

**Subject: Specialised Services Circular (SSC)**

**Sent on behalf of: Chair of the SW Specialised Service Circular Group**

Dear Colleagues,

Please find attached the following Specialised Services Circular(s):

<b>SSC Number</b>	<b>SSC Title</b>	<b>Trusts approved to prescribe in accordance with the SSC, providing appropriate internal governance arrangements are in place</b>
<b>2699</b>	<b>Treatment breaks for TKI's in the treatment of metastatic renal cell carcinoma</b>	All South West Acute Trusts

**Is an implementation plan required from all SW trusts (regardless of commissioned status) for this SSC? **No****

**For all other South West region trusts this is for information only.**

Trusts should ensure that use is registered on the Blueteq system (if appropriate).

Treatment will only be funded where the drugs minimum dataset is fully and accurately populated.

Please direct any queries to: [england.speccomm-southwest@nhs.net](mailto:england.speccomm-southwest@nhs.net)

**All Chief Executives**

**All Medical Directors**

**All Chief Pharmacists**

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23 August 2024

Dear Colleagues,

**UPDATE – Treatment breaks for TKI’s in the treatment of metastatic renal cell carcinoma**

I am writing to advise you regarding an update to the requirement for treatment break applications when using TKI’s for the treatment of metastatic renal cell carcinoma. Following publication of the results of the STAR trial, NHS England now allow patients receiving treatment with a TKI for renal cell carcinoma to have a planned treatment break in line with the STAR trial<sup>1</sup> protocol.

Further information on the STAR trial is available at: [https://doi.org/10.1016/S1470-2045\(22\)00793-8](https://doi.org/10.1016/S1470-2045(22)00793-8).

NHS England currently commissions the following TKI’s for the treatment of metastatic renal cell carcinoma:

Prior approval (Blueteq) form required:

- **CABO2** – Cabozantinib for previously treated advanced renal cell carcinoma (TA463)
- **CABO3** – Cabozantinib for patients treatment-naïve to vascular endothelial growth factor (VEGF)-targeted therapy and with intermediate or poor risk advanced renal cell carcinoma (TA542)
- **TIV1** – Tivozanib for treating advanced renal cell carcinoma (TA512)

No prior approval (Blueteq) form required

- Sunitinib for the first-line treatment of advanced and/or metastatic renal cell carcinoma (TA169)
- Pazopanib for the first-line treatment of advanced renal cell carcinoma (TA215)

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<sup>1</sup> Brown, J.E., Royle, K.L., Gregory, W., Ralph, C., Maraveyas, A., Din, O., Eisen, T., Nathan, P., Powles, T., Griffiths, R. and Jones, R., 2023. Temporary treatment cessation versus continuation of first-line tyrosine kinase inhibitor in patients with advanced clear cell renal cell carcinoma (STAR): An open-label, non-inferiority, randomised, controlled, phase 2/3 trial. *The Lancet Oncology*, 24(3), pp.213-227.

- Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment (TA333)

The following exemption from the treatment break policy now applies for the indications listed above:

- Following 24 weeks of continuous TKI therapy and if there is no evidence of disease progression whilst on treatment, patients and clinicians may choose to stop treatment for a planned drug free interval/treatment break and then restart on disease progression as per the STAR trial design.
- Trusts must ensure that patients who undergo planned treatment breaks must have regular clinical and radiological assessments.
- If the patient benefits from restarting after the first planned treatment break, they can take further planned treatments breaks following the same strategy, i.e. after a further 24 weeks on treatment.

The NHS England treatment break policy will be updated to reflect these changes in due course.

I would be grateful if you could cascade this information to relevant clinical teams within your organisation to support the consistent adoption of the policy nationally.

With best wishes,



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Region & Consultant Orthopaedic Surgeon



Tracey Williams  
Principal Pharmacist