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: .....

Sirolimus

INITIATION

Prerequisites (tick box where appropriate)

○ For rescue therapy for an organ transplant recipient

Note: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:

- GFR < 30 ml/min; or
- Rapidly progressive transplant vasculopathy; or
- Rapidly progressive obstructive bronchiolitis; or
- HUS or TTP; or
- Leukoencepthalopathy; or
- Significant malignant disease

INITIATION – severe non-malignant lymphovascular malformations*

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

○ Patient has severe non-malignant lymphovascular malformation*

and

○ Malformations are not adequately controlled by sclerotherapy and surgery

or

○ Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate

or

○ Sirolimus is to be used to reduce malformation prior to consideration of surgery

and

○ Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team

and

○ Patient has measurable disease as defined by RECIST version 1.1 (see Note)

CONTINUATION – severe non-malignant lymphovascular malformations*

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

○ Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note)

or

○ Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes

and

○ No evidence of progressive disease

and

○ The treatment remains clinically appropriate and the patient is benefitting from the treatment

Note: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer et al. Eur J Cancer 2009;45:228-47)

Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sirolimus *- continued*

INITIATION – renal angiomyolipoma(s) associated with tuberous sclerosis complex*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist or urologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has tuberous sclerosis complex*

and

- ○ Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth

CONTINUATION – renal angiomyolipoma(s) associated with tuberous sclerosis complex*
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Documented evidence of renal angiomyolipoma reduction or stability by magnetic resonance imaging (MRI) or ultrasound

and

- ○ Demonstrated stabilisation or improvement in renal function

and

- ○ The patient has not experienced angiomyolipoma haemorrhage or significant adverse effects to sirolimus treatment

and

- ○ The treatment remains appropriate and the patient is benefitting from treatment

Note: Indications marked with * are unapproved indications

INITIATION – refractory seizures associated with tuberous sclerosis complex*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has epilepsy with a background of documented tuberous sclerosis complex*

and

- ○ Vigabatrin has been trialled and has not adequately controlled seizures

and

- ○ Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least two of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note)

or

- ○ Vigabatrin is contraindicated

and

- ○ Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least three of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note)

and

- ○ Seizures have a significant impact on quality of life

and

- ○ Patient has been assessed and surgery is considered inappropriate for this patient, or the patient has been assessed and would benefit from mTOR inhibitor treatment prior to surgery

Note: Those of childbearing potential are not required to trial phenytoin sodium, sodium valproate, and topiramate. Those who can father children are not required to trial sodium valproate.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sirolimus *- continued*

CONTINUATION – refractory seizures associated with tuberous sclerosis complex*
Re-assessment required after 12 months

Prerequisites (tick box where appropriate)

❍ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Demonstrated significant and sustained improvement in seizure rate (e.g. 50% reduction in seizure frequency) or severity and/or patient quality of life compared with baseline prior to starting sirolimus treatment

Note: Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....