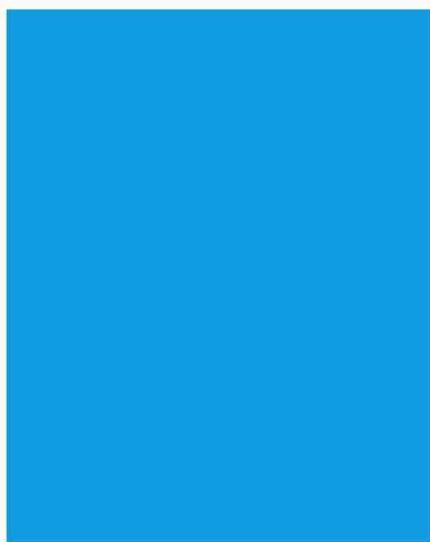


**Clinical Commissioning
Policy: Hyperbaric Oxygen
Therapy**

April 2013

Reference: NHSCB/ D11/P/a



NHS Commissioning Board

Clinical Commissioning Policy: Hyperbaric Oxygen Therapy

First published: April 2013

**Prepared by the NHS Commissioning Board Clinical Reference Group for
Hyperbaric Oxygen Therapy**

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Policy Statement

The NHS Commissioning Board (NHS CB) will commission hyperbaric oxygen therapy (HBOT) in accordance with the criteria outlined in this document for the following indications: decompression illness; gas embolism; acute carbon monoxide (CO) poisoning.

HBOT will not be commissioned routinely for other indications. If exceptional clinical circumstances arise for patients with conditions other than those listed above these will be considered under the NHS CB Individual Funding Request Policy.

The NHS CB will support the treatment costs of HBOT in other indications where these are part of well-designed multi-centre trials that will answer questions of clinical and cost effectiveness. This will only be the case where funding of these trials is agreed with the NHS CB prior to commencement.

In creating this policy the NHS CB has reviewed this intervention and the range of clinical conditions for which it is used. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

Plain Language Summary

HBOT is the delivery of oxygen at a pressure greater than normal so that a higher level of oxygen can be dissolved in the patient's blood plasma. HBOT is used for an increasing number of medical conditions.

For some of these conditions, however, the theoretical basis for HBOT is unclear and, in the majority of cases, the scientific evidence of clinical and cost effectiveness is not established. The use of HBOT is supported by this policy for medical emergencies: for decompression illness (arising from dissolved gases coming out of solution into bubbles inside the body on depressurisation); gas embolism (air bubbles in the blood vessels); and acute CO poisoning.

1. Introduction

HBOT has been used for an increasing number of medical conditions since its first introduction for the treatment of decompression illness over 50 years ago. For some of these conditions, however, the theoretical basis for HBOT is unclear and, in the majority of cases, the evidence of clinical and cost effectiveness is not established.^{1,2,3} The use of HBOT is most widely accepted for treatment of divers who are suffering from the consequences of ascending from depth. In most other applications, it has been used in addition to standard methods of treatment.

2. Definitions

HBOT is the delivery of oxygen at a partial pressure greater than 100 kPa. This takes place within a treatment chamber which may accommodate one or more patients and attendant staff.

3. Aim and objectives

This policy seeks to ensure equity of access to this treatment in England. It reflects both the 2007 systematic review by NHS Quality Improvement Scotland² and the subsequent 2008 draft commissioning policy for funding of HBOT which was developed for all Specialised Commissioning Groups in England.⁴ It identifies those conditions which, based on the current evidence available, will be funded routinely.

4. Criteria for commissioning

HBOT will be commissioned for indications where the evidence base is commensurate with that usually considered sufficient to ensure a good use of NHS resources. Consequently the use of HBOT is supported for the following indications:

- Decompression illness
- Gas embolism
- Acute CO poisoning

HBOT will not be routinely commissioned for other indications. If exceptional clinical circumstances arise for patients with conditions other than those listed above these will be considered under the NHS CB Individual Funding Request Policy. The NHS CB will support the treatment costs of HBOT in other indications where these are part of well-designed multi-centre trials that will answer questions of clinical and cost effectiveness. This will only apply to trials agreed with the NHS CB prior to commencement of treatment.

5. Patient pathway

The use of HBOT for decompression illness, gas embolism and acute CO poisoning is a medical emergency. Patients are referred directly from:

HM Coast Guard

Duty Diving Medical Officer (Institute of Naval Medicine)

Other British Hyperbaric Association advice line

An ambulance service

An emergency department

A secondary care clinician

A general practitioner

A patient directly accessing a provider

The patient pathway is described in detail in the service specification.

6. Governance arrangements

The detailed governance is covered in the service specification. In summary, all facilities are required to:

- be a member of the British Hyperbaric Association (BHA).
- work in accordance with the BHA publication 'Health and Safety for Therapeutic Hyperbaric Facilities. A Code of Practice.'
- be registered with the Care Quality Commission as a Level 1 or Level 2 hyperbaric facility.
- satisfy the requirements of a Category 1, 2 or 4 hyperbaric facility as defined by the Cox Report.
- operate under the clinical responsibility of a suitably qualified and experienced fully registered medical practitioner; the Medical Director as defined by the Cox Report.
- have robust clinical governance systems in place and conduct a rolling programme of clinical audits.
- ensure that all decisions regarding HBOT will be undertaken by a Hyperbaric Physician who has specialist knowledge and experience of the use of HBOT. This medical practitioner will be responsible for HBOT until it stops or until the case is handed over to another hyperbaric physician with the requisite knowledge and experience.
- declare to the BHA whether they are registered with the Care Quality Commission to provide treatment to children.
- ensure that children treated at the unit have their care overseen by a paediatric consultant.

In addition, CQC Level 1 / Cox Category 1 facilities will be required to:

- declare to BHA whether they can accommodate ventilated patients on a continuous basis limited only by capacity of the host hospital critical care unit or if the capability is intermittent and to what extent that capability is predictable.
- ensure that sedated, ventilated patients are overseen by trained anaesthetic /
- intensive care staff in or next to the chamber, as appropriate.
- have a written agreement with their provider of medical cover that they will receive every reasonable level of support required, including the provision of trained professionals to assist with appropriate interventions if patients develop complications during treatment.

7. Epidemiology and needs assessment

Spending time at raised environmental pressure (e.g. SCUBA diving, compressed air work such as tunnelling) causes additional inert gas from air or other breathing mixtures to dissolve in the tissues. A return to a lower pressure is known as decompression. If decompression is sufficiently controlled, the excess gases can be excreted in exhaled breath by the lungs. If decompression occurs too quickly to allow excretion by the lungs, these gases can form bubbles (gas emboli) within the tissues, most often in venous blood. If lung tissue is ruptured by expansion of gas during decompression, emboli can escape into the systemic arterial circulation via the pulmonary veins and the left heart. Decompression to sub-atmospheric pressures, such as during altitude training for aircraft pilots, can also generate gas emboli. Once present, the gas emboli can cause clinical manifestations ranging from lethargy and pain to severe neurological impairment, multi-organ failure and death.

The term decompression sickness describes the medical condition caused by gas coming out of solution and forming emboli during decompression (evolved gas disease). The term decompression illness describes the medical conditions caused either by evolved gas disease or by intravascular emboli resulting from gas that has escaped from lung tissue ruptured during the decompression (escaped gas disease). It is often not possible to determine whether a patient has evolved gas disease, escaped gas disease or both.

Gas embolism can also occur when bubbles of gas enter the circulation during medical procedures such as renal dialysis, mechanical ventilation (life support machines) or certain types of surgery.

The application of high environmental pressure forces gas emboli to dissolve once more, allows the gas to be excreted through the lungs and discourages formation of new emboli. Administration of oxygen at high partial pressure ensures more complete removal of inert gas from the tissues, reduces the likelihood of further bubbling and is associated with more complete and rapid resolution of the clinical manifestations of bubble-related injury.

Data supplied by the BHA⁵ records that its members treated between 400 and 500 incidents of decompression illness with HBOT in each of years 2002 to 2007. In the case of gas embolism, data is available for 2005 to 2007 and indicates between 1 and 3 cases annually. A more extensive data collection exercise is currently in progress through the Hyperbaric Oxygen Therapy Clinical Reference Group. It will report all NHS funded activity in England for the past three financial years and the data will become available over July and August 2012.

CO is the most common cause of fatal poisoning in the USA and Europe and HBOT is widely used as a therapeutic intervention.

8. Evidence base

The Department of Health (DH), and a number of professional groups, have provided guidance on conditions for which they consider HBOT to be appropriate standard care or adjunctive therapy.^{6, 7}

In 2007, a systematic review² of the clinical and cost effectiveness of HBOT for the range of conditions for which it has been used was commissioned following discussion among the UK Public Health Specialised Commissioner Group regarding NHS provision of the intervention. The report was published in April 2008 and a summary of the key findings of the review by condition is shown in Appendix 2.

The review was based on a horizon scanning report produced by the Agency for Healthcare Research and Quality (AHRQ) USA⁸ and attempted to identify all the indications for which HBOT has been suggested as an appropriate intervention. Paediatric studies and reports published in languages other than English were excluded. Reports considering the safety of HBOT were included.

The review identified that randomised control trial (RCT) evidence was not available for a substantial number of the HBOT treatment indications. Furthermore, RCTs may be considered inappropriate for some conditions, such as decompression illness where the theoretical rationale for therapy is accepted. For those conditions where RCTs had been conducted, the quality or reporting of many trials was considered too poor to provide robust conclusions. As a result, therapeutic efficacy was suggested for a number of HBOT indications, but rigorous testing is required to confirm the findings.

For the majority of conditions considered within this report it is concluded that there is insufficient evidence to support the routine use of HBOT. For some conditions observational studies have suggested that HBOT may be of some benefit, but conclusive evidence in the form of RCTs is required. A large number of such trials are currently underway and this should provide a better evidence base.

The cost-effectiveness evidence base was limited, with economic evaluations having been carried out for only a few conditions. The majority of these studies reported on diabetic foot ulceration but a small number also considered non-diabetic wound healing and osteoradionecrosis.

Evidence of effectiveness for specific conditions

Decompression sickness

A Cochrane review¹¹ and two Health Technology Assessment (HTA) reports^{12, 13} have considered the effectiveness and safety of HBOT for decompression sickness. These concluded that recompression therapy is standard treatment for decompression sickness although there is no supportive RCT evidence. Given the theoretical evidence, observational case series data and widespread clinical use, HBOT remains the treatment of choice for decompression sickness.

Gas Embolism

The AETMIS HTA¹² reviewed the use of HBOT for gas embolism and reported that the evidence was not robust and only based on case series data. These observational studies do indicate that the treatment is effective and, given the theoretical basis for treatment and clinical consensus, HBOT has become the standard treatment in severe cases.

Carbon monoxide poisoning

The Department of Health issued a statement on 11 November 2010 advising that HBOT may be used in CO poisoning.⁹ More recently the National Poisons Information Service has advised against the use of HBOT for this indication stating that the evidence base is insufficient to warrant the transfer of patients to HBOT facilities.¹⁰

The RCT evidence for the clinical effectiveness of HBOT for CO poisoning (compared to normobaric oxygen) is conflicting but needs to be considered in the light of the theoretical basis for HBOT therapy. Criteria for selecting HBOT versus normobaric oxygen for CO intoxication have been published which identify neurological deficit; loss of consciousness; cognitive impairment as key indicators for emergency treatment.

The Department of Health statement⁹ advised that:

A COHb concentration of >20% should be an indication to consider HBOT and the decision should be taken on the basis of the indicators listed below:

- Loss of consciousness at any stage
- Neurological signs other than a headache
- Myocardial ischaemia / arrhythmia diagnosed by ECG
- The patient is pregnant

HBOT is also thought to be of use for extensive exposure to CO and if neurological damage is suspected. Its use should be on a case by case basis.

Summary of evidence of clinical and cost effectiveness of HBOT

In its overall findings, the systematic review by NHS Quality Improvement Scotland concluded that, for the majority of conditions, the existing clinical effectiveness evidence did not support routine use of HBOT as a therapeutic intervention. While in some instances, there appeared to be trends towards positive outcomes for patients receiving HBOT, this could not be used as justification for routine application of the technology.

The use of hyperbaric oxygen as standard care for decompression illness, gas embolism and carbon monoxide poisoning is not supported by RCT level data but, given the good theoretical basis, long-standing use and clinical consensus it would be hard to justify further trials in these treatment areas.

A recent review of HBOT by the West Midlands Commissioning support unit came to similar conclusions and advised commissioners to adopt a national policy for the use of HBOT.

9. Rationale behind the policy statement

A Cochrane review¹¹ and two Health Technology Assessment (HTA) reports^{12,13} have considered the effectiveness and safety of HBOT for decompression sickness. These concluded that recompression therapy is standard treatment for decompression sickness although there is no supportive RCT evidence. Given the theoretical evidence, observational case series data and widespread clinical use, HBOT remains the treatment of choice for decompression sickness.

The AETMIS HTA¹² reviewed the use of HBOT for gas embolism and reported that the evidence was not robust and was based only on case series data. These observational studies do indicate that the treatment is effective and, given the theoretical basis for treatment and clinical consensus, HBOT has become the standard treatment in severe cases.

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The use of hyperbaric oxygen as standard care for decompression illness, gas embolism and acute carbon monoxide poisoning is not supported by RCT level data but, given the good theoretical basis, long-standing use and clinical consensus, it would be hard to justify further trials in these treatment areas.

The most recent review of the literature completed in March 2012³ confirmed that the evidence base remains unchanged.

Thus, based on the quality of evidence available, HBOT will only be commissioned for the following indications:

- Decompression illness
- Gas embolism
- Acute CO poisoning

No other indications are commissioned as there is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.

10. Mechanism for funding

From April 2013 the NHS CB will be responsible for commissioning in line with this policy on behalf of the population of England.

11. Audit requirements

As outlined in the service specification:

Patients will be treated by the service within the timescales agreed with the commissioning authority, recognising that, in some instances, 'time to treatment' may be prolonged due to factors entirely outside of a facility's control.

Patients will receive a discharge letter on completion of treatment, onward referral if required and educational information at discharge.

Providers will have sufficient capacity to accept patients at the level agreed with the commissioning authority.

Feedback from patient experience outcome measures will be sought at least annually and will be acted upon as appropriate.

Whenever circumstances reasonably permit, patients will be fully informed about why they should receive HBOT and why it may be beneficial to them. This should include clear written information.

Mortality rates for each condition being treated shall not exceed the standardised mortality rates that would be expected if HBOT was not being administered.

Each provider will complete the quality dashboard with the required frequency and within the required timeframe. Any measure that is below the accepted standard will be addressed by the provider and all reasonable measures taken to rectify the shortcoming in future.

12. Documents which have informed this policy

All references. In addition, summary extracts from the following are in Appendices 1 and 2 respectively:

West Midlands Commissioning Support Unit. Hyperbaric Oxygen Therapy: Technical Report, 2012. ³

The clinical and cost effectiveness of hyperbaric oxygen therapy; HTA Programme: Systematic Review. NHS Quality Improvement Scotland 2008. ²

13. Links to other policies

This policy is informed by the generic NHS CB commissioning policies covering experimental treatments and the process by which individual funding requests (IFR) are handled.

14. Date of review

A decision on when to review of this policy will be taken in April 2014

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Appendix 1: Hyperbaric oxygen therapy : Technical Report.

Section 1: Pragmatic review of evidence for efficacy and safety³ Summary

The purpose of this review was to assess the evidence for efficacy of HBO therapy to allow identification of the conditions for which its use could be justified.

The review was based on the Health Technology Assessment produced by NHS Quality Improvement Scotland in 2008, relevant Cochrane reviews, and the results of a search for controlled trials and systematic reviews published since 2007. Where necessary, the primary evidence was examined in detail. The conditions for which HBO has been used were grouped into several categories based on the evidence.

HBO was considered to be accepted standard therapy for decompression sickness and gas embolism associated with decompression sickness or trauma, based on the theoretical rationale for such treatment and clinical experience, although there was no robust evidence for efficacy.

No robust evidence was found for the treatment of carbon monoxide poisoning with HBO either soon after acute poisoning, or for delayed effects of acute poisoning. HBO treatment for acute carbon monoxide poisoning is not currently recommended by the UK National Poisons Information Service (on Toxbase) or NHS Direct; these bodies recommend the use of normobaric 100% oxygen. However, the national position was confused by a statement issued by the Department of Health in November 2010 that the use of HBO therapy should be considered for patients with CO poisoning who met specific criteria, but that advice from Toxbase should be considered.

Reasonable evidence indicated that HBO was not efficacious for the treatment of multiple sclerosis, and its use for this indication is not recommended by NICE Clinical Guideline 8.

Several controlled trials, including those with adequate randomisation, suggested possible efficacy for the use of HBO for the treatment of chronic diabetic foot ulcer, and one for chronic refractory radiation-induced proctitis. However, no clear conclusions could be drawn because of serious weaknesses in the design and reporting of most of the trials and inconsistency in the results between trials. The current body of evidence does not support the routine treatment of these indications with HBO, but does justify further research (as also reflected by NICE Clinical Guideline 119). Large and robustly designed double-blind randomised controlled trials, with meaningful outcomes and appropriate comparator therapy, are needed to establish whether HBO therapy is effective for the treatment of diabetic foot ulcer and radiation-induced soft-tissue injury.

For nearly 40 other indications for which HBO is used or has been suggested, the current evidence is clearly inadequate in quality or quantity to support the use of HBO therapy.

For most of the indications, justification of the use of HBO is based on expert opinion rather than robust evidence.

Appendix 2: Systematic review by NHS Quality Improvement Scotland.

Summary of findings²

Condition	European consensus conference recommendations	Report findings
Decompression illness	Major accidents should be treated using hyperoxygenation tables at moderate or high pressure. Minor accidents (pain only) should be treated with recompression tables at a maximum of 2.8 atmospheres absolute (ATA).	Empirical evidence together with the theoretical basis and clinical consensus supports the use of HBOT as standard care.
Gas embolism	HBOT strongly recommended.	Empirical evidence is lacking, but the theoretical basis and clinical consensus supports the use of HBOT as standard care in severe cases.
Carbon monoxide (CO) poisoning	HBOT is strongly recommended for patients with diagnosed CO poisoning, who are at high risk (unconscious; clinical neurological, cardiac, respiratory or psychological symptoms; pregnant women) of immediate or long-term complications.	Empirical evidence together with theoretical basis and clinical consensus supports the use of HBOT as part of algorithms for the management of CO poisoning.
Diabetic lower extremity ulcers	HBOT is recommended if peri-lesional transcutaneous oxygen pressures, measured under hyperbaric conditions, are higher than 100 mmHg.	There is some evidence which indicates that HBOT is effective in reducing the number of major amputations required. Ongoing large clinical trials should provide further evidence which may provide support for the routine use of HBOT.
Venous ulcers	HBOT is recommended if peri-lesional transcutaneous oxygen pressures measured	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to

Condition	European consensus conference recommendations	Report findings
Pressure ulcers	under hyperbaric conditions are higher than 50mmHg.	standard care. There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Other chronic wounds		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Crush injuries	HBOT is strongly recommended in posttraumatic crush injury of Gustilo type III B and C. Measurement of transcutaneous oxygen pressure is recommended to confirm the indication and to direct treatment.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Blunt chest injury		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Calciphylaxis		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Grafts and flaps	HBOT is recommended for compromised skin grafts and myocutaneous flaps. Measurement of transcutaneous oxygen pressure is recommended to confirm the indication and to direct treatment.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Necrotising soft tissue infections	HBOT is strongly recommended for the treatment of anaerobic or mixed bacterial necrotising soft tissue infection.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.

Condition	European consensus conference recommendations	Report findings
Surgical site infections		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Livedoid vasculopathy		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Acute coronary syndrome		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Stroke		The evidence does not support the use of HBOT.
Traumatic brain injury		There is insufficient evidence to support the routine use of HBOT.
Soft-tissue Radionecrosis		There is evidence to support the use of HBOT for patients with radiation-induced proctitis. There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care for patients with other forms of soft-tissue radionecrosis.
Osteoradionecrosis	HBOT is strongly recommended for radionecrosis of the mandible and recommended for radionecrosis of other bones.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Cancers and tumour sensitisation to radiotherapy	HBOT is recommended as adjunctive therapy for patients with stage IV neuroblastoma.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care. Ongoing large clinical trials should provide further evidence (see Appendix 7).

Condition	European consensus conference recommendations	Report findings
		The adverse events associated with HBOT combined with radiotherapy need to be further evaluated.
Orthopaedics	HBOT is recommended for chronic refractory osteomyelitis.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Surgery		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Cardiopulmonary bypass		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Urology		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Headache		The evidence does not support the use of HBOT.
Hearing disorder	HBOT is recommended for sudden deafness but awaits the results of ongoing (2004) RCTs.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Multiple sclerosis		The evidence does not support the use of HBOT.
Thermal burns	HBOT is optional when second or third degree burns exceed 20% of the body surface.	There is currently insufficient evidence to support the use of HBOT to treat thermal burns.
Sports injuries		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Osteonecrosis of the mandible		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to

Condition	European consensus conference recommendations	Report findings
Peridontitis		standard care. There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Chronic hepatitis		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Crohn's disease		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Bell's palsy		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Pain syndromes		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Cognitive impairment		The evidence does not support the use of HBOT.
Eye disorders	HBOT is optional in acute ophthalmological ischaemia.	There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Infertility		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Severe anaemia		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.
Malignant otitis externa		There is currently insufficient evidence to support the routine use of HBOT as an adjunct to standard care.

**Change Notice for Published Specifications and Products
developed by Clinical Reference Groups (CRG)**

Amendment to the Published Products

Product Name

Hyperbaric Oxygen Therapy

Ref No

D11/P/a

CRG Lead

Hyperbaric Oxygen Therapy

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
The use of Hyperbaric Oxygen Therapy	Hyperbaric Oxygen Therapy	Title page and 2 nd page	To standardise naming and coding of products	Programme of Care Director for Trauma	September 2013