Standard Operating Procedure for the processing of requests for prior authorisation for treatment abroad under Articles 10 and 11 of the national Cross Border Healthcare Regulations (S.L 528.03)[1]

1. Policy and objectives

1.1. The policy is to ensure a fair and equitable process based on objective, non discriminatory criteria, when processing requests for prior authorisation for treatment abroad under the Cross Border Healthcare Regulations 2013.

1.2. In line with these regulations, prior authorisation is required for those procedures found in the prior authorisation list. This list was notified to the Commission as per Article 8 of the Cross Border Directive. Also this list can be accessed on the Department of Health website https://ehealth.gov.mt/HealthPortal/chief_medical_officer/cross_border_healthcare/information.aspx.

1.3. Requests for prior authorisation are initially vetted by the National Contact Point (NCP), and then referred to Cross Border Prior Authorisation Committee (CBPAC) for a decision.

1.4. The aim of this standard operating procedure is to describe the procedure to be followed to ensure that all prior authorisation requests received for evaluation by the CBPAC are reviewed at the earliest, to ascertain that all requests are assessed according to the criteria laid down in this SOP, and to relay the decisions taken by the Committee back to the person making the request for the patient.

2. Responsibility

2.1. It is the responsibility of the Chairperson and Members of the Committee to ensure a fair decision for all cases being assessed in line with the set criteria.

2.2. It is the responsibility of the National Contact Point to bring to the attention of the Committee cases for discussion, provide the Committee with any information it might require, enabling it to reach an informed decision. Decisions taken should be minuted by the Committee Secretary.

2.3. It is the responsibility of the NCP to inform the patient in writing of the board`s decision and any accompanying justification whenever necessary.

[1] These Regulations have originated from the transposition of the EU Directive 2011/24/EU on the application of patient rights in cross border healthcare to local legislation.

3. Action

3.1. The CBPAC meets every month or as dictated by specific medical conditions and urgency in individual circumstances. In very urgent cases endorsement via electronic means may be requested from the committee members.

3.2. The following is a step-by-step guide highlighting the main procedures to be followed before requests for prior authorisation reach the Committee for discussion for endorsement or otherwise:

3.2.1 Prior Authorisation Request Forms (Appendix 1) are received by the NCP, where they are checked to confirm that all information requested in the request form has been inputted. The form is supported by a letter of referral from the specialist doctor caring for the patient and a medical summary.

3.2.2 The National Contact Point will then proceed to check whether Malta is the Member State of Affiliation[2]. If in the affirmative, the following steps of this procedure will be carried out. If in the negative, this is communicated to the patient who is directed accordingly.

3.2.3 The National Contact point will need to check that the treatment being requested forms part of the Register[3] as per Article 25 of the Health Act 2013. If in the affirmative, the eventual rate of reimbursement is communicated to the patient. In case of doubt, this is discussed and decided by the CBPAC.

3.2.4 The patient or when and where appropriate, the NCP may request a check if the eventual healthcare provider of the procedure/service is legally entitled to practice under the legislation of the recipient member state through the use of the IMI system (http://ec.europa.eu/internal_market/imi-net/index_en.htm).

3.2.5 Request forms are discussed with the Chairperson of CBPAC prior to the meeting and subsequently cases are circulated to the board members.

3.2.6 Prior authorisation requests for cross border treatment are registered by the National Contact Point in an excel sheet (or database) for ease of reference and statistical purposes.

3.3. During the CBPAC meeting, all cases are reviewed to confirm that the criteria set out in Article 8 of the Cross Border Regulations are satisfied.

3.3.1 If not already established by the NCP, the board confirms whether the treatment in question forms part of the Register[3] as per Article 25 of the Health Act 2013. Once this is confirmed, the Board will proceed to clinically evaluate the case to ascertain the following criteria.

[2] The Member State of Affiliation refers to that Member State in which the patient is insured for healthcare and hence liable to cover the expenses related to cross border care.
[3] The Register includes all the benefits, services, interventions and treatments provided by the public healthcare system.

3.3.2 Establish whether this can be offered locally without undue delay[4]. Medical specialists are consulted to confirm whether actually there is a waiting list and if yes to confirm that the relevant waiting time is medically justifiable and is consonant with the patient`s current clinical picture. If it is confirmed that the waiting time is detrimental, then the patient is referred for treatment under *Article 20 of E.C. Regulation 883/04* or the *National Highly Specialized Referrals Programme*, whichever is more medically appropriate for the specific case.

3.3.3 Without prejudice to the general principle of mutual recognition the following criteria in Article 8 (6) (a) (b) and (c) of the Directive must also be taken into account in assessing a request for prior authorisation:[5]:

3.3.3.1 Whether the patient will be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare.

3.3.3.2 Whether the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question.

3.3.3.3 Whether the healthcare provider in the Member State of treatment raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision.

3.3.4 Referring clinicians at times may be invited for board meetings to present specific and complicated cases.

3.3.5 When a patient affected, or suspected of being affected, by a rare disease applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found locally or if the expert's opinion is inconclusive, the CBPAC may request expert advice from abroad.

[4] Undue delay "is determined by whether the waiting time is medically justifiable and is based on an objective medical assessment of the individual patient's condition, including the patient's medical history, the probable course of the disease, the extent of the patient's pain, disability, discomfort or other suffering attributable to the medical condition; whether that pain, disability or discomfort makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks; and the extent to which the service would be likely to alleviate or enable alleviation of the pain, disability, discomfort or suffering".

[5] *"The clauses on using prior authorisation with regards to the quality and safety of healthcare given by other providers are not simple to use since this would involve Member States in making decisions about providers in other Member States. This would represent an exception to the principle of mutual recognition which underpins the Directive. We would therefore also work on the basis that these clauses may be used only in serious cases, after individual assessment of the concerned provider (e.g. in cases of constant trend of outcomes much worse than the acceptable average, taking into account risk adjustment of patients combined). Therefore we think that any transposition which indicates that these clauses may be used systematically will need to be scrutinised carefully." Non-paper on Prior authorisation, EU Commission, 2013.*

3.4 The following is a list of actions that may be taken by the Committee:

3.4.1 Approve referrals for treatment abroad via the Cross Border Regulations if the criteria under point 3.3 above are satisfied.

3.4.2 Refer to the Treatment Abroad Committee for treatment abroad via another route as per point 3.3.2.

3.4.3 Should the criteria set in point 3.3 not be satisfied the committee may refuse to grant prior authorisation.

3.4.4 Request further information to ascertain that patients will be receiving the best possible care.

3.4.5 Request further information to ascertain that the request is truly justified.

3.5 Minutes of the meeting are taken for record purposes and to demonstrate transparency with regards to decisions taken. Minutes are circulated after the meeting to give Committee Members time to review them.

3.6 After the meeting, the National Contact Point will revert back to the patient with the decision taken and accompanying justifications. The patient will be informed via a written communication (including electronic means) and via telephone as necessary. (Appendix 2)

3.7. If treatment has been approved patient will be guided to follow application for reimbursement in line with established standard procedure.

3.8 If treatment has been refused patient has the right to redirect his/her request to an appeals board constituted by the Directorate for Policy in Health, who may reconsider the case.

4. Data

4.1. All referrals and Cross Border Prior Authorisation Committee decisions are recorded in the Patients' database held at the National Contact Point.

5. Appendices

Appendix 1: Standard Operating Procedure for the processing of requests for prior authorisation for treatment abroad under Articles 10 and 11 of the Cross Border Healthcare Regulations.

6. Cross Reference

Health Act 2013
Cross Border Health Care Regulations 2013, SL 528.03

7. Reference

Cross Border Directive: Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. Available from:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

Regulation (EC) 883/2004 of the European Parliament and the Council of 29 April 2004. Available from:
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0883R(01)&from=EN

8. Revision History

Effective Date - 30/03/2019 – Review Date November 2022
The initial document was prepared by Mr. Silvio Camilleri.
Update prepared by Dr. Anthony Gatt.

9. Key words

Prior authorisation
Cross Border Prior Authorisation Committee