

ISTITUTO IPERBARICO S.p.A.

VILAFRANCA DIVERONA



October 2015

Services

Charter Guide for Users of Hyperbaric Oxygen Therapy

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Dear Client,

I am pleased to present to you the Services Charter of the Company Istituto Iperbarico S.p.A. of Villafranca. (Hyperbaric Institute)

The Services Charter provides summary information with a view to raising awareness of the Istituto Iperbarico amid the range of medical facilities in the Region; above all, it provides details that I hope will be useful as a basis for commencing discussions between the Client and Istituto Iperbarico.

Detailed information on hyperbaric medicine and on our Institution together with a more in-depth perception of the Client's needs may help to create a range of quality services, aimed at a more informed and beneficial ability to use them.

Yours faithfully

The Managing Director
Istituto Iperbarico S.p.A

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INTRODUCTION

This "SERVICES CHARTER" is a "mini guide" containing information that may be useful for users - or clients - using the Hyperbaric Institution facility and for Doctors sending their patients for hyperbaric therapies.

The CHARTER clearly defines the technical aspects and organisational procedures, with the aim of facilitating the information and participation of clients.

The aim is to activate forms of collaboration with a view to improving the

quality of the service and contributing to the awareness of hyperbaric medicine. Finally, it provides information on the facility's organisation, its services, types of therapies and their main indications, the professionals involved and their duties.

The Institution is committed to providing a quality service, guaranteeing adequate standards of efficiency and effectiveness of the procedures as well as mechanisms of verification linked to the same.

HYPERBARIC OXYGEN THERAPY

Hyperbaric oxygen therapy (HOT) is the inhalation of pure oxygen particularly in closed environments (hyperbaric chambers) pressurised to a pressure higher than atmospheric pressure. That system facilitates the solution of oxygen in plasma at a concentration 12-15 times higher than normal. This concentration increase allows oxygen to travel by spreading throughout the body, even to places where red blood cells cannot reach.

Hyperbaric oxygen therapy requires the respiration of oxygen to occur at pressure of at least 4

1.4 Absolute Pressure. Exposure to lower pressures or of parts of the body to oxygen are not and do not constitute hyperbaric oxygen therapy.

HOT can be crucial in resolving acute pathologies representing, for some, a life-saving treatment or in improving patients' prognosis. In chronic pathologies, HOT plays an important and adjuvant role in resolving or improving pathological patterns having their main cause in the insufficient supply of oxygen (hypoxia) or in infection.

If the information contained in this booklet does not satisfy all your queries, please contact our Institution directly, at any time, on the following details:

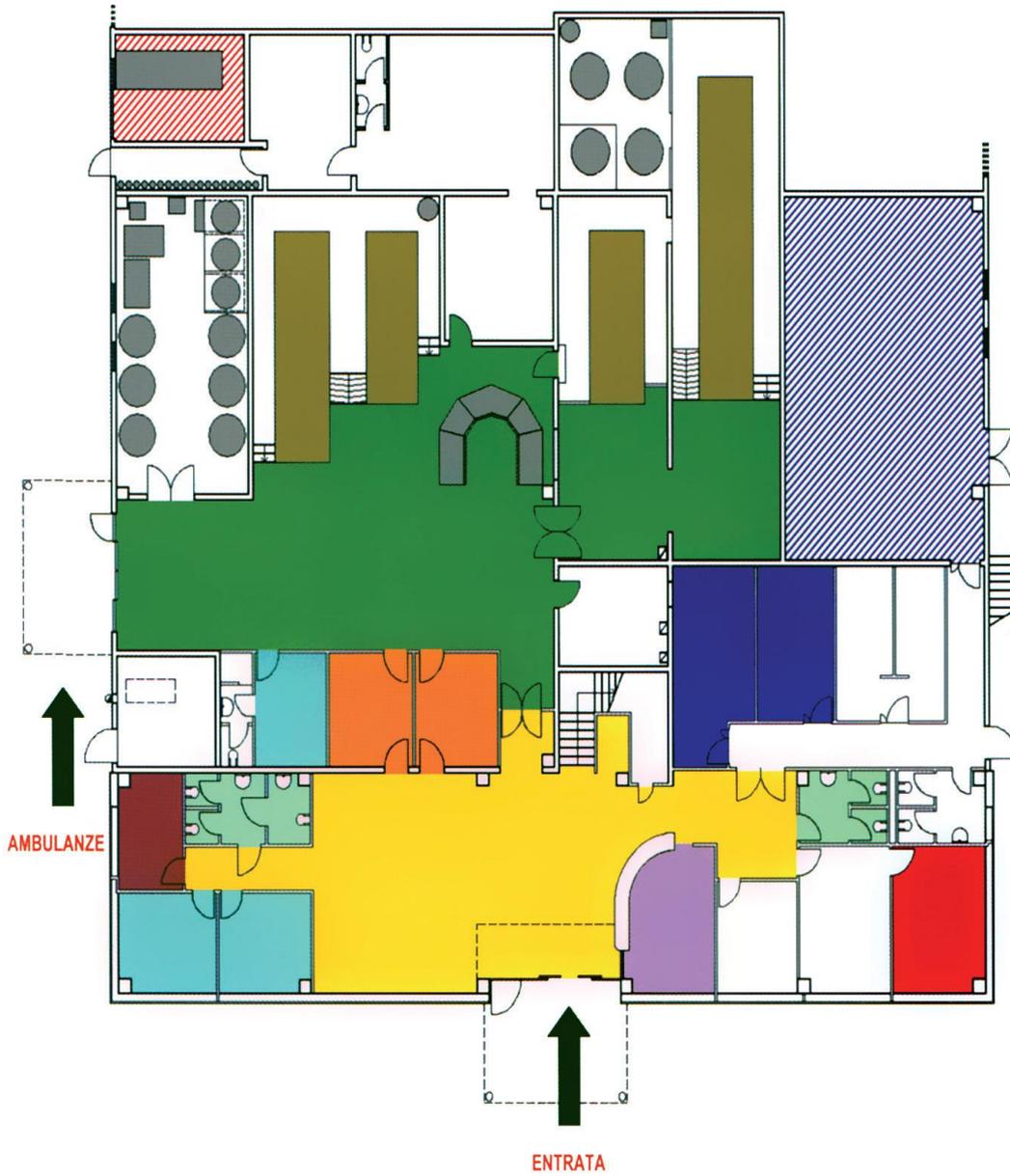
Telephone: 045 6300300 (5 lines, automatic line selection)

Fax: 045 6300597

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e-mail: istituto@terapiaiperbarica.com

PLAN



- | | |
|---|--|
| SALA D'ATTESA | DIREZIONE SANITARIA |
| SEGRETERIA | CENTRALE OPERATIVA |
| SERVIZI IGIENICI | CAMERE IPERBARICHE |
| SPOGLIATOI (MASC./FEM.) | SALA CONFERENZE |
| SALE MEDICAZIONE | GRUPPO ELETTOGENO |
| AMBULATORI MEDICI | LOCALI DI SERVIZIO |
| DISTRIBUTORI AUTOMATICI BEVANDE E SNACK | |

THE MAIN PRINCIPLES

In providing the service, the Hyperbaric Institution bases its actions on the following principles:

Equality and impartiality The Institution ensures that its facilities and services may be used by all, without distinction on social status, colour or religion. The services are differentiated so as to meet the requirements of patients needing particular assistance (unconscious persons, the elderly, children, disabled, etc.).

Continuity

The continuity of support to Clients within the facility is guaranteed, from the time of admission to the end of the therapy, with the adequate and competent presence of medical, nursing, technical and administrative personnel.

Efficiency and effectiveness

The Hyperbaric Institution has implemented, in the field of hyperbaric therapy, cutting-edge treatment methods and support procedures in order to optimise its ability to admit and to provide medical treatment to its Clients.

Personnel

The Institution is constantly engaged in ensuring its personnel adopt professional and courteous conduct towards Clients, aimed

at establishing a relationship of trust and collaboration.

THE FACILITY

The Hyperbaric Institution of Villafranca was founded, constructed and organised to administer a therapy, defined as Hyperbaric Oxygen Therapy (HOT).

A large parking area is fully available to users, with specific spaces for the disabled.

It is prohibited to park outside the specific areas and the signage must be respected.

The portico in front of the entrance can be reached both on foot and by car via a dedicated access road.

A specific portico, located to the left of the building, is used by ambulances accompanying patients on stretchers or in wheelchairs.

The institution has a large waiting room available to Clients and their companions for waiting periods.

There is also a snack area, public telephone and toilets, including disabled toilets.

There are lockers in the changing rooms, assigned to each Client, for storing the gowns and clogs provided by the Institution (to be worn during the HOT) and for storing clothes and objects that, as noted on a daily basis by our staff, are incompatible with the hyperbaric chamber environment

Clients are strongly requested not to leave personal objects outside the aforementioned lockers, to avoid mix-ups or thefts, and not to wear precious objects, as the Institution will not be liable in any way for any losses.

During the performance of the therapies, it is strictly prohibited to enter the hyperbaric treatment area or to speak with the technical personnel involved.

THE ORGANISATION

The Hyperbaric Institution of Villafranca provides services consisting of specialist examinations of hyperbaric medicine, hyperbaric oxygen therapy treatments, medications, check-up examination and examinations such as transcutaneous oximetry, audiometry, tympanometry, glycemia, etc. The examinations, medications and check-ups are performed in the clinic of the Institution and the HOT treatments are provided using four hyperbaric chambers.

The Institution provides information by way its Reception Service from 7am to 5pm, Monday to Friday. The therapies are provided every weekday from Monday to Friday, during the following times:

(08:00-10:00)

(10:00-12:00)

(12:00-14:00)

(14:00-16:00)

Patients are asked to arrive at the Institution 15 minutes prior to the therapy. Patients must notify the Institution by telephone of any absence due to medical or personal reasons. The reasons for any absence must be important, as they affect the organisation of the therapy. Sessions not completed are recovered at the end of the treatment cycle, subject to agreement with reception. In the event of an unjustified absence for more than two sessions, the Institution will reschedule the "Flight plan".

Any temporary suspension of the treatment plan must not exceed one month. If this occurs, the case will be closed and it will be necessary to re-start the administrative process with the Local Health Service to which the Client belongs in order to complete the remaining treatments.

THE VILLAFRANCA CENTRE IS CLASSIFIED AS AN "INSTITUTION FOR HYPERBARIC OXYGEN THERAPY": THAT SERVICE IS COVERED BY THE NHS UNDER THE HOSPITAL AND CLINICAL REGIME BY RESOLUTION OF THE LOCAL HEALTH SERVICE NO. 33 OF VENETO NO. 7889 DATED 26/05/1994 CONFIRMED BY DECREE OF THE REGIONAL HEALTH AND SOCIAL SECRETARY NO. 113 DATED 15 DECEMBER 2009.

PROFESSIONALS

The professionals that make up the team are (see organisation chart):

Healthcare Director: specialist in Anaesthesia and Resuscitation, medical director of the facility. He manages the activity and supervises the organisation; he performs training, study and research activities.

Head Doctors: specialists in Anaesthesia and Resuscitation in charge of performing the admission and conclusion examinations, the treatment control, the prescription of therapies and any necessary therapeutic interventions.

Assistant Doctors: in charge of assisting patients during therapy in the hyperbaric chamber.

Hyperbaric Technicians: in charge of managing and maintaining the hyperbaric system.

Professional Nurses: they work actively with the doctors and other operators to best protect the quality of health of the patients.

Administrative Personnel and Reception: personnel who perform administrative activities, admission, switchboard, provide the requested information and deal with invoicing.

Cleaning Personnel: contribute daily to the hygiene and comfort of the Institution.

Health is one of the most precious assets held by human beings: its protection and preservation is the result of the activity of many medical operators working in close collaboration to implement correctly and professionally the procedures established by the Institution.

TREATABLE PATHOLOGIES

The indications for HOT set out below are the result of the development and update of the scientific research in question, put into effect by the indications of SIAARTI (Società Italiana di Anestesia, Analgesia,

Rianimazione e Terapia Intensiva), of SIMSI (Società Italiana di Medicina Subacquea e Iperbarica) and of Società Scientifiche Europee (ECHM).

The scientific documents produced were translated into regional rules by the Regional Council of Veneto, with Resolutions 05/03/1996 no. 852 and 05/05/1998 no.1422.

The pathologies treatable under the NHS regime are identified in the following list:

Category I

Election indications for which hyperbaric oxygen therapy must be implemented as soon as possible. The pathologies with asterisk (*) must be treated as emergencies:

- * Decompression sickness
- * Arterial gas embolism
- * Poisoning by CO, smoke, cyanides, methaemoglobin substances
- * Clostridial gas gangrene
- * Severe infections of the soft tissues (from mixed bacterial flora)
- * Crush syndrome
- Moist gangrene
- Severe acute anaemia (in the impossibility of transfusion)
- Thrombosis of the central artery of the retina
- Sudden deafness of traumatic or vascular origin

Category II

Indications for which hyperbaric oxygen therapy is definitely advantageous, alone or associated with other medical or surgical treatments:

- Diseases from radiation
- Chronic refractory osteomyelitis
- Peripheral vascular impairment (with or without trophic lesions)
- Algodystrophy syndrome (Sudeck's syndrome)
- Refractory actinomycosis
- Infected pseudoarthrosis
- At risk skin transplants
- At risk fractures
- Replants of limbs or segments
- Aseptic osteonecrosis
- Extensive burns or illness from burns

Category III

Non-comprehensive indications, for which hyperbaric oxygen therapy may be beneficial, but which require at least one of the following conditions:

1. Precise trial protocols.
 2. Special controls and/or monitoring for patients coming from medical facility admissions
- Intracranial abscesses
 - Acute post-anoxic cerebral oedema
 - Trauma of the spinal cord
 - Migraine of vasomotor origin
 - Periodontal diseases
 - Diabetic retinopathy
 - Cerebral vascular illnesses
 - Multiple sclerosis (sphincter disorders)

– Ulcerous pseudomembranous colitis
NON-URGENT THERAPIES AND SERVICES

Hyperbaric oxygen therapy services are provided in the clinic, planning the treatments with Clients, and on an emergency/urgent basis for patients sent from hospitals or care homes.

Routine treatments are provided on a daily basis (1/day) for 5 days per week, subject to exceptions agreed for particular situations.

Clients may contact the Institution in person or by telephone (045.6300300) and Reception will give or send to the Client a printed form setting out the methods for accessing the therapy, (including the need for any examinations such as an ECG and chest X-ray) and for the correct compilation of the referral. Having obtained the referral from the specialist doctor, the Client sends it to the Institution

by FAX so that the details can be checked. An appointment is then scheduled (date and time) for the first medical examination and the Client is informed of the day on which the therapy will be started.

Upon arrival at the Institution, the Client is welcomed by Reception which proceeds:

- to ascertain the validity of the documentation requesting the therapy
- to register on the computer the personal and clinical data, in respect of legal regulations
- to photocopy the clinical documentation

For a referral, a medical fee must be paid or an exemption must be obtained in accordance with legal regulations.

Reception will provide instructions in that regard and will assign to each user a locker equipped with a lock in which to place personal items

during the therapy.

The Client is then met by a professional nurse who will also provide, where necessary, a wheelchair or stretcher. The nurse will accompany the Client to view a hyperbaric chamber and then to see a doctor for the first examination to start the therapy. The start of the therapy cycle will usually occur the next day.

EMERGENCY AND URGENT THERAPIES

The Institution is willing to provide emergency and urgent therapies, recognised by the regional regulations, every day, 24 hours a day.

The documentation required for the aforementioned therapies is the following:

- request from A&E Specialist or admission department for one or more sessions of HOT (written on the A&E admission form, or on the prescription pad).
- Standard chest X-ray
- Electrocardiogram ECG
- Any other tests agreed between the Department and the Institution

For emergency treatment, the patient is not required to pay the medical fee.

WHAT TO BRING ON THE FIRST DAY

- Health card
- Prescription(s) on national prescription pad of Specialist Doctor to access the hyperbaric services identifying the number of sessions to be performed and the diagnosis in line with the indications of regional regulations (see page 9)

FOR FOREIGNERS

Please bring an identification document (passport or other equivalent document).

FOR FOREIGNERS

Please bring an identification document (for non-EU citizens, a passport is required)

- Chest X-ray dated no more than six months earlier
- Electrocardiogram ECG dated no more than six months earlier
- Any other supplementary documentation:
 - Recent discharge letters.
 - Recent instrumental examinations relating to the disease.
 - Copy of the medical records of recent admissions.

N.B.:

One HOT cycle corresponds to the prescription of 10 hyperbaric treatments.

Clients are asked to inform the Institution's Head Doctors of the course of their disease, particularly in the case of surgical interventions or new diagnostic assessments.

INFORMED CONSENT TO THERAPY

The therapy may only be accessed subject to the issuance of authorisation for sensitive data processing by signing the specific form at reception during admission. (Law 625/1996).

In addition, the client must express the "informed consent" to the performance of the therapy itself, which will only be given when the client feels sufficiently informed by the doctor on the type of therapy to be performed and on the risks that it may involve. The informed consent is expressed by signing the special form provided and illustrated at the first examination, containing an indication of the person(s) authorised to request information on your health conditions.

The Hyperbaric Institution undertakes to adopt suitable measures to guarantee, in the organisation of the services, respect of the rights and dignities of the interested parties (Italian Legislative Decree no. 196/2003).

PREPARATION FOR FIRST EXAMINATION AND HYPERBARIC OXYGEN THERAPY SESSION

From the first examination, the doctor and nurses will make clients aware that when accessing the therapy it is very important, for the purposes of personal safety and the safety of others, to respect the following rules of conduct:

1) Do not bring cigarette lighters, matches, mobile telephones, pens, batteries, radios, torches, weapons, watches, keys with batteries, hand warmers and in general any object extraneous to the therapy into the chamber.

Those objects, including bags and other items that are not required for the therapy, should always be stored in the lockers provided in the changing rooms before accessing the chamber. The Institution does not accept any liability for any loss or theft of those objects.

2) It is strictly prohibited to wear creams, gels or any cosmetics in general (perfumes, aftershave, disinfectant detergents, hair oil, hair sprays, etc.). In addition, clients must not wear surgical medication material with fatty substance and/or alcohol base.

3) Clients must wear the gown and clogs provided and must only enter the hyperbaric chamber area after the nurse has authorised the same, announcing the start of the therapy.

4) Non-autonomous clients (those in wheelchairs or requiring walking assistance) may be assisted by the nursing staff, who will also place into the specific storage areas the crutches and walking sticks.

5) After entering the hyperbaric chamber, each client is asked to get into position and to check that they have not inadvertently brought objects that are dangerous to the therapy (see point 1). Please contact the Assistant Doctor if you have any queries.

6) During therapy, it is prohibited to tamper with tubes, masks, regulators and other parts of the chamber. If you are in any doubt, please contact the assistant doctor in the chamber.

7) Clients are kindly asked to use the blankets and cushions provided by the Institution; if you have any additional requirements, please ask our staff.

8) Please note that it is prohibited for relatives and friends to enter the treatment room, especially during therapies.

9) It is absolutely prohibited to smoke anywhere in the hyperbaric institution. We also recommend that you do not smoke for at least 10 minutes after the hyperbaric therapy.

1) There are no particular dietary restrictions for performing the therapy, except limiting the use of carbonated drinks and the consumption of excessively large meals.

2) Users are asked to notify Reception of any absence as soon as possible. In the case of repeated absences two or more times, the Institution reserves the right to reschedule the "Flight plan".

The Hyperbaric Institution undertakes to adopt suitable measures to guarantee, in the organisation of the services, respect of the rights and dignities of the interested parties (Italian Legislative Decree no. 196/2003).

SERVICE METHODS

Clients must attend the Institution 15 minutes before the therapy, except where they have been informed by Reception to arrive at a certain time for a follow-up examination or for medication.

During the therapy, we guarantee the presence in the chamber of a doctor with specific training who, during the treatment, assists patients for all medical requirements that occur such as, for example, implementing the balancing manoeuvres, wearing and removing the mask, regulating the flow of oxygen, etc.

At the start of the hyperbaric session, called "compression", the client:

- Feels a sensation of closure of the ears which requires a "balancing" manoeuvre, which is explained and tested during the first examination. It is essential that the patient communicates to the Assistant Doctor any balancing difficulties, painful sensations and any other disorder that may occur during the session;
- Feels a warm sensation due to the temperature increase during the air compression in the chamber;
- Wears, when instructed by the hyperbaric technician, a mask through which to breathe 100% oxygen for a period of 24 minutes, after which the mask is removed and ambient air is breathed for 5 minutes. This cycle is repeated three times.

At the end of the treatment, during the period known as "decompression", the patient feels a cool sensation due to the drop of temperature in the chamber as a result of the reduction of air pressure.

During the stay in the chamber, patients are asked not to touch or tamper with any tool and to remain seated in position, subject to authorisation from the Assistant Doctor.

MEDICATIONS AND EXAMINATIONS

The doctor, if necessary, will perform or will instruct a nurse to perform a medication at the start and at the end of the therapeutic cycle, in order to assess the state of evolution of the pathology.

We recommend not using alcohol compresses or fatty substances on ulcers before the therapy; otherwise, it will be necessary to eliminate the medication and to renew it after the session.

INTERMEDIATE EXAMINATIONS

If there are doubts or particular problems, patients can contact the doctor at any time during the whole therapeutic cycle to arrange check-up examinations.

CONCLUSIVE EXAMINATION

On the day before the end of the whole cycle of sessions, the client must come to the Institution half an hour before the start of the session, to undergo

a conclusive examination. On the last day, the patient will be provided with a letter for his/her GP, with the conclusive medical report.

EXTRA EXAMINATION

After some time has passed, the Doctor who performed the conclusive examination may ask the client to return to the Institution for a check-up examination to ascertain the results of the therapy. This extra examination will be entirely free of charge.

SATISFACTION QUESTIONNAIRE

At the beginning of the final treatment the patient will be provided with an anonymous questionnaire to be filled in. This is to express the level of satisfaction with the environment, personnel, organisation and, in general, the Institution. The completed questionnaire should be posted in the special drawer located in the changing room corridor.

We ask all patients to give their opinion freely. The analysis of the questionnaire is, for us, an opportunity to improve the satisfaction of our customers, through advice, suggestions or complaints.

WAITING TIMES

The Hyperbaric Institution of Villafranca has structured and organised its activity so as to give a response as soon as possible to requests from citizens contacting the Institution (see performance indicators, page 19). Therefore, the first examination of routine therapies, which represents the first contact between the Centre and the client, is performed within a few days and in any case within one week from the request.

In the case of therapies requested by hospitals for urgent/emergency treatment, the Institution guarantees the performance of the therapy within the timescales agreed with the treating doctors and in any case within 60 minutes from the request.

SERVICE AND QUALITY

The introduction of the "SERVICES CHARTER" is aimed at improving the relationship between the medical facility and the citizen, who is considered the "Client", explicitly illustrating the organisational aspects of the service and the structural, human and technological components forming part of the same.

From a different aspect, it constitutes one of the essential factors for defining, maintaining and increasing the capacity to guarantee recognisable and measurable quality standards, producing, at the same time, a cultural and managerial evolution, in line with legal regulations and with ethical guidelines in the medical field.

OUR INSTITUTION HAS PROMOTED THE CREATION OF A "QUALITY SYSTEM" COMPLIANT WITH THE REQUIREMENTS OF THE UNI EN ISO 9001:2008 REGULATION, CERTIFIED BY DNV (DET NORSKE VERITAS)

QUALITY INDICATORS

Services for clients with reduced mobility

- absence of architectural barriers
- presence of stretchers
- presence of wheelchairs
- accessibility to all services
- transportation with hospital ambulances and vehicles of voluntary associations

Services for clients and companions

- outdoor car park
- large waiting room
- separate spacious changing rooms
- presence of snack and drinks vending machines
- public telephone
- presence of toilets, also for the disabled
- possibility of musical background

Verifications of quality system

Internal and external verifications on the quality system and Management Review of quality factors: 1 every six months

Every six months a review or quality verification is performed by Management by analysing the indicators concerning customer satisfaction, waiting times, user comments and any non-conformities identified. Management, together with the Quality Representative, undertake to define the suitable actions to continuously improve the organisational, medical and technical aspects.

Performance indicators See attachment page 19

ORGANISATION CHART

MD
MANAGING DIRECTOR

QM
QUALITY MANAGEMENT REPRESENTATIVE

WSR
WORKERS' SAFETY REPRESENTATIVE

QA
QUALITY ASSURANCE ASSISTANT

CD
COMPANY DOCTOR

HPPS
HEAD OF PREVENTION AND PROTECTION SERVICE

DPM
DATA PROCESSING MANAGER

AES
A&E SERVICE

FPT
FIRE PREVENTION TEAM

TM
TECHNICAL MANAGER

RAS
RECEPTION AND ADMINISTRATION STAFF

AD
ANAESTHETIST DOCTORS

AD
ASSISTANT DOCTORS

PN
PROFESSIONAL NURSES

HT

HYPERBARIC TECHNICIANS BOOKING OXYGEN THERAPY - WHAT IS NEEDED

Documentation required for booking

- Health card
- Chest x-ray (max 6 months)
- Electrocardiogram ECG (max 6 months)
- Previous clinical documentation (X-ray, MRI, CT, scintigraphy, audiometry, etc.)
- Referral of NHS specialist doctor on regional prescription pad
- Any documentation for medical fee exemption.

Important indication for preparing the referral

- The basic pathology must correspond exactly to what is indicated by Decree of the Regional Council no. 852/96 (the permitted indications are identified on page 8 of this "Services Charter")
 - The use of synonyms is not permitted (e.g.: Patient suffering from "sudden deafness of vascular origin" may not be sent with request of "hypoacusis")
 - The anatomical part affected by the basic pathology must be indicated - where necessary
 - Each line of the referral may contain the prescription of a HOT cycle and for each the oxygen therapy code, which is 93.95.1, must be indicated;
 - The referral must be completed by the Doctor in all its parts, including any exemption code, provincial code, local health authority code and priority class
- 18 • If the referral is completed by hand, its written contents must be perfectly legible

Example of referral (the specialist doctor may prescribe from 1 to 6 cycles)

The form is titled "SERVIZIO SANITARIO NAZIONALE REGIONE VENETO". It contains the following fields and sections:

- Patient Information:** COGNOME E NOME DELL'ASSISTITO (O INIZIALI OVE PRESORITTO DALLA LEGGE), INDIRIZZO (OVE PRESORITTO DALLA LEGGE).
- Administrative Data:** CODICE FISCALE, SIGLA PROVINCIA, CODICE ASL.
- Medical Data:** CODICE ESEZIONE, REDDITO, FIRMA AUTOCERTIFICANTE.
- Prescription Section:** Labeled "PRESCRIZIONE" on the left, it contains three rows of prescriptions, each with the code "93.95.1 OSSIGENOTERAPIA IPERBARICA 10".
- Notes and Priority:** (Barra se non utilizzata), NOTA, SUGG., RIGOV., ALTRO, U, B, D, P, PRIORITÀ DELLA PRESTAZIONE.
- Receipt Details:** TIPO DI RICETTA (with a white box containing "indication of initial pathology"), DATA, NUMERO CONFEZIONI / PRESTAZIONI.
- Barcode and Tracking:** CODICE, NUMERO (multiple instances).
- Doctor's Section:** TIMBRO E FIRMA DEL MEDICO, DATA SPEDIZIONE / TIMBRO STRUTTURA EROGANTE.
- Progressive Number:** NUMERO PROGRESSIVO, IMPORTI, TICKET, SALE, DIR. CHIR., ALTRO.

Users, once in possession of the listed documentation, may contact Reception at the Hyperbaric Institution (tel. 045.6300300) to schedule an examination and the sessions. They will be asked to send the referral, together with the telephone number, in advance, by fax or e-mail, to check its accuracy. Personnel of the Institution will then contact the patient to communicate the dates for the booking.

If the referral does not exactly respect the rules listed above (established by the Veneto Region), the same may not be deemed to be valid and must be prepared once again before the prescribed sessions can be booked.

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