APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA2270
January 2025

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: .....

Sirolimus (Rapamune)

Initial application
Applications from any medical practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick box where appropriate)

☐ The drug is to be used 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

Initial application — severe non-malignant lymphovascular malformations*
Applications from any relevant practitioner. Approvals valid for 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)

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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Sirolimus (Rapamune) *- continued*

Renewal — severe non-malignant lymphovascular malformations*

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

Applications from any relevant practitioner. Approvals valid for 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

Initial application — renal angiomyolipoma(s) associated with tuberous sclerosis complex*

Applications only from a nephrologist or urologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

☐ Patient has tuberous sclerosis complex*

and

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

Renewal — renal angiomyolipoma(s) associated with tuberous sclerosis complex*

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

Applications from any relevant practitioner. Approvals valid for 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

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Sirolimus (Rapamune) *- continued*

Initial application — refractory seizures associated with tuberous sclerosis complex*
Applications only from a neurologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ 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 age potential are not required to trial phenytoin sodium, sodium valproate, or topiramate. Those who can father children are not required to trial sodium valproate.

Renewal — refractory seizures associated with tuberous sclerosis complex*

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

Applications only from a neurologist. Approvals valid for 12 months.
Prerequisites(tick box where appropriate)

☐ 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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