online 08.04.2026</p>

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

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Table 1 Recommended Vorasicidenib Dosage Modifications and Management for Adverse Reactions

Adverse Reaction	Severity ^a	Management and Dosage Modifications
Hepatotoxicity (Elevation of ALT or AST)	Grade 1 ALT or AST increase >ULN to 3 x ULN <i>without</i> concurrent total bilirubin >2 x ULN	Continue vorasicidenib at current dose. Monitor liver enzymes weekly until recovery to <Grade 1.
	Grade 2 ALT or AST >3 to 5 x ULN <i>without</i> concurrent total bilirubin >2 x ULN	First Occurrence: Withhold vorasicidenib and monitor liver enzymes twice per week until recovery to ≤Grade 1 or baseline. <ul style="list-style-type: none"> Recovery in ≤28 days, resume vorasicidenib at the same dose. Recovery in >28 days, resume vorasicidenib at reduced dose. Recurrence: Withhold vorasicidenib and monitor liver enzymes twice per week until recovery to ≤Grade 1 or baseline, and resume vorasicidenib at reduced dose.
	Grade 3 ALT or AST >5 to 20 x ULN <i>without</i> concurrent total bilirubin >2 x ULN	First Occurrence: Withhold vorasicidenib and monitor liver enzymes twice per week until recovery to ≤Grade 1 or baseline. <ul style="list-style-type: none"> Recovery in ≤28 days, resume vorasicidenib at reduced dose. If not recovered in ≤28 days, permanently discontinue vorasicidenib. Recurrence: Permanently discontinue vorasicidenib and monitor liver enzymes twice per week until recovery to ≤Grade 1 or baseline.
	Grade 2 or 3 Any ALT or AST >3 to 20 x ULN <i>with</i> concurrent total bilirubin >2 x ULN in absence of clear alternative explanation. ^b	Permanently discontinue vorasicidenib and monitor liver enzymes twice per week until recovery to ≤Grade 1 or baseline.
	Grade 4 Any ALT or AST >20 x ULN	Permanently discontinue vorasicidenib and monitor liver enzymes twice per week until recovery to ≤Grade 1 or baseline.
Other Adverse Reactions	Grade 3	First Occurrence: Withhold vorasicidenib until recovery to ≤Grade 1 or baseline. <ul style="list-style-type: none"> Resume vorasicidenib at reduced dose. Recurrence: Permanently discontinue vorasicidenib.
	Grade 4	Permanently discontinue vorasicidenib.

Abbreviations: ALT = Alanine aminotransferase; AST = Aspartate aminotransferase; ULN = Upper limit of normal

^a Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0.

^b If an alternative aetiology is identified, consider resuming vorasicidenib at reduced dose following resolution to Grade 1 or baseline.

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Repeat every 28 days

TTO	Drug	Dose	Route	Directions
Day 1	VORASIDENIB	40mg	PO	<p>OD continuously. Take at approximately the same time each day at least 2 hours before food and do not consume any food for 1 hour after the dose.</p> <p>Swallow whole, do not chew, crush or split the tablets.</p> <p>Available as 10mg and 40mg tablets.</p>
	Loperamide	2-4mg	PO	<p>Take 4mg (2 capsules) initially, then 2mg (1 capsule) after each loose stool when required. Maximum 16mg (8 capsules) a day.</p> <p>Dispense 30 capsules on cycle 1 then only if required.</p>

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