# Audit of the use of Sunitinib maleate in metastatic renal cell carcinoma in the North of England Cancer Network (NECN)

**Descriptor:**

Audit of Sunitinib malaete in metastatic renal cell carcninoma carried out to compare use against NICE guidelines and to establish patient outcomes compared to published trial populations.

**Background:**

Metastatic renal cell carcinoma (mRCC) has a poor prognosis and Sunitinib gained NICE approval in March 2009 as first line treatment. The NECN was the first in the UK to approve its use in July 2007.

## The Cycle

**The standard:**

1) Patient selection:

   • mRCC

   • WHO performance status (PS) 0,1

2) Treatment schedule:

   • 4 weeks on 2 weeks off at 50 mg OD

   • Reduced to 37.5mg or 25mg OD to manage toxicity

3a) Trial median progression free survival (PFS):

   • 11 months [2]

3b)Trial overall survival (OS):

   • 26.4 months

**Target:**

• 100 % Performance status 0-1

• 100 % Sunitinib given as described in the standard

• Comparable OS/PFS

## Assess local practice

**Indicators:**

As part of early Sunitinib use at NECN, local agreement was to audit this patient population.

**Data items to be collected:**

• Centre

• DOB

• Gender

• Performance status

• Diagnosis date,

• Nephrectomy?

• Mets identified date

• Pre-sunitinib treatment

• Sunitinib start date

• Best CT response

• Best CT response date

• Sunitinib Stop date

• Reason for stopping

• Haem Grade 3/4 toxicity

• Non-haem Grade 3/4 toxicity

• Hypothyroid date Dx

• New Hypertension date

• Interruption (Y/N)

• Interruption cycle

• Dose Modified (Y/N)

• Dose modifications (mg)

• Dose modified (cycle)

• Schedule change (Y/N)

• Schedule change (type)

• Progression

• Progression date

• Last seen/death date

• Current status (dead/alive)

• Post-sunitinib treatment

• Anything noteworthy?

**Suggested number:**

~100 patients

This number should allow a multivariate analysis.

**Suggestions for change if target not met:**

- Target 1 - performance status - significant determinant of outcome. If not met - explore reasons for treating poor performance status patients. Is PS an accurate representation of patient fitness?

- Target 2 - dose and scheduling. Aim to start all patients on full dose as modifications are easy to implement and lower starting doses associated with poorer outcomes

- Since completion of this audit Pazopanib has become available for first line treatment as an alternative to Sunitinib and this may be a suitable alternative to dose reductions or for patients which are considered less fit

- In addition Temsirolimus is available for high risk patients. Therefore, data collection could be adapted to include MSKCC risk factors

**Resources:**

• Data collection was carried out using electronic records available at out cancer centres

• Two SpRs updated the patient information over an 8 month period

**References:**

1. NICE Technology Appraisal 169, March 2009, <http://guidance.nice.org.uk/TA169>
2. Motzer RJ et al. Overall survival and updated results for sunitinib compared with interferon alfa in patients with metastatic renal cell carcinoma. J Clin Oncol. 2009 Aug 1;27(22):3584-90

**Editor's comments:**

Audit presented at 2012 RCR Audit Meeting.

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