

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
- Leukoencephalopathy; 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.

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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

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