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Deputy Denis Naughten, T.D.,
Dail Eireann,
Kildare Street,
Dublin 2.

1st June 2022.

Ref PQ 28096/22
To ask the Minister for Health the reason that the HSE will not approve surgical interventions for Ehlers Danlos Syndrome under the European Union Cross-Border Directive or the treatment abroad scheme; the treatments that are presently available in Ireland for patients; and if he will make a statement on the matter. -Denis Naughten

Dear Deputy Naughten,

Thank you for your parliamentary question referenced above which has been forwarded to me for direct response. I will address each part of your question individually to ensure completeness of this response.

...the reason that the HSE will not approve surgical interventions for Ehlers Danlos Syndrome under the European Union Cross-Border Directive or the treatment abroad scheme;
In general, the Treatment Abroad Scheme (TAS) allows the funding of public patients who have applied and received prior approval in respect of a referral abroad for treatment, which is not available in this country to the public healthcare system of another EU/EEA country or Switzerland. The patient in conjunction with his/her treating consultant complete an application form to the TAS which is submitted with a copy of the referral letter identifying the specific treatment which the patient is being referred for which is not available in Ireland. Each application is assessed on a case-by-case basis and a decision issued in writing including the right to appeal in the case of a declined decision.

In general, the Cross Border Directive (CBD) scheme allows public patients to access healthcare in another EU/EEA country, which they are entitled to access in Ireland. The patient pays for the treatment up front and claims reimbursement upon return to Ireland. Reimbursement is at the cost of the treatment abroad or the cost of the treatment in Ireland whichever is the lesser. Public patient pathways as they apply to accessing the healthcare in Ireland equally apply to accessing the healthcare abroad under the CBD. Adherence to public patient pathways is required for the purpose of claiming a reimbursement for healthcare accessed under the CBD.

I am enclosing information leaflets on the above schemes for your information. Access to healthcare for Ehlers Danlos Syndrome is available under both schemes subject to the qualifying criteria.

EDS presents in different ways for individual patients and EDS patients have been referred abroad for specific treatments in respect of their respective EDS condition. For example, EDS patients have been referred abroad via the TAS for treatments as diverse as small bowel transplant or orthopaedic treatment. Similarly, patients seeking Multi-Disciplinary Team rehab or orthopaedic treatments access these via the CBD.

.... the treatments that are presently available in Ireland for patients;

In general, EDS patients are managed in Ireland by the local services without recourse to the TAS. I refer you to AQ No 22975/19 of 2019 "*As it is a rare condition the diagnosis of Ehlers Danlos Syndrome is usually dependent on access to specialist consultant such as a paediatric rheumatologist for children and an adult rheumatologist for adults. Treatment of hypermobility largely consists of education, counselling, physiotherapy, occupational therapy, and pain management including psychology, all of which are available through the HSE.*"

I also wish to bring to your attention that in 2017, the European Commission launched 24 European Reference Networks (ERNs). ERNs are unique and innovative cross-border co-operation platforms between specialists for the diagnosis and treatment of rare or low prevalence complex diseases.

ERNs consist of 900 healthcare units across Europe working together in 24 thematic networks (24 ERNs). The ERNs cover a wide range of conditions. ERNs are part of a broader strategy to make national and European health systems more efficient, accessible and resilient.

It is envisaged that ERNs will seek to provide assistance to doctors throughout the EU/EEA treating patients with rare diseases. It is also expected that ERNs will serve as research and knowledge centers, updating and contributing to the latest scientific findings, assisting in or treating patients from other Member States. In general it is not envisaged that patients would travel to ERNs for treatment but rather that doctors treating patients with rare diseases would use the ERNs as a resource of expert advice and guidance.

These ERNs fall under the provisions of the Cross Border Directive. A memo of information on ERNs was circulated to all hospital consultants via the CEOs of the Hospital Groups nationally.

I recommend that any patient with concerns about access to treatment for EDS should discuss the matter with his/her treating GP or Consultant.

I trust the foregoing addresses the issues you raised but if you have any further queries please do not hesitate to contact me (catherinet.donohoe@hse.ie or 087 2668759).

Yours sincerely,

Catherine Donohoe

Catherine Donohoe
General Manager

A Guide to the Treatment Abroad Scheme

first things first

What is the Treatment Abroad Scheme (TAS)?
The HSE operates a Treatment Abroad Scheme (TAS) for public patients entitled to treatment in another EU/EEA member state or Switzerland. Under the scheme, a patient who is normally resident in Ireland can be referred for treatment in the specified countries by a consultant if the treatment is not available in Ireland and once the qualifying criteria are met.

What are the qualifying criteria for the TAS?

1. The treatment must be medically necessary.

Medical necessity is demonstrated in a number of ways but the most important way is through a referral letter from a consultant in Ireland. You must include a copy of the referral letter with your application form before the application can be processed.

A referral letter of itself does not entitle a patient to funding under the TAS.

2. You must be a public patient in Ireland.

   Private patients should apply to their private health insurance provider, which organises access to healthcare abroad in the same way as the TAS. However, if the private health insurance provider declines your request for assistance, you may apply to the TAS and your application will be given consideration. A copy of the decline and appeals correspondence from the private health insurance provider should be included with your application.

3. The treatment must be considered a proven form of treatment.

   An unproven or experimental treatment may, for a variety of reasons, be offered to public patients in another EU/EEA country or Switzerland; this does not mean the treatment is no longer unproven or experimental. The HSE will decide on the basis of clinical advice whether the treatment in question is a proven treatment or not for the purpose of funding under the TAS.

4. The treatment being applied for must be a treatment which you could legally avail of in the public healthcare system in Ireland, if the treatment was available in Ireland.

   Some treatments are available in the private healthcare system in Ireland but not in the public healthcare system as the treatments are not deemed medically

necessary, e.g. certain cosmetic surgery etc. So this provision also extends to treatments which are or would be funded by the HSE for public patients in Ireland.

5. You must have authorisation from the HSE before accessing the healthcare.

   You must receive prior authorisation in advance of accessing any part of the healthcare abroad in order to be eligible for funding under the TAS. This is a fundamental provision of the EU Regulation and if you do not receive prior authorisation before accessing the treatment, you will not be eligible for funding under the TAS.

   Note: there are exceptions to the prior authorisation rule, e.g. a patient who requires emergency transfer for a life-saving intervention which is not scheduled, e.g. ECMO, paediatric heart transplant or a paediatric liver transplant.

6. The treatment will be provided in a recognised public hospital facility abroad. Only public hospitals can accept an E112 (or S2), which is the mechanism by which the HSE pays the country abroad for the treatment.

How do I apply?
To apply for funding for treatment under the TAS, you must be attending a consultant in a public capacity. It will be the consultant's decision whether or not to submit an application to the TAS.

During your treatment with a consultant, the consultant may recognise or decide that you require a treatment which he/she or the hospital cannot provide. Often such treatments are available in specialist or tertiary centres in Ireland. The majority of healthcare that patients require is available in Ireland; it is only very rare cases that will require travel to the EU/EEA for a treatment which is not available in Ireland. The patient must be attending the consultant on a regular and current basis in person. Telemedicine including web conference cannot be used for the purpose of an application to the TAS.

Questions to be addressed before submitting an application:

- Have all the avenues of treatment available in Ireland been exhausted?
- Can it be demonstrated that all avenues of treatment in Ireland have been exhausted? If so, make sure you include evidence of this with your application form.
- Has a specific treatment been identified? In order for an application to be examined against the qualifying criteria, the specific treatment must be identified.
- Has a specific doctor in a public hospital abroad been identified that could provide the treatment? If so, has a referral been made?

Making an application
The application form for the TAS is quite simple. It is broken down into two distinct sections. Section A is completed by the patient and records basic personal information. Section B is completed by the patient's treating consultant. In section B, the consultant must identify the treatment he/she is referring the patient abroad for.

In a situation where the consultant is seeking to refer a patient to a specialist centre abroad for a treatment which is not specifically identified, the consultant should include evidence from the relevant clinical specialists in that field in Ireland. The evidence should demonstrate that the specialists have reviewed either the patient and/or the patient's medical notes and are of the opinion that further specialist input is required.

Identifying a patient's condition is not sufficient for the TAS application; the consultant must identify the treatment. It is the availability of the treatment in Ireland which will determine the approval or otherwise of the application.

In some cases, more technologically advanced treatments are available in other EU/EEA countries or Switzerland. This does not mean that an application will be approved. If a less advanced treatment is available in Ireland then there is no automatic right to access the more technologically advanced treatment abroad. In these instances, patients use the Cross Border Directive to access the more technologically advanced treatment. (See the Cross Border Directive webpage.)

Any approval given will be specific to the treatment identified on the application form. If the treatment requires a number of different episodes of care then we advise that all the anticipated episodes of care are listed. For example, if the patient will require an outpatient assessment (1st episode of care), a surgery (2nd episode of care) and a follow-up assessment (3rd episode of care) then all should be listed on the application form so that additional applications are not required for each one.

Submitting an application

You must submit a fully completed application form along with a copy of the referral letter from your consultant. You can submit your application form by post, email or fax.

The TAS office checks each application to ensure it is fully completed and includes a copy of the consultant's referral letter. In the case of a private patient, the TAS office

will also check to ensure a copy of the decision and appeal letter from the private health insurance provider is also included.

Applications which are incomplete are returned to the patient to be fully completed and resubmitted.

Application Process
A fully completed application form is recorded on the TAS database. It is examined and, based on the treatment identified, it is sent to a panel of clinical advisors that the TAS use to determine if the treatment is a proven treatment, is clinically necessary, that the treatment or an equivalent treatment is not available in Ireland and is not contrary to Irish legislation. If the application refers to a treatment which is available in Ireland, the TAS may not require independent clinical advice and the decision will be issued almost immediately.

An application is required to meet all the criteria for the scheme.

It can take up to 20 working days to process an application; however, the majority of cases are processed within a much shorter timeframe. The 20 day processing period may be necessary to allow for the clinical advice the TAS .

Decisions on applications are issued in writing to the patient and the referring consultant.

What if an application is declined?

If an application is declined, the patient is automatically given the right to appeal.

APPEAL

Making an appeal

All decline letters explain the reason an application has been declined. You should consider the reasons for the decline before submitting the appeal.

An appeal should be made within 10 working days from the date of the decline letter. If you cannot submit the appeal before that date, you should contact the TAS office and seek an extension.

In making the appeal, consider the reasons the application was declined. If possible, include any and all documentation that would address the reason the application was declined and support a reversal of the decision.

Appeals are submitted to:
Assistant National Director,
Commercial Unit,
Acute Hospitals Division, HSE,
Office 3,
Kilcreene,
Kilkenny.

The appeal process

The appeals officer will review the entire file including the original application and the appeals documentation. If necessary, the appeal officer will access your hospital medical record (this is rarely required).

The appeals officer will examine if the original decision was correct based on the information submitted at the application stage.
The appeals officer will also examine if new information submitted at the appeals stage now addresses the criteria under which the original decline decision was issued.

Sometimes the appeals officer requires certain other evidence/documentation which is usually requested in writing.
The appeals officer usually accesses further independent clinical advice for the purpose of the appeal.

An appeal decision is issued within 10 working days unless there is a delay in receiving clarifications.

An approved application

The majority of applications are approved. When an application is processed and approved, a letter is issued to the patient and the referring consultant.

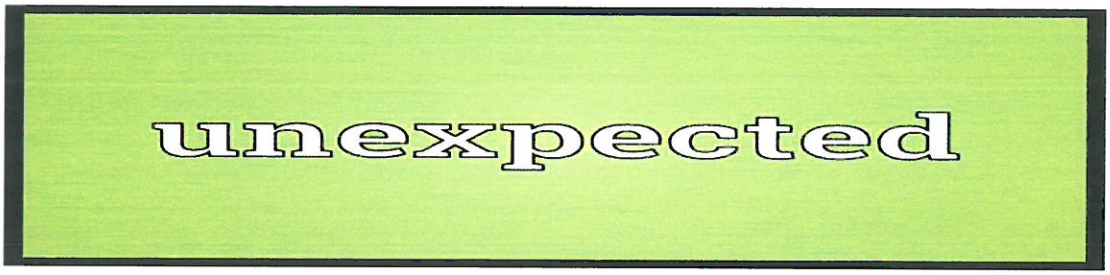
When you receive your approval letter, you can accept an appointment you may be offered by the service abroad. When you have an appointment date, you should submit the appointment date to the TAS office so that they can issue an E112 form.

An E112 form is the mechanism by which the HSE pays the government abroad for the treatment the patient is accessing. An E112 form is issued in triplicate: one copy to the patient, one to the hospital abroad and one to the competent institution (the department of the government abroad, which will ultimately issue the invoice to the HSE).

Treatment abroad
When a patient is approved for a treatment and the E112 form is issued, that approval is specific to the treatment applied for. Once that specific treatment or episode of care is completed, the patient reverts to the care of the consultant that referred the patient from Ireland.

When a patient is discharged abroad, a discharge letter is issued to the consultant in Ireland who referred the patient. The consultant in Ireland then becomes responsible for the patient again and is also responsible for organising any follow up care here in Ireland.

What happens if further treatment abroad is required?
For most patients, one episode of care abroad is all that is required. However, for others, additional or ongoing care may be required. This is a very rare occurrence but it may happen.



- Additional care abroad
    - If the consultant abroad determines that additional care is required over and above that which was applied for and approved, the consultant abroad will contact the referring consultant in Ireland. The referring consultant will in turn contact the TAS and request approval for the additional care. Any identified additional care is subject to the same criteria as the original approved treatment. Decisions on additional care are usually given within the shortest possible timeframe.
- Ongoing care abroad
    - Some patients require to attend a service abroad for specific periods of time, for example for an annual review. In these circumstances, each episode of care requires a new application to be submitted, but this is dependent on the specifics of the case.

Second or Specialisit Opinion

In general the TAS does not fund access to second or specialist opinion. Second or specialist opinion can be easily accessed under the provisions of the Cross Border Directive (CBD).

Also, consultants seeking second or specialist opinion should consider using the expertise available through European Reference Networks which were established under the CBD.

These networks seek to share knowledge, provide advice on diagnosis and treatment through virtual consultations between healthcare providers across Europe, and thus raise standards of care.

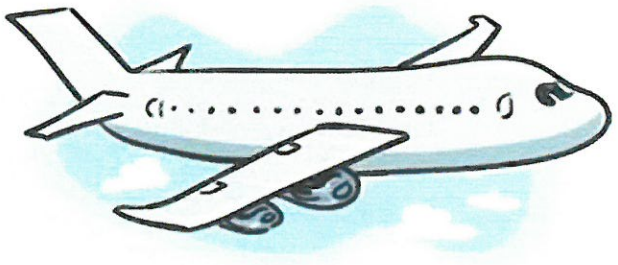
Access to treatment in a non-EU/EEA country

There is no entitlement to funding for healthcare in a non-EU/EEA country orSwitzerland.

All applications to the TAS for healthcare outside the EU/EEA or Switzerland are automatically declined and are sent straight to the appeals process.

An application for funding of healthcare in a non-EU/EEA country requires documentary evidence of the non-availability of the healthcare or an equivalent healthcare in the EU/EEA as well as in Ireland. There is no entitlement to such funding so any such funding is at the discretion of the appeals officer in the HSE.

Travel



The EU Regulations do not include a right to travel or subsistence expenses incurred when accessing healthcare abroad. However, the HSE does reimburse the flight or sea fares of the patient and in the case of a child the flights/sea fares of an accompanying adult are also reimbursed.

Undue delay

There is a provision in the EU Regulation that allows a patient who is experiencing undue delay in receiving treatment to access that treatment under the TAS. However, since then, the European Commission has transposed the Cross Border Healthcare Directive specifically to deal with patients experiencing undue delay. While the provision for undue delay remains in the TAS criteria, it is not recommended as the most appropriate mechanism as the "bar" for accessing healthcare on the basis of undue delay via the TAS is very high. The patient's treating consultant is required to evidence how the patient's condition will deteriorate beyond a point which can be achieved by an earlier intervention.

Incomplete applications

The TAS application records the minimum dataset the TAS office requires in order to process an application against the qualifying criteria.

The TAS office will return incomplete applications to the patient, outlining the information needed.

Amended or adjusted application forms

It is not acceptable for the TAS application or the conditions of application thereon to be amended or adjusted. Any such amendment or adjustment to the application form will render the application invalid and no further consideration will be given to it.

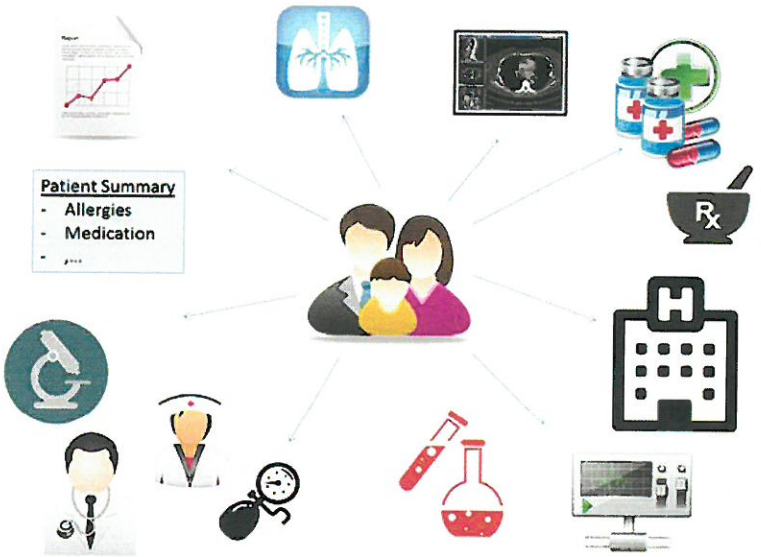
Inaccurate, misleading or false information

In submitting an application to the TAS, a patient and consultant are certifying that the information on the application form is accurate and true. An application to the TAS is an application for public funding. In an instance where an application is submitted and the TAS becomes aware at any time including in the future that information on the application form is inaccurate, untrue or misleading, the TAS will immediately cancel any E112 issued and advise the hospital abroad that the patient is liable for the costs incurred. Furthermore, it is the policy of the TAS to advise the appropriate authority which may include Internal Audit, the IMO and/or An Garda Síochana of the false misleading or inaccurate information.

The Cross Border Directive

Typical Public Patient Pathway

How do I access Hospital Care Abroad under the provisions of the Cross Border Directive (CBD)?
(A typical patient pathway to hospital care – A guide)



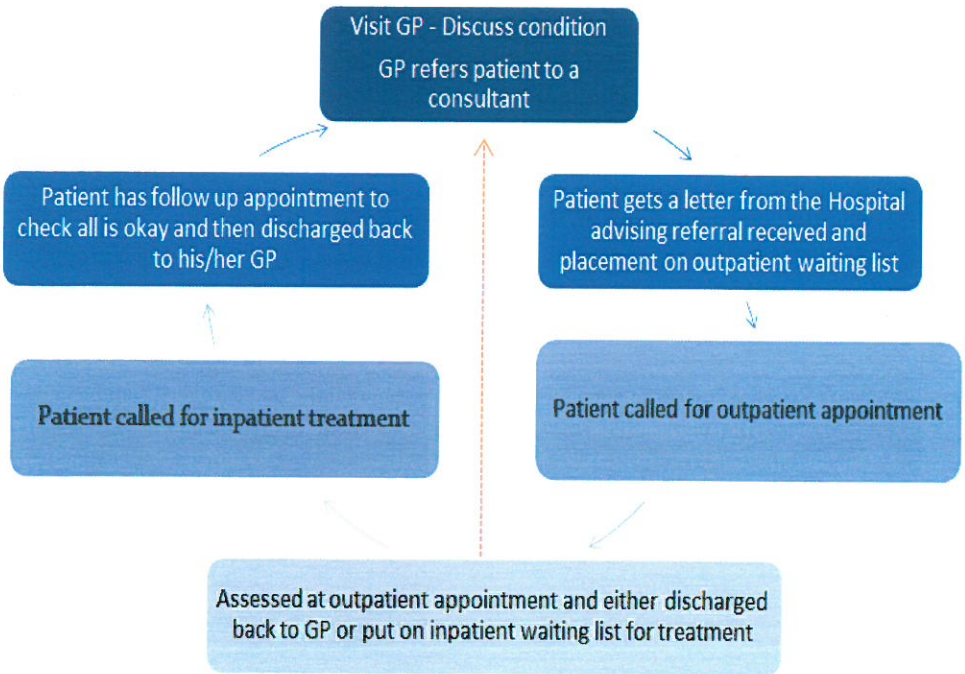
This page is designed to guide a patient through a typical patient pathway for accessing healthcare under the provisions of the CBD generally accessed in an acute hospital setting. Please bear in mind that this is only a guide on the most common pathway and access to certain types of care will require a different pathway so if in doubt – ask!! Also please read the other pages of this webpage in conjunction with this guide. Any queries should be made to the National Contact Point (NCP) as per the contact details.

First things first:

1. The CBD allows a public patient to access healthcare which he/she is entitled to access in Ireland. Therefore:
    - A patient may not use a private appointment in Ireland to circumvent any part of the patient journey. For example you cannot use a private outpatient appointment in Ireland for the purposes of accessing healthcare under the CBD.
2. The CBD does not give a patient additional rights – it simply gives the patient an option to access necessary care in any country in the EU/EEA. The same requirements of that access apply as applies in Ireland. For example a patient cannot simply present at an outpatient clinic in a hospital in Ireland and expect to be seen: the patient must have a referral from his/her GP in the first instance.

A typical Public Patient Pathway
A patient is not classified public or private at GP stage.

At any stage during the process represented below the patient may opt to use the provisions of the NIPHS. Please note an outpatient consultation may not take place on the date of admission it must take place on a date prior to admission for an inpatient or day case treatment.



For the purposes of this webpage the following will describe how a patient can access hospital care in another country under the CBD.

Step 1: Establishing necessary care – referral.
Visit your GP/primary care clinician and discuss your condition. The GP/primary care clinician will evaluate the information and based on same may decide to refer you to a public hospital consultant. Alternatively remember the GP/primary care clinician may decide that your condition is such that a more conservative approach is appropriate at this time and seek to manage same without referral to a hospital consultant.

If your GP/primary care clinician deems it appropriate he/she will write what is known as a referral letter which is a letter to a hospital consultant. A referral letter must contain the following information (ICGP Guidelines):

- Name and address of a hospital consultant (while the referral letter must be to a named doctor at an identified hospital/facility that is not to say that that is the specific doctor and hospital the patient must attend).
- Personal details of the patient, name, address, date of birth, etc.
- Outline of the patient's current health and any other relevant information.
- Outline of the issue for which the patient is being referred.
- GP signature and date.

Things to note:

- The NCP will not accept a referral letter which is not signed by the clinician (e.g. it cannot be signed by his/her secretary or nurse).
- The NCP will not accept a referral letter which is not dated. Remember the referral letter must be issued and thus dated before accessing the healthcare abroad under the CBD.
- The referral letter must be properly addressed to a named doctor, an identified specialty and an identified facility.

Other things to note:

- Just as a GP may refer a patient, likewise a consultant that the patient is attending in a public capacity may also refer the patient.
- A GP may not be comfortable referring a patient to a doctor and/or facility abroad that he/she does not know. In this scenario the GP may address the referral to a hospital consultant he/she is familiar with and the patient may then choose to use that referral to access healthcare abroad. In doing so the patient accepts all clinical liability for his/her choice of provider abroad.

Step 2: Arrange an outpatient appointment.
Now that the patient has a referral letter he/she may decide to access that healthcare in another jurisdiction in the EU/EEA.

The CBD allows the patient to access the healthcare in the public or private sector abroad. Remember the healthcare must be accessed abroad and not in Ireland – the patient must travel.

When the patient has identified a provider abroad he/she makes contact with that provider to arrange an outpatient appointment. Remember the patient must travel abroad for the outpatient appointment – telemedicine e.g. video conferencing, skype, etc. may not be used. If a patient uses telemedicine rather than travel abroad then he/she will not be eligible for reimbursement for the telemedicine care or any care that is provided in follow up.

The outpatient appointment takes place on a date prior to any inpatient or day case treatment. The reasons for this are:

- Only after assessing the patient can a consultant make a decision as to future care needs and if inpatient or day case treatment is warranted the consultant can discuss same with the patient prior to scheduling such treatment.
- It ensures the patient leaves the consultant's rooms and has time away from the healthcare facility to consider:
  - Whether he/she wishes to proceed with the treatment/with the consultant (informed consent),
  - Any further questions he/she may wish to explore prior to making a decision to proceed with the treatment as proposed.

The hospital abroad will likely seek a copy of the referral and may ask for your medical records. Access to medical records from a hospital should be requested directly from the specific hospital.

The patient receives an appointment for an outpatient consultation with the consultant in the hospital abroad.

Step 3: Outpatient consultation/assessment – necessary care.
The patient has now received an appointment for an outpatient consultation with the consultant abroad.

The patient travels abroad. Travel expenses incurred etc. are not eligible for reimbursement under the scheme and are therefore a cost the patient will incur.

Most hospitals abroad will seek payment upfront from the patient for the outpatient attendance and likely for all other attendances. The maximum reimbursement rate for the outpatient attendance is €178.

There are many variations of an outpatient attendance for example:

- Meeting and examination by a consultant.
- Examination by a consultant with x-rays, lab tests, bloods, etc.
- Examination by a consultant with a minor procedure e.g. removal of a lump or bump for biopsy or otherwise, etc.
- MRI or CT.

At the outpatient attendance the consultant may decide the patient requires an inpatient or day case procedure. If so we recommend the patient considers applying for prior authorisation from the NCP.

Prior authorisation is optional but the NCP introduced it for the following reasons:

- It requires the consultant abroad to fill in section B of the prior authorisation form thus identifying the proposed treatment and the cost of same.
- It requires the consultant abroad to identify the DRG code for the treatment from the HSE's ready reckoner (on the webpage) which identifies the maximum reimbursement rate.
- It allows the patient time to leave the consulting rooms and by submitting the prior authorisation application form to the NCP, the patient then has what is effectively a cooling off period in which to decide whether or not:
  a. He/she can afford the treatment upfront or can secure the funding.
  b. Whether or not he/she is comfortable with the consultant and the facility abroad.
  c. Consider any shortfall between the cost abroad and the reimbursement rate from the HSE and if in the event there is a shortfall that he/she is happy/willing to proceed.

Please be aware that prior authorisation and the proposed treatment identified is just that "proposed treatment". At the time of the treatment the consultant may change the treatment or may require to provide additional treatment. Therefore the actual treatment may differ from the proposed treatment. It is the actual treatment which will be eligible for reimbursement. Remember a patient is entitled to be reimbursed for the treatment actually provided not for the treatment which was indicated at prior authorisation but not provided.

The hospital abroad will schedule your inpatient or day case treatment.

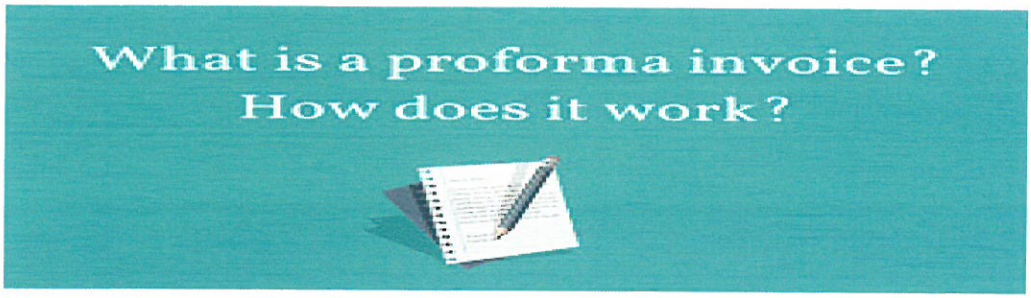
Warning!!
It is our experience that consultant abroad often identify the incorrect code at Prior Authorisation stage. At reimbursement stage the HSE reserves the right to have a DRG code identified by a consultant abroad independently reviewed and it is the outcome of that independent review which will be used.

A patient may submit the invoice, receipt and proof of travel for the outpatient consultation at this stage or hold same and submit at the conclusion of all the treatment to be provided.

Step 4: Inpatient Care
Inpatient or day case treatment abroad. The patient will be given a date for the inpatient or day case treatment. The patient will likely be asked to attend the hospital early or even the night before for what is known as a pre-op assessment. Most hospitals abroad will require payment upfront before the patient is admitted for the treatment.

The patient is admitted, has the treatment and is then discharged.

The hospital will provide the patient with a discharge letter which will be addressed to the GP that referred the patient. Or the hospital may post the discharge letter directly to the GP.



Before leaving the hospital ask the consultant to fill in part B of the pro-forma invoice. The use of the pro-forma invoice form is optional but if it is fully completed in English, the NCP should have all the information required to process a reimbursement for the patient. For example the pro-forma invoice requires the consultant abroad to identify the DRG code for the treatment he/she has provide.

Step 5: Discharged

Upon discharge the patient should submit any and all invoices for the treatment he/she received. The following are the documents that should be submitted:

- Original invoice(s) from the hospital abroad.
- Original receipt(s) from the hospital abroad.
- Proof of travel.
- Pro-forma invoice (optional but in the absence of same the patient will be required to provide documentation from the hospital abroad as to the DRG code of the treatment provided).
- Vendor form. The vendor form provides the details the HSE requires to transfer the reimbursement to the patient's bank account. The reimbursement will only be made to the patient except in certain circumstances e.g. parent of a child where the child is the patient.

Step 6: Reimbursement

Reimbursement is made as soon as possible upon receipt of all the necessary documentation but we aim to ensure it is received by the patient within 20 working days.