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|--|---------------------------|-------------------------------|
| 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
- Leukoencephalopathy; 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)

| | |
|--------------------------|--|
| <input type="checkbox"/> | Patient has severe non-malignant lymphovascular malformation* |
| and | |
| <input type="checkbox"/> | Malformations are not adequately controlled by sclerotherapy and surgery |
| or | |
| <input type="checkbox"/> | Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate |
| or | |
| <input type="checkbox"/> | Sirolimus is to be used to reduce malformation prior to consideration of surgery |
| and | |
| <input type="checkbox"/> | Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team |
| and | |
| <input type="checkbox"/> | 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 Health New Zealand, 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 trialed 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

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