SCHEDULE 2 – THE SERVICES

Service Specification No:	1652
Service	Specialised Maternity Care for Patients (child bearing age) Diagnosed with Abnormally Invasive Placenta
Commissioner Lead	
Provider Lead	

1. Scope

1.1 Prescribed Specialised Service

Specialised maternity care for women suspected of, and diagnosed with, abnormally invasive placenta (AIP).

1.2 Description

AIP, also known as placenta accreta spectrum, or accreta, increta and percreta, is a potentially life-threatening pregnancy complication with an increasing incidence worldwide. Given the complexity of the pelvic surgery often required at delivery, maternal morbidity is high.

Caesarean delivery is associated with an increased risk of abnormally invasive placenta (AIP) in subsequent pregnancies accounting for around 95% of the cases. Other risk factors such as assisted reproductive technology and prior uterine surgery may also increase the risk. Specialised maternity care for women suspected of and diagnosed with AIP includes services provided by Specialised AIP Centres delivered as part of a regional network arrangement inclusive of local maternity services.

NHS England commissions specialist maternity care services for women suspected of, and diagnosed with, AIP from AIP Centres. This includes specialist prenatal diagnosis, risk assessment and definitive treatment of AIP by a multidisciplinary team (MDT) with expertise in complex pelvic surgery. AIP Centres have antenatal imaging (fetal medicine or radiology), adult intensive care, level three neonatal intensive care services and immediate access to blood products.

1.3 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

CCGs commission all other maternity services.

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

AIP Centres provide specialised treatment as part of a regional network arrangement with local maternity services in accordance with predefined referral guidelines and protocols.

Elective pathway

Women with confirmed diagnosis of AIP as outlined in Annex 1 must be referred to the AIP Centre.

Women reviewed in the AIP Centre and assessed as being at high risk or confirmed with AIP must be delivered by the MDT in the AIP Centre.

The AIP Centre must ensure that women who require treatment are fully informed of the risks, the treatment and the post-operative care and are fully consented.

Non-elective pathway
If at the time of an elective repeat caesarean section, where both mother and baby are stable, it is immediately apparent that abnormally invasive placenta is present on opening the abdomen, delivery should be delayed until the appropriate staff and resources have been assembled and adequate blood products are available. This may involve the closure of the maternal abdomen and urgent transfer to the AIP Centre. These cases will be managed according to a predefined protocol.

If emergency delivery is required, the baby may be delivered via a uterine incision which avoids the placenta. If the mother remains stable, the hysterotomy may be closed leaving the placenta in situ and the patient transferred urgently to the designated AIP Centre. If the mother is unstable, definitive treatment must occur without transfer to the AIP Centre.

If the AIP is diagnosed after vaginal delivery the cases will be dealt with on an individual basis following discussion with the AIP centre in accordance with predefined guidance and protocols.

Clinical classification of AIP at delivery – International Federation of Gynaecology and Obstetrics (FIGO)
This specification covers the spectrum of AIP. The following FIGO grades are used to classify the clinical diagnosis of AIP at delivery: -

Grade 1: Abnormal adherent placenta (placenta adherent or creta)

Grade 2: Abnormally invasive placentation (placenta increta)

Grade 3a, b and c: Abnormally invasive placentation (placenta percreta)

A full description of the FIGO classification is outline in Annex 2.

Diagnostic service
An expert-led diagnostic service (usually ultrasound based but may include magnetic resonance imaging: MRI) to diagnose AIP and assess the level of risk posed by the AIP.

Experienced surgical team working to predefined intra-operative criteria for clinical confirmation of AIP.

Pathological expertise working to predefined criteria for histological confirmation of the diagnosis.

Multidisciplinary Team
- Named expert AIP diagnostic specialists (usually foetal medicine doctors or radiologist)
- Named obstetricians with experience in high risk intra-partum care including massive obstetric haemorrhage (MOH)
- Named specialist surgeons with experience in complex pelvic surgery (usually gynae-oncologists)
- Named consultant urologists experienced in bladder and ureteric reconstruction
- Named obstetric anaesthetists with experience in high risk intra-partum care
- Named consultant neonatologist

Other services
- Haematology team (consultant and technician)
- Perinatal pathology
- On site level 3 neonatal critical care
- On site fetal medicine services
- On site adult intensive care unit
- Midwifery staff trained in postnatal care of the seriously ill woman

Data management, audit and governance
The AIP service is responsible for ensuring that it delivers this specialised service as part of a regional network.

The network should have a Network Governance Group that meets at least quarterly to provide oversight and monitoring of the AIP service. The group should include:

- AIP clinical lead/chair.
- Representation from referring organisations in the network.

Clinical representation from the following disciplines:
- Neonatology.
- Foetal medicine imaging.
- Obstetrics.
- Gynaecology.
- Interventional radiology.
- Midwifery.

The Network Governance Group must have terms of reference in place for the network that include
- Referral guidelines and protocols
- Non-elective guidelines and protocols
- Guidance and protocols for AIP post vaginal delivery
- Protocol for major obstetric haemorrhage (including the use of cell salvage)

The network should audit and review patient outcomes and review all adverse incidents.

Regional Abnormally Invasive Placenta Services must present data and discuss outcomes at an annual AIP Services Clinical Summit.

2.2 Interdependence with other Services

AIP generates complex problems which cannot be managed solely in an obstetric environment.

Essential services
- Specialist AIP diagnostic imaging
- Complex pelvic surgery (usually gynae-oncology)
- Obstetric anaesthesia
- Transfusion services including cell salvage
- Interventional radiology
- Urology support (with oncology experience including open bladder surgery)
- General surgery
- Vascular surgery
- Adult intensive care
- Neonatology
- Pathology service

Interdependent services
- Specialist midwifery care
- Neonatal Critical Care Operational Delivery Networks and Local Maternity Systems
- Perinatal mental health services
- Perinatal pathology

3. Population Covered and Population Needs

3.1 Population Covered by this Specification

This service is for all patients falling within the direct commissioning responsibilities of NHS England.

3.2 Population Needs

AIP is a rare and potentially fatal pregnancy complication where the placenta is abnormally adherent to the womb (accreta), invades into the wall of the womb (increta) or even through the wall and out into the pelvis (percreta). If an attempt is made to forcibly remove the placenta catastrophic maternal haemorrhage can ensue.

AIP appears to be the result of the placenta implanting inside scarring to the uterus from previous uterine surgery and so can occur anywhere that there is scarring. The most common uterine surgery however, and demonstrably the single greatest risk factor for AIP, is previous caesarean delivery (CD). As a previous CD scar is usually in the anterior lower segment of the uterus if the placenta implants over it, this results in AIP complicating a placenta previa. This combination poses multiple problems including increased risk of antenatal bleeding, difficult access to the baby for delivery and the relatively poor contractility of the lower segment leading to greater blood loss.

This is a heterogeneous condition with multiple potential management strategies but at the severe end of the spectrum it is extremely dangerous. The maternal mortality rate with the severe AIP (percreta) has been estimated to be as high as 7% (2) (900 times the background risk of maternal death).

AIP is a rare condition and the average obstetric unit will only see about one case per year arising in their locally based population. A population-based descriptive study using the UK Obstetric Surveillance System (UKOSS) in 2011 identified 134 women with AIP in UK. This gives a UK estimated incidence of 1.17 AIPs per 10,000 cases of pregnancy.

These figures are lower than the numbers that were being reported anecdotally by English clinicians. As a consequence, and for planning purposes, the recently published estimate of 344 procedures per year, which is highlighting an estimate of 5.2 cases per 10,000 births over the last five years, has been used.

3.3 Expected Significant Future Demographic Changes

According to studies published in the last two decades, the incidence of AIP has increased 10-fold throughout the world. This is largely due to the increasing caesarean section (CS) rate as caesarean delivery is the single greatest risk factor for AIP particularly placenta previa with AIP.

CS rates in England:
2011/12 - 25%
2012/13 – 25.5%
2013/14 – 26.2%

3.4 Evidence Base

Multiple studies have shown that both maternal mortality and morbidity are reduced when women with AIP deliver in an AIP centre with a multidisciplinary care team who have experience in managing the risks and challenges presented by AIP. This relies on both recognition of the women at risk of AIP and accurate antenatal diagnosis, a challenge highlighted in the 7th Confidential Enquiry into Maternal and Child Health (CEMACH) report ‘Saving Mothers’ lives’.

Current antenatal diagnosis rests on subjective interpretation of ‘typical’ sonographic findings with 2-dimensional (2D) greyscale and colour Doppler ultrasound. Many signs have been suggested in the literature with varying reports as to their sensitivity and specificity. To improve consistency and allow appropriate comparison of different imaging markers, panels of experts have recently published consensus statements aiming to standardise the descriptions and minimum requirements for an ultrasound scan to diagnose AIP (Collins et al and Alfirevic et al). Magnetic resonance imaging (MRI), although widely employed, has yet to clearly demonstrate an improvement in management or pregnancy outcomes and is currently only recommended as an adjunct to ultrasound in the current RCOG guidelines. Irrespective of the imaging modality used, diagnosis is entirely subjective with accuracy depending on the level of experience of the operator, which is limited by the rarity of the condition. Inexperienced operators have a tendency to ‘over-call’ the diagnosis potentially resulting in maternal morbidity from measures taken to reduce potential haemorrhage including unnecessary hysterectomy and vertical abdominal incision.

The involvement of a MDT is vital as peri-operative measures such as placement of ureteric stents and insertion of occlusion balloons in the pelvic vessels may reduce maternal morbidity. However, such interventions risk significant maternal morbidity such as arterial emboli from balloon occlusion of pelvic vessels and bladder rupture from ureteric stent insertion. Consequently, careful risk assessment must be undertaken regarding the potential benefit of any such adjuncts on a case by case basis. This requires consideration from previous experience, communication and excellent MD team-working.

The National Patient Safety Agency (NPSA) recommends that cases where AIP is suspected, and therefore where major post-partum haemorrhage (PPH) is likely, that the management protocol should include the use of cell salvage.

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aims of Service

The aims of the service are to:

To accurately diagnose AIP and determine the clinical risk it poses.

To maximise safety for the mother by providing high quality specialist multidisciplinary care for the delivery of women at high risk of AIP. This involves:

- Preventing avoidable deaths in a population at very high risk of mortality
- Minimising ITU admission and length of stay in ITU
- Reducing blood product administration
- Reducing the risk of severe maternal morbidity such as cardiac arrest, fistula formation and lower urinary tract trauma
- Reducing risk of unnecessary surgical procedures including vertical abdominal incision and hysterectomy
- Reducing the risk of iatrogenic injury to women from false positive diagnoses
- To improve safety for the baby by minimising iatrogenic premature delivery
- To ensure that the quality of the care provided is nationally monitored and subject to a process of continued improvement (though a national dashboard).
- To participate in national data collection to improve understanding

NHS Outcomes Framework Domains

Domain 1	**Preventing people from dying prematurely**	**X**
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**

Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

4.2 Indicators Include:

Number	Indicator	Data Source	Outcome Framework Domain	CQC Key question
Clinical Outcomes				
101	Proportion of patients diagnosed with Abnormally Invasive Placenta (AIP)	Provider	2,3,5	effective
102	Proportion of patients with AIP who delivered electively in the centre	Provider	2,3,5	effective
103	Proportion of patients with AIP who delivered as an emergency in the centre	Provider	2,3,5	effective
104	Number of patients with FIGO Grade 1 AIP	Provider	2,3,5	effective
105	Number of patients with FIGO Grade 2 AIP	Provider	2,3,5	effective
106	Number of patients with FIGO Grade 3a AIP	Provider	2,3,5	effective
107	Number of patients with FIGO Grade 3b AIP	Provider	2,3,5	effective
108	Number of patients with FIGO Grade 3c AIP	Provider	2,3,5	effective
109	Mortality rate post delivery	Provider	2,3,5	effective
110	Major morbidity rate post delivery	Provider	2,3,5	effective
111	Proportion of patients having primary hysterectomy directly after delivery	Provider	2,3,5	effective
112	Proportion of patients having primary local resection directly after delivery	Provider	2,3,5	effective

113	Proportion of patients with placenta in situ following delivery	Provider	2,3,5	effective
114	Proportion of patients with lower urinary tract trauma following delivery	Provider	2,3,5	effective
115	Proportion of patients having secondary (return to theatre following initial alternative management) hysterectomy	Provider	2,3,5	effective
116	Neonatal/Perinatal mortality rate	Provider	2,3,5	effective
117	Proportion of patients admitted to ITU	Provider	2,3,5	effective
118	Proportion of patients who experienced a massive blood loss and consequent transfusion of between 3 - 5 l	Provider	2,3,5	effective
119	Proportion of patients who experienced a massive blood loss and consequent transfusion of between 5 - 10 l	Provider	2,3,5	effective
120	Proportion of patients who experienced a massive blood loss and consequent transfusion of over 11 l	Provider	2,3,5	effective
Patient Experience				
201	Patients and carers are provided with information	Self-declaration	4	caring, responsive
202	Feedback from patients is reviewed and informs service development and improvements	Self-declaration	4	caring, responsive
Structure and Process				
001	There is an agreed network	Self-declaration	2,3,5	Well led
002	There is a specialist team	Self-declaration	2,3,5	effective, safe

003	There is a major obstetric haemorrhage protocol and haematology advice	Self-declaration	2,3,5	effective, safe
004	There are network agreed clinical guidelines in place	Self-declaration	2,3,5	effective, safe
005	There are network agreed pathways in place	Self-declaration	2,3,5	effective, safe

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

NICE Guidance on Caesarean Section
(ttp://www.nice.org.uk/nicemedia/live/13620/57163/57163.pdf)

5.2 Other Applicable National Standards to be met by Commissioned Providers
Royal College of Obstetricians and Gynaecologists (RCOG) Guidance
(http://www.rcog.org.uk/womens-health/clinical-guidance/placenta-praevia- and-placenta-praevia-accreta-diagnosis-and-management

6. Designated Providers (if applicable)

Not applicable

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

Abnormally invasive placenta (AIP)

Multi- Disciplinary Team (MDT)
Magnetic Resonance Imaging (MRI)
Massive Obstetric Haemorrhage (MOH)
Caesarean Delivery (CD)
Clinical classification of AIP at delivery – International Federation of Gynaecology and Obstetrics (FIGO)
UK Obstetric Surveillance System (UKOSS)
Confidential Enquiry Into Maternal And Child Health (CEMACH)
National Patient Safety Agency (NPSA)
Post- partum Haemorrhage (PPH)
Intensive therapy unit (ITU)

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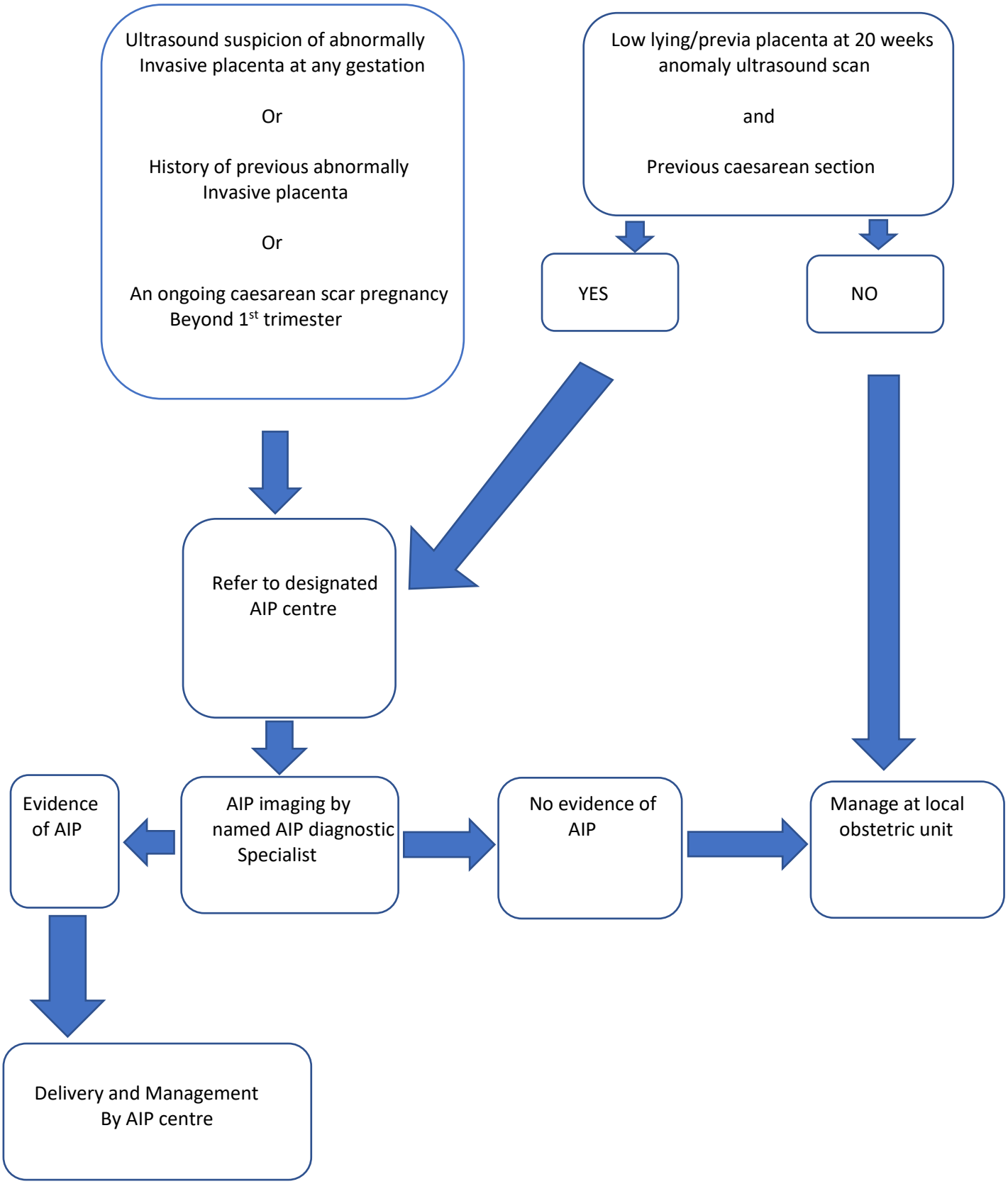
Annex 1 Abnormally Invasive Placenta Risk Factor and Elective Pathway



Annex 2:
1 General classification of placenta accreta spectrum*

Grade 1: Abnormal adherent placenta (placenta adherent or creta)
Clinical criteria

- At vaginal delivery
    - No separation with synthetic oxytocin and gentle controlled cord traction.
    - Attempts at manual removal of the placenta results in heavy bleeding from the placenta implantation site requiring mechanical or surgical procedures
- If laparotomy is required
    - Same as above.
    - Macroscopically, the uterus shows no obvious distension over the placental bed (placental “bulge”), no placental tissue is seen invading through the surface of the uterus, and there is no minimal neovascularity.

Histologic criteria

- Microscopic examination of the placental bed samples from hysterectomy specimen shows extended areas of absent decidua between villous tissue and myometrium with placental villa attached directly to the superficial myometrium.
- The diagnosis cannot be made on just delivered placenta tissue nor on random biopsies of the placental bed

Grade 2: Abnormally invasive placentation (placenta increta)
Clinical criteria

- At laparotomy
    - Abnormal macroscopic findings over the placental bed: bluish/purple colouring, distension (placental “bulge”)
    - Significant amounts of hypervascularity (dense tangled bed of vessels or multiple vessels running parallel craniocaudially in the uterine serosa.
    - No placental tissue seen to be invading through the surface of the uterus.
    - Gentle cord traction results in the uterus being pulled inwards without separation of the placenta (so-called the dimple sign).

Histologic criteria

- Hysterectomy specimen or partial myometrial resection of the increta area shows placental villi within the muscular fibers and sometimes in the lumen of the deep uterine vasculature (radial or arcuate arteries)

Grade 3: Abnormally invasive placentation (placenta percreta)
Grade 3a: Limited to the uterine serosa
Clinical criteria

- At laparotomy

    - Abnormal macroscopic findings on uterine surface (as above) and placental tissue seen to be invading through the surface of the uterus (serosa).
    - No invasion into any other organ, including the posterior wall of the bladder (a clear surgical plane can be identified between the bladder and uterus)

- Histologic criteria
    - Hysterectomy specimen showing villous tissue within or breaching the uterine serosa.

Grade 3b: With urinary bladder invasion
Clinical criteria

- At laparotomy
    - Same as 3a.
    - Placental villi are seen to be invading into the bladder but no other organs.
    - Clear surgical plane cannot be identified between the bladder and the uterus.

Histologic criteria

- Hysterectomy specimen showing villous tissue breaching the uterine serosa and invading the bladder wall tissue or urothelium.

Grade 3c: With invasion of other pelvic tissue/organs.
Clinical criteria

- At laparotomy
    - Same as 3a.
    - Placental villi are seen to be invading into the broad ligament, vaginal wall, pelvic sidewall or any other pelvic organ (with or without invasion of bladder).

Histologic criteria

- Hysterectomy specimenshowing villous tissue breaching the uterine serosa and invading pelvic tissue/organs.

*For the purposes of this classification, “uterus” includes the uterine body and uterine cervix.