## Individual Patient Use (IPU) Application

# Use this form to apply for approval for hospital use of a medicine in an individual patient under the care of Canberra Hospital and Health Services.

# *Completion of this application is the responsibility of the treating specialist.*

The Drug and Therapeutics Committee will assess the application based on previous treatment failure with standard therapy, the risk associated with the proposed therapy, evidence of effectiveness and financial implications. High cost and high risk treatment options require rigorous review to ensure that the risk benefit ratio is adequately evaluated.An outpatient approved regimen will require the patient to pay a general or concessional copayment toward the cost of the medicine at the time of dispensing.

# Patient Details

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| --- | --- |
| Patient Name: | Mark Spittle |
| MRN:  | 20441431 |
| Date of Birth: | 26/06/1965 |
| Ward / Outpatient Location: | Outpatient |

# Standard application review time is five business days. If you require more urgent assessment of your application please contact the formulary management pharmacist on ext 42721, or email dtc@act.gov.au to discuss an appropriate timeframe.

# Details of Medicine

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| --- | --- |
| Australian approved (generic) name: | Cinacalcet |
| Dose, frequency, route:  | 60mg daily |
| Proposed indication for use: | Refractory primary hyperparathyroidism |
| Proposed duration of therapy: | Ongoing |

Hospital formulary listing of the medicine: (please answer **ONE** of the following)

The medicine:

[ ]  Is not listed on hospital formulary

[x]  Is listed on hospital formulary, but the proposed ***indication*** is outside hospital formulary restriction

Will the patient be eligible for ongoing supply through the Pharmaceutical Benefits Scheme?

 ~~YES~~/NO

If no, explain implications for continuity of supply. (For example, will the drug be supplied for inpatient use, outpatient use, or both? Will the hospital be required to provide ongoing therapy after discharge?)

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| Drug needs to be supplied for ongoing outpatient use. |

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| Cost per month: | $90 |
| Expected annual number of patients presenting with this therapy requirement | 1 (current application) |

**Reasons for Application**

Detail your reasons for applying to use this medicine.

**Address the following points and provide published evidence as support (in full-text PDF format)**:

* Patient specific details; including past treatment options and response
* Alternative treatment options; including non-pharmacological options and treatment plan if DTC approval is not obtained
* Expected patient outcomes with planned objective measurements for achieving these outcomes
* Potential for adverse drug reaction and risk profile of the medicine

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| Persistent hypercalcaemia despite 3 parathyroid operations. Patient initially diagnosed with primary hyperparathyroidism in 2015. Inconclusive Sestamibi scan. Sub total parathyroidectomy and hemithyroidectomy but had persistent postoperative hypercalcaemia. Subsequent Sestamibi scan showed a large parathyroid adenoma in the chest (initial scan did not include chest) which was removed in early 2016 by a thoracic surgeon. Patient initially had normal calcium and parathyroid hormone levels but about 18 months later these levels rose again. A 4D CT scan suggested a parathyroid adenoma but this was found, at a third operation, to be a lymph node. He had two parathyroid glands and the remainder of his thyroid removed but his calcium remained high following this. A post-operative Sestamibi scan was negative. Latest corrected calcium 2.62mmol/l on 60mg cinacalcet daily. Patient is currently self-funding this but has difficulty meeting cost.No alternative options are available. Bisphosphonates only have a transient effect, are less effective than cinacalcet and need to be administered intravenously. Intravenous hydration not feasible in outpatient setting.Patient risks severe hypercalcaemia and hypercalcaemic crisis if untreated.Aim for corrected calcium in normal range or 0.05mmol/l above normal range. No symptoms of hypercalcaemia.Patient currently able to tolerate treatment, so no adverse effects expected. Infrequent side effects include seizure, cardiac arrhythmia, hypersensitivity |

**Declaration by Requesting Consultant**

By signing below, I certify that:

I agree to provide written feedback by requested due dates regarding the patient in the format requested by the Drug and Therapeutics Committee.

If the medicine is ***not*** registered for use in Australia, I will complete and submit the necessary TGA approval forms and obtain patient consent.

[x]  I am not aware of any potential conflicts of interest that may arise from this application

**OR**

[ ]  I may have a conflict of interest: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Details of Requesting Consultant**

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| Name of Treating Specialist: | Robert Schmidli |
| Specialty: | Endocrinologist |
| Signature: |       | Date: | 30/07/2020 |
| Contact number: | 0413 614 456 |

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| **The Drug & Therapeutics Committee will determine the need for and frequency of progress reports at initial application assessment. When the Committee receives a progress report, if approved for continued therapy, the Committee will notify the applicant without requesting further endorsement from the Head of Unit, or Executive Director. The Committee agrees to forward a monthly report of approvals and expenditure for the unit. The Committee will notify the Head of Unit and Executive Director if concerns regarding ongoing approval costs are identified.** |

**Declaration by Clinical Director of Specialty**

By signing below, I certify that:

[ ]  I approve the journaling of cost of treatment to the unit for the duration approved by the Drug & Therapeutics Committee.

**OR**

[ ]  I approve the journaling of cost of treatment to the unit for the duration approved by the Drug & Therapeutics Committee in the initial approval. I request a copy of each progress report to approve ongoing costs.

**Endorsed by:**

|  |  |
| --- | --- |
| Name of Clinical Director of Specialty |       |
| Position / Appointment |       |
| Signature |       | Date |       |

If cost for 12 months treatment is more than $2,000 endorsement by financial delegate (Divisional Executive Director) is required. This will be obtained via the DTC Secretariat.

*Committee Use Only*

**Financial Delegate Approval:**

**Declaration by Executive Director**

By signing below, I certify that:

[ ]  I approve the journaling of cost of treatment to the unit for the duration approved by the Drug & Therapeutics Committee.

**OR**

[ ]  I approve the journaling of cost of treatment to the unit for the duration approved by the Drug & Therapeutics Committee in the initial approval. I request a copy of each progress report to approve ongoing costs.

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| Name of Executive Director |       |
| Signature |       | Date |       |

#### Forward the completed application and associated evidence via email to the Secretary of the Drug and Therapeutics Committee dtc@act.gov.au