

## Integrated Impact Assessment Report for Clinical Commissioning Policies

<b>Policy Reference Number</b>	1691		
<b>Policy Title</b>	Temozolomide as adjuvant treatment for people with newly diagnosed anaplastic astrocytoma without 1p/19q codeletion following surgery and radiotherapy (Adults) Proposal <b><u>for routine commission</u></b> (ref A3.1)		
<b>Lead Commissioner</b>	Suzanne Fennah	<b>Clinical Lead</b>	Claire Hobbs
<b>Finance Lead</b>	Justine Stalker-Booth	<b>Analytical Lead</b>	Not applicable.

### Integrated Impact Assessment – Index

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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.	<p>There are around 11,500 new brain, other central nervous system and intracranial tumours cases in the UK every year. Astrocytomas account for one third of all brain cancer diagnoses in the UK. Incidence rates for brain tumours are projected to rise by 6% in the UK between 2014 and 2035, to 22 cases per 100,000 people by 2035. (Cancer Research UK)</p> <p><i>Source: Policy Proposition, Section 6</i></p>
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	<p>200</p> <p><i>Source: Policy Proposition, Section 6</i></p>
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	<b><u>Adults</u></b>
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	<p>Anaplastic astrocytomas are more common in adults between the ages of 30 and 70 years, and are more common in males.</p> <p><i>Source: Policy Proposition, Section 1/Section 6</i></p>
A1.5 How is the population currently distributed geographically?	<b><u>Evenly</u></b>

A2 Future Patient Population & Demography								
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?	<p><b><u>Increasing</u></b></p> <p>Incidence rates for brain tumours are projected to rise by 6% in the UK between 2014 and 2035.</p> <p><i>Source: Cancer Research UK</i></p>							
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<p><b><u>No</u></b></p>							
<p>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?</p> <p>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</p>	<table border="1"> <tbody> <tr> <td>Year 2</td> <td>3</td> </tr> <tr> <td>Year 5</td> <td>6</td> </tr> <tr> <td>Year 10</td> <td>10</td> </tr> </tbody> </table> <p><b><u>Yes</u></b></p>		Year 2	3	Year 5	6	Year 10	10
Year 2	3							
Year 5	6							
Year 10	10							
A3 Activity								
A3.1 What is the purpose of new policy?	<p><b><u>Confirm routine commissioning position of an additional new treatment</u></b></p>							

A3.2 What is the annual activity associated with the existing pathway for the eligible population?	200  <i>Source: Policy Working Group</i>
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	200  <i>Source: Policy Working Group</i>
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.	Not applicable.  <i>Source: Policy Working Group</i>
<b>A4 Existing Patient Pathway</b>	
A4.1 <b>Existing pathway:</b> Describe the relevant currently routinely commissioned: <ul style="list-style-type: none"> <li>• Treatment or intervention</li> <li>• Patient pathway</li> <li>• Eligibility and/or uptake estimates.</li> </ul>	The standard treatment for people with newly diagnosed anaplastic astrocytomas is surgery followed by adjuvant radiotherapy.  <i>Source: Policy proposition section 3</i>
A4.2. What are the current treatment access and stopping criteria?	The decision to treat is be made by the neuro-oncology multi-disciplinary team (MDT) and the patient.  <i>Source: Policy working group</i>

<p>A4.3 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>	<ul style="list-style-type: none"> <li>a) 100%</li> <li>b) 0%</li> <li>c) 100%</li> <li>d) 100%</li> <li>e) 100%</li> </ul> <p><i>Source: Policy Working Group</i></p>
<p><b>A5 Comparator (next best alternative treatment) Patient Pathway</b>  (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p>	
<p><b>A5.1 Next best comparator:</b>  Is there another 'next best' alternative treatment which is a relevant comparator?  <i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment or intervention</i></li> <li>• <i>Patient pathway</i></li> <li>• <i>Actual or estimated eligibility and uptake</i></li> </ul>	<p><b><u>No</u></b></p>
<p>A5.2 What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>	<p>Not applicable.</p>

## A6 New Patient Pathway

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?

- a) 100%
- b) 0%
- c) 100%
- d) 100%
- e) 100%

*Source: Policy Working Group*

A6.2 Specify the nature and duration of the proposed new treatment or intervention.

### **Time limited**

Temozolomide to be given for up to 12 cycles with each cycle lasting four weeks and administered at 150-200 mg/m<sup>2</sup> on days 1 to 5 of each cycle.

*Source: Policy Proposition section 3*

## A7 Treatment Setting

A7.1 How is this treatment delivered to the patient?

Emergency/Urgent care attendance	<input type="checkbox"/>
Acute Trust: inpatient	<input type="checkbox"/>
Acute Trust: day patient	<input type="checkbox"/>
Acute Trust: outpatient	<input checked="" type="checkbox"/>

	<table border="1"> <tr> <td>Mental Health provider: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Community setting</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Homecare</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input checked="" type="checkbox"/></td> </tr> </table>	Mental Health provider: inpatient	<input type="checkbox"/>	Mental Health provider: outpatient	<input type="checkbox"/>	Community setting	<input type="checkbox"/>	Homecare	<input type="checkbox"/>	Other	<input checked="" type="checkbox"/>	<p>Temozolomide is taken orally/</p>
Mental Health provider: inpatient	<input type="checkbox"/>											
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Community setting	<input type="checkbox"/>											
Homecare	<input type="checkbox"/>											
Other	<input checked="" type="checkbox"/>											
<p>A7.2 What is the current number of contracted providers for the eligible population by region?</p>	<p>Chemotherapy can be prescribed and delivered at any provider commissioned by NHS England; this includes Cancer Centres, Teaching Hospitals and District General Hospitals in line with the service specification.</p>											
<p>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p><b><u>No</u></b></p>											
<p><b>A8 Coding</b></p>												
<p>A8.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p>	<table border="1"> <tr> <td>Aggregate Contract Monitoring *</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level contract monitoring</td> <td><input type="checkbox"/></td> </tr> </table>		Aggregate Contract Monitoring *	<input type="checkbox"/>	Patient level contract monitoring	<input type="checkbox"/>						
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Other**	<input type="checkbox"/>																	
<p>A8.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>OPCS v4.8</td> <td><input type="checkbox"/></td> </tr> <tr> <td>ICD10</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Treatment function code</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Main Speciality code</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>HRG</td> <td><input type="checkbox"/></td> </tr> <tr> <td>SNOMED</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical coding / terming methodology used by clinical profession</td> <td><input type="checkbox"/></td> </tr> </table>	OPCS v4.8	<input type="checkbox"/>	ICD10	<input type="checkbox"/>	Treatment function code	<input checked="" type="checkbox"/>	Main Speciality code	<input checked="" type="checkbox"/>	HRG	<input type="checkbox"/>	SNOMED	<input type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input type="checkbox"/>			
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<p><b>A8.3 Identification Rules for Drugs:</b> How are drug costs captured?</p>	<p><b><u>Already specified in current NHS England Drugs List document</u></b></p> <p>Temozolomide, chemotherapy</p>																	

<b>A8.4 Identification Rules for Devices:</b> How are device costs captured?	<u><b>Not applicable</b></u>						
<b>A8.5 Identification Rules for Activity:</b> How are activity costs captured?	<u><b>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</b></u>  NCBPS01C Chemotherapy						
<b>A9 Monitoring</b>							
<b>A9.1 Contracts</b> Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	<u><b>None</b></u>						
<b>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)</b> 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.	<table border="1"> <tr> <td data-bbox="1084 858 1509 914">Drugs or Device MDS</td> <td data-bbox="1509 858 1599 914"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 914 1509 970">Blutecq</td> <td data-bbox="1509 914 1599 970"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1084 970 1509 1026">Other prior approval</td> <td data-bbox="1509 970 1599 1026"><input type="checkbox"/></td> </tr> </table>	Drugs or Device MDS	<input checked="" type="checkbox"/>	Blutecq	<input checked="" type="checkbox"/>	Other prior approval	<input type="checkbox"/>
Drugs or Device MDS	<input checked="" type="checkbox"/>						
Blutecq	<input checked="" type="checkbox"/>						
Other prior approval	<input type="checkbox"/>						
<b>A9.3 Business intelligence</b> Is there potential for duplicate reporting?	<u><b>No</b></u>						
<b>A9.4 Contract monitoring</b>	<u><b>Yes</b></u>						

Is this part of routine contract monitoring?	Monitored through SACT database.
<b>A9.5 Dashboard reporting</b> Specify whether a dashboard exists for the proposed intervention?	<b><u>No</u></b>
<b>A9.6 NICE reporting</b> Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	<b><u>No</u></b>
<b>Section B - Service Impact</b>	
<b>B1 Service Organisation</b>	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Chemotherapy can be prescribed and delivered at any provider commissioned by NHS England, this includes Cancer Centres, Teaching Hospitals and District General Hospitals
B1.2 Will the proposition change the way the commissioned service is organised?	<b><u>No</u></b>
B1.3 Will the proposition require a new approach to the organisation of care?	<b><u>No change to delivery of care</u></b>

## B2 Geography & Access

B2.1 Where do current referrals come from?

*Select all that apply:*

GP	<input type="checkbox"/>
Secondary care	<input checked="" type="checkbox"/>
Tertiary care	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

B2.2 What impact will the new policy have on the sources of referral?

**No impact**

B2.3 Is the new policy likely to improve equity of access?

**Increase**

Being routinely commissioned will be an additional treatment option for this patient cohort.

*Source: Policy Proposal Section 1*

B2.4 Is the new policy likely to improve equality of access and/or outcomes?

**Increase**

Improved progression free and overall survival for this patient cohort.

*Source: Policy Proposal Section 7*

## B3 Implementation

B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?

**No action required**

<b>B3.2 Time to implementation:</b> Is a lead-in time required prior to implementation?	<u><b>No - go to B3.4</b></u>			
<b>B3.3 Time to implementation:</b> If lead-in time is required prior to implementation, will an interim plan for implementation be required?	<u><b>No - go to B3.4</b></u>			
B3.4 Is a change in provider physical infrastructure required?	<u><b>No</b></u>			
B3.5 Is a change in provider staffing required?	<u><b>No</b></u>			
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<u><b>No</b></u>			
B3.7 Are there changes in the support services that need to be in place?	<u><b>No</b></u>			
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	<u><b>No</b></u>			
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	<u><b>No change</b></u>			
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	<div> <i>Select all that apply:</i> </div> <table border="1" data-bbox="1088 1302 2000 1361"> <tr> <td data-bbox="1088 1302 1883 1361">           Publication and notification of new policy         </td> <td data-bbox="1890 1302 2000 1361"> <input checked="checked" type="checkbox"/> </td> </tr> </table>		Publication and notification of new policy	<input checked="checked" type="checkbox"/>
Publication and notification of new policy	<input checked="checked" type="checkbox"/>			

	Market intervention required	<input type="checkbox"/>					
	Competitive selection process to secure increase or decrease provider configuration	<input type="checkbox"/>					
	Price-based selection process to maximise cost effectiveness	<input type="checkbox"/>					
	Any qualified provider	<input type="checkbox"/>					
	National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>					
	Procurement	<input type="checkbox"/>					
	Other	<input type="checkbox"/>					
<b>B4 Place-based Commissioning</b>							
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	<u>No</u>						
<b>Section C - Finance Impact</b>							
<b>C1 Tariff/Pricing</b>							
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	<i>Select all that apply:</i> <table border="1"> <tr> <td rowspan="2"><b>Drugs</b></td> <td>Not separately charged – part of local or national tariffs</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Excluded from tariff – pass through</td> <td><input checked="" type="checkbox"/></td> </tr> </table>		<b>Drugs</b>	Not separately charged – part of local or national tariffs	<input type="checkbox"/>	Excluded from tariff – pass through	<input checked="" type="checkbox"/>
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	Excluded from tariff – pass through	<input checked="" type="checkbox"/>					

		Excluded from tariff - other	<input type="checkbox"/>
	<b>Devices</b>	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
		Excluded from tariff (excluding ZCM) – pass through	<input type="checkbox"/>
		Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>
		Via Zero Cost Model	<input type="checkbox"/>
	<b>Activity</b>	Paid entirely by National Tariffs	<input checked="" type="checkbox"/>
		Paid entirely by Local Tariffs	<input type="checkbox"/>
		Partially paid by National Tariffs	<input type="checkbox"/>
		Partially paid by Local Tariffs	<input type="checkbox"/>
		Part/fully paid under a Block arrangement	<input type="checkbox"/>
		Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>
		Part/fully paid under Other arrangements	<input type="checkbox"/>

  

<p><b>C1.2 Drug Costs</b></p> <p>Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.</p> <p>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p>The dose/cycle proposed is for up to 12 cycles with each cycle lasting four weeks and administered at 150-200 mg/m2 on days 1 to 5 of each cycle.</p> <p>The average NHS Indicative Price (list price) for 5 capsules is as follows:</p> <table border="1"> <thead> <tr> <th></th> <th>Ex-VAT</th> <th>Incl VAT</th> </tr> </thead> <tbody> <tr> <td>5mg</td> <td>£2.64</td> <td>£3.17</td> </tr> <tr> <td>20mg</td> <td>£10.60</td> <td>£12.72</td> </tr> <tr> <td>100mg</td> <td>£53.02</td> <td>£63.62</td> </tr> <tr> <td>140mg</td> <td>£75.47</td> <td>£90.56</td> </tr> <tr> <td>180mg</td> <td>£96.44</td> <td>£115.72</td> </tr> <tr> <td>250mg</td> <td>£133.95</td> <td>£160.74</td> </tr> </tbody> </table>		Ex-VAT	Incl VAT	5mg	£2.64	£3.17	20mg	£10.60	£12.72	100mg	£53.02	£63.62	140mg	£75.47	£90.56	180mg	£96.44	£115.72	250mg	£133.95	£160.74
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180mg	£96.44	£115.72																				
250mg	£133.95	£160.74																				

	The above is based on the BNF listed prices. The actual price paid will depend on commercial in confidence discounts.
<b>C1.3 Device Costs</b> Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> 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.
<b>C1.4 Activity Costs covered by National Tariffs</b> List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %) 	The cost of delivery would be covered by the HRG:  SB11Z - Deliver Exclusively Oral Chemotherapy which has a national tariff of £114 It is anticipated that there would be 12 (cycles) x SB11Z per patient
<b>C1.5 Activity Costs covered by Local Tariff</b> 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 it has been derived, validated and tested.	Not Applicable.
<b>C1.6 Other Activity Costs not covered by National or Local Tariff</b> Include descriptions and estimates of all key costs.	Not applicable.



C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	<u>No</u>		
<b>C2 Average Cost per Patient</b>			
C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?	YR1	£15,085	
	YR2	£15,085	
	YR3	£15,085	
	YR4	£15,085	
	YR5	£15,085	
Are there any changes expected in year 6-10 which would impact the model?	No		
<b>C3 Overall Cost Impact of this Policy to NHS England</b>			
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	<p><b><u>Cost pressure</u></b></p> <p>Please specify:</p> <p>Year 1 £3,032.0k</p> <p>Year 2 £3,062.2k</p> <p>Year 5 £3,107.4k</p> <p>The above is based on the NHS Indicative (List) Price incl VAT and an assumed 12 cycles per patient. The actual cost per patient will be lower depending on commercial in confidence discounts.</p>		

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?	Not applicable
<b>C4 Overall cost impact of this policy to the NHS as a whole</b>	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	<p>Budget impact for CCGs: <b><u>No impact on CCGs</u></b></p> <p>Budget impact for providers: <b><u>Cost neutral</u></b></p>
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><b><u>Cost pressure</u></b></p> <p>As per Section C3.1</p>
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?	<b><u>Unknown</u></b>

<b>C5 Funding</b>	
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.	CPAG prioritisation reserve.
<b>C6 Financial Risks Associated with Implementing this Policy</b>	
C6.1 What are the material financial risks to implementing this policy?	There are not expected to be any material financial risks associated with implementing this policy.
C6.2 How can these risks be mitigated?	Not applicable.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	PWG estimate the cohort to be 185 based on available data (i.e. CRUK surgery numbers and PWG clinical estimates)
C6.4 What scenario has been approved and why?	Not applicable.
<b>C7 Value for Money</b>	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	<b><u>There is no published evidence of cost-effectiveness</u></b>

<p>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</p>	<p>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</p>	<input type="checkbox"/>
	<p>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</p>	<input type="checkbox"/>
	<p>Available clinical practice data suggests the new treatment has the potential to improve value for money</p>	<input type="checkbox"/>
	<p>Other data has been identified</p>	<input type="checkbox"/>
	<p>No data has been identified</p>	<input checked="" type="checkbox"/>
	<p>The data supports a high level of certainty about the impact on value</p>	<input type="checkbox"/>
	<p>The data does not support a high level of certainty about the impact on value</p>	<input type="checkbox"/>
<p><b>C8 Cost Profile</b></p>		
<p>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</p>	<p><u>No</u></p>	
<p>C8.2 If yes, confirm the source of funds to meet these costs.</p>		