Australian Government

Department of Health

Application 1467:

Obstetric MRI

PICO Confirmation

(to guide a new application to MSAC)

(Version 1.0)

This PICO Confirmation Template is to be completed to guide a new request for public funding for new or amended medical service(s) (including, but not limited to the Medicare Benefits Schedule (MBS)). It is relevant to proposals for both therapeutic and investigative medical services.

Please complete all questions that are applicable to the proposed service, providing relevant information only.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment (HTA Team) on the contact number and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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Version Control

Document History

Version Number	Date Changed	Author	Reason for Change
0.1	10 March 2016	MSAC Reforms	Final template for publication
0.2	19 May 2016	MSAC WEB	Template accessibility compliance

Document Approval

Version Number	Date Changed	Author	Reason for Change
1.0	19 May 2016	MSAC Web	Template released for online publication

Summary of PICO/PPICO criteria to define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Component	Description
Patients	Pregnant patients of >18 weeks gestation for suspected fetal abnormality following indeterminate, incomplete tertiary ultrasound by a maternal fetal medicine specialist service, or where there is an elevated risk of structural abnormality which is under-diagnosed by tertiary ultrasound.
Prior tests	Tertiary obstetric ultrasound
Intervention	Fetal MRI
Comparator	Tertiary obstetric ultrasound
Outcomes	*Patient relevant* • The increase in diagnostic accuracy of MRI compared to tertiary US • Changes in prognosis based on MRI compared to US • A difference in level of certainty/confidence in diagnosis with MRI compared to US • Changes in patient and fetal management as a result of changes to diagnostic accuracy • Impact of MRI results of patient counselling compared to US results alone • Patients perspectives towards counselling and confidence in decision making • Any adverse events to the patient or fetus associated with the intervention or comparator tests • Quality of life outcomes including patient acceptability of MRI *Healthcare system* • Cost of MRI scans • Cost savings from reduced US use for follow-up • Costs of counselling • Costs of termination for true positive cases • Cost-savings associated with true negatives • Costs associated with continued pregnancy and/or postnatal care for the parent and child for both false positives (increased monitoring, counselling) and false negatives (pregnancy, birth and child raising) • Costs associated with other management of false positives (counselling, termination).

Component	Description
Patients	Pregnant patients of >28 weeks gestation for suspected placental adhesion disorder following indeterminate or incomplete ultrasound performed at a centre providing obstetric/surgical care for pregnant patients with placental adhesion disorders.
Prior tests	Tertiary obstetric ultrasound
Intervention	MRI of the placenta
Comparator	Tertiary obstetric ultrasound
Outcomes	*Patient relevant* • Maternal mortality • Fetal mortality • Rates of uterine conservation • Rates of post-operative complications • Changes to management (medical and surgical) of the placental adhesion • Diagnostic performance of MRI compared to US • Any adverse events associated with the intervention or comparator tests • Quality of life outcomes including patient acceptability of MRI *Healthcare system* • It is not expected that the introduction of MRI will reduce the use of US scans in this population. • Cost of MRI scans • Costs associated with treatment (either hysterectomy of fertility preserving treatment) • Costs associated with complications.

Suggested sensitivity analyses:

Based on PASC feedback, the following subgroup/sensitivity analyses have been suggested in this PICO confirmation if the information is available in the primary literature:

- Differences in performance of MRI by training/experience of the radiologists and radiographer performing the MRI scan
- Sensitivity analysis of the proposed fee for fetal MRI to assess the impact of a lower fee aligned to other MBS items for MRI.

PICO or PPICO rationale for therapeutic and investigative medical services only

Population

There are two populations relevant to this application:

1. Pregnant patients of > 18 weeks gestation for suspected fetal abnormality following indeterminate or incomplete obstetric tertiary ultrasound (as defined in the Prior test section of the document) by a maternal fetal medicine specialist service or where there is an elevated risk of structural abnormality which is under-diagnosed by tertiary ultrasound.
2. Pregnant patients of >28 weeks gestation for suspected placental adhesion disorder following indeterminate or incomplete obstetric tertiary ultrasound performed at a centre providing obstetric / surgical care for pregnant patients with placental adhesion disorders.

Population 1

Pregnant patients >18 weeks gestation for suspected fetal abnormality following indeterminate or incomplete obstetric tertiary ultrasound by a maternal fetal medicine specialist service, or where there is an elevated risk of structural abnormality which is under-diagnosed by tertiary ultrasound. This may include where:

a) A tertiary ultrasound (US) has raised suspicion of an abnormality and further characterisation is required.
b) A tertiary US has detected an abnormality which required perinatal treatment/ patient counselling and further information is required.
c) The fetus is at elevated risk of recurrence of a structural abnormality which is likely to be under diagnosed by US.

Fetal anomalies affect approximately one in twenty pregnancies in Australia (Howell et al. 2011); however, not all anomalies are associated with significant rates of morbidity and mortality (Department of Health & Human Services 2012). Ultrasound (US) is the primary technique used to image the developing fetus, with Australian guidelines recommending that all pregnant patients be offered an US to assess fetal development and placenta placement at between 18 and 20 weeks of gestation (Australian Health Ministers' Advisory Council 2014). If an anomaly is suspected the patient may be referred for further tests such as an obstetric tertiary US (RANZCOG 2015).

Most abnormalities are identified by the tertiary US. However, some anomalies may require further assessment. For these patients, MRI may offer more information to aid in patients counselling and decision making.

The applicant listed the following abnormalities as potentially benefiting from MRI scans:

- Isolated fetal ventriculomegaly on antenatal ultrasound
- Suspected absence / abnormality of the corpus callosum
- Suspected brainstem or cerebellar abnormality
- Suspected malformation of cortical development (e.g. lissencephaly, polymicrogyria)
- Following treatment for twin transfusion syndrome or cotwin demise in a monochorionic pregnancy
- Evaluation of the fetal airway in the setting of fetal neck mass to facilitate delivery planning

- Confirmation of diagnosis, assessment of prognosis, and treatment planning in congenital diaphragmatic hernia
- Diagnosis of lung masses
- Diagnosis of the cause for and prognosis of abdominal masses, cysts, and dilated bowel when this is uncertain on ultrasound
- Diagnosis of the cause(s) of kidney and bladder malformations / obstruction
- Evaluation of any abnormality of the fetal cranium when abnormality is suspected but not fully characterised on ultrasound
- Evaluation of skeletal dysplasia's when US is incomplete or inconclusive
- Evaluation of the fetus at increased risk of a genetic abnormality that is incompletely or inaccurately diagnosed with ultrasound
- Evaluation of cardiac or vascular abnormalities/malformations not fully characterised with ultrasound

The ABS data reported that there were a total of 305,377 births registered in Australia in 2015 (ABS 2016) noting that this likely underestimates the number of pregnancies per annum. Data from South Australia shows that the number of terminations due to fetal anomalies equated to 0.84 per cent of the number of live births in 2014 (Schell et al. 2016). The number of still births equates to 0.70 per cent of live births (Maternal and Perinatal Mortality Committee 2016). Therefore, extrapolating this data to the whole of Australia, adjusting the number of registered births upwards by 1.54 per cent may better estimate the number of pregnancies per annum (not including pregnancies terminated for reasons other than fetal anomaly). This gives an estimate of 310,080. Based on the applicant's estimate of 0.5-1 per cent (excluding cardiac anomalies), the number of major anomaly findings is expected to be between 1,550 and 3,100 annum. The applicant advised that less than 30 per cent of these are expected to be referred for an MRI; therefore, expected utilisation of the proposed item in this population is expected to be between 465 and 930 per annum. Based on their experience, the applicant estimates more than 80 per cent of fetal MRIs are performed for suspected brain abnormalities.

Fetal MRI may also be indicated when US is unable to provide sufficient information, due to a maternal condition (e.g. maternal obesity or abdominal scarring) (Prayer et al. 2010). The applicant advised that MRI is very rarely indicated for these reasons, and is not likely to significantly impact expected utilisation. The applicant also advised that MRI may be indicated where there is a genetic basis to suspect (including family history) that the fetus will have an abnormality that is known to not be suitably visualised on US.

PASC confirmed the proposed items for MRI should not to be used as stand-alone screening tests, and should always follow a tertiary US.

Following diagnosis of a fetal abnormality the patient will be counselled on the details of the abnormality and on the prognosis and possible implications to the fetus, patient and future pregnancies (McLennan and Walker 2016). Based on this counselling; patients will make a decision on the next steps which may involve continuation of the pregnancy with specialist support, neonatal palliation in the case of a terminal abnormality and continuing pregnancy or termination of the pregnancy.

Rationale

The applicant estimated between one and two per cent of US scans return a major anomaly finding, and cardiac anomalies, which make up approximately half of these, are better diagnosed using US than MRI. Advice from the applicant indicated fetal cardiac MRI is experimental, unlikely to replace US, and unlikely to enter routine clinical practice in the next five years.

Population 2

Pregnant patients >28 weeks gestation for suspected placental adhesion disorder following indeterminate or incomplete ultrasound performed at a centre providing obstetric / surgical care for pregnant patients with placental adhesion disorders.

Placental adhesion disorder describes a range of conditions that are characterised by abnormal adhesion of the placenta. This prevents the normal separation of the placenta from the uterus following birth. Risk factors for the disorder include placenta praevia (where the placenta covers the lower uterine segment) and previous caesarean sections. There are three main variants of placental adhesion disorder:

- Placenta accreta where the chorionic villi attach to the myometrium;
- Placenta increta where the chorionic villi invade into the myometrium; and,
- Placenta percreta where the chorionic villi invade through the myometrium.

Placental adhesion increases the risk of peripartum haemorrhage, hysterectomy, damage to adjacent organs and postoperative complications (D'antonio et al. 2016). The applicant advises that the usual treatment for the condition is planned caesarean section with peripartum hysterectomy.

It is estimated that the incidence of placental adhesion disorder ranges from one in 2500 to one in 500 pregnancies, and the incidence appears to be rising due to increases in rates of caesarean section (D'antonio et al. 2016). The applicant estimated that, in Australia, the incidence is three in 1000 deliveries, which, based on ABS data of 305,377 births in Australia in 2015 (ABS 2016), would equate to 916 cases of placental adhesion disorder annually. Advice from RANZCOG and the applicant is that 50 to 75 per cent of cases can be adequately diagnosed using a tertiary US; therefore, expected utilisation of the proposed item for this service is between 200 and 500 services per year. MRI is required where the obstetric tertiary US is indeterminate, unable to identify the nature of the adhesion of the placenta to the surrounding tissue, or where peripartum hysterectomy is not going to be performed to preserve fertility.

Rationale

Suspicion of placental adhesion disorder arises from the patient's history and/or identification of placenta praevia at the 20-week morphology scan. A finding of placenta praevia at the 20-week scan prompts the scheduling of the 28-week scan to reassess the placental position. Most cases of placenta praevia have resolved by the 28-week scan. The applicant advised that placental adhesion disorder is suspected following the identification of placenta praevia at a 28-week US along with a history of prior caesarean sections, and other signs of the disorder (placental lacunae, chaotic internal placental vascularity, loss of retroplacental clear space, evidence of vascularity in the bladder wall). Confirmation of placenta praevia at the 28 week scan and suspicion of placental adhesion disorder leads to referral to a centre specialising in the management of patients with the

condition and the performance of a tertiary US to assess the patient (applicant advice).Fertility preserving surgery to treat placental adhesion disorder is becoming increasingly common and requires the additional diagnostic information provided by the MRI for surgery planning (applicant advice). Therefore, utilisation of the proposed item may increase over time. Independent expert advice is that the tertiary US can provide important diagnostic information, even in cases where MRI is also required; therefore MRI should always be used in conjunction with tertiary US in this population as proposed by the applicant.

Prior test

For both populations the prior test is an obstetric tertiary ultrasound. MRI is only indicated when the tertiary US does not provide sufficient information to diagnose the condition and/or counsel the patient on treatment options.

For the purposes of this application an obstetric tertiary ultrasound has been defined by the applicant as "obstetric ultrasound performed by or under the direct supervision of a medical specialist with a recognized subspecialist qualification in obstetric and gynaecological ultrasound and/or maternal-fetal medicine".

Intervention

The intervention for both populations is an MRI scan. MRI is proposed as an additional test following tertiary US where the US has not provided sufficient or complete diagnostic information required. The applicant claims that for both populations MRI provides more accurate diagnostic information to inform patient counselling and treatment planning. The applicant advised that, under the current management algorithm, patients in the proposed populations may have access to obstetric MRI via the public health system, may be referred for an MRI in a private clinic (with associated out of pocket costs), or may be managed without MRI. Independent expert advice confirmed that the current clinical pathways associated with use of the intervention in the three populations reflect clinical practice.

MRI uses magnetic fields to investigate the anatomy, function and characterisation of different organs and systems in the human body. When the protons in hydrogen atoms in the body are exposed to the magnetic field they align along its rotational axis. A sequence of smaller magnetic pulses is then targeted to the anatomic area of interest, exciting the protons causing them to release radiofrequency signal on relaxation. These signals are used to generate the image of the area of interest.

For both populations, the applicant advises that studies can be performed on a 1.5 or 3.0T machine. There are 346 (169 full and 177 partial) Medicare-eligible MRI units in Australia (The Department of Health 2016). These devices are classified as Class IIa (low-medium risk) or Class IIb (medium-high risk) devices according to the Australian Regulatory Guidelines for Medical Devices (noting that these guidelines are currently under review) (TGA 2011).

MRI is generally considered safe in the second and third trimester of pregnancy. The maternal risks of MRI are the same as for non-pregnant patients and are considered minor for most patients. Exposure to the magnetic field can affect implanted medical devices and these should be checked for MRI compatibility before the scan (Schenck 2001; Shellock 2001). Pregnant patients may face an additional risk of hypotension due to prolonged time spent in the supine position which may lead to

compression of the vena cava (Patenaude et al. 2014). Hypotension can be avoided by using other lateral oblique or lateral decubitus positioning.

The biggest risk to fetal health from MRI is due to thermogenesis. Practitioners can avoid this by using an MRI protocol used to ensure that body temperature does not rise by more than 0.5 degrees Celsius (Patenaude et al. 2014; Pugash et al. 2008; Shellock FG 2001). Results from animal studies have indicated that there may be additional risks to the fetus from MRI scans conducted in the first trimester which may result in miscarriage, disturbances to growth or malformations (Patenaude et al. 2014). The applicability of these studies to humans is unknown and these risks are not considered relevant to this application as proposed items limit the use of MRI to the second and third trimesters.

When gadolinium contrast is used in pregnancy it can cross the placenta and is excreted by fetal kidneys into the amniotic fluid. Exposure to the contrast may therefore be for an extended period of time (Patenaude et al. 2014). In very rare circumstances gadolinium contrast may be required but the applicant advises that use of contrast is usually avoided in pregnant patients.

Rationale

Fetal MRI (Population 1) is currently almost exclusively performed in specialised metropolitan centres, mainly in public hospitals. The applicant advises that due to the complex nature of fetal MRI scans, building and maintaining necessary skills requires a critical mass of caseload, therefore it is unlikely that the number of centres offering fetal MRI will markedly increase. Patients with a suspected fetal anomaly on US or complex pregnancy management issues are referred to these centres by their obstetrician or GP. Specialists working at the centres then refer patients for MRI if required following tertiary US.

MRI for suspected placental adhesion disorder (Population 2) is less complex than fetal MRI and can be performed at a wider range of centres. Patients with suspected placental adhesion disorder will be referred by their obstetrician and the scan will be mostly performed at centres specialising in management of the disorder.

MRI in the two populations is intended for a single use during pregnancy; however, a small number of patients may require a more than one MRI during pregnancy. The applicant advised that:

- 20 per cent of patients requiring fetal MRI would require a second scan to monitor a progressing or regressing situation (e.g. dural sinus formation or brain injury following twin transfusion syndrome). Less than 10 per cent of patients would require three or more scans.
- Less than 10 per cent of patients with placental adhesion disorder would require more than one MRI scan during pregnancy

All providers, at a minimum, will be Fellows of the Royal Australian and New Zealand College of Radiologists (FRANZCR). There is currently no formalised training program for any of the indications in this application. The applicant advised that training for fetal MRI is currently offered through a paediatric radiology fellowship at a few of the centres that provide paediatric imaging fellowship training. However, many radiologists who currently perform fetal MRI did not gain their experience and training via this path. Training for all indications (fetal and placental MRI) can be obtained through visiting specialist centres and conference attendance. Lack of a formal subspecialty training program for obstetric MRI is consistent with training requirements for most radiology subspecialties.

Fetal MRI is more complex than MRI for placental adhesion disorder and is associated with a longer learning curve.

PASC noted that there may be potential for a RANZCR obstetric MRI credentialing program for radiologists to report fetal and/or placental MRI scans and that there is potential for an ASMIRT obstetric credentialing program for MRI medical radiation practitioners. In light of this, MSAC may be interested in a sensitivity analysis exploring the impact of radiologist and/or radiographer training and experience for both populations if this information is reported in the primary literature.

The applicant advised that fetal MRI takes up to two hours to perform, comprising up to one hour of scanning (requiring a senior MRI radiographer with a senior radiologist either directly supervising the conduct of the examination (by personal attendance) or by being available to review the images before the patient leaves), and up to one hour of reporting by the senior radiologist. Movement of the fetus requires checking of technical adequacy during (or at the very least, at the completion of) the scan, so any images can be repeated if necessary, at the same appointment. This makes these scans more complicated than other types of MRI. MRI for placental adhesion disorder is expected to require the presence of a senior radiographer for half an hour to perform the scan, 5-10 minutes for a quality check at the end of the scan (senior radiologist), and 20 minutes to report the scan (senior radiologist). While the placental MRI scan does not always require personal attendance of the senior radiologist, as for all MRI scans, it is a requirement under the *Health Insurance (Diagnostic Imaging Services Table) Regulation 2016* that the scan must be performed under the professional supervision of the eligible provider, including (if necessary) by personal attendance on the patient.

Comparator

For both populations, the comparator is an obstetric tertiary US (as defined in the Prior Test section of this document). If the proposed items are listed on the MBS, MRI will be offered in addition to the tertiary US.

US imaging is the primary means of abdominal imaging in pregnant patients and is well established in antenatal care in Australia (Australian Health Ministers' Advisory Council 2014). US uses sound waves to generate an image on the internal structures; no ionising radiation is used during the procedure. There have been no confirmed risks to maternal or fetal health associated with the imaging, and US is considered safe for use in pregnancy (McLennan and Walker 2016). US is performed at 19-22 weeks gestation to evaluate the fetus for structural abnormalities and assess position of the placenta (RANZCOG 2016). A suspected fetal anomaly at the screening US will prompt referral for an obstetric tertiary US if further assessment is required. Observance of low-lying placenta or placental praevia at the screening US leads to a follow-up US at 28 weeks when, in most cases, placental position is normalised. Suspicion of placental adhesion disorder at the 28 week US prompts referral for an obstetric tertiary US to assess the condition.

Rationale

In both populations, US would remain the primary imaging modality. There are some indications for which obstetric tertiary US may not provide sufficient diagnostic information, due to limitations with the technique. Imaging of the fetal brain, for example, may be difficult with US, due to acoustic shadowing from the ossified cranium (Pugash et al. 2008). Fetal and placental imaging may be obscured by overlaying parts of the fetus. In these cases, MRI is claimed to provide better diagnostic

imaging, because orthogonal slices of the region of interest are taken, which allows visualisation regardless of obstruction or acoustic shadowing (Pugash et al. 2008). On the other hand, for some indications such as those requiring an assessment of dynamic processes (e.g. cardiac activity and blood flow), US is reported to provide superior diagnostic information compared to MRI (Deakin Health Evaluation Group 2010). MRI is therefore not intended to replace US under the proposed items, but as an additional and complementary diagnostic test, where sufficient diagnostic information is unable to be obtained from US imaging.

The applicant advised that, currently, some patients with an equivocal obstetric tertiary US would receive counselling about their or their fetus' diagnosis and prognosis, based on information available through US imaging. Some patients will receive multiple follow-up obstetric tertiary US scans, some of which may be avoided if the proposed MRI items are listed. Some patients will be referred to public tertiary centres, where MRI is usually provided at no cost to the patient if they are under the care of a public fetal diagnostic or maternal fetal medicine service. However, fetal MRI services are currently also provided by a few private sector radiologists, with subspecialty interest in paediatric or obstetric imaging. In these cases, an out-of-pocket fee is incurred by the patient.

Reference standard

PASC advised that the reference standard for both populations should be US (both general and tertiary).

Outcomes

Population 1

Patient relevant

The primary effectiveness outcomes for the Assessment are;

- The increase in diagnostic accuracy of MRI compared to tertiary US
- Changes in prognosis based on MRI compared to US
- A difference in level of certainty/confidence in diagnosis with MRI compared to US
- Changes in patient and fetal management as a result of changes to diagnostic accuracy
- Impact of MRI results of patient counselling compared to US results alone
- Patients perspectives towards counselling and confidence in decision making
- Quality of life outcomes including patient acceptability of MRI

The primary safety outcomes for the assessment are:

- Any adverse events to the patient or fetus associated with the intervention or comparator tests

Healthcare system

Outcomes that should be considered include cost of MRI scans, cost savings from reduced US use for follow-up, costs of counselling, costs per additional correct diagnosis, costs of termination for true positive cases, cost-savings associated with true negatives, costs associated with continued pregnancy and/or postnatal care for the parent and child for both false positives (increased

monitoring, counselling) and false negatives (pregnancy, birth and child raising) and costs associated with other management of false positives (counselling, termination).

Rationale

While diagnostic performance is not a patient-relevant outcome, differences in diagnostic accuracy between the intervention and comparator tests may lead to subsequent changes in management, which may lead to changes in prognosis. In the absence of direct evidence on the impact of MRI on patient prognosis, a linked evidence assessment will be required.

The most important patient-relevant outcomes are likely to be those that capture the patients' perspective on quality of care and confidence in decision making based on available information.

Safety outcomes are unlikely to be of high importance in this population as both the intervention (MRI) and comparator (US) are considered safe for use in pregnancy for both maternal and fetal health. There may be some adverse events associated with use of MRI contrast material although the applicant advises that gadolinium contrast agents are rarely used in pregnant patients.

Population 2

Patient relevant

The primary effectiveness outcomes for the assessment are;

- Maternal mortality
- Fetal mortality
- Rates of uterine conservation
- Rates of post-operative complications
- Changes to management (medical and surgical) of the placental adhesion
- Diagnostic performance of MRI compared to US
- Quality of life outcomes including patient acceptability of MRI

The primary safety outcomes for the assessment are:

- Any adverse events associated with the intervention or comparator tests

Healthcare system

It is not expected that the introduction of MRI will reduce the use of US scans in this population.

Outcomes that should be considered include cost of MRI scans, costs associated with treatment (either hysterectomy of fertility preserving treatment), costs associated with complications.

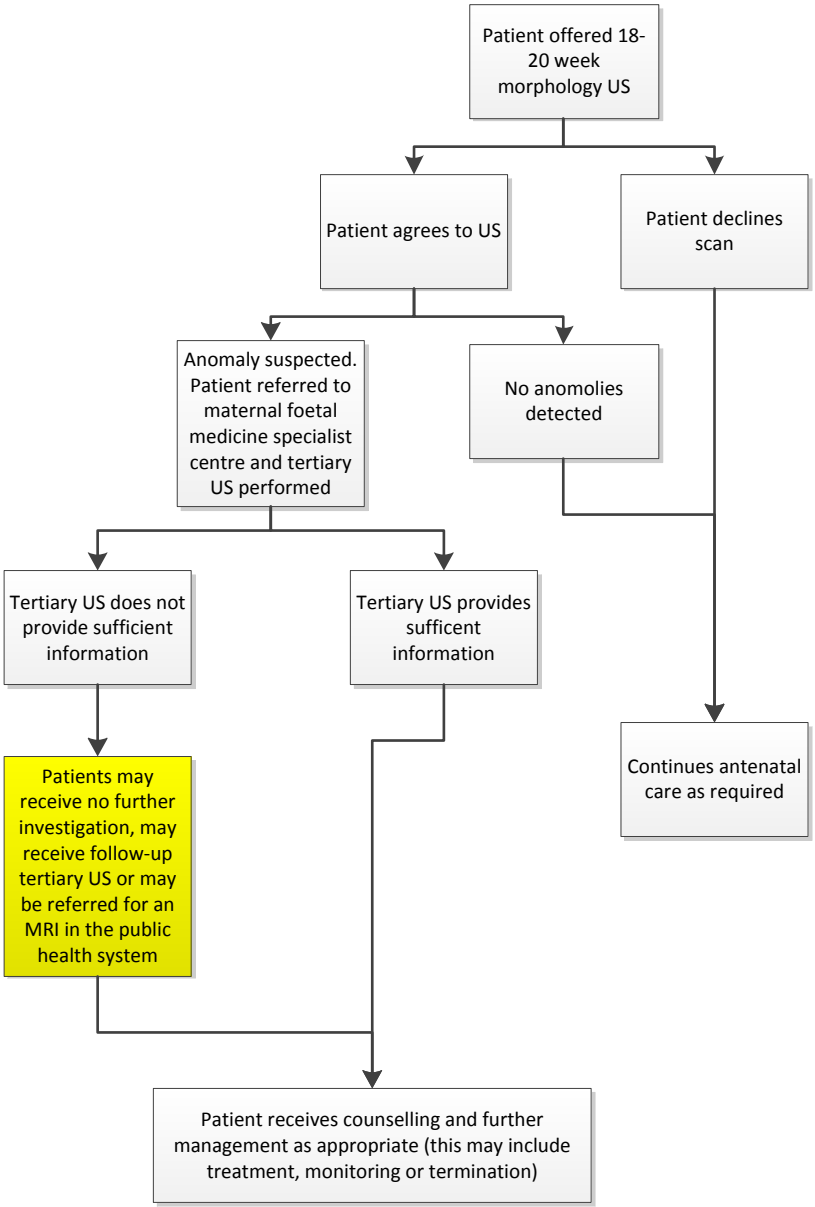
Rationale

While diagnostic performance is not a patient-relevant outcome, differences in diagnostic accuracy between the intervention and comparator tests may lead to subsequent changes in management, which may lead to changes in patient prognosis. In the absence of direct evidence on the impact of MRI on patient prognosis, a linked evidence assessment will be required.

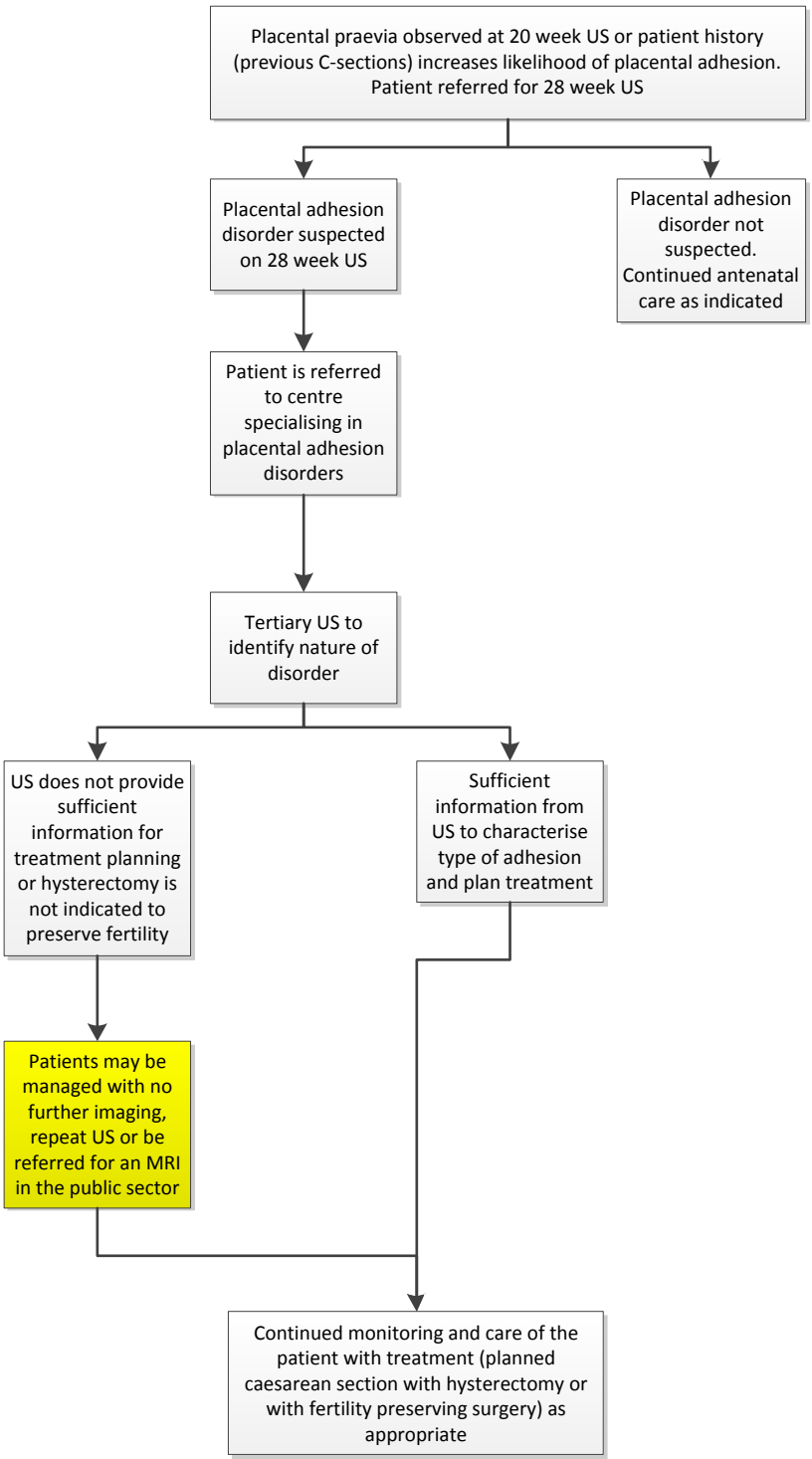
Safety outcomes are unlikely to be high importance in this population as both the intervention (MRI) and comparator (US) are considered safe for use in pregnancy for both maternal and fetal health. There may be some adverse events associated with use of MRI contrast material, although the applicant advised that gadolinium contrast agents are rarely used in pregnant patients, and are not useful in any case for diagnosis and assessment of severity of placental adhesion disorders.

Current clinical management algorithm for identified population

Population 1: Fetal anomalies

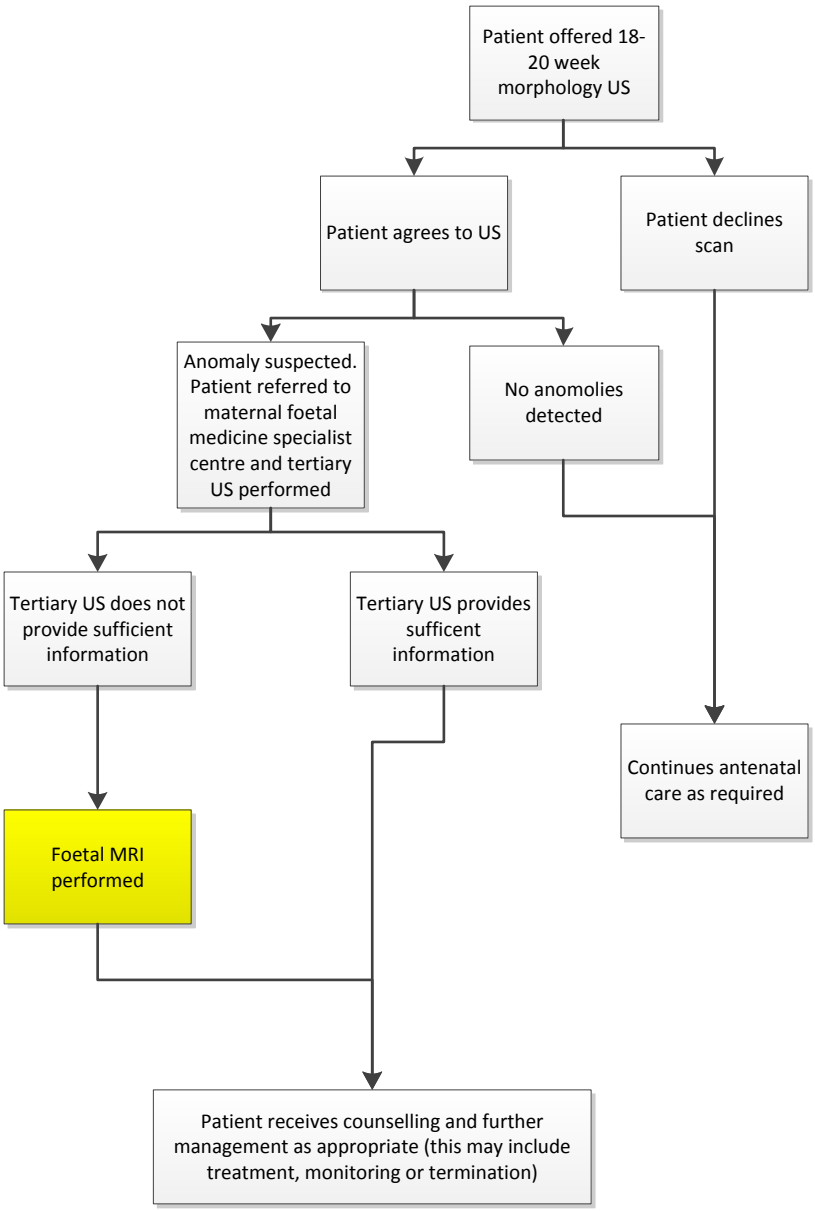


Population 2: Placental adhesion disorder

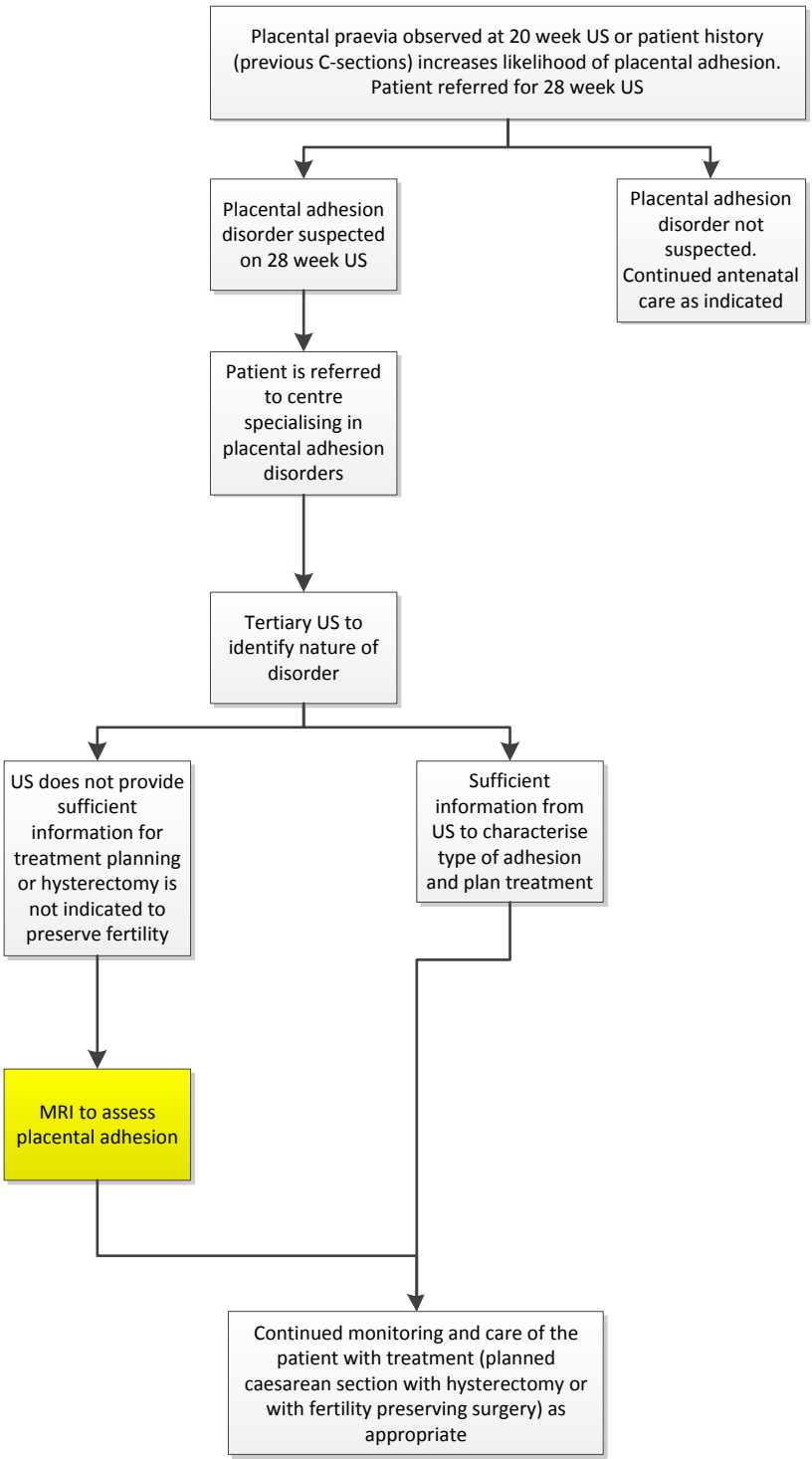


Proposed clinical management algorithm for identified population

Population: Fetal anomalies



Population 2: Placental adhesion disorder



Proposed economic evaluation

The applicant claimed that, for both populations, MRI provides superior diagnostic ability compared to the comparator, for particular fetal abnormalities/conditions and for placental adhesion disorders that cannot be adequately characterised or diagnosed with ultrasound. Introduction of MRI is claimed to impact management by leading to a potential reduction in fetal and maternal mortality, more accurate surgical and medical pregnancy management, and better prognostic genetic and family counselling.

MRI is claimed to have non-inferior safety compared to US.

Should these clinical claims be confirmed following assessment of the evidence, a cost-effectiveness analysis/cost-utility analysis would be appropriate.

Given the ethical and practical issues surrounding calculation of an ICER for termination of pregnancy, PASC confirmed that the incremental cost per additional patient with a correct diagnosis following MRI approach (taken in the 2010 report on use of fetal MRI in the Victorian public health sector (Deakin Health Evaluation Group 2010)) would be an appropriate approach to take for the economic evaluation of Population 1.

Proposed item descriptor

Following discussion with the applicant, they advised there are two proposed MBS items, based on the proposed populations:

Population 1

Category 5 - DIAGNOSTIC IMAGING SERVICES
MAGNETIC RESONANCE IMAGING performed under the professional supervision of an eligible provider at an eligible location for the following indications: Pregnant woman 18 weeks gestation or greater with suspected fetal abnormality, based on tertiary ultrasound or family / past pregnancy history or genetic risk, referred by an appropriate specialist or maternal fetal medicine specialty unit where diagnosis is indeterminate on tertiary ultrasound MBS Fee: $1,400-$,1500

Population 2

Category 5 - DIAGNOSTIC IMAGING SERVICES
MAGNETIC RESONANCE IMAGING performed under the professional supervision of an eligible provider at an eligible location for the following indications: Pregnant woman 28 weeks gestation or greater with suspected placental adhesion disorder, referred by an obstetric specialist involved in treatment and pregnancy management where: 1. Diagnosis is indeterminate on tertiary ultrasound OR 2. MRI is required for surgical planning of either hysterectomy or uterine conservation interventions MBS Fee: $500-$600

MBS fees for the proposed items have been estimated by the applicant on the basis that, in their experience:

- a fetal MRI costs between $1,400 and $1,500 and takes up to two hours to perform, is a complex scan requiring the direct involvement/consultation (not presence, in the applicant's experience) of a senior radiologist across the two hours, and a senior radiographer for one hour; and
- an MRI for placental adhesion disorder costs between $500 and $600 and takes approximately one hour to perform (comprising half an hour of the radiologist's time and half an hour of the radiographer's time) and is similar in complexity to MBS item 63473 (Pelvic and upper abdomen MRI), which has a fee of $627.20

PASC noted consultation feedback was received suggesting that the proposed fee for fetal MRI may be too high; therefore, a sensitivity analysis should be performed to assess the impact of lowering the proposed fee in line with other MRI items currently listed on the MBS.

Both PASC and the applicant advised that the proposed items should be limited to specialist referral. PASC also advised that MRI should not be available as a stand-alone screening test for fetal anomalies, but should always be following a tertiary US.

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