Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)
Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Commissioning Policy: CP97

Specialised Fetal Medicine

October 2023
Version 3.0

PARCH - RESPECT
PARTNERIAETH - PARTNERSHIP
GWELLA AC ARLOESI - IMPROVEMENT & INNOVATION

Document information	
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Document name	Specialised Fetal Medicine
Author	Welsh Health Specialised Services Committee
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Target audience	Chief Executives, Medical Directors, Directors of Finance, Chief Pharmacists, Obstetric Consultants, Gynaecology Consultants, Neonatal Consultants, Midwives, Radiography, Paediatric Cardiologists, Paediatric Surgeons, Cleft Lip and Palate MDT and Paediatric Nephrologists
Description	NHS Wales propose to routinely commission this specialised service in accordance with the criteria described in this policy
Document No	CP97
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Contents

Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission specialised fetal medicine in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the clinical condition and the requirements that are expected to deliver this service. It has considered the benefit to patients (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Welsh Language

WHSSC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the Welsh Language Act (1993), the Welsh Language (Wales) Measure 2011 and the Welsh Language Standards (No.7) Regulations 2018.

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this WHSSC is committed to working closely with providers to ensure that in the absence of a welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

WHSSC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the WHSSC commitment.

Disclaimer

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

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in

consultation with the patient and/or their carer or guardian, or Local Authority.

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

1. Introduction

This policy has been developed as a Commissioning Policy for the planning and delivery of specialised fetal medicine services for people with complex pregnancies where the fetus (or fetuses) has (have) a confirmed, suspected or risk of a disorder. 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 Plain Language Summary

Specialised fetal medicine is the branch of medicine that provides care for the fetus (or fetuses) and mother. This includes the assessment of fetal growth and wellbeing and the diagnosis and management of fetal disorders (including fetal abnormalities) and counselling and support for the parents.[1]

Specialised fetal medicine services cover rare or complex conditions and/or unusual treatments as well as more common conditions where severity or uncertainty of the particular case and/or co-morbidities require treatment in a specialist centre.

A specialist fetal medicine centre is staffed by sub-specialist consultants, who have completed Royal College of Obstetricians and Gynaecologists (RCOG) sub-specialty training in maternal and fetal medicine or equivalent, and can provide a full range of prenatal diagnostic and fetal therapeutic services in collaboration (and co-located) with other specialist services.

If the confirmed or suspected fetal anomaly is cardiac in nature the staff within the specialist unit will be Fetal Cardiologists.

Extremely rare and highly complex therapies are only provided in a more limited number of centres often referred to as highly specialised or quaternary services. These centres may include the provision of fetal MRI and some specific invasive techniques and fetal surgery.

The rationale for these services being specialised is the complexity of the investigations and/or treatment involved, and requires a sufficient volume of cases to be concentrated in a specialist centre to maintain expertise, for example, management of a potentially correctable fetal malformation.

[1] E12/S/a NHS Standard Contract for Fetal Medicine (england.nhs.uk)

Once the diagnosis is confirmed (it is not always possible to make a definitive diagnosis), a number of pregnancies will require joint management with other specialities including:

- Medical genetics
- Radiology
- Virology
- Microbiology
- Neonatology
- Paediatric surgery
- Paediatric cardiology
- Paediatric nephrology/urology
- Facial cleft services
- Specialist gynaecology
- Palliative Care
- Paediatric Infectious Disease
- Paediatric neurology
- Transfusion medicine

Delivery or termination of pregnancy may be arranged at the woman's local hospital.

1.2 Aims and Objectives

This policy aims to define the commissioning position of WHSSC on the use of specialised fetal medicine for people with complex pregnancies where the fetus (or fetuses) has (have) a confirmed, suspected or risk of a significant disorder.

The objectives of this policy are to:

- ensure commissioning for the use of specialised fetal medicine is evidence based;
- ensure equitable access to specialised fetal medicine including fetal cardiology and fetal MRI;
- define criteria for people with complex pregnancies where the fetus (or fetuses) has (have) a confirmed or suspected disorder to access treatment;
- improve outcomes for people with complex pregnancies where the fetus (or fetuses) has (have) a confirmed or suspected disorder;
- ensure family centred care, to support and counsel women and families.

1.3 Epidemiology

In approximately two to three of every 100 pregnancies, the baby is affected by a condition that requires specialist care before or after birth[2].

1.4 What NHS Wales has decided

WHSSC has carefully reviewed the evidence of fetal medicine for women with complex pregnancies where the fetus (or fetuses) has (have) a confirmed or suspected disorder to access specialised assessment and treatment. We have concluded that there is enough evidence to fund the use of specialised fetal medicine, within the criteria set out in section 2.1.

1.5 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).

- **National Institute of Health and Care Excellence (NICE) guidance**
  - Antenatal care . NICE guideline (NG201) August 2021.
  - Antenatal Care. NICE Quality Standard (QS22) updated August 2021.
  - Twin and triplet pregnancy. NICE guideline (NG137) September 2019.
  - Diabetes in pregnancy: management of diabetes and its complications from pre-conception to the postnatal period NICE guideline (NG3) December 2020.
  - Antenatal and postnatal mental health: clinical management and service guidance NICE Clinical guidance (CG192) updated February 2020.
  - Preterm labour and birth. NICE Guideline (NG25) June 2022

- **Relevant NHS England documents**
  NHS Standard Contract for Fetal Medicine, Service Specification E12/S/a 2013

Other

- Obstetric Ultrasound Handbook for Sonographers Delivering the Antenatal Screening Programme in Wales 4th edition (2020)

[2] https://www.ouh.nhs.uk/maternity/antenatal/care/fetal-medicine/

- Amniocentesis and Chorionic Villus Sampling (Green-top Guideline No.8). Royal College of Obstetricians and Gynaecologists. October 2021

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of specialised fetal medicine services for people with complex pregnancies where the fetus (or fetuses) has (have) a confirmed, suspected or risk of a significant disorder, are resident in Wales and in line with the criteria identified in this policy.

2.1 Inclusion Criteria

Referrals

Referral to specialist fetal medicine services applies in the following circumstances:

- Fetal abnormality suspected/detected during ultrasound screening
- Pregnancy complicated by a genetic abnormality (suspected recurrence)
- Pregnancy complicated by possible fetal infection
- Exposure to teratogens
- Severe growth restriction (most commonly presenting before 32 weeks gestation)
- Twin pregnancy with fetal complications
- Triplet and higher order multiple pregnancy.

Full details are set out in Annex i.

Fetal Cardiology

Following initial screening (usually undertaken in the local Health Board) the specialist fetal cardiology service will provide management of any fetuses with cardiac anomalies or suspected cardiac anomalies, including further assessment, detailed counselling, multidisciplinary management planning and post pregnancy counselling. The fetal cardiology service may refer to the specialised fetal medicine service for assessment of the whole fetus. The maximum time that parents are expected to wait for an appointment will be defined by the network, and it is envisaged that delays will be limited to 5 working days[3] in the majority of cases.

Highly Specialised Fetal Medicine

There will be some rare instances where a woman may need to be referred to a NHS England quaternary fetal medicine service for treatment that

[3] Fetal Cardiology Standards (bcca-uk.org)

cannot be provided by the local tertiary service in Wales. This includes the following:

- fetoscopic laser ablation in twin to twin syndrome (TTTS) of monochorionic twins
- cord occlusion for selective fetocide in monochorionic twins
- intrafetal laser ablation or radiofrequency ablation in twin reversed arterial perfusion (TRAP) sequence
- invasive therapeutic procedures
- fetoscopic tracheal occlusion (FETO) for severe congenital diaphragmatic hernia
- FETO reversal
- highly specialised fetoscopic procedures
- selective feticide in second /third trimester
- fetal surgery for spina bifida

2.2 Exclusion Criteria

- Routine screening for fetal abnormalities and fetal diseases such as red cell alloimmunisation, as well as routine assessment of fetal wellbeing, is undertaken by most maternity units and is not a specialised service.
- Chorionic Villus Sampling (CVS) and amniocentesis that takes place in a non-specialist centre is not a specialised fetal medicine service.
- In some cases, for example common fetal abnormalities with a clear prognosis such as anencephaly, the assessment (typically involving ultrasound scanning) will be performed by an appropriately trained sonographer or an obstetrician with a special interest in fetal medicine (Advanced Training Skills Module in Fetal Medicine) at the woman's local hospital. If the same obstetrician can manage the pregnancy, it will not fall under the criteria of a specialised service.
- The specialised service may also provide non-specialised fetal medicine services for its own resident local Health Board and on agreement with other local Health Boards. This service provision is outside the remit of this commissioning policy and commissioning agreement with WHSSC.
- The service does not provide an obstetric delivery service – delivery should be arranged at the woman's local hospital or in a specialist centre, under consultant led obstetric care if specialist delivery and neonatal care is required.

2.3 Continuation of Treatment

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

2.4 Acceptance Criteria

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

2.5 Patient Pathway (Annex ii)

Local Health Boards will have their own forms for referral to the specialised fetal medicine service. See section 2.1 (above) for the circumstances for which referral to specialised fetal medicine services is appropriate.

Clear documented pathways for care should be in place between local fetal medicine providers and specialist centres.

Referral for specialised fetal medicine services should be made by an obstetrician, GP or midwife. Fetal Medicine lead clinicians in local services will act as gatekeepers to the specialist centre.

Referral to the specialised fetal medicine service is primarily for diagnosis and advice to support the ongoing management of care, and if suitable, delivery should take place within the women's local Health Board.

The specialised fetal medicine service should have access when required to fetal brain MRI. The indications and pathways for referral to this diagnostic tool should be agreed by the proposed network.

The specialised fetal medicine service should provide invasive therapeutic procedures and invasive procedures relating to the termination of pregnancy. For some rare cases, women may be referred to quaternary services in England for the appropriate invasive procedures or fetal surgery. The indications and pathways for referral for this service should be agreed by the proposed network.

2.6 Designated Centre

Referral flows to specialised and highly specialised services should originate from local services dependent on where women receive their antenatal care.

2.6.1 Specialised fetal medicine service

North Wales

The specialised fetal medicine service is provided by Liverpool Women's Hospital NHS Foundation Trust.

- Liverpool Women's Hospital NHS Foundation Trust
  Crown Street
  Liverpool
  L8 7SS

South Wales

The specialised fetal medicine is provided by Cardiff and Vale University Health Board.

- University Hospital of Wales
  Heath Park
  Cardiff
  CF14 4XW

2.6.2 Fetal Cardiology Service

North Wales

Fetal Cardiology services for patients in north Wales are accessed at:

- Liverpool Women's Hospital NHS Foundation Trust
  Crown Street
  Liverpool
  L8 7SS

South Wales

Although Fetal Cardiology services are delivered in the University Hospital of Wales, women may be referred to United Hospitals of Bristol NHS Trust or Birmingham Women's Hospital NHS Trust for delivery so that the baby can undergo the necessary paediatric cardiac surgery within the appropriate children's Hospital after delivery.

Powys

In Mid Wales, where required, women may be referred to Birmingham Women's Hospital NHS Trust for delivery so that the baby can undergo the necessary paediatric cardiac surgery within Birmingham Children's Hospital.

2.6.3 Highly Specialised Fetal Medicine

Dependent on the nature of the anomaly the following highly specialised centres are accessed for Welsh patients.

- Birmingham Women's Hospital
  Mindelsohn Way
  Birmingham
  B15 2TG

- Bristol Fetal Medicine Unit
  St Michaels Hospital
  Southwell Street
  Bristol
  BS2 8EG

- King's College Hospital
  Denmark Hill
  London
  SE5 9RS

- Liverpool Women's Hospital NHS Foundation Trust
  Crown Street
  Liverpool
  L8 7SS

  University College Hospital
  235 Euston Road
  London
  NW1 2BU

2.7 Exceptions

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

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

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

2.8 Clinical Outcome and Quality Measures

The Provider should work to written quality standards and provide monitoring information to the lead commissioner. The quality management systems should be externally audited and accredited.

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

2.9 Key Performance Indicators

Quality data should be collected at two 'levels'. This will measure key performance indicators and metrics and also encompasses the management of risk.

Level 1

Level one will be a standardised generic quality scorecard, which will apply to every provider and which will be submitted to WHSSC on a quarterly basis.

Level 2

The level two scorecard will be speciality specific and Providers are expected to comply with the following:

- Nationally Reported Incidents reported externally to STEIS, Welsh Government or equivalent should be shared with WHSSC at time of reporting, and
- Annual information to be received regarding:
  - Number of serious incidents reported externally
  - Number of concerns received, response timescales, lessons learnt and action plans
  - Patient Experience
  - Compliance with safety notices e.g., NRLS Rapid Response Reports;
  - Monitor the number of amniocentesis and chorionic villus sampling performed by each operator to ensure they are in line with the RCOG guidance.
- Perform routine audit on invasive procedures including:
  - Rate of pregnancy loss at any gestation after a procedure
  - Rate of pregnancy loss less than 24+0 weeks after a procedure
  - Rate of pregnancy loss within 14 days of procedure
  - Local cytogenetic laboratory culture failure rates for amniocentesis and CVS
  - Proportion of procedures requiring more than one needle insertion
  - Proportion of procedures with failure to obtain an adequate sample
  - Complication rates ('bloody' tap, amniotic fluid leakage)
  - Maintenance of a register of invasive diagnostic procedures to facilitate audit. Audit should be performed annually and the results made accessible to patients

  - Rate of anti–D prophylaxis for women who are RhD-negative undergoing amniocentesis or CVS
  - Benchmark activity and outcomes at an annual audit day.
- Provide services and procedures in line with RCOG guidance.
- Ensure staff in the specialist centre have the relevant training to provide subspecialist services.
- Provide clinical leadership to the network of health boards and support, including training, to Consultants with a special interest in fetal medicine.
- Pregnant patients referred to local fetal medicine services should be seen by a local Consultant with a Fetal Medicine interest within 5 working days and if specialist intervention is necessary:
  - Urgent referrals should be seen by the specialist centre with 5 working days
  - Routine referrals should be seen by the specialist centre at the earliest clinically appropriate time

2.10 Responsibilities

Referrers should:

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

Clinicians considering treatment should:

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

In all other circumstances an IPFR must be submitted.

3. Evidence

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

3.1 References

- Antenatal care . NICE guideline (NG201) August 2021.
- Antenatal Care. NICE Quality Standard (QS22) updated August 2021.
- Twin and triplet pregnancy. NICE guideline (NG137) September 2019.

3.2 Date of Review

This document is scheduled for review before 2026, where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

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

4. Equality Impact and Assessment

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

Care and information should be appropriate and the woman's cultural practices should be taken into account. All information should be provided in a form that is accessible to women, their partners and families, taking into account any additional needs, such as physical, cognitive or sensory disabilities, and people who do not speak or read English.

Women and their families should always be treated with kindness, respect and dignity. The views, beliefs and values of the woman, her partner and her family in relation to her care and that of her baby should be sought and respected at all times.

The service will be flexible and responsive, adapting to the individual needs of the baby and family.

The provider will provide a service that is based on the principle of equal access for all and one that is responsive to diverse needs and is free from stereotyping and discriminatory practices.

This policy has been subjected to an Equality Impact Assessment.

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

5. Putting Things Right:

5.1 Raising a Concern

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

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

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

5.2 Individual Patient Funding Request (IPFR)

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

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

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

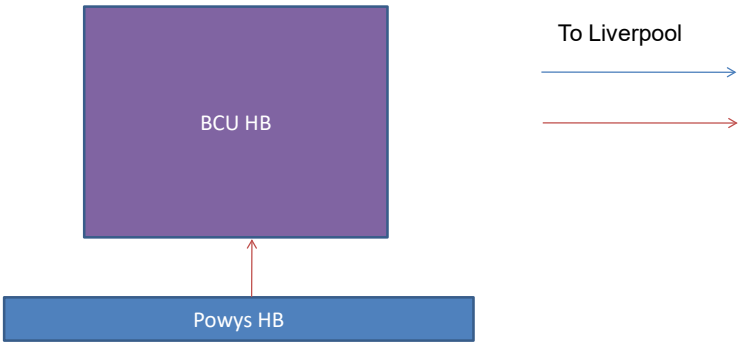
Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

Annex i – Inclusion Criteria

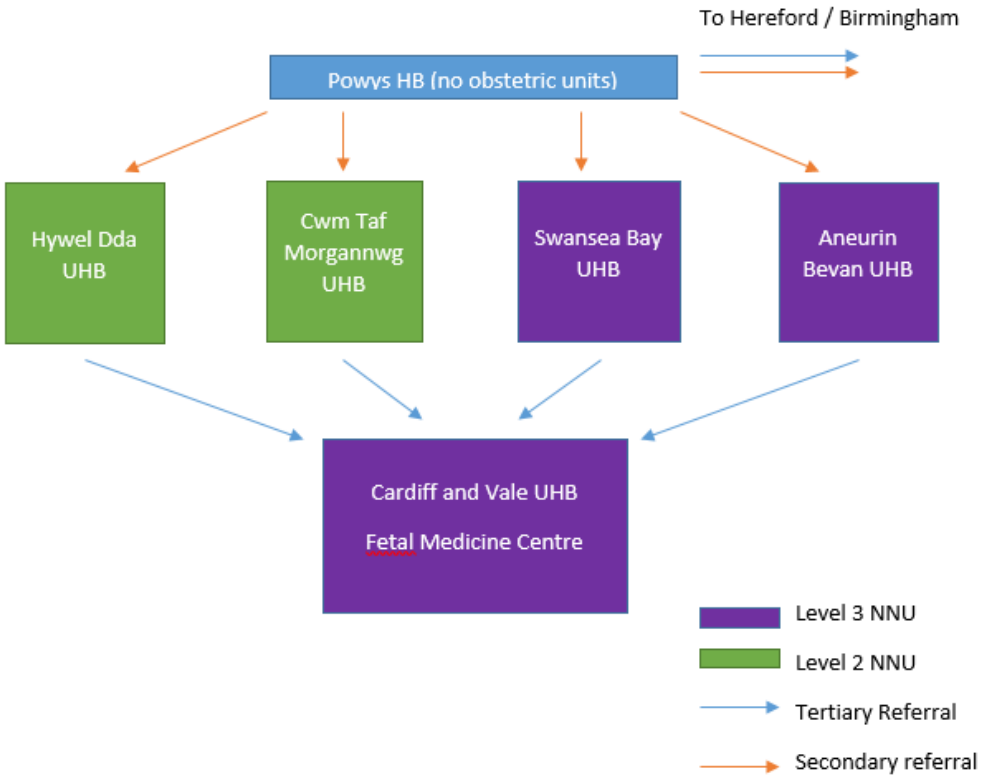
Invasive diagnostic procedures
○ Chorionic villus sampling (CVS), where this is not provided as a local service. Amniocentesis for complex procedures particularly multiple pregnancies ○ Fetal blood sampling and fetal transfusion
Invasive therapeutic procedures
○ Amniotic fluid drainage ○ Amniotic fluid infusion ○ Transfusion therapy for alloimmune red cell disease ○ Transfusion therapy for alloimmune platelet disease ○ Intravenous immunoglobulin therapy for alloimmune platelet disease ○ Feto-amniotic shunting – pleuroamniotic shunt, vesico-amniotic shunt ○ Cyst aspiration ○ Fetoscopic laser ablation in twin to twin syndrome (TTTS) of monochorrionic twins
Invasive procedures relating to termination of pregnancy
○ Feticide ○ Selective feticide in first trimester ○ Feticide or selective feticide in second/third trimester
Assessment and management of complicated twin pregnancies and high order multiple pregnancies (3 or more)
○ All invasive diagnostic tests in twins or higher order multiple pregnancies ○ Management of monochorionic, monoamniotic twins from time of diagnosis ○ Monochorionic diamniotic twins with discordant nuchal translucency at 11-14 weeks gestation ○ Monochorionic diamniotic twins with discordant growth or liquor volume ○ Monochorionic diamniotic twins with discordant anomaly ○ Suspected or confirmed TRAP sequence ○ Monochorionic twins where there has been single fetal death
Second opinion or advice on the detailed assessment of fetuses at risk of and /or, with growth restriction, malformations or dysmorphic syndromes ○ Fetal growth <3rd centile <32/40 gestation
Access to specialist paediatric input

Annex ii Patient Pathway

Referral Flows for fetal medicine services North Wales



Referral Flows for Fetal medicine services south and mid Wales



Annex iii Abbreviations and Glossary

Abbreviations

CVS Chronic Villus Sampling

FETO Fetoscopic Tracheal Occlusion

GP General Practitioner

IPFR Individual Patient Funding Request

MRI Magnetic Resonance Imaging

NICE National Institute for Health and Care Excellence

RCOG Royal College of Obstetricians and Gynaecologists

TRAP Twin Reversed Arterial Perfusion

TTTS Twin to twin syndrome

WHSSC Welsh Health Specialised Services

Glossary

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

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