Indication	Renal cell carcinoma
Treatment Intent	Palliative
Frequency and number of cycles	Repeat every 28 days Axitinib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, or axitinib can be stopped for a planned treatment break following the protocol used in the STAR trial; i.e. following 24 weeks of continuous therapy, and if there is no evidence of disease progression on therapy, patients and clinicians may choose to stop treatment for a planned drug free interval/treatment break and then restart axitinib on disease progression. (Further planned treatments breaks following the same strategy are allowed).
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. • **Blood pressure (BP):** Blood pressure should be well-controlled prior to initiating axitinib. Monitor BP every 2 weeks for the first 2 months and then before each cycle thereafter. Patients should be treated as needed with standard anti-hypertensive therapy. In the case of persistent hypertension, despite use of anti-hypertensive medicinal products, the axitinib dose should be reduced. For patients who develop severe hypertension, temporarily interrupt axitinib and restart at a lower dose once the patient is normotensive. • **ECG** prior to cycle 1 and then as clinically indicated, monitor patients for symptoms of cardiac dysfunction throughout treatment. • **ECHO:** at baseline for at risk patients, then every 6/12 as clinically indicated. • **Thyroid function** must be assessed at baseline then every 12 weeks. • Monitor FBC, LFT's and U&E's prior to each cycle. • If neuts <1.0 and/or PLT <50 d/w consultant. • **Urine dipstick** each cycle to check for proteinuria. • **Hepatic impairment:** No dose reduction required in mild hepatic impairment. A dose decrease is recommended in moderate hepatic impairment (Child-Pugh class B) (e.g. the starting dose should be reduced from 5mg twice daily to 2 mg twice daily). Not to be used in severe hepatic impairment. • **Renal impairment:** No dose reduction required in renal impairment if CrCl >/=15ml/min. • **Management of adverse reactions and dose adjustments:** • *Patients who tolerate the axitinib starting dose of 5mg twice daily with no adverse reactions >Grade 2 for two consecutive weeks may have their dose increased to 7mg twice daily unless the patient's blood pressure is >150/90 mmHg or the patient is receiving antihypertensive treatment. Subsequently, using the same criteria, patients who tolerate an axitinib dose of 7mg twice daily may have their dose increased to a maximum of 10mg twice daily. Management of some adverse reactions may require temporary or permanent discontinuation and/or dose reduction of axitinib therapy. When dose reduction is necessary, the axitinib dose may be reduced to 3mg twice daily and further to 2mg twice daily. • Axitinib should be used with caution in patients at risk of or with a history of embolic and thrombolic events. • Patients should be advised to moisturize regularly, and creams containing 10% urea are recommended. • **Wound healing:** Axitinib may adversely affect wound healing, axitinib therapy should be stopped at least 24 hours prior to planned surgery. The decision to resume axitinib following surgery should be based upon clinical judgment of recovery from surgery.

	• **Posterior reversible encephalopathy syndrome (PRES)** has been reported with axitinib. In patients developing signs or symptoms of PRES temporary interruption or permanent discontinuation of axitinib treatment is recommended. • **Common drug interactions (for comprehensive list refer to BNF/SPC):** Avoid concomitant treatment with potent CYP3A4/5 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, erythromycin) or inducers (e.g. rifampicin, dexamethasone, phenytoin, carbamazepine). If concomitant use of axitinib with a strong CYP3A4 inhibitor or strong CYP3A/5 inducer cannot be avoided the dose of axitinib may be adjusted (see SPC). Avoid grapefruit juice throughout the course of treatment. • **Missed dose:** If a dose is missed the patient should not take an additional dose, take next dose at usual time. • **Driving and machinery:** Patients should be advised to be cautious when driving or using machines in case they experience fatigue or dizziness during treatment. • For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Cancerbackup information sheet
References	ARIA regimen RCC-005 V1 KMCC proforma V3 SPC accessed online 15.10.2024 Inlyta 5 mg film-coated tablets Pfizer limited

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

Repeat every 28 days

TTO	Drug	Dose	Route	Directions
Day 1	**AXITINIB**	**5mg starting dose**	PO	Starting dose: 5mg BD *See notes above for further dose administration. Swallow whole do not crush or chew. Available as 1mg, 3mg, 5mg and 7mg tablets.
	Metoclopramide	10mg	PO	TDS PRN Do not take for more than 5 days continuously. Dispense 28 tablets on cycle 1, then only if required.
	Loperamide	2mg-4mg	PO	Take 4mg initially then 2mg after each loose stool when required (max. 16mg a day) Dispense 30 capsules on cycle 1 then only if required.