REQUEST FOR FUNDING FOR A DRUG, DEVICE OR PROCEDURE EXCLUDED FROM THE PAYMENT BY RESULTS TARIFF

- For drugs this form only needs to be submitted if the price per course or price p.a. is **above £5000**. This threshold will be reviewed at intervals.
- Please ensure this form is completed accurately. Post-payment verification will take place.
- Incomplete forms are likely to be returned to the hospital without agreement to fund.

On completion, please email to Laverne Coyle for forwarding to the relevant PCT.

CONTACT INFORMATION

Trust Name	Hammersmith Hospitals	
1. Patient	**Initials:**	
	Hospital ID number:	
	NHS number:	
	DoB:	
	Registered GP name:	
	Registered GP postcode:	
2. Patient's consultant and a second doctor who can be contacted about this funding request if necessary	**Consultant:**	
	Speciality:	
	Tel:	
	email:	
	Another doctor who can be contacted about this request if necessary	
	Designation:	
	Tel:	
	email:	

DRUG, DEVICE OR PROCEDURE THE FUNDING IS REQUESTED FOR

3. Patient's diagnosis and the indication for the drug, device or procedure	**Acromegaly**	
4. Details of the drug, device or procedure	**Name:**	Pegvisomant
	Dose and frequency:	
	Planned duration of treatment with the drug:	
	Anticipated cost (inc VAT)	Email Paul Bains to complete this once form has been completed.

5. Is this patient's treatment with this drug, device or procedure in line with a technology appraisal or interventional procedure guidance from NICE (or, for beta-interferon, in line with the ABN criteria for starting and stopping treatment)?

If **yes**, specify the guidance NO

Date……

Then STOP HERE. There is no need to complete the rest of this proforma.

If the treatment is not in line with a technology appraisal or interventional procedure guidance from NICE, and it is a drug treatment, go to box 6 below. For non-drug treatments go to box 7.

6. Is this patient's treatment with this drug in line with a protocol agreed by the Trust's New Drugs Panel?

If **yes**, specify the protocol No

Date……

Then STOP HERE. There is no need to complete the rest of this proforma.

If the treatment is not in line with a protocol agreed by the Trust's New Drugs Panel, go to box 7.

7. Is this treatment being given as part of a clinical trial the patient has entered?	Delete as appropriate: If **Yes**, give details (e.g. name of trial, is it an MRC/National trial?) No		
8. (a) What would be the standard treatment at this stage?	**Pituitary surgery/radiotherapy** **Somatostatin analogues** **Dopamine agonists**		
(b) If the treatment being given to this patient is not the standard treatment, what are the circumstances that make the latter inappropriate for this patient?	Intolerance to dopamine agonists Inadequate reduction of growth hormone burden with somatostatin analogues Failure to control growth hormone burden with radiotherapy **Delete as necessary**		
9. (a)In case of intervention for **cancer**:	What is disease status? (e.g. at presentation,1st, 2nd or 3rd relapse)		N/A
	How advanced is the cancer? (stage)		N/A
	Describe any metastases:		N/A
(b) In case of intervention for **non-cancer**:	What is the patient's clinical severity? (Where possible use standard scoring systems)		**See attached patient narrative**
10. Summary of previous intervention(s) this patient has received for the condition. * Reasons for stopping may include: ▪ Course completed ▪ No or poor response ▪ Disease progression ▪ Adverse effects/poorly tolerated	**Dates**	**Intervention (e.g. drug / surgery)**	**Reason for stopping* / Response achieved**
		Somatostatin analogues – delete if treatment has not been tried	
		Dopamine agaonists – delete if treatment has not been tried	

11. Anticipated start date			
12. (a) How will you monitor the effectiveness of this treatment?	Serum IGF-1 levels		
(b) What would you consider to be a successful outcome for this treatment in this patient?	Reduction of serum IGF-1 levels to approximately the middle of the normal range		
(c) What will be the criteria for stopping treatment?	Intolerance to pegvisomant – eg side effects, inability to manage once-daily self-injection		
13. Are there any circumstances that are specific to this patient that you would like to highlight?	Delete as appropriate:		

CLINICAL EVIDENCE

14. Would you like to cite any published trial evidence in support of this drug treatment (optional)?	**PUBLISHED**[1] **trials/data** - please forward papers / web links for peer-reviewed papers where available 1. Rajasoorya C, Holdaway IM, Wrightson P, Scott DJ, Ibbertson HK. Determinants of clinical outcome and survival in acromegaly. Clin Endocrinol (Oxf) 1994; 41(1):95-102. 2. Swearingen B, Barker FG, Katznelson L et al. Long-term mortality after transsphenoidal surgery and adjunctive therapy for acromegaly. J Clin Endocrinol Metab 1998; 83(10):3419-3426. 3. Holdaway IM, Rajasoorya C. Epidemiology of acromegaly. Pituitary 1999; 2(1):29-41. 4. Abosch A, Tyrrell JB, Lamborn KR, Hannegan LT, Applebury CB, Wilson CB. Transsphenoidal microsurgery for growth hormone-secreting pituitary adenomas: initial outcome and long-term results. J Clin Endocrinol Metab 1998; 83(10):3411-3418. 5. Trainer PJ, Drake WM, Katznelson L et al. Treatment of acromegaly with the growth hormone-receptor antagonist pegvisomant. N Engl J Med 2000; 342(16):1171-1177. 6. Paisley AN, Trainer PJ, Drake WM. The place of pegvisomant in the acromegaly treatment algorithm. Growth Horm IGF Res 2004; 14 Suppl A:S101-S106. 7. van der Lely AJ, Hutson RK, Trainer PJ et al. Long-term treatment of acromegaly with pegvisomant, a growth hormone receptor

	antagonist. Lancet 2001; 358(9295):1754-1759. 8. Herman-Bonert VS, Zib K, Scarlett JA, Melmed S. Growth hormone receptor antagonist therapy in acromegalic patients resistant to somatostatin analogs. J Clin Endocrinol Metab 2000; 85(8):2958-2961. 9. Drake WM, Parkinson C, Akker SA, Monson JP, Besser GM, Trainer PJ. Successful treatment of resistant acromegaly with a growth hormone receptor antagonist. Eur J Endocrinol 2001; 145(4):451-456.

Who completed this proforma?	Name: Post: Signature: Date: