

## Integrated Impact Assessment Report for Clinical Commissioning Policies

<b>Policy Reference Number</b>	ID011		
<b>Policy Title</b>	Idebenone for treating people over 12 years of age with Leber's Hereditary Optic Neuropathy Proposal <b><u>for routine commission</u></b> (ref A3.1)		
<b>Lead Commissioner</b>	Nicola Symes	<b>Clinical Lead</b>	Fion Bremner
<b>Finance Lead</b>	Craig Charlton	<b>Analytical Lead</b>	

### 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

<p>A1.1 Prevalence of the disease/condition.</p>	<p>The policy proposes <b>to not routinely commission</b> the use of idebenone for treating Leber’s Hereditary Optic Neuropathy (LHON). The prevalence of LHON is 3.22 to 4.4 people per 100,000 population. Using a mid-point of 3.8 and applying this to population projections for 2018/19 [people aged 12 and over 47,871,600], this gives 2,072 people in England with LHON. This is expected to increase by 38 people per year.</p> <p>Source: <b>Prevalence:</b> Gorman GS, Schaefer Am et al. Prevalence of nuclear and mitochondrial DNA mutations related to adult mitochondrial disease. <i>Annals of Neurology</i> (2015);77 (5): 753-9.</p> <p><b>Incidence:</b> No published incidence figures are available for LHON. Based on the average duration of disease of 55 years (average age at onset between 20 and 30 years), and life expectancy of approx. 80 years (ONS life expectancies 2014-16), the incidence in England is expected to be (2072/55=) 38 patients per year.</p> <p><b>Population:</b>  <a href="#">ONS population projections for England</a></p>
<p>A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.</p>	<p>Not applicable as the proposition is do not routinely commission.</p>
<p>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</p>	<p><b>Other</b></p> <p>The age group for which the treatment is proposed is children and adolescents from the age of 12, and all adults. There is no upper age limit for receiving treatment. The summary of product characteristics (SMPc)</p>

	states 'The safety and efficacy of Raxone in LHON patients under 12 years of age have not yet been established'.								
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	<p>LHON may affect patients at any age. From the literature, the youngest patient was 4 years old and the oldest was 87 years old; however, most people are affected between 15 to 35 years of age. Onset may arise earlier in men (from age 12).</p> <p><i>Source: Company submission and clinical expert consultation comments.</i></p> <p>There is no evidence that LHON impacts mortality, therefore the distribution of patients is expected to be equal across the age range.</p>								
A1.5 How is the population currently distributed geographically?	<p><b><u>Evenly</u></b></p> <p>If unevenly, estimate regional distribution by %:</p> <table border="1" data-bbox="1088 647 1599 865"> <tr> <td>North</td> <td></td> </tr> <tr> <td>Midlands &amp; East</td> <td></td> </tr> <tr> <td>London</td> <td></td> </tr> <tr> <td>South</td> <td></td> </tr> </table> <p>There are no factors which would suggest that there is geographical variation between regions of England.</p>	North		Midlands & East		London		South	
North									
Midlands & East									
London									
South									
<b>A2 Future Patient Population &amp; Demography</b>									
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>Changes in incidence and prevalence are based on a constant estimate of cases diagnosed each year (A1.1), adjusted for standard population mortality. This is shown in the table below.</p>								

	<table border="1"> <thead> <tr> <th>Projected change in epidemiology</th> <th>Year 2</th> <th>Year 5</th> <th>Year 10</th> </tr> </thead> <tbody> <tr> <td>Prevalence (a)</td> <td>2,148</td> <td>2,262</td> <td>2,452</td> </tr> <tr> <td>Incidence (b)</td> <td>38</td> <td>38</td> <td>38</td> </tr> <tr> <td><b>Target population:</b></td> <td></td> <td></td> <td></td> </tr> <tr> <td>People with disease onset within the last 5 years (9% prevalent population) (a x 9%)</td> <td>192</td> <td>202</td> <td>219</td> </tr> <tr> <td>Incident population (b x 100%)</td> <td>38</td> <td>38</td> <td>38</td> </tr> <tr> <td><b>Total eligible</b></td> <td><b>230</b></td> <td><b>240</b></td> <td><b>257</b></td> </tr> </tbody> </table> <p><i>Source: These figures are based on the company submission (referenced in 1.2 above).</i></p>	Projected change in epidemiology	Year 2	Year 5	Year 10	Prevalence (a)	2,148	2,262	2,452	Incidence (b)	38	38	38	<b>Target population:</b>				People with disease onset within the last 5 years (9% prevalent population) (a x 9%)	192	202	219	Incident population (b x 100%)	38	38	38	<b>Total eligible</b>	<b>230</b>	<b>240</b>	<b>257</b>
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A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<p><b>No</b></p> <p>The treatment is not commissioned in England and therefore there are no current contracted providers that would be influenced by changes in demography of the patient population.</p> <p><i>Source: Company submission.</i></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?	<table border="1"> <tbody> <tr> <td>YR2 +/-</td> <td>+7</td> </tr> <tr> <td>YR3 +/-</td> <td>+10</td> </tr> <tr> <td>YR4 +/-</td> <td>+14</td> </tr> <tr> <td>YR5 +/-</td> <td>+17</td> </tr> <tr> <td>YR10 +/-</td> <td>+34</td> </tr> </tbody> </table>	YR2 +/-	+7	YR3 +/-	+10	YR4 +/-	+14	YR5 +/-	+17	YR10 +/-	+34																		
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<p>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</p>	<p><b><u>No</u></b></p> <p>The expected change in the number of people eligible for the service is based on incidence assumptions described in A1.2 and A2.1 above, adjusted for the target population (people who have disease onset within the past 5 years) and uptake of the treatment. This is because LHON develops later in life, therefore changes in epidemiology depend on age at diagnosis which could be from age 12 to 25 in men. Women tend to be affected at an older age, often around the time of oestrogen loss.</p> <p>For people receiving treatment, this would have been greatest in the first 2-3 years (prevalent + incident populations) but less every year thereafter as the prevalent population would have been treated.</p>
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**A3 Activity**

<p>A3.1 What is the purpose of new policy?</p>	<p><b><u>Confirm non-routine commissioning position of an additional new treatment</u></b></p>
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<p>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</p>	<p>There are no treatments currently available to treat LHON, therefore patients are only able to access best supportive care (BSC). The annual activity is therefore assumed to be the percentage of the prevalent population with disease onset within the last 5 years plus the incident population. For years 0 to 5 this is as follows:</p> <table border="1" data-bbox="1086 1177 1377 1343"> <thead> <tr> <th>Year</th> <th>Activity</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>223</td> </tr> <tr> <td>1</td> <td>226</td> </tr> </tbody> </table>	Year	Activity	0	223	1	226
Year	Activity						
0	223						
1	226						

2	230
3	233
4	237
5	240

*Source: Company submission – see A1.1 and A1.2 above*  
 BSC includes neuro-ophthalmologist outpatient visits, lifestyle advice, referral to low-vision services and genetic counselling.

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.

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.

There are no licensed comparator treatments. Best supportive care is the existing pathway.  
*Source: Company submission.*

**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 with onset of LHON usually present to their GP or local A&E department with loss of central vision and or colour contrast, referral is then made to ophthalmology or neurology specialist service in secondary care. Diagnosis is made upon clinical presentation and family history in most cases with genetic confirmation available through mtDNA testing.

Upon suspicion or diagnosis of LHON, an individual is referred to a service with expertise in LHON - a neuro-ophthalmologist, neurologist or expert in mitochondrial disorders in a secondary or tertiary setting. Treatment is currently to offer BSC.

The estimated number of people currently receiving BSC in the relevant population group (includes neuro-ophthalmologist outpatient visits, lifestyle advice, referral to low-vision services and genetic counselling) is summarised in the table below.

Treatment	%	Year 1	Year 2	Year 5	Year 10
BSC	100%	226	230	240	257

*Source:* Estimates using epidemiology data (see A1.1 above)

A4.2. What are the current (proposed) treatment access and stopping criteria?

There are 19 ophthalmology services for people with inherited eye conditions throughout the UK. This includes one national service at Moorfields Eye hospital in London. In the regions, many services are very small and operate on an infrequent basis without the full establishment of health professional staff. For example, only 5 services see more than 200 patients per year and 5 see fewer than 50.

Service components include:

- Ensuring access to specialist services for people with inherited eye disorders
- Ensuring timely and accurate diagnosis of people with inherited eye disorders – this is via specialist clinical diagnosis confirmed by genetic test results
- Ensuring access to a high quality prevention, treatment and follow up service
- Meeting the needs of the family

Other than idebenone, there are no licensed treatments available. There is no established pathway of care in LHON due to its rarity and lack of treatment options. Treatment is currently to offer BSC (see A4.1 above).



	<p>Source: <i>Clinical expert preliminary policy proposal</i>;  <a href="#">NHS UK genetic testing network: Commissioning guide - Ophthalmology services for patients with inherited eye conditions</a></p>
<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) 0%</li> <li>b) 0%</li> <li>c) 0%</li> <li>d) 0%</li> <li>e) 0%</li> </ul> <p>Currently everybody receives BSC.</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> </ul>	<p>Not applicable as policy is to not routinely commission.</p>

c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	
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**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?	Not applicable.
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A6.2 Specify the nature and duration of the proposed new treatment or intervention.	<b>Not applicable as not routinely commissioned</b>
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**A7 Treatment Setting**

A7.1 How is this treatment delivered to the patient?	<table border="1"> <tr> <td data-bbox="1086 1126 1637 1185">Emergency/Urgent care attendance</td> <td data-bbox="1637 1126 1715 1185"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1185 1637 1244">Acute Trust: inpatient</td> <td data-bbox="1637 1185 1715 1244"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1244 1637 1303">Acute Trust: day patient</td> <td data-bbox="1637 1244 1715 1303"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1303 1637 1362">Acute Trust: outpatient</td> <td data-bbox="1637 1303 1715 1362"><input type="checkbox"/></td> </tr> </table>	Emergency/Urgent care attendance	<input type="checkbox"/>	Acute Trust: inpatient	<input type="checkbox"/>	Acute Trust: day patient	<input type="checkbox"/>	Acute Trust: outpatient	<input type="checkbox"/>
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Other	<input type="checkbox"/>											
<p>A7.2 What is the current number of contracted providers for the eligible population by region?</p>	<table border="1"> <tr> <td>NORTH</td> <td>5</td> </tr> <tr> <td>MIDLANDS &amp; EAST</td> <td>3</td> </tr> <tr> <td>LONDON</td> <td>3</td> </tr> <tr> <td>SOUTH</td> <td>4</td> </tr> </table>	NORTH	5	MIDLANDS & EAST	3	LONDON	3	SOUTH	4	<p>Source: <a href="http://www.phgfoundation.org/documents/167_1210674534.pdf">http://www.phgfoundation.org/documents/167_1210674534.pdf</a></p>		
NORTH	5											
MIDLANDS & EAST	3											
LONDON	3											
SOUTH	4											
<p>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p>No This policy is to not routinely commission.</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>	<p><b><u>Not applicable.</u></b></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> <tr><td>Patient level drugs dataset</td><td><input type="checkbox"/></td></tr> <tr><td>Patient level devices dataset</td><td><input type="checkbox"/></td></tr> <tr><td>Devices supply chain reconciliation dataset</td><td><input type="checkbox"/></td></tr> <tr><td>Secondary Usage Service (SUS+)</td><td><input type="checkbox"/></td></tr> <tr><td>Mental Health Services DataSet (MHSDS)</td><td><input type="checkbox"/></td></tr> <tr><td>National Return**</td><td><input type="checkbox"/></td></tr> <tr><td>Clinical Database**</td><td><input type="checkbox"/></td></tr> <tr><td>Other**</td><td><input type="checkbox"/></td></tr> </table> <p>:</p>	Aggregate Contract Monitoring *	<input type="checkbox"/>	Patient level contract monitoring	<input type="checkbox"/>	Patient level drugs dataset	<input type="checkbox"/>	Patient level devices dataset	<input type="checkbox"/>	Devices supply chain reconciliation dataset	<input type="checkbox"/>	Secondary Usage Service (SUS+)	<input type="checkbox"/>	Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>	National Return**	<input type="checkbox"/>	Clinical Database**	<input type="checkbox"/>	Other**	<input type="checkbox"/>
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<p>A8.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><b><u>Not applicable.</u></b></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 type="checkbox"/></td></tr> <tr><td>Main Speciality code</td><td><input 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 type="checkbox"/>	Main Speciality code	<input 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><u>Not applicable</u></p>						
<p><b>A8.4 Identification Rules for Devices:</b> How are device costs captured?</p>	<p><u>Not applicable</u></p>						
<p><b>A8.5 Identification Rules for Activity:</b> How are activity costs captured?</p>	<p><b><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u></b>          If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).          NCBPS23N OPHTHALMOLOGY CHILDREN          NCBPS37Z OPHTHALMOLOGY ADULTS          It is unlikely patients with LHON would be specifically identified within the full data set, however this is where activity would be captured.</p>						
<p><b>A9 Monitoring</b></p>							
<p><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.</p>	<p><u>None</u></p>						
<p><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.</p>	<p><i>Not applicable</i></p> <table border="1" data-bbox="1088 1161 1599 1337"> <tr> <td>Drugs or Device MDS</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Blueteq</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other prior approval</td> <td><input type="checkbox"/></td> </tr> </table>	Drugs or Device MDS	<input type="checkbox"/>	Blueteq	<input type="checkbox"/>	Other prior approval	<input type="checkbox"/>
Drugs or Device MDS	<input type="checkbox"/>						
Blueteq	<input type="checkbox"/>						
Other prior approval	<input type="checkbox"/>						

<b>A9.3 Business intelligence</b> Is there potential for duplicate reporting?	<b><u>No</u></b>
<b>A9.4 Contract monitoring</b> Is this part of routine contract monitoring?	<b><u>No</u></b>
<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.)	Specialised ophthalmology services are provided in a network model that builds on existing strengths and established networks and shared care practices. There would be an operational delivery network model or other network models as appropriate to the particular service. <i>Source:</i> NHS standard contract for specialised ophthalmology (adult) <a href="#">Service specifications specialised ophthalmology D12/S/a</a> ; <a href="#">Service specifications spec-ophthalmo-paed (children)</a>

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>								
<b>B2 Geography &amp; Access</b>									
B2.1 Where do current referrals come from?	<table border="1" data-bbox="1088 576 1599 815"> <tr> <td data-bbox="1088 576 1509 635">GP</td> <td data-bbox="1509 576 1599 635"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 635 1509 694">Secondary care</td> <td data-bbox="1509 635 1599 694"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 694 1509 753">Tertiary care</td> <td data-bbox="1509 694 1599 753"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 753 1509 815">Other</td> <td data-bbox="1509 753 1599 815"><input type="checkbox"/></td> </tr> </table> <p data-bbox="1088 871 2119 1090">People with onset of LHON will usually present to their GP or local A&amp;E department with loss of central vision and/or colour contrast. People may be referred to a neuro-ophthalmologist as an outpatient via various routes, including from GPs, A&amp;E departments and from other general ophthalmologists in secondary care. Once referred, the person will be assessed by a specialist multidisciplinary team.</p>	GP	<input checked="" type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input type="checkbox"/>	Other	<input type="checkbox"/>
GP	<input checked="" type="checkbox"/>								
Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input type="checkbox"/>								
Other	<input type="checkbox"/>								
B2.2 What impact will the new policy have on the sources of referral?	<b><u>No impact</u></b>								
B2.3 Is the new policy likely to improve equity of access?	<b><u>No impact</u></b>								

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B2.4 Is the new policy likely to improve equality of access and/or outcomes?	<b><u>No impact</u></b>
<b>B3 Implementation</b>	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<b><u>No action required</u></b>
B3.2 <b>Time to implementation:</b> Is a lead-in time required prior to implementation?	<b><u>No - go to B3.4</u></b>
B3.3 <b>Time to implementation:</b> If lead-in time is required prior to implementation, will an interim plan for implementation be required?	<b><u>No - go to B3.4</u></b>
B3.4 Is a change in provider physical infrastructure required?	<b><u>No</u></b>
B3.5 Is a change in provider staffing required?	<b><u>No</u></b>



B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<b><u>No</u></b>																
B3.7 Are there changes in the support services that need to be in place?	<b><u>No</u></b>																
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	<b><u>No</u></b>																
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	<b><u>No change</u></b> Not applicable as the policy is to not routinely commission.																
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	<p><b><u>Not applicable</u></b></p> <table border="1" data-bbox="1088 820 2000 1359"> <tr> <td data-bbox="1088 820 1886 880">Publication and notification of new policy</td> <td data-bbox="1886 820 2000 880"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 880 1886 941">Market intervention required</td> <td data-bbox="1886 880 2000 941"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 941 1886 1034">Competitive selection process to secure increase or decrease provider configuration</td> <td data-bbox="1886 941 2000 1034"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1034 1886 1126">Price-based selection process to maximise cost effectiveness</td> <td data-bbox="1886 1034 2000 1126"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1126 1886 1187">Any qualified provider</td> <td data-bbox="1886 1126 2000 1187"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1187 1886 1248">National Commercial Agreements e.g. drugs, devices</td> <td data-bbox="1886 1187 2000 1248"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1248 1886 1308">Procurement</td> <td data-bbox="1886 1248 2000 1308"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1308 1886 1359">Other</td> <td data-bbox="1886 1308 2000 1359"><input type="checkbox"/></td> </tr> </table>	Publication and notification of new policy	<input 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"/>
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## 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

#### Not applicable

<b>Drugs</b>	Not separately charged – part of local or national tariffs	<input type="checkbox"/>
	Excluded from tariff – pass through	<input 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 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> 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. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	Not applicable as the position is to not routinely commission.		
<p><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.</p>	Not applicable.		
<p><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 %)</p>	Not applicable as the position is to not routinely commission.		
<p><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</p>	Not applicable.		

indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	
<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?	<b><u>No</u></b>
<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?  Are there any changes expected in year 6-10 which would impact the model?	Not applicable.
<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.	<b><u>Cost neutral</u></b> The policy is to not routinely commission.

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:  <u><b>No impact on CCGs</b></u></p> <p>Budget impact for providers:  <u><b>No impact on providers</b></u></p>										
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><u><b>Cost neutral</b></u> The policy is to not routinely commission.  Please specify:</p> <table border="1"> <thead> <tr> <th>Year</th> <th>£000s</th> </tr> </thead> <tbody> <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> </tbody> </table>	Year	£000s	1	0	2	0	5	0	10	0
Year	£000s										
1	0										
2	0										
5	0										
10	0										

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>No</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.	The policy is to not routinely commission idebenone, therefor there will not be a cost pressure.
<b>C6 Financial Risks Associated with Implementing this Policy</b>	
C6.1 What are the material financial risks to implementing this policy?	No material financial risks have been identified as a result of 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?	Not applicable.
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>A cost-effectiveness evidence review has not been undertaken.</u></b> :
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	<b><u>Not applicable.</u></b>
	Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment <input type="checkbox"/>
	Available pricing data suggests the treatment is lower cost compared to current/comparator treatment <input type="checkbox"/>
	Available clinical practice data suggests the new treatment has the potential to improve value for money <input type="checkbox"/>
	Other data has been identified <input type="checkbox"/>
	No data has been identified <input type="checkbox"/>
	The data supports a high level of certainty about the impact on value <input type="checkbox"/>
	The data does not support a high level of certainty about the impact on value <input type="checkbox"/>
<b>C8 Cost Profile</b>	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	<b><u>No</u></b>

C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable.
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