ACT Government | Canberra Health Services

Drug and Therapeutics Committee

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 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 co-payment toward the cost of the medicine at the time of each dispensing.

Patient Details

Patient Name:	Susanne BRUHN
MRN:	11024543
Date of Birth:	06/08/1951
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 43054, or email dtc@act.gov.au to discuss an appropriate timeframe.

Details of Medicine

Australian approved (generic) name:	Degarelix
Dose, frequency, route:	80mg, approx. 4-monthly
Proposed indication for use:	Metastatic steroid cell ovarian cancer, hyperandrogenism
Proposed duration of therapy:	Indefinite

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

The medicine:

☐ Is not listed on hospital formulary

☒ 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?)

Outpatient use

Cost per month:	$333 per dose (3-monthly) - $111 per month

Expected annual number of patients presenting with this therapy requirement	<1

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

Patient presented with virilising symptoms and testosterone level in male range (12.0nmol/L) in late 2017. Diagnosed with a left ovarian steroid cell tumour after laparoscopic bilateral salpingo-oophorectomy, hysterectomy and D&C in December 2017. No adjuvant therapy. Re-presented in 2021 with virilising symptoms and testosterone level 11.9nmol/l. Diagnostic laparoscopy in July 2021 showed widespread peritoneal deposits; histology confirmed recurrent Sertoli-Leydig cell tumour. Not considered suitable for peritonectomy. Conventional chemotherapy considered excessively toxic compared to hormonal therapy. Hormonal treatment recommended by Australian Rare Cancer Portal. Degarelix is a pure GnRH antagonist, compared to more commonly used agonists. We have previously treated a patient with ovarian hyperthecosis with testosterone level 22nmol/L with a single dose of Degarelix 80mg, resulting in permanent suppression of testosterone levels and improvement in clinical features (PMID 34877444).

Current patient was treated with Degarelix 80mg SC on 29/9/21 as compassionate supply from Ferring. Testosterone, LH, FSH, estradiol levels dropped to undetectable until 11/2/22, when testosterone rose to 7.1nmol/L. Several case reports have documented responses to GnRH agonists in similar cases:

PMID 9496356: No disease progression at 26 months. Normalisation testosterone.

PMID 31372485: Normalisation testosterone, radiological partial response

PMID 9764654: Progressive disease following chemotherapy. Robust radiological response to GnHa

PMID 10502449: Normalisation of testosterone after one cycle of GnRHa

ACT Government | Canberra Health Services

Drug and Therapeutics Committee

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.

☒ 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

Name of Treating Specialist:	Robert Schmidli		
Specialty:	Endocrinologist		
Signature:		Date:	15/02/2022
Contact number:	0413 614 456		
Additional contact e.g. Reg/RMO:			

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. (If requesting Consultant is the Head of Department, then approval from a senior specialist within the speciality or a peer review is required).
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	

ACT Government | Canberra Health Services

Drug and Therapeutics Committee

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.

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