

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**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

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: .....