

APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER** Reg No:

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

Sunitinib

Initial application — RCC

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

The patient has intermediate or poor prognosis defined as:

Lactate dehydrogenase level > 1.5 times upper limit of normal

or

Haemoglobin level < lower limit of normal

or

Corrected serum calcium level > 10 mg/dL (2.5 mmol/L)

or

Interval of < 1 year from original diagnosis to the start of systemic therapy

or

Karnofsky performance score of less than or equal to 70

or

2 or more sites of organ metastasis

and

Sunitinib to be used for a maximum of 2 cycles

Initial application — GIST

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Sunitinib - continued

Renewal — RCC

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

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

Note: 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

Renewal — GIST

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

Note: 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.

Renewal — GIST pandemic circumstances

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

The patient has unresectable or metastatic malignant gastrointestinal stromal (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 Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

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