HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

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

or

- ○ 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: .....