Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1698		
Policy Title	Metreleptin Congenital Leptin Deficiency Proposal **for routine commission** (ref A3.1)		
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About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes. • Each theme sets out a number of questions. • All questions are answered by selecting a drop down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text. • Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Congenital leptin deficiency is a rare disorder. Only a small number of cases have been reported in the medical literature. Prevalence in England is 0.16 patients per million. This condition is inherited in an autosomal recessive pattern□, which means both copies of the gene in each cell have mutations. The parents of an individual with an autosomal recessive condition each carry one copy of the mutated gene, but they typically do not show signs and symptoms of the condition *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	Since first being described by Montague et al in 1997, a total of forty individuals with congenital leptin deficiency have been identified worldwide as at 2011. 20 cases are now being treated at ADH in Cambridge, 7 from England, 1 from Scotland (remainder from overseas). There are no other known cases being treated elsewhere in the UK. *Source: Evidence Review*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages** Please specify The European CHMP Medicines Agency has recommended approval of metreleptin (Myalepta) for treatment of leptin deficiency in patients to treat complications of leptin deficiency in patients with congenital or acquired generalised lipodystrophy and in a subset of patients with partial lipodystrophy. A licensing application has been submitted in the EU for metreleptin. Marketing Authorisation is expected by the end of August. Following marketing authorisation, use of metreleptin in patients with for congenital leptin deficiency would be classed as an off-label use of an

<table>
<tr><td></td><td>approved medication. Currently metreleptin is provided free of charge by Aegerion Pharmaceuticals for the seven patients from England as part of a named patient programme for compassionate use.</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>In the UK the known population ranges from 5 years to 30 years
Source: ADH Cambridge</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Evenly</u>
If unevenly, estimate regional distribution by %:<table><tr><td>North</td><td>0</td></tr><tr><td>Midlands & East</td><td>0</td></tr><tr><td>London</td><td>0</td></tr><tr><td>South</td><td>0</td></tr></table>Source: ADH Cambridge</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?</td><td><u>Constant</u>
Incidence could be at the rate of 1 patient per year
Source: Medical literature and past experience of incidence allowing for improved awareness of the condition leading to diagnosis at a younger age.</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>
Please specify
Experience of incidence from 2011. As this is a recessive condition,</td></tr>
</table>

<table>
<tr><td></td><td>assuming the prevalence of consanguineous marriage remains the same (local and migrants), the incidence is unlikely to change. Source: Medical literature and past experience of incidence</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td><table><tr><td>YR2 +/-</td><td>0</td></tr><tr><td>YR3 +/-</td><td>0</td></tr><tr><td>YR4 +/-</td><td>0</td></tr><tr><td>YR5 +/-</td><td>0</td></tr><tr><td>YR10 +/-</td><td>0</td></tr></table>Source: Service specification proposition section 3.1

<u>No</u>
The patient population is so small ONS growth populations have not been taken into consideration as irrelevant</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new treatment</u></td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>4 follow up outpatient appointments per year/per patient Patients are currently on metreleptin compassionate use.
Source: ADH Cambridge</td></tr>
</table>

A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	4 follow up outpatient appointments per year/per patient *Source:* Clinical advice on observed pathway for patients currently on compassionate use
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	7 patients in year 1. If the drug was to be withdrawn from Year 6 a 50% mortality rate maybe observed. *Source:* See A2.1 Please specify Lead clinician specifying patient pathways
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Patients are currently referred to the Genetics of Obesity team at Addenbrookes Hospital Cambridge. Diagnosis is based on measurement of serum leptin levels, which are undetectable in those with congenital leptin deficiency followed by sequencing of the leptin gene. All patients are currently on compassionate use metreleptin via homecare with 4 follow up appointments*at* ADH /year. .
A4.2. What are the current treatment access and stopping criteria?	Criteria for starting treatment: undetectable levels of leptin and homozygous mutation in the leptin gene AND measureable leptin with homozygous mutation in the leptin gene (ideally supported by studies of biological activity).

	Stopping Criteria: Failure of leptin therapy as indicated by: Reduction in body mass index of; in adults less than 5 kg/m2 after one year of therapy; in children a Z score persistently greater than 3 after one year of therapy.
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, a) 100 b) 0% c) 100% d) 100% e) 100% *Source:* Observed experience
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No** There is no alternative treatment. Untreated there is a very high mortality (>50%). If yes, Click here to enter text. *Source: required*
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following	Total estimated eligible a) na b) na c) na

<table>
<tr><td>assessment
c) Choose to initiate treatment
d) Comply with treatment
e) Complete treatment?</td><td>d) na
e) na
Source: required</td></tr>
<tr><td colspan="2">A6 New Patient Pathway</td></tr>
<tr><td>A6.1 What percentage of the total eligible population is expected to:
a) Be clinically assessed for treatment
b) Be considered to meet an exclusion criteria following assessment
c) Choose to initiate treatment
d) Comply with treatment
e) Complete treatment?</td><td>If not known,
a) 100%
b) 0%
c) 100%
d) 100%
e) 100%
Source: PWG</td></tr>
<tr><td>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</td><td><u>Life long</u>
For time limited treatments, specify frequency and/or duration.</td></tr>
<tr><td colspan="2">A7 Treatment Setting</td></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td>Select all that apply:<table><tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr><tr><td>Acute Trust: inpatient</td><td>☐</td></tr><tr><td>Acute Trust: day patient</td><td>☐</td></tr><tr><td>Acute Trust: outpatient</td><td>☒</td></tr></table></td></tr>
</table>

	<table><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table> Please specify: Medtreleptin would be delivered to the patient at home. However it is expected that initiation treatment, initial monitoring and dose changes would be carried out at the tertiary treatment centres (or in conjunction with them, e.g. via telephone consultation). Once a person is stabilised on metreleptin, then repeat prescriptions could be provided locally (and delivered via home delivery).
A7.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>0</td></tr><tr><td>MIDLANDS & EAST</td><td>0</td></tr><tr><td>LONDON</td><td>0</td></tr><tr><td>SOUTH</td><td>0</td></tr></table>
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** Please specify: All patients are currently managed at the one centre at Addenbrooke's Hospital in Cambridge. *Source:* PWG

A8 Coding

A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity

Select all that apply:

Aggregate Contract Monitoring *	☒
Patient level contract monitoring	☐
Patient level drugs dataset	☒
Patient level devices dataset	☐
Devices supply chain reconciliation dataset	☐
Secondary Usage Service (SUS+)	☒
Mental Health Services DataSet (MHSDS)	☐
National Return**	☐
Clinical Database**	☐
Other**	☐

**If National Return, Clinical database or other selected, please specify: Metreleptin is distributed via home delivery. ADH will be able to provide data and Blueteq could be used.

A8.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply:

OPCS v4.8	☒
ICD10	☒
Treatment function code	☒
Main Speciality code	☒
HRG	☐

	SNOMED ☒ Clinical coding / terming methodology used by clinical profession ☐
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**<u>Already specified in current NHS England Drugs List document</u>** If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication: METRELEPTIN – but not for this indication If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead: Not applicable
A8.4 **Identification Rules for Devices:** How are device costs captured?	**<u>Not applicable</u>** If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance). If the device is not excluded from Tariff **nor** covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team.
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**<u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool</u>** If activity costs are already captured please specify the specialised service code and description NCBPS23E CHILDRENS SERVICES - ENDOCRINOLOGY NCBPS27Z ENDOCRINOLOGY

<table>
<tr><td></td><td>If activity costs are already captured please specify whether this service needs a separate code.
If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team.

If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team.</td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u>
Please specify
No changes to the commissioning of any service activity are planned</td></tr>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.</td><td>Select all that apply:<table><tr><td>Drugs or Device MDS</td><td>☐</td></tr><tr><td>Blueteq</td><td>☒</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table></td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u></td></tr>
<tr><td>A9.4 Contract monitoring</td><td><u>No</u></td></tr>
</table>

Is this part of routine contract monitoring?	
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No**
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**No**
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	All patients are managed by ADH Cambridge
B1.2 Will the proposition change the way the commissioned service is organised?	**No**
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care** Please specify: The treatment is administered subcutaneously, twice daily and continues for the lifetime of the patient. Dosage may vary depending on age, weight, gender and clinical response to treatment. Metreleptin will delivered to patients via homecare for self or carer administration

<table>
<tr><th colspan="2">B2 Geography & Access</th></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☐</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>

Source: Equalities Impact Assessment</td></tr>
<tr><td>B2.4 Is the new policy likely to improve equality of access and/or outcomes?</td><td><u>Increase</u>
Please specify:
NICE ID861 is for metreleptin for generalised and partial lipodystrophy. This Highly Specialised Technology Appraisal is not for congenital leptin deficiency and so has no impact on the provisional policy proposal presented here. The expected publication date of HST ID861 is the 26 September 2018.
A licensing application has been submitted in the EU by Aegerion for metreleptin to be used to treat complications of leptin deficiency in patients with congenital or acquired generalised lipodystrophy and in a subset of patients with partial lipodystrophy which also results in a lack of leptin.
The 7 patients from England are currently on compassionate drug use. Agerion have given notice that pending the Marketing Authorisation new</td></tr>
</table>

	patients will not be agreed for compassionate use supply of metreleptin for congenital leptin deficiency. If agreed this policy will allow new patients to access metreleptin and will allow current patients to continue on treatment, there is no alternative treatment for these patients and therefore agreement of this policy will improve outcomes for patients. *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** Please specify: Introduction of prior approval (Blueteq)
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Not applicable
B3.4 Is a change in provider physical infrastructure required?	**No**
B3.5 Is a change in provider staffing required?	**No**
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**

<table>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u></td></tr>
<tr><td>B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region</td><td><u>Increase</u>
Please complete table:
<table>
<tr><th>Region</th><th>Current no. of providers</th><th>Future
State expected range</th><th>Provisional or confirmed</th></tr>
<tr><td>North</td><td>0</td><td></td><td>select</td></tr>
<tr><td>Midlands & East</td><td>0</td><td>1</td><td>select</td></tr>
<tr><td>London</td><td>0</td><td></td><td>select</td></tr>
<tr><td>South</td><td>0</td><td></td><td>select</td></tr>
<tr><td>Total</td><td>0</td><td></td><td>select</td></tr>
</table>
Please specify:
ADH Cambridge currently treat the patients through compassionate funding</td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:
<table>
<tr><td>Publication and notification of new policy</td><td>☒</td></tr>
<tr><td>Market intervention required</td><td>☐</td></tr>
<tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr>
</table></td></tr>
</table>

	<table><tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr><tr><td>Any qualified provider</td><td>☐</td></tr><tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☐</td></tr><tr><td>Procurement</td><td>☐</td></tr><tr><td>Other</td><td>☒</td></tr></table> Please specify: Single Tender Procurement
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	**No**
Section C - Finance Impact	
C1 Tariff/Pricing	
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	*Select all that apply:* <table><tr><td rowspan="3">Drugs</td><td>Not separately charged – part of local or national tariffs</td><td>☐</td></tr><tr><td>Excluded from tariff – pass through</td><td>☒</td></tr><tr><td>Excluded from tariff - other</td><td>☐</td></tr><tr><td>Devices</td><td>Not separately charged – part of local or national tariffs</td><td>☐</td></tr></table>

		Excluded from tariff (excluding ZCM) – pass through	☐
		Excluded from tariff (excluding ZCM) – other	☐
		Via Zero Cost Model	☐
	Activity	Paid entirely by National Tariffs	☐
		Paid entirely by Local Tariffs	☐
		Partially paid by National Tariffs	☐
		Partially paid by Local Tariffs	☐
		Part/fully paid under a Block arrangement	☐
		Part/fully paid under Pass-Through arrangements	☐
		Part/fully paid under Other arrangements	☐

C1.2 **Drug Costs**

Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if applicable and any other key information e.g. Chemotherapy Regime.

NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.

Metreleptin

Vial Size	**List Price**	**Dose to Vial Look Up**	**VAT**
10mg	£2,335	'After reconstitution with 2.2 mL water for injections (see section 6.6), each mL contains 5 mg of metreleptin.'	Not applicable as Delivered via Homecare Services
5mg	£1,168		
3mg	£584		

C1.3 **Device Costs**

Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information.

NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.

Not applicable

<table>
<tr><td>C1.4 Activity Costs covered by National Tariffs
List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</td><td>Not applicable</td></tr>
<tr><td>C1.5 Activity Costs covered by Local Tariff
List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.</td><td>No additional costs covered by local tariff are anticipated</td></tr>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>No additional activity costs not covered by National or Local tariff are anticipated.</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>Yes</u>
Please specify: Blueteq for the high cost drug</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?</td><td><table>
<tr><td></td><td>£</td></tr>
<tr><td>YR1</td><td>£6.392m</td></tr>
<tr><td>YR2</td><td>£6.392m</td></tr>
<tr><td>YR3</td><td>£6.392m</td></tr>
<tr><td>YR4</td><td>£6.392m</td></tr>
<tr><td>YR5</td><td>£7.244m</td></tr>
</table></td></tr>
</table>

Are there any changes expected in year 6-10 which would impact the model?	No If yes, please specify: The modelling is based on current patient cohorts if further patients were identified, in the early year the cost per patient is c£0.5m
C3 Overall Cost Impact of this Policy to NHS England	
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	**Cost pressure** Please specify: Current treatment is provided by the drug company on a compassionate basis free of charge.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	No
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **No impact on CCGs** Budget impact for providers: **Cost neutral** Please specify:

	Click here to enter text.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Please specify: Year 1: £6.392m Year 2: £6.392m Year 5: £7.244m
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify: Click here to enter text.
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	The funding will be from within the CPAG Prioritisation reserve
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	The risk is that further patients are identified which will increase the cost pressure by £0.5m per patient in the early years increasing as the weight of the patient increases to more than 40 kg.

C6.2 How can these risks be mitigated?	A careful assessment of medical literature and experience from the current service has deemed this a very low risk.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	A scenario has been explored where the treatment is costed using 10mg vials as this size is currently only available. Whilst this will be a significant increase (almost double) the Company (Aegerion) has committed to providing metreleptin at the costs as if the 3mg and 5mg smaller vials are available. If the company withdraws the drug and NHS England does not commissioning this policy proposition, patients will require further outpatients/ emergency admissions/ and potentially receive orthopaedic surgery and thereby, incur additional costs to manage this condition.
C6.4 What scenario has been approved and why?	The scenario based on 3 size of vials has been used based on (Aegerion) commitment to supply the drug at these costs.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**There is no published evidence of cost-effectiveness** Please specify: Click here to enter text.
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐ Available pricing data suggests the treatment is lower cost compared to current/comparator treatment ☒

	Available clinical practice data suggests the new treatment has the potential to improve value for money	☐
	Other data has been identified	☐
	No data has been identified	☐
	The data supports a high level of certainty about the impact on value	☐
	The data does not support a high level of certainty about the impact on value	☐
C8 Cost Profile		
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No**	
C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable	