

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to [Section H](#) of the Pharmaceutical Schedule. For community funding, see the [Special Authority Criteria](#).

PRESCRIBER

PATIENT:

Name:

Name:

Ward:

NHI:

Sunitinib

INITIATION – RCC

Re-assessment required after 3 months

Prerequisites (tick boxes where appropriate)

The patient has metastatic renal cell carcinoma
and

The patient is treatment naive
or
 The patient has only received prior cytokine treatment
or
 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval
and

The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance
and
 The cancer did not progress whilst on pazopanib

and

The patient has good performance status (WHO/ECOG grade 0-2)
and
 The disease is of predominant clear cell histology
and

Lactate dehydrogenase level > 1.5 times upper limit of normal
and
 Haemoglobin level < lower limit of normal
and
 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L)
and
 Interval of < 1 year from original diagnosis to the start of systemic therapy
and
 Karnofsky performance score of less than or equal to 70
and
 2 or more sites of organ metastasis

and

Sunitinib to be used for a maximum of 2 cycles

Note: RCC - Sunitinib treatment should be stopped if disease progresses.
Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.

CONTINUATION – RCC

Re-assessment required after 3 months

Prerequisites (tick boxes where appropriate)

No evidence of disease progression
and
 The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: Date:

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PRESCRIBER

Name:

Ward:

PATIENT:

Name:

NHI:

Sunitinib - continued

INITIATION – GIST

Re-assessment required after 3 months

Prerequisites (tick boxes where appropriate)

- The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST)
- and
- The patient's disease has progressed following treatment with imatinib
- or
- The patient has documented treatment-limiting intolerance, or toxicity to, imatinib

CONTINUATION – GIST

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:**
- The patient has had a complete response (disappearance of all lesions and no new lesions)
- or
- The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non-measurable disease)
- or
- The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression
- and
- The treatment remains appropriate and the patient is benefiting from treatment

CONTINUATION – GIST pandemic circumstances

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST)
- and
- The patient is clinically benefiting from treatment and continued treatment remains appropriate
- and
- Sunitinib is to be discontinued at progression
- and
- The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector

Note: GIST - It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

I confirm that the above details are correct:

Signed: Date: