

Specialised Services Commissioning Policy: CP07

Hyperbaric Oxygen Therapy

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission Hyperbaric Oxygen Therapy in accordance with the revised criteria outlined in this document.

In creating this policy WHSSC has reviewed the place of enhanced prosthetic limbs 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.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This policy has been developed for the planning and delivery of Hyperbaric Oxygen Therapy (HBOT) for people resident in Wales. This service is only commissioned by the Welsh Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain Language Summary

Hyperbaric oxygen therapy (HBOT) is breathing 100% oxygen while under increased atmospheric pressure. When a patient is given 100% oxygen under pressure, haemoglobin is saturated, but the blood can be hyperoxygenated by dissolving oxygen within the plasma.

It is most commonly known for treatment of dive injuries when divers have come to the surface of the water too quickly. It is also used for routine wound care and treatment of patients who are ventilated or in critical care.

1.2 Aims and Objectives

This policy aims to define the commissioning position of WHSSC on the use of HBOT for the following:

- Emergency indications (see 2.1.1)
 - Decompression illness
 - Crush injuries and other traumatic ischaemia with compromised circulation

The objectives of this policy are to:

- ensure commissioning for the use of HBOT is evidence based
- ensure equitable access to HBOT
- define criteria for people with decompression illness/gas embolism and other elective indications to access treatment
- improve outcomes for people with decompression illness/gas embolism and other elective indications.

1.3 Background

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. Decompression to sub-atmospheric pressures, such as during altitude training for aircrew or an ascent to altitude after diving, can also generate or exacerbate gas emboli. Disease caused by evolved gas in this manner is known as decompression sickness. In most cases, symptoms

typically present themselves within 24 hours of the causation event, and in almost 100% of cases symptoms present within 48 hours.

If lung tissue is ruptured by expansion of gas during decompression, gas can escape into the systemic arterial circulation via the pulmonary veins and the left heart and usually causes brain injury. This escaped gas is termed arterial gas embolism.

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.

Regardless of mechanism of injury, the gas emboli can cause clinical manifestations ranging from lethargy and pain to severe neurological impairment, multi-organ failure and death.

The term decompression illness encompasses decompression sickness and gas embolism. In a diver, it is often not possible to determine whether a patient has evolved gas disease, escaped gas disease or both.

1.4 Current Treatment

The application of high environmental pressure (recompression) forces gas emboli to dissolve once more and discourages formation of new emboli. Slow, controlled decompression then allows the gas to be excreted safely through the lungs.

Administration of oxygen at a partial pressure significantly higher than 100 kilopascals (kPa) is known as hyperbaric oxygen therapy (HBOT). It takes place in a chamber. It was first introduced over 50 years ago for the treatment of decompression illness along with recompression as described, for example, by Goodman et al $(1965)^1$.

- If a diver develops an air embolism, the only effective treatment is immediate recompression treatment in a special pressurised room called a hyperbaric chamber.
- The diver should be given 100% oxygen and laid horizontally until they reach the hyperbaric chamber.
- Recompression treatment involves lying in a hyperbaric chamber, usually for several hours, and breathing a mixture of gases and oxygen under pressure. The high pressure can restore normal blood

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Goodman MW, Workman RD. 1965. Minimal-recompression, oxygen breathing approach to treatment of decompression sickness in divers and aviators. *US Navy Experimental Diving Unit* Report No 5-64, Washington DC.

flow and oxygen delivery to the body's tissues and reduce the size of the air bubbles in the body.

However, it is recognised that the evidence base supporting the use of HBOT in the treatment of decompression illness and gas embolus is not well developed and the rationale for treatment has been based on knowledge of the gas laws of physics, observational symptom resolution and the absence of a credible alternative. There is no relevant NICE guidance.

For patients receiving HBOT in an elective capacity, patients are also laid horizontally in a hyperbaric chamber with 100 percent oxygen circulated for them to breathe. These conditions deliver high concentrations of oxygen to the blood stream which helps the healing process by helping to fight infection and improve circulation.

There are a number of potential risks and side effects of HBOT. Most are often mild and reversible but some can be severe and life threatening (Leach, Rees & Wilmshurst, 1998)². Overall, severe central nervous system symptoms occur in 1-2% of treated patients, symptomatic reversible barotrauma in 15-20%, pulmonary symptoms in 15-20%, and reversible optic symptoms in up to 20% of patients (Leach, Rees & Wilmshurst, 1998). Reversible myopia, due to oxygen toxicity on the lens, is the commonest side effect and can last for weeks or months (Leach, Rees & Wilmshurst, 1998). This is almost exclusively a side effect of elective therapies since emergency treatment are rarely prolonged to cause such an effect.

Table 1 provides a summary of risks.

Table 1: Summary of risks						
General	Claustrophobia, Reversible myopia, Fatigue, Headache, Vomiting					
Oxygen Toxicity	Convulsions, Psychological, Lung, Pulmonary oedema, haemorrhage, pulmonary toxicity, Respiratory failure					
Barotrauma	Ear damage, Sinus damage, Ruptured middle ear, Lung damage					

1.5 What NHS Wales has decided

WHSSC has carefully reviewed the evidence of the use of HBOT for several indications. We have concluded that there is enough evidence to fund the use of HBOT within the criteria set out in section 2.1.

1.6 Relationship with other documents

This document should be read in conjunction with the following documents:

²Leach RM, Rees PJ, Wilmshurst P. Hyperbaric oxygen therapy. *BMJ: British Medical Journal*. 1998;317(7166):1140-1143.

NHS Wales

 All Wales Policy: <u>Making Decisions in Individual Patient Funding</u> <u>requests</u> (IPFR).

Relevant NHS England policies

- NHS England Specialised Services clinical commissioning policy: <u>HBOT for Decompression Sickness and Gas Embolism</u>
- NHS England Specialised Service clinical commissioning policy: <u>HBOT for Necrotising Soft Tissue Infections</u>
- NHS England Specialised Service clinical commissioning policy: HBOT for Carbon Monoxide Poisoning
- NHS England Specialised Services clinical commissioning policy: <u>HBOT for Soft Tissue Radiation Damage in patients with a history</u> of Pelvic Irradiation

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee will approve funding of HBOT for patients resident in Wales for the emergency indications as set out in section 2.1.1 and the elective indications as set out in section 2.1.2.

2.1 Inclusion Criteria

2.1.1 Emergency Indications

Emergency indications for treatment are:

Decompression illness/gas embolism

or

 Crush injuries and other traumatic ischemia with compromised circulation.

Decompression Illness

Inclusion criteria

Patients satisfying all of the following criteria are eligible for hyperbaric oxygen therapy:

 a history of decompression, with or without an inert gas burden, within the 72 hours prior to onset of symptoms or signs

and

 all reasonable efforts commensurate with the urgency of the situation have been taken to exclude causes other than bubble-mediated disease

and

- i. a history of one or more of the following persisting at the time of assessment:
 - o limb Pain
 - pain presenting in a thoracolumbar dermatomal distribution (Girdle Pain)
 - o subjective or objective Neurological deficit
 - o audiovestibular symptoms or signs
 - o cardio-pulmonary symptoms or signs
 - o cutaneous symptoms or signs (pruritis, rash, discoloration)
 - lymphatic symptoms or signs (painful or swollen lymph nodes, regional oedema)
 - constitutional symptoms or signs (such as headache, fatigue, malaise, nausea, vomiting and anorexia) severe enough to affect quality of life or function

or

ii. omitted more than 20 minutes of planned decompression (not including safety stops) and remain asymptomatic and can

present at a hyperbaric facility within 60 minutes of the decompression insult

or

iii. a history clearly consistent with arterial gas embolism, are now asymptomatic with no abnormal neurological signs, and for whom there is no other obvious cause, if they can present at a hyperbaric facility within 6 hours of the decompression insult.

Point at which HBOT is appropriate for management of the condition

• Treatment is appropriate as soon as it is established that the inclusion criteria are fulfilled and that there are no exclusions.

Gas embolism

Patients satisfying all of the following criteria are eligible for hyperbaric oxygen therapy:

 a history of an event which could plausibly have introduced gas into a blood vessel

and

all reasonable efforts commensurate with the urgency of the situation have been taken to exclude causes other than bubble-mediated disease

and

- i. a history of one or more of the following persisting at the time of assessment:
 - Subjective or objective Neurological deficit
 - Cardio-pulmonary symptoms or signs

or

ii. a history clearly consistent with arterial gas embolism, are now asymptomatic with no abnormal neurological signs, and for whom there is no other obvious cause, if they can present at a hyperbaric facility within 6 hours of the decompression insult

2.1.2 Elective Indications

Elective indications for treatment are:

Chronic Refractory Osteomyelitis

All the following criteria apply:

- after assessment and discussion with the DDRC a relevant MDT believes that:
 - there is a clear case for treatment, and

- o there is a significant probability of successful treatment, and
- surgery to remove dead tissue has been or will be performed, if appropriate. HBO may be given peri-operatively, and
- where conservative treatment, including appropriate high dose antibiotics, has not been successful over a 6 weeks of intensive treatment.

Point at which HBOT is appropriate for management of the condition

• Treatment is appropriate as soon as it is established that the inclusion criteria are fulfilled and that there are no exclusions.

2.2 Exclusion Criteria

2.2.1 Emergency Indications

A patient is not eligible for hyperbaric oxygen therapy if:

- a reason other than bubble-mediated disease for the signs or symptoms is identified
- they have an untreated tension pneumothorax

In line with the NHS England NOT COMMISSIONED policies, a patient is also not eligible for hyperbaric oxygen therapy for:

Carbon Monoxide poisoning (all ages)

2.2.2 Elective Indications

Only the indication in 2.1.2 is funded.

In line with the NHS England NOT COMMISSIONED policies, a patient is also not eligible for hyperbaric oxygen therapy for:

- Prevention of Osteo-radionecrosis for Head and Neck Surgery
- Necrotising soft tissue infections (all ages)
- Soft tissue radiation damage in patients with a history of pelvic irradiation for malignant disease (all ages)
- Malignant otitis externa (all ages)

In line with NICE guidance, a patient is also not eligible for hyperbaric oxygen therapy for:

Diabetic Foot Ulcers

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.4 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i and Annex ii)

Elective referrals can only be received directly from a relevant secondary care multi-disciplinary team (MDT) that has assessed the case, and after discussion with the DDRC Healthcare believes that there is a clear case for treatment and a significant probability of successful treatment. Cases will be assessed by a doctor within DDRC before treatment is commenced.

2.6 Designated Centre

The main providers for emergency HBOT commissioned for patients from NHS Wales are DDRC Healthcare and North West Emergency Recompression Unit. Treatment chambers are in the following locations:

DDRC Healthcare, The Hyperbaric Medical Centre
Plymouth Science Park
Research Way
Plymouth Science Park
Plymouth
Devon
PL6 8BU

North West Emergency Recompression Unit

Murrayfield Hospital

Holmwood Drive

Heswall

Barnston

Wirral

CH61 1AU

All emergency indications must be clinically assessed by a physician qualified in diving diseases and hyperbaric oxygen treatment. These chambers take both NHS and non-NHS patients.

Emergency HBOT to treat decompression sickness is regularly included in diving insurance, particularly for diving trips abroad. At present, due to HBOT funding from the NHS in the UK, Divers Alert Network (DAN)/UK-

based dive insurance becomes invalid once the diver has returned to the UK - i.e. it can only be used if the diver is abroad³. However, a non-NHS entitled diver's insurance will be valid for treatment in the UK.

2.7 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

2.8 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

2.9 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinician considering treatment should:

- discuss all the alternative treatment with the patient;
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

³ 1. Divers Alert Network: <u>Decompression Illness: What Is It and What Is The Treatment?</u>

3. Evidence

WHSSC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

3.1 Date of Review

This document is scheduled for review before 2022 where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

If an update is carried out the policy will remain extant until the revised policy is published.

4. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender reassignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

5. Putting Things Right: Raising a Concern

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

Annex i Patient Pathway (Emergency Indications)

Decompression Illness/Gas Embolism

The use of HBOT for decompression illness and gas embolism is a medical emergency and patients should be referred to the nearest chamber to receive emergency treatment. Cases will be assessed by a doctor within DDRC before treatment is commenced. Prior approval for treatment is not required.

Patients are referred directly from:

- HM Coast Guard.
- Duty Diving Medical Officer (Institute of Naval Medicine).
- British Hyperbaric Association National Diving Accident Advice Line.
- Another hyperbaric unit.
- Ambulance service.
- Emergency department.
- Secondary care clinician.
- General practitioner.
- A patient, or an individual acting on behalf of the patient, directly accessing a provider.

Crush Injuries and Other Traumatic Ischemia with Compromised Circulation

Referrals can only be received directly from a secondary care Consultant. Cases will be assessed by a doctor within DDRC before treatment is commenced. Prior approval for treatment is not required.

Annex ii Patient Pathway (Elective Indications)

Secondary care MDT

HBOT Centre

- DDRC Plymouth
- North West Emergency Recompression Unit, Wirral

Annex iii Checklist

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The following checklist should be completed for every patient to whom the policy applies:

- Where the patient meets the criteria and the procedure is included in the contract and the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.
- The patient meets the criteria **and** is received at an agreed centre, but the procedure is not included in the contract. The checklist must be completed and submitted to WHSSC for prior approval to treatment.
- The patient meets the criteria but wishes to be referred to a noncontracted provider. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration.
- If the patient does not meet the criteria for treatment as outlined in this
 policy, an Individual Patient Funding Request (IPFR) can be submitted
 for consideration in line with the All Wales Policy: Making Decisions on
 Individual Patient Funding Requests. The request will then be considered
 by the All Wales IPFR Panel.

Annex iv Codes

Code Category	Code	Description
ICD-10	T70.0	Otitis barotrauma
ICD-10	T70.1	Sinus barotrauma
ICD-10	T70.3	Caisson disease (decompression sickness)
		Compressed air disease
		Diver's palsy or paralysis
ICD-10	T79.0	Air embolism (traumatic)
ICD-10	T80.0	Air embolism following infusion, transfusion and therapeutic injection
ICD-10	T81.7	Vascular complications following a
		procedure not elsewhere classified
		air embolism following procedure NEC
ICD-10	T53	Toxic effects of halogen derivatives of
		aliphatic and aramatic carbons
ICD-10	T53.0	Carbon tetrachloride
		Tetrachloromethane
ICD-10	T58	Toxic effect of carbon monoxide
ICD-10	D62	Acute post haemorrhagic anaemia
ICD-10	X47*	Accidental poisoning by and exposure to
		other gases and vapours
ICD-10	Y17*	Poisoning by and exposure to other gases
		and vapours, undetermined intent
ICD-10	T66	Unspecified effects of radiation
ICD-10	K10.2	Osteoradionecrosis of jaw
ICD-10	N30.4	Irradiation cystitis
ICD-10	L55- 59	Radiation related disorders of the skin and
		subcutaneous tissue
ICD-10	K52.0	Gastroenteritis and colitis due to radiation
ICD-10	M86.4	Chronic osteomyelitis with draining sinus
ICD-10	M86.6	Other osteomyelitis
ICD-10	K10.2	Inflammatory conditions of jaws - osteoradionecrosis
ICD-10	T01.0	Open wounds involving head and neck
ICD-10	T01.1	Open wounds involving thorax with abdomen, lower back and pelvis
ICD-10	T01.2	Open wounds involving multiple regions of
165 10	101.2	upper limb(s)
ICD-10	T01.3	Open wounds involving multiple regions of
		lower limb(s)
ICD-10	T01.6	Open wounds involving multiple regions of upper limb(s) with lower limb(s)
ICD-10	T01.8	Open wounds involving other combinations
ICD 10	T01 C	of body regions
ICD-10	T01.9	Multiple open wounds, unspecified

ICD-10	T14.1	Open wound of unspecified body region
ICD-10	E14	Diabetes mellitus (relating to wound). This code would be in addition to the code for the specified wound.
ICD-10	T14.7	Crushing injury and traumatic amputation of unspecified body region. • Crushing Injury NOS • Traumatic amputation NOS
ICD-10	T04	Crushing injuries involving multiple body regions
ICD-10	T04.0	Crushing injuries involving multiple body regions
ICD-10	T04.1	Crushing injuries involving thorax with abdomen, lower back and pelvis
ICD-10	T04.2	Crushing injuries involving multiple regions of upper limb(s)
ICD-10	T04.3	Crushing injuries involving multiple regions of lower limb(s)
ICD-10	T04.4	Crushing injuries involving multiple regions of upper limb(s) with lower limb(s)
ICD-10	T04.7	Crushing injuries of thorax with abdomen, lower back and pelvis with limb(s)
ICD-10	T04.8	Crushing injuries involving other combinations of body regions
ICD-10	T04.9	Multiple crushing injuries, unspecified
ICD-10	G06.0	Intra-cranial abscess and granuloma
ICD-10	A48.0	Gas gangrene (including cellulitis)

Annex v Abbreviations and Glossary

Abbreviations

IPFR Individual Patient Funding Request

WHSSC Welsh Health Specialised Services

HBOT Hyperbaric Oxygen Therapy

DAN Divers Alert Network

Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.