

|                                                |                           |                               |
|------------------------------------------------|---------------------------|-------------------------------|
| <b>APPLICANT</b> (stamp or sticker acceptable) | <b>PATIENT</b> NHI: ..... | <b>REFERRER</b> 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)

- ☐ Patient has severe non-malignant lymphovascular malformation\*
- and
- or

☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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| .....                                          | .....                     | .....                         |
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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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| .....                                          | .....                     | .....                         |
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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)

|                          |                                                                                                                                                                                                                                                                                        |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> | Patient has epilepsy with a background of documented tuberous sclerosis complex                                                                                                                                                                                                        |
| and                      |                                                                                                                                                                                                                                                                                        |
| <input type="checkbox"/> | Vigabatrin has been trialed and has not adequately controlled seizures                                                                                                                                                                                                                 |
| and                      |                                                                                                                                                                                                                                                                                        |
| <input type="checkbox"/> | 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                       |                                                                                                                                                                                                                                                                                        |
| <input type="checkbox"/> | Vigabatrin is contraindicated                                                                                                                                                                                                                                                          |
| and                      |                                                                                                                                                                                                                                                                                        |
| <input type="checkbox"/> | 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                      |                                                                                                                                                                                                                                                                                        |
| <input type="checkbox"/> | Seizures have a significant impact on quality of life                                                                                                                                                                                                                                  |
| and                      |                                                                                                                                                                                                                                                                                        |
| <input type="checkbox"/> | 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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