GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

# Specialised Services
# Service Specification: CP79

## Haematopoietic stem cell transplantation for adults

*January 2020*

*Version 2.0*

| Document information | |
|---|---|
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| **Description** | NHS Wales will routinely commission this specialised service in accordance with the criteria described in this document. |
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# Contents

# Statement

Welsh Health Specialised Services Committee (WHSSC) will commission the service of Haematopoietic stem cell transplantation (HSCT) for adults in accordance with the revised criteria outlined in this document.

In creating this document WHSSC has reviewed the requirements and standards of care that are expected to deliver this service.

## Disclaimer

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

This document 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 document.

# 1. Introduction

This document has been developed as the Service Specification for the planning and delivery of Haematopoietic Stem Cell Transplantation (HSCT) for adults resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

## 1.1 Background

Haematopoietic Stem Cell Transplantation (HSCT) is also known as Blood and marrow transplantation (BMT). HSCT is a term that encompasses a variety of procedures. Its essence is the ablation and replacement of the bone marrow. It is used to treat a wide spectrum of disorders and is broadly divided into two main groups, autologous and allogeneic transplantation.

Allogeneic transplantation is used to treat carefully selected patients with a range of malignant and non-malignant blood-related disorders and other specific disorders of the immune system. It involves replacing the bone marrow stem cells of a patient following high-dose therapy, with stem cells from a tissue-type matched or mismatched donor.

Autologous transplantation uses the patient's own stem cells, which are harvested prior to high-dose therapy. It enables the patient to be treated with doses of chemotherapy which are higher than would be possible without subsequent replacement of the harvested cells, because the therapy destroys the patient's remaining stem cell tissue.

The source of the progenitor cells (stem cells) also varies. Currently stem cells obtained from peripheral blood are the most common source of cells for transplantation. Bone marrow itself or umbilical cord blood can also be used as sources for stem cells.

There are several methods by which the marrow is prepared including large doses of chemo-radiotherapy (traditional transplants) or by using primarily immunosuppressive strategies (reduced intensity transplants, mini transplants, micro transplants).

The procedure for transplantation can be divided into several phases:

- **Pre-transplant work-up**: Pre-transplant work-up includes assessment of eligibility for transplantation, tissue typing of donors if applicable and basic investigations for fitness of both donor and recipient.
- **Mobilisation**: Mobilisation involves collection of stem cells from either the donor or the patient and processing the cells in the laboratory.
- **Conditioning**: Conditioning prepares the marrow for transplantation by either myeloablation or immunosuppression.

- **Transplantation and engraftment**: The cells are transplanted in the form of an intravenous infusion and the patients are then monitored until they have recovered enough neutrophil numbers to reduce the risk of infection.
- **Post-transplant follow-up**: Post transplant follow-up varies according to the nature of the transplant itself, complications and late effects. Complications such as infection and graft versus host disease need to be managed by the transplant team.

## 1.2 Epidemiology

The data below are taken from the British Society of Blood and Marrow Transplantation (BSBMT)[1] registry for stem cell transplant procedures undertaken by BMT centres in the UK and Republic of Ireland. The figures include repeat transplants (including donor lymphocyte infusions) in patients who have previously been transplanted. There are considerable year to year fluctuations in numbers, but an underlying increasing trend.

**Table 1: Number of transplants by transplant type 2006-2016 inclusive**

| Year | Allografts | Autografts | Total | % Increase |
|---|---|---|---|---|
| 2006 | 1144 | 1562 | 2706 | 0 |
| 2007 | 1198 | 1569 | 2767 | 2.2 |
| 2008 | 1263 | 1676 | 2939 | 5.8 |
| 2009 | 1200 | 1623 | 2823 | -4.11 |
| 2010 | 1321 | 1919 | 3240 | 12.9 |
| 2011 | 1443 | 1917 | 3360 | 3.6 |
| 2012 | 1453 | 2163 | 3616 | 7 |
| 2013 | 1615 | 2225 | 3840 | 5.8 |
| 2014 | 1678 | 2344 | 4022 | 4.5 |
| 2015 | 1610 | 2503 | 4113 | 2.2 |
| 2016 | 1680 | 2718 | 4398 | 6.9 |

Table 2 shows a breakdown of first transplants by clinical indication for 2016. Myelomas and lymphomas remain the most common indications for autologous transplantation. Most allogeneic transplants are for acute leukaemias, followed by the lymphomas.

**Table 2: Number of first transplants by disease category and transplant type 2016**

| Indication | Allograft | Autograft | Total |
|---|---|---|---|
| Plasma Cell Disease | 43 | 1467 | 1510 |
| Lymphoma | 206 | 756 | 962 |
| Acute Leukaemia | 801 | 9 | 810 |
| MDS/MPS | 261 | 0 | 261 |
| Solid Tumour | 0 | 143 | 143 |
| Chronic Leukaemia | 78 | 2 | 80 |

[1] http://bsbmt.org/activity/2016/

| | | | |
|---|---|---|---|
| Primary Immune Deficiency | 59 | 0 | 59 |
| Bone Marrow Failure | 87 | 4 | 91 |
| Haemoglobinopathy | 29 | 0 | 29 |
| Inherited Disorders of | 17 | 0 | 17 |
| Auto Immune Diseases | 8 | 41 | 49 |
| Other | 14 | 2 | 16 |
| Total | 1603 | 2474 | 4027 |

## 1.3 Aims and Objectives of the service

The aim of this service is to define the requirements and standard of care essential for delivering Haematopoietic stem cell transplantation (HSCT) for people resident in Wales.

The objectives of this service specification are to:

- detail the specifications required to deliver blood and marrow transplantation services for people who are resident in Wales
- ensure minimum standards of care are met for delivering blood and marrow transplantation in accordance with the Haematological Cancers: Improving Outcomes. NICE Guideline (NG47) NICE National Guidance for Improving Outcomes in Haematology Cancers and current FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration.
- ensure equitable access to blood and marrow transplantation
- identify centres that are able to provide blood and marrow transplantation for Welsh patients
- improve outcomes for people accessing blood and marrow transplantation services

## 1.4 Relationship with other documents

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

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

- **WHSSC policies and service specifications**
  - Blood and Marrow Transplantation for Adults, (PP142). Policy Position Statement. (Publication Date to be confirmed)
  - Extra corporeal Photophoresis (ECP) for the Treatment of Chronic Graft versus Host Disease in Adults (CP91). WHSSC, Specialised Services Commissioning Policy, November 2015.
  - Extracorporeal Photophoresis (ECP) for the Treatment of Cutaneous T-cell Lymphoma (CP92). WHSSC Specialised Services Commissioning Policy. November 2015.

- **National Institute of Health and Care Excellence (NICE) guidance**
  - Haematological Cancers: Improving Outcomes. NICE Guideline NG47, May 2016.

- **Relevant NHS England policies**
  - Haematopoietic Stem Cell Transplantation (HSCT) All Ages, Revised. Clinical Commissioning Policy, NHS England B04/P/a. January 2015.
  - 2013/2014 NHS Standard Contract for Haematopoietic Stem Cell Transplantation (Adult). NHS England Service Specification, B04/S/a. October 2013.

- **Other published documents**
  - FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration. March 2018.
  - BSBMT Indications for Adult BSBMT, British Society of Blood and Marrow Transplantation.

# 2. Service Delivery

The Welsh Health Specialised Services Committee will commission the service of a Haematopoietic stem cell transplantation (HSCT) for adults in-line with the revised criteria identified in this document.

## 2.1 Access Criteria

This section should be read in conjunction with section 2.1 of the WHSSC policy position statement for Haematopoietic stem cell transplantation (HSCT) for Adults (PP142).

## 2.2 Service description

In addition to the standards required within the Contract, specific quality standards and measures will be expected. The provider should also meet the standards as set out in the FACT-JACIE standards for Haematopoietic Cellular Therapy, Product Collection, Processing and Administration Part B.

### Clinical Standards

Deliver a high quality service in accordance with current JACIE standards, including meeting the standards for:

- Treating patients in line with the agreed criteria for transplantation.
- Optimising patient outcome after autologous and allogeneic stem cell transplantation.
- Treating patients according to protocols as curative or life extending treatments.
- Reduction of morbidity and mortality associated with transplantation.
- Reducing unacceptable variation in clinical practice.
- Development and production of appropriate patient and carer information.
- Entry of patients to clinical trials and collection of national clinical trial data.

## 2.3 Interdependencies with other services or providers

- Donor registries
- Histocompatability and Immunogenetics Laboratories
- Haematology and transfusion laboratories
- Haematology and cancer services
- Fertility services

### Co-located Services

- Haematology
- Immunology
- Cardiology

- Critical care
- Interventional radiology
- Renal
- Medical Oncology (Please read in conjunction with the JACIE Standards).

**Interdependent services**

- Gastroenterology
- Respiratory medicine
- Dermatology
- Endocrinology
- Genetics
- Occupational Therapy
- Physiotherapy
- Dietetics
- Pharmacy

**Related services**

- Psychology
- Social Workers
- Palliative Care Team

## 2.4 Exclusion Criteria

This service specification does not cover Haematopoietic stem cell transplantation (HSCT) patients under 18 years. All treatment outside the indications in the WHSSC Policy Position Statement, Haematopoietic stem cell transplantation (HSCT) for adults (PP142) is excluded unless formal prior approval has been given.

## 2.5 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.

The criteria for acceptance of referrals is outlined in the WHSSC Policy Position Statement, Haematopoietic stem cell transplantation (HSCT) for adults (PP142).

## 2.6 Patient Pathway (Annex i)

Referral is from secondary care consultant clinicians including haematologists, oncologists and, rarely, from other non-cancer specialists such as neurologists, immunologists and rheumatologists.

All patients with haematological malignancies should be discussed at, and referred by, their local Haematology Cancer MDT.

Referrals should be made to the blood and marrow transplant centre.

A clearly defined aftercare programme shall be developed with the patient and the referring provider unit. Communication with general practitioners and staff in primary care and the referring clinician shall be timely, efficient and continuous. The GP shall be informed at all stages of the patient's treatment. Patients will be informed how to access advice and urgent care at all stages of their treatment.

Unless the urgent need for treatment precludes the possibility, all patients of reproductive age shall be offered a review by reproductive medicine prior to starting infertility-inducing treatment.

### Commissioning of care

With regard to the commissioning of care, this is divided into distinct phases of treatment. WHSSC is responsible for:

- Assessment by the transplant team for suitability
- Stem cell collection
- All Haematopoietic stem cell transplantation (HSCT) related treatment and conditioning within the 30 days before transplant
- All care until 100 days post-transplant, including critical care and high-cost drugs given within this timeframe related to the transplant episodes.

Health Boards will be responsible for the cost of care after 100 days post-transplant and this includes management of long term complications by the transplant team.

## 2.7 Service provider/Designated Centre

The providers of care for Welsh adults are:

- Cardiff and Vale UHB (with network centre at Singleton Hospital in Swansea Bay UHB):
  University Hospital of Wales, Heath Park Way, Cardiff CF14 4XW
  Singleton Hospital, Sketty Ln, Sketty, Swansea SA2 8QA
- Betsi Cadwaladr UHB:
  Ysbyty Gwynedd, Penrhosgarnedd, Bangor, LL57 2PW
- Royal Liverpool and Broadgreen NHS Trust:
  Royal University Liverpool Hospital, Prescot St, Liverpool L7 8XP
- The Christie Hospital NHS Trust:
  The Christie Hospital, Wilmslow Rd, Manchester M20 4BX
- University Hospitals Birmingham NHS Foundation Trust:

Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Birmingham B15 2TH
- University Hospitals Bristol NHS Foundation Trust Marlborough Street, Bristol BS1 3NU

Note that formal clinical and contracting arrangements for a defined clinical network are in place between Cardiff and Vale UHB and Swansea Bay UHB as per the JACIE standards but development of any other network arrangements for the Welsh population requires WHSSC approval.

## 2.8 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

# 3. Quality and Patient Safety

The provider should work to written quality standards and provide monitoring information to the lead commissioner. The quality management systems must be externally audited and accredited by JACIE, HTA and MHRA.

The centre should enable the patients, carers and advocates informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

All transplants should take place in JACIE accredited centres. Please refer to section 2.7 for Welsh providers.

Following a JACIE inspection, the provider should share the inspection report with WHSSC. WHSSC will then put in place appropriate monitoring mechanisms with the provider regarding the maintenance of accreditation if required.

Centres should also comply with their host provider clinical governance arrangements. Any serious clinical incidents, serious complaints or concerns or escalating numbers of complaints or concerns must be declared immediately to WHSSC and appropriate monitoring will be put in place. Any issues that are likely to attract media or government interest must also be immediately declared to WHSSC.

All patients should be given details of their Key Worker and how to contact them at all stages of their treatment. Support and counselling should be available, either in person or by telephone. Feedback from patients regarding their experience should be gained in a structured manner at least annually and reported to WHSSC. This feedback should also be used to make service change where required.

WHSSC will undertake a programme of quality and monitoring visits to Haematopoietic stem cell transplantation (HSCT) facilities in conjunction with the representatives of the Health Boards.

## 3.1 Quality Indicators (Standards)

All centres must put in place systems to monitor waiting times on a monthly basis and immediate clinical incident reports must be provided to WHSSC if patients relapse due to the waiting time for a transplant.

Tissue typing turnaround times are agreed as:

- 96 hour turnaround for extremely urgent patients
- 5-10 working days for all other patients according to clinical need

Immediate exception reports must be provided to WHSSC if these times are not met and the Haematopoietic stem cell transplantation (HSCT) is delayed as a result.

All centres must submit all transplants to the BSBMT and European BMT Register via the BSBMT Data Office in a timely manner to ensure that a complete set of data for each provider can be reported in the annual BSBMT report. WHSSC will monitor this following the publication of the annual report each year and providers may be financially penalised if there is not full compliance with data entry.

Mortality rates at 100-day, 1-year and 5-year will be monitored by WHSSC on an annual basis following the publication of the BSBMT report. However providers have a duty to report any issues regarding their mortality rates to WHSSC immediately if they come to light outside of this reporting timetable.

Providers are also expected to comply with the English national BMT Dashboard reporting timetable and requirements.

Each Welsh provider will provide six-monthly audit data regarding compliance with the Policy, specifically showing the BSBMT classification of indication for all patients treated, and on the waiting list. English providers will apply for prior approval for each case as detailed in the Commissioning Policy.

All transplant centres must adhere to the JACIE Standards as a minimum. These can be found on the JACIE website.

Providers must meet the JACIE standards for critical mass (B1.5 and B1.6). Providers undertaking autologous transplants must undertake at least 5 of these per year and providers undertaking allogeneic transplants must undertake at least 10 of these per year.

**Discharge**

Discharge information shall be sent to the relevant healthcare professionals on the day of the patient's discharge. A clearly defined after care programme should be communicated to the patient and communication should be timely and continuous.

The transplant team must report back to the referring consultant team on the progress of the patient in a timely and continuous manner. The follow-up process may run for up to ten years depending on the type of transplant and any complications. See also "Follow-up" section below and "Patient care post-transplant" in section 2.6.

Good quality written information must be made available to patients in line with the JACIE standards. This will be reviewed every two years in line with the JACIE standards.

**Follow-up**

Post-transplant follow-up varies according to the nature of the transplant itself and can take up to ten years. Complications such as infection and graft versus host disease will be managed by the transplant team. Patients with invasive fungal infections will be also be treated by the transplant team and early accurate diagnosis and appropriate treatment have a major impact on survival. High quality care requires a multidisciplinary approach to diagnosis and management. The use of CT scans and the use of medical mycology tests shall be undertaken to ensure accurate prescribing.

Please also refer to the section "Patient care post-transplant" in section 2.6.

## 3.2 National Standards

National Guidance and European Guidance includes:

- Haematological cancers: improving outcomes, NICE Guideline 47, 25 May 2016
- BSBMT Indications Table
- Joint Accreditation Committee EBMT (JACIE) Standards and Handbook
- National and European registration requirements.
- European Blood and Marrow Transplantation Group (EBMT).
- British Society for Medical Mycology standards of care for patients with invasive fungal infections, Denning, David W., Kibbler, Christopher C. and Barnes, Rosemary Ann 2003

## 3.3 Other quality requirements

- the provider will have a recognised system to demonstrate service quality and standards
- the service will have detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site
- the quality system and its treatment protocols will be subject to regular clinical and management audit
- the provider is required to undertake regular patient surveys and develop and implement an action plan based on findings.

# 4. Performance Monitoring and Information Requirement

## 4.1 Performance Monitoring

WHSSC will be responsible for commissioning services in line with this document. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this document the following approach will be adopted:

- Service providers to evidence quality and performance controls
- Service providers to evidence compliance with standards of care

WHSSC will conduct performance and quality reviews on an annual basis.

## 4.2 Key Performance Indicators

The providers will be expected to monitor against the full list of Quality Indicators derived from the service description components described in Section 2.2 and FACT-JACIE standards for Haematopoietic Cellular Therapy, Product Collection, Processing and Administration Part B.

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

In particular, the provider will be expected to monitor against the following target outcomes:

- The BSBMT and European BMT Register
- The national Dashboard for BMT. The full dashboard can be found at: https://www.england.nhs.uk/wp-content/uploads/2018/03/bone-marrow-transplant-adult-metric-definitions-2018-19.pdf

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

The additional data required to comply with this service specification is as follows:

- Six monthly report on activity and waiting times by BSBMT Classification of Indication and compliance with the WHSSC Haematopoietic Stem Cell Transplantation (HSCT) Policy Position Statement (PP142)
- Immediate exception reports on clinical incidents regarding patients relapsing whilst waiting for a HSCT if due to a failure of process
- Immediate exception reports if patients breach the tissue typing turnaround standards and the HSCT is delayed as a result
- Annual report on patient experience.

## 4.3 Date of Review

This document is scheduled for review before 2024 where we will check if any new evidence is available.

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

# 5. 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 re-assignment, 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.

# 6. Putting Things Right: Raising a Concern

## 6.1 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.

## 6.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this document, 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.

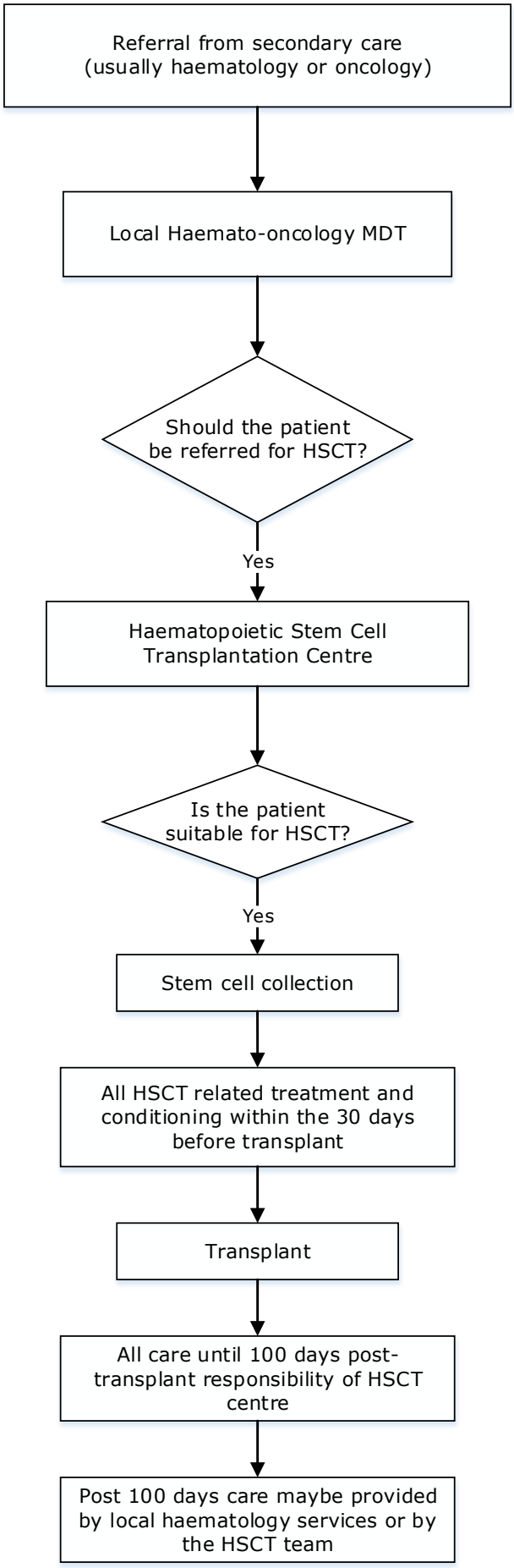
If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent 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, 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

# Annex i Patient Pathway

Adult Haematopoietic Stem Cell Transplantation pathway


Referral from secondary care (usually haematology or oncology)
Local Haemato-oncology MDT
Should the patient be referred for HSCT?
Yes
Haematopoietic Stem Cell Transplantation Centre
Is the patient suitable for HSCT?
Yes
Stem cell collection
All HSCT related treatment and conditioning within the 30 days before transplant
Transplant
All care until 100 days post-transplant responsibility of HSCT centre
Post 100 days care maybe provided by local haematology services or by the HSCT team

# Annex ii Codes

| Code Category | Code | Description |
|---|---|---|
| OPCS | W341 | Autograft of bone marrow |
| | W342 | Allograft of bone marrow NEC |
| | W343 | Allograft of bone marrow from sibling donor |
| | W344 | Allograft of bone marrow from matched unrelated donor |
| | W345 | Allograft of bone marrow from haploidentical donor |
| | W346 | Allograft of bone marrow from unmatched unrelated donor |
| | W348 | Other specified graft of bone marrow |
| | W349 | Unspecified graft of bone marrow |
| | W991 | Allograft of cord blood stem cells to bone marrow |
| | W998 | Other specified graft of cord blood stem cells to bone marrow |
| | W999 | Unspecified graft of cord blood stem cells to bone marrow |

# Annex iii Abbreviations and Glossary

## Abbreviations

**AWMSG** All Wales Medicines Strategy Group

**IPFR** Individual Patient Funding Request

**SMC** Scottish Medicines Consortium

**WHSSC** Welsh Health Specialised Services Committee

## 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 who 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 robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.