

Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1779		
Policy Title	Hyperbaric Oxygen Therapy for Diabetic Foot Ulcers Proposal not for routine commission (ref A3.1)		
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Integrated Impact Assessment - Index		
Section A - Activity	Section B - Service	Section C - Finance
A1 Current Patient Population & Demography/ Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this Policy to NHS England
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile
A9 Monitoring		

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 annual incidence of foot ulcers among people with diabetes has been estimated at between 2.5% and 10.7% This translates into between 58,470 and 250,252 potential cases of foot ulcers in England Source: Policy Proposition section 6
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	N/A do not routinely commission. 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 %

	M	
	Midlands & East	enter %
	London	enter %
	South	enter %
	Source: Policy Pro	position section 6
	Please specify	
	Click here to enter	text.
A2 Future Patient Population & Demography		
72 Tatare Tatient Topalation a Belliography		
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in	Constant	
2, 5, and 10 years?	If other Click here	to enter text
	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	<u>No</u>	
population and would this impact on activity/outcomes?	Please specify	
	Click here to enter	
	Source: Policy Pro	position section 6/other
A2.3 Expected net increase or decrease in the number of patients	YR2 +/-	0
who will be eligible for the service, according to the proposed policy commissioning criteria, per year in years 2-5 and 10?	YR3 +/-	0
Commissioning Criteria, per year in years 2-3 and 10?	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 restrict 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 Diabetic Lower Limb Ulceration (Diabetic Foot Ulcer)
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	See A1.1 There is currently some access to HBOT for this intervention 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	Unknown

the only alternative is the existing pathway, please state 'not applicable' and move to A4.	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.	Standard treatment of diabetic foot ulcers requires a multidisciplinary team comprising a podiatrist, an orthotist, a specialised nurse and a diabetologist. Treatment options include close monitoring, intensive systemic antibiotic therapy, wound dressings and removal of dead tissue (debridement). Revascularisation is also usually considered (National Institute for Health and Care Excellence 2015). Additionally there is currently some HBOT access for this intervention Source: 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:	<u>Yes</u>	
Is there another 'next best' alternative treatment which is a relevant comparator? If yes, describe relevant Treatment or intervention Patient pathway Actual or estimated eligibility and uptake	Treatment options include close monitoring, intensive systemic antibiotic therapy, wound dressings and removal of dead tissue (debridement). Revascularisation is also usually considered (National Institute for Health and Care Excellence 2015). 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	If not known, please specify N/A a) 0% b) 0% c) 0%	

d) Comply with treatment e) Complete treatment?	d) 0% e) 0% Source: Current published policy and re	evised policy proposition
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	Time limited For time limited treatments, specify free N/A Source: N/A do not routinely commission	
A7 Treatment Setting		
A7.1 How is this treatment delivered to the patient?	Select all that apply:	
	Emergency/Urgent care attendance	
	Acute Trust: inpatient	
	Acute Trust: day patient	
	Acute Trust: outpatient	
	Mental Health provider: inpatient	
	Mental Health provider: outpatient	
	Community setting	
	Homecare	
	Other	
	Please specify: HBOT centres	

A7.2 What is the current number of contracted providers for the eligible population by region?	NORTH	2	
	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 subsequent procurement Source: Commissioning p	ent	the service review and
A8 Coding			
A8.1 Specify the datasets used to record the new patient pathway activity.	Not applicable:		
*expected to be populated for all commissioned activity	Aggregate Contract Mon	itoring *	
expected to be populated for all commissioned detivity			
	Patient level contract mo	nitoring	
	Patient level contract mo		
		et	-
	Patient level drugs datas	et aset	
	Patient level drugs datas	et aset conciliation dataset	
	Patient level drugs datas Patient level devices data Devices supply chain rec	et aset conciliation dataset e (SUS+)	
	Patient level drugs datas Patient level devices data Devices supply chain red Secondary Usage Services	et aset conciliation dataset e (SUS+)	

	Clinical Database**	
	Other**	
	**If National Return, Clinical database or other International registry hosted in England by Arde	
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:	Not applicable	
How are drug costs captured?	If the drug has already been specified in the cu 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.	
A8.4 Identification Rules for Devices:	Not applicable	

How are device costs captured?	If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).
	Click here to enter text.
	If the device is not excluded from Tariff nor covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team. 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	None
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 Cost Model)	Select all that apply:
For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device	Drugs or Device MDS □
	Blueteq
monitoring required, for example reporting or use of prior approval systems.	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	No
Is this part of routine contract monitoring?	If yes, please specify contract monitoring requirement:
the part of reduine contract memoring.	Click here to enter text.
A9.5 Dashboard reporting	No not for this indication as not routinely commissioned 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	Yes
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	- 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 delivering this service			
	Please specify:			
	Click here to enter text.			
	Source: Service review gateway documents			
D4.0 M/9/4				
B1.3 Will the proposition require a new approach to the organisation of care?	As detailed in B1.2			
of care?	Please specify:			
	Click here to enter text.			
B2 Geography & Access				
	1 - x//a			
B2.1 Where do current referrals come from?	N/A			
	Select all that apply:			
	GP ⊠			
	Secondary care			
	Tertiary care			
	Other			
B2.2 What impact will the new policy have on the sources of	Decrease			
referral?	Please specify:			
	HBOT for is not currently commissioned for this indication, however there			

	has been some limited access for patients, this policy changes that position and consequently patients 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	<u>Decrease</u>
outcomes?	Please specify:
	Click here to enter text.
	Source: Equalities Impact Assessment
B3.1 Will commissioning or provider action be required before	Procurement action
implementation of the proposition can occur?	Please specify:
	Procurement as part of the outcome of the associated service review anticipated to commence Sep 2018.
B3.2 Time to implementation:	<u>Yes - go to B3.3</u>
Is a lead-in time required prior to implementation?	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:	<u>Yes</u>
If lead-in time is required prior to implementation, will an interim	If yes, outline the plan:

plan for implementation be required?	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 an award of the procurement exercise.			
B3.4 ls a change in provider physical infrastructure required?	No Please specify: Click here to enter text.			
B3.5 ls a change in provider staffing required?	No Please specify: Click here to enter text.			
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	No Please specify: Click here to enter text.			
B3.7 Are there changes in the support services that need to be in place?	No Please specify: Click here to enter text.			
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	No Please specify: Click here to enter text.			
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	Choose an item. Please complete table:			
	Region Current no. of Future Provisional			

		providers	State expected range	or confirmed	
	North	2	2	<u>P</u>	
	Midlands & East	2	2	<u>P</u>	
	London	2	1	<u>P</u>	
	South	4	3	<u>P</u>	
	Total	10	8	<u>P</u>	
	Please specify: Pending outcome of procurement				
B3.10 Specify how revised provision will be secured by NHS	Select all that apply:				
England as the responsible commissioner.	Publication and notification of new policy				
	Market intervention required				
	Competitive selection process to secure increase or decrease provider configuration			\boxtimes	
	Price-based selection process to maximise cost effectiveness			\boxtimes	
	Any qualified provider			\boxtimes	
	National Commercial Agreements e.g. drugs, devices			s 🗆	
	Procurement			\boxtimes	
	Other			\boxtimes	
	Please specific Click here to	=			

	•	
- Finance Ir	mpact	
Select all	that apply:	
	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	
Dovices	Excluded from tariff (excluding ZCM) – pass through	
Devices	Excluded from tariff (excluding ZCM) – other	
	Via Zero Cost Model	
Activity	Paid entirely by National Tariffs	
	Paid entirely by Local Tariffs	\boxtimes
	Partially paid by National Tariffs	
	Partially paid by Local Tariffs	tariffs
	Part/fully paid under a Block arrangement	\boxtimes
	Please specific control of the contr	Please specify: Click here to enter text. Select all that apply: Not separately charged – part of local or national tariffs Excluded from tariff – pass through Excluded from tariff - other Not separately charged – part of local or national tariffs Excluded from tariff (excluding ZCM) – pass through Excluded from tariff (excluding ZCM) – pass through Excluded from tariff (excluding ZCM) – other Via Zero Cost Model Paid entirely by National Tariffs Partially paid by National Tariffs Partially paid by Local Tariffs Partially paid by Local Tariffs

	Part/fully paid under Pass-Through arrangements
	Part/fully paid under Other arrangements
C1.2 Drug Costs	N/A
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.	
C1.3 Device Costs	N/A
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.	
C1.4 Activity Costs covered by National Tariffs	N/A
List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	
C1.5 Activity Costs covered by Local Tariff	N/A
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.	
C1.6 Other Activity Costs not covered by National or Local Tariff	The current spend/budget for HBOT services (England) is £8.8m There are various models across the country with variation in costs. This

Include descriptions and estimates of all key costs.	will be addressed within the current budget during the service review procurement.		
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	No 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 years 1-5, including follow-up where required?	YR1	N/A	
	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, pleas Click here t	se specify: o 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 neutr	<u>al</u>	
relation to the relevant pathway.	Please specify:		
		budget will be used 4/7 access for emer	I to provide reduced number of centres gency treatment.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.			ed to be cost neutral, the procurement may 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 effective as evidenced in the evidence review?	There is no published evidence of cost-effectiveness Please specify: Click here to enter text.			
C7.2 Has other data been identified through the service	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	\boxtimes			
	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.				