

Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1777		
Policy Title	Hyperbaric Oxygen Therapy for Malignant Otitis Externa Proposal not 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.	MOE is an uncommon c Source: Policy Propositi		inly found in the elderly or in diabetics
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	N/A do not routinely com Source: Policy proposition Please specify Click here to enter text.		
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	All ages Please specify Click here to enter text.		
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	N/A Source: required Please specify Click here to enter text.		
A1.5 How is the population currently distributed geographically?	unknown If unevenly, estimate regional distribution by %:		
	North	enter %]
40	Midlands & East	enter %	
	London	enter %	
	South	enter %	

	Source: Policy Proposition section 6 Please specify Click here to enter text.	
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?	Constant If other, Click here to enter text. Source: Policy Proposition section 6	
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	No Please specify Click here to enter text. Source: Policy Proposition section 6/other	
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed policy commissioning criteria, per year in years 2-5 and 10?	YR2 +/- 0	
	YR3 +/- 0	
	YR4 +/- 0	
	YR5 +/- 0	
	YR10 +/- 0	
Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	N/A do not commission policy	
	Source: Service specification proposition section 3.1	

	No Click here to enter text.
A3 Activity	
A3.1 What is the purpose of new policy?	Revise existing policy (expand or resrtict an existing treatment threshold / Add an additional line of treatment / stage of treatment Please specify This policy confirms a do not routinely commission for the use of Hyperbaric Oxygen Therapy for Malignant Otitis Externa
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	See A1.1 There is currently some access for this intervention with some HBOT units not taking referrals for this indication. Source: Capacity and activity returns from providers Please specify Click here to enter text.
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	N/A do not routine commission policy proposition Source: Policy proposition Please specify 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.	Unknown Source: Evidence review Please specify Click here to enter text.

A4 Existing Patient Pathway		
A4.1 Existing pathway: Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Most patients would receive wound care management and antibiotics Additionally there is currently some access for this intervention but some HBOT units do not take referrals for this indication Sourc Current policy and new policy proposition	
A4.2. What are the current treatment access and stopping criteria?	N/A. Source: policy proposition	
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, please specify Not known as not routinely commissioned a) 0% b) 0% c) 0% d) 0% e) 0% Source: Evidence review	
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	Yes If yes, Patients will receive wound care and antibiotics and management of underlying cause.	

 Treatment or intervention Patient pathway Actual or estimated eligibility and uptake 	Source: ER
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?	Total estimated eligible N/A as do not routinely commission policy a) enter % b) enter % c) enter % d) enter % e) enter % Source: required
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?	If not known, please specify N/A a) 0% b) 0% c) 0% d) 0% e) 0% Source: Current published policy and revised policy proposition
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	Time limited For time limited treatments, specify frequency and/or duration. N/A

	Source: N/A do not routinely	commission	on	
A7 Treatment Setting				
A7.1 How is this treatment delivered to the patient?	Select all that apply:			
	Emergency/Urgent care att	endance		
	Acute Trust: inpatient		\boxtimes	
	Acute Trust: day patient			
	Acute Trust: outpatient			
	Mental Health provider: inp	atient		
	Mental Health provider: out	tpatient		
	Community setting			
	Homecare			
	Other	Other 🖂		
	Please specify:			
A7.2 What is the current number of contracted providers for the	NORTH	2		
eligible population by region?	MIDLANDS & EAST	2		
	LONDON	2		
	SOUTH	4		

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	Not yet known Please specify: Any change will be subject to the outcome of the subsequent procurement Source: Commissioning plan	ne service review and	
A8 Coding			
A8.1 Specify the datasets used to record the new patient pathway	Not applicable:		
activity.	Aggregate Contract Monitoring *		
*expected to be populated for all commissioned activity	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 International registry hosted in England by Ard	, i	
A8.2 Specify how the activity related to the new patient pathway will be identified.	Not applicable		

	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?	Not applicable If the drug has already been specified in the cur List please specify drug name and drug indicati Click here to enter text. If the drug has NOT already been specified in the Drug List please give details of action required been discussed with the pharmacy lead: Click here to enter text.	on: he current NHS England
A8.4 Identification Rules for Devices: How are device costs captured?	Not applicable If the device is covered by an existing category the Device Category (as per the National Tariff Guidance). Click here to enter text. If the device is not excluded from Tariff nor cov National or Local prices please specify details of confirm that this has been discussed with the H	Payment System vered within existing of action required and

	Click here to enter text.		
A8.5 Identification Rules for Activity:	Not captured by an existing specialised service line		
How are activity costs captured?	If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).		
	Click here to enter text.		
	If activity costs are already captured please specify whether this service needs a separate code. Choose an item.		
	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. Click here to enter text.		
	If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. No		
A9 Monitoring			
A9.1 Contracts	<u>None</u>		
Specify any new or revised data flow or data collection	Please specify		
requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	International registry to be completed by all providers		
A9.2 Excluded Drugs and Devices (not covered by the Zero	Select all that apply:		
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.	Drugs or Device MDS □		
	Blueteq		
	Other prior approval		

	Please specify: Click here to enter text.	
A9.3 Business intelligence	<u>No</u>	
Is there potential for duplicate reporting?	If yes, please specify mitigation:	
	Click here to enter text.	
A9.4 Contract monitoring	<u>No</u>	
Is this part of routine contract monitoring?	If yes, please specify contract monitoring requirement:	
	Click here to enter text.	
A9.5 Dashboard reporting	No not for this indication as not routine commission proposal	
Specify whether a dashboard exists for the proposed intervention?	If no, will one be developed?	
	Click here to enter text.	
A9.6 NICE reporting	<u>Yes</u>	
Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new	If yes, specify how performance monitoring data will be used for this purpose.	
policy?	Part of dashboard requirements	
Section B	3 - Service Impact	
B1 Service Organisation		
B1.1 Describe how the service is currently organised? (i.e. tertiary	Click here to enter text.	
centres, networked provision etc.)	Source: required	
B1.2 Will the proposition change the way the commissioned service	The proposition will not change this however there is a service	
is organised?	review that will result in a national procurement which may reduce	

	the number of centres delive	oring this corpies	
	the number of centres delivering this service		
	Please specify:		
	Click here to enter text.		
	Source: Service review gatew	av documents	
B1.3 Will the proposition require a new approach to the organisation	As detailed in D4.0		
of care?	As detailed in B1.2		
	Please specify:		
	Click here to enter text.		
B2 Geography & Access			
22 000g.up.i.) u 7100000			
B2.1 Where do current referrals come from?	N/A		
B2.1 Where do current referrals come from?	N/A		
	Select all that apply:		
	GP		
	Secondary care		
	Secondary care		
	Tertiary care		
	Other		
DO O Miller Construction of the language of the construction of th	Barraga		
B2.2 What impact will the new policy have on the sources of	<u>Decrease</u>		
referral?	Please specify:		
		rna is not currently commissioned, however	
		access for patients, this policy changes that	
		ients will no longer have access to this	
	treatment.		
B2.3 Is the new policy likely to improve equity of access?	<u>Decrease</u>		

	Please specify: Click here to enter text. Source: Equalities Impact Assessment
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	Decrease Please specify: Click here to enter text. Source: Equalities Impact Assessment
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	Procurement action Please specify: Procurement as part of the outcome of the associated service review anticipated to commence early 2018.
B3.2 Time to implementation: Is a lead-in time required prior to implementation?	Yes - go to B3.3 If yes, specify the likely time to implementation: The updated policy will be published at the same time as the outcome and timelines for procurement are released.
B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Yes If yes, outline the plan: Current services will continue to provide care until the completion of the national procurement. There will be no changes to either activity or contracts until notice of change has been released after completion and award of the procurement exercise.

B3.4 Is a change in provider physical infrastructure required?	No Please specifical Click here to	•	.00	
B3.5 Is a change in provider staffing required?	No Please specif Click here to			
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	No Please specif Click here to			
B3.7 Are there changes in the support services that need to be in place?	No Please specif	•		
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	No Please specif Click here to	•		
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and	Choose an item. Please complete table:			
estimated number of providers required in each region	Region	Current no. of providers	Future State expected range	Provisional or confirmed
	North Midlands &	2	2 2	<u>P</u>

	East				
	London	2	1	<u>P</u>	
	South	4	3	<u>P</u>	
	Total	10	8	<u>P</u>	
	Please specif				ļ
	Pending outc	ome of procurem	ent		
B3.10 Specify how revised provision will be secured by NHS	Select all the	at apply:			
England as the responsible commissioner.	Publication a	and notification of	new policy		
	Market inter	vention required			
		selection process	s to secure increase or	\boxtimes	
	Price-based effectivenes		s to maximise cost	\boxtimes	
	Any qualified	d provider		\boxtimes	
	National Co	mmercial Agreem	ents e.g. drugs, devices	S 🗆	
	Procuremen	t			
	Other				
	Please specifical Click here to	•			
B4 Place-based Commissioning					
B4.1 Is this service currently subject to, or planned for, place-based	<u>No</u>				

commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	Please specify: Click here to enter text.		
Section C	· Finance In	npact	
C1 Tariff/Pricing			
C1.1 How is the service contracted and/or charged? Select all that apply:			
Only specify for the relevant section of the patient pathway		Not separately charged – part of local or national tariffs	
	Drugs	Excluded from tariff – pass through	
		Excluded from tariff - other	
		Not separately charged – part of local or national tariffs	
	Devices	Excluded from tariff (excluding ZCM) – pass through	
		Excluded from tariff (excluding ZCM) – other	
		Via Zero Cost Model	
		Paid entirely by National Tariffs	
		Paid entirely by Local Tariffs	\boxtimes
		Partially paid by National Tariffs	
	Activity	Partially paid by Local Tariffs	
		Part/fully paid under a Block arrangement	\boxtimes
		Part/fully paid under Pass-Through arrangements	
		Part/fully paid under Other arrangements	\boxtimes

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.	N/A
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.	N/A
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 %)	N/A
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.	N/A
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	The current spend/budget for HBOT services (England) is £8.8m There are various models across the country with variation in costs. This will be addressed within the current budget during the service review procurement.
C1.7 Are there any prior approval mechanisms required either	<u>No</u>

during implementation or permanently?	Please specify: Click here to enter text.		
C2 Average Cost per Patient			
C2.1 What is the estimated cost per patient to NHS England, in	YR1	N/A	
years 1-5, including follow-up where required?	YR2	N/A	
	YR3	N/A	
	YR4	N/A	
	YR5	N/A	
Are there any changes expected in year 6-10 which would impact the model?	If yes, please specify: Click here to enter text.		
C3 Overall Cost Impact of this Policy to NHS England			
C3.1 Specify the budget impact of the proposal on NHS England in	Cost neutral		
relation to the relevant pathway.	Please specify:		
	The current budget will be used to provide reduced number of cer providing 24/7 access for emergency treatment.		
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Whilst the proposal is anticipated to be cost neutral, the procurement may result in some savings but this is currently unknown.		
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?	N/A		

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: No impact on providers 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 neutral Please specify: Click here to enter text.
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Click here to enter text.
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.	N/A

C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	No risk if this is published alongside the outcome of the procurement and associated contract awards.
C6.2 How can these risks be mitigated?	Click here to enter text.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Click here to enter text.
C6.4 What scenario has been approved and why?	Click here to enter text.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost	There is no published evidence of cost-effectiveness
effective as evidenced in the evidence review?	Please specify:
&O'	Click here to enter text.
C7.2 Has other data been identified through the service	Select all that apply:
specification development relevant to the assessment of value for money?	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	
	Please specify: Click here to enter text.	
C8 Cost Profile		
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	No If yes, specify type and range: Click here to enter text.	
C8.2 If yes, confirm the source of funds to meet these costs.	Click here to enter text.	