

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: Name:

Ward: 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 documented 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:

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Name: Name:

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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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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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Signed: Date: