Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	ID009		
Policy Title	Telotristat for Treating Carcinoid Syndrome		
Lead Commissioner	Barry O'Neil	**Clinical Lead**	Martyn Caplin
Finance Lead	Craig Charlton	**Analytical Lead**	Carl Prescott

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.	The policy proposes **to not routinely commission** the use of telotristat for treating carcinoid syndrome. The incidence of diagnosed Neuroendocrine tumours (NET) is 8.84 in 100,000. The prevalence is estimated to be 34.9 per 100,000. This equates to a prevalence of 15,385 and an incidence of 3,897, giving a total population of 19,282. *Source: UK and Ireland Neuroendocrine Tumour Society*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	Not applicable as the proposition is do not routinely commission Click here to enter text.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Adults** Telotristat ethyl is indicated for the treatment of CS diarrhoea in combination with somatostatin analogue (SSA) therapy in adults (over 18 years) “inadequately controlled” by SSA therapy. However the proposal is to not routinely commission this treatment.
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	Please see above
A1.5 How is the population currently distributed geographically?	**Evenly** There are presently 10 ENETS centres of excellence in England and 13 other centres that provide NET MDT’s. *Source: Company submission page 43 /* http://www.ukinets.org/net-clinics-clinical-practice/

<table>
<tr><td></td><td></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>

No known changes

Source: Company submission page 9, agreed as a reasonable assumption by the clinical experts on the PWG.</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>

No Known changes
Source: Company submission page 9, agreed as a reasonable assumption by the clinical experts on the PWG.</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?</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>
<u>Yes</u>
Click here to enter text.</td></tr>
</table>

<table>
<tr><td>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td></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 non-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>The estimated annual number of people who have CS across the lung and small intestinal NET group and will be receiving long acting SSA’s (somatostatin analogues) are estimated to be as below:

<table><tr><td>YR0</td><td>185</td></tr><tr><td>YR1</td><td>186</td></tr><tr><td>YR2</td><td>187</td></tr><tr><td>YR5</td><td>191</td></tr><tr><td>YR10</td><td>197</td></tr></table>
Source: Resource impact template based on Dasari et al 2017, Lamarca et al 2016 and Caplin et al 15 applied to the latest ONS population numbers

Presently all people with CS diarrhoea would be on one of the two forms of SSA’s Octreotide or Lanreotide.</td></tr>
</table>

A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	*Not applicable, the policy is to not routinely commission* *Sources:* Click here to enter text.
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
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Diarrhoea caused by CS occurs in people with advanced disease (when the tumour has spread to other organs). There are a number of treatment options including treatment for helping to stop or reduce diarrhoea, and also to treat the NETs that are causing the diarrhoea. The choice of treatment will vary depending on factors such as the size and location in the body of the NETs, how many NETs there are, and the general health of the person with CS. A multidisciplinary team (MDT) of healthcare specialists with different roles in the care of people with NETs will be involved in helping the patient to decide which treatment is best. These treatments may include: • Treatment with drugs known as somatostatin analogues (Octreotide or lanreotide). SSAs help to reduce the secretion of hormones the body is making and may also slow or stop tumour growth. • If treatment with normal doses of SSAs do not work, the dose can be increased to the maximum amount that the patient is able to cope with, either by increasing the dose or increasing how often the dose is taken. • Surgery to remove or reduce the tumour (only if possible – some people's disease will not be treatable with surgery due to the site or stage of disease).

	• Other treatments which try to reduce the size of the tumour *Source: DPP*
A4.2. What are the current (proposed) treatment access and stopping criteria?	Not applicable *Source: DPP*
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 (i.e. they have a co-morbidity where treatment would be contraindicated). c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	a) 0% b) 0% c) 0% d) 0% e) 0% *Source:* Click here to enter text.
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 (not currently in use) which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway*	**No** Not applicable as position is to not routinely commission. *Source: Not applicable*

• *Actual or estimated eligibility and uptake*	
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 assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Not applicable as position is to not routinely commission Total estimated eligible a) enter % b) enter % c) enter % d) enter % e) enter % *Source: Not applicable*
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 (i.e. they have a co-morbidity where treatment would be contraindicated). c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Not applicable a) enter % b) enter % c) enter % d) enter % e) enter % *Source: Not applicable*

<table>
<tr><td>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</td><td><u>Not applicable as not routinely commissioned</u></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><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>Not applicable as not routinely commissioned</td></tr>
<tr><td>A7.2 What is the current number of contracted providers for the eligible population by region?</td><td><table><tr><td>NORTH</td><td>8</td></tr><tr><td>MIDLANDS & EAST</td><td>7</td></tr><tr><td>LONDON</td><td>5</td></tr><tr><td>SOUTH</td><td>3</td></tr></table></td></tr>
</table>

	Source: http://www.ukinets.org/net-clinics-clinical-practice/
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** Please specify: This policy is to not routinely commission.
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	Not applicable *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: Telotristat is a high cost drug excluded from tariff. The dataset used to record activity would be the high cost drug dataset for routine commissioning. A pre-approval mechanism could also be introduced.

<table>
<tr><td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td><td>Not applicable

Select all that apply:<table><tr><td>OPCS v4.8</td><td>☐</td></tr><tr><td>ICD10</td><td>☐</td></tr><tr><td>Treatment function code</td><td>☐</td></tr><tr><td>Main Speciality code</td><td>☐</td></tr><tr><td>HRG</td><td>☐</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table></td></tr>
<tr><td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td><td><u>Not applicable</u></td></tr>
<tr><td>A8.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u></td></tr>
<tr><td>A8.5 Identification Rules for Activity:
How are activity costs captured?</td><td><u>Not captured by an existing specialised service line</u>
Not applicable due to the policy recommending to not routinely commission
If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. <u>No</u></td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
</table>

<table>
<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></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>Not applicable:<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
Is this part of routine contract monitoring?</td><td><u>No</u></td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u>
Not applicable due to the policy recommending to not routinely commission
If no, will one be developed?</td></tr>
<tr><td>A9.6 NICE reporting</td><td><u>No</u></td></tr>
</table>

Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (I.e. tertiary centres, networked provision etc.)	There are presently 10 ENETS centres of excellence in England and 13 other centres that provide NET MDT's. *Source:* UK and Ireland Neuroendocrine Tumour Society
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**
B2 Geography & Access	
B2.1 Where do current referrals come from?	*Select all that apply:* GP ☐ Secondary care ☒ Tertiary care ☐ Other ☐

	Please specify: Current diagnosis and treatment should be referred through one of the 23 NETs MDT centres in England (including the 10 ENETS Centres of Excellence).
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?	**No impact** Please specify:
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**No impact** Please specify:
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required**
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
B3.3 **Time to implementation:**	**No - go to B3.4**

If lead-in time is required prior to implementation, will an interim plan for implementation be required?	
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**
B3.7 Are there changes in the support services that need to be in place?	**No**
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No**
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	**No change** Not applicable as the policy is to not routinely commission.

<table>
<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><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>Not applicable</td></tr>
<tr><td colspan="2">B4 Place-based Commissioning</td></tr>
<tr><td>B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)</td><td><u>No</u></td></tr>
<tr><td colspan="2">Section C - Finance Impact</td></tr>
<tr><td colspan="2">C1 Tariff/Pricing</td></tr>
</table>

C1.1 How is the service contracted and/or charged?

Only specify for the relevant section of the patient pathway

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	☒
	Excluded from tariff – pass through	☐
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	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

Not applicable as the position is to not routinely commission

subject to commercial confidentiality and must not be disclosed.	
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
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 %)	Not applicable as position is to not routinely commission.
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.	Not applicable

<table>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>Not applicable</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>No</u></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?

Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><th>Year</th><th>Net cost per patient per year (£)</th></tr><tr><td>YR1</td><td>0</td></tr><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></table>
Not applicable</td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2"></td></tr>
</table>

<table>
<tr><th colspan="2">C3 Overall Cost Impact of this Policy to NHS England</th></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost neutral</u>
Please specify:
The policy is to not routinely commission
<table><tr><td>Year</td><td>£000s</td></tr><tr><td>1</td><td>0</td></tr><tr><td>2</td><td>0</td></tr><tr><td>5</td><td>0</td></tr><tr><td>10</td><td>0</td></tr></table></td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Not applicable</td></tr>
<tr><td>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?</td><td>Not applicable</td></tr>
<tr><th colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</th></tr>
<tr><td>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</td><td>Budget impact for CCGs:
<u>No impact on CCGs</u>

Budget impact for providers:
<u>No impact on providers</u></td></tr>
</table>

<table>
<tr><td>C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.</td><td><u>Cost neutral</u>

<table><tr><td>Year</td><td>£000s</td></tr><tr><td>1</td><td>0</td></tr><tr><td>2</td><td>0</td></tr><tr><td>5</td><td>0</td></tr><tr><td>10</td><td>0</td></tr></table></td></tr>
<tr><td>C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured</td><td>Not applicable</td></tr>
<tr><td>C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?</td><td><u>No</u></td></tr>
<tr><td colspan="2">C5 Funding</td></tr>
<tr><td>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.</td><td>Due to the policy being to not routinely commission there will not be a cost pressure.</td></tr>
<tr><td colspan="2">C6 Financial Risks Associated with Implementing this Policy</td></tr>
</table>

<table>
<tr><td>C6.1 What are the material financial risks to implementing this policy?</td><td>No material financial risks have been identified as a result of implementing this policy</td></tr>
<tr><td>C6.2 How can these risks be mitigated?</td><td>Not applicable</td></tr>
<tr><td>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</td><td>Not applicable</td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>Not applicable</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost-effective as evidenced in the evidence review?</td><td><u>A cost-effectiveness evidence review has not been undertaken.</u></td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table><tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr><tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr><tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☐</td></tr><tr><td>Other data has been identified</td><td>☐</td></tr></table></td></tr>
</table>

	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	☐
	Not applicable	
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	