Application for MBS eligible service or health technology

ID:
HPP200169

Application title:
Review of MBS items for clinically indicated gross and histologic examination of placentas in perinatal deaths

Submitting organisation:
THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

Submitting organisation ABN:
52000173231

Application description

Succinct description of the medical condition/s:
Gross & microscopic examination of the placenta, umbilical cord, and fetal membranes by a trained pathologist in the investigation and evaluation of possible causes of perinatal death. Evaluation of the placenta in these cases provides helpful information in 69.5-95.7% of cases. Of the 3,004 perinatal (stillbirth & neonatal) deaths in Australia in 2020, 1,043 (37.2%) underwent an autopsy, including an examination of the placenta.
The Perinatal Society of Australia & NZ's Clinical Practice Guidelines recommend:
1. Perinatal post-mortem: Placentas should be sent for examination by perinatal/paediatric pathologist regardless of whether consent for an autopsy has been gained following stillbirths, neonatal deaths in the delivery room or birth of high-risk infants.
2. Investigations of neonatal death:
-Detailed macroscopic examination of the placenta & cord with findings documented in the medical record by obstetric staff;
-Histopath exam of fresh & unfixed placenta, cord & membranes

Succinct description of the service or health technology:
The majority of placentas examined from public hospital births in Australia are billed based on MBS Item 72823. This fee is based on a single specimen from a gastrointestinal biopsy with a relative time unit (RTU) of 5 minutes. The time & expertise required to perform a detailed placental examination is significantly longer. The average examination time for one placenta, including gross examination & measurements, sampling for ancillary studies, dissection, tissue processing, staining, microscopy and reporting, is estimated to be a minimum of 30 mins and, in cases of a complex placenta such as associated with a neonatal death or stillbirth, would increase to 45-60 mins. Due to lack of funding, many stillbirth/neonatal autopsies are currently not conducted, & placental examinations are being delayed or not performed by pathologists with appropriate expertise.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?
Applicant

Are you applying on behalf of an organisation, or as an individual?
Organisation

Is the applicant organisation the organisation you are representing in the HPP today?
Yes

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?
No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?
Amendment

What is the nature of the amendment?
An amendment to the time and complexity of an existing item(s)

Justification for amendment:
In May 2017, the Pathology Clinical Committee recommended that the examination of the placenta, when clinically indicated (i.e., in an abnormal gestation), in the absence of fetal demise, should be increased from level 4 to level 5 complexity. The PCC also recommended that the examination of the placenta of a stillborn baby (when no examination of the fetus/baby is conducted) be increased to level 6. To date, these PCC recommendations have not been implemented.

The complexity levels and their associated fees have remained unchanged since their introduction 25 years ago.

This application, therefore, seeks a revision of the complexity levels and their associated MBS fees for the examination of placental specimens by a perinatal/paediatric pathologist. Noting that the number of specimens per examination is usually one (one placenta), with the exception of multiple births (e.g. twins).

Please select any relevant MBS items.

MBS item number	Selected reason type
72823	Expansion or amendment to existing item
72824	Expansion or amendment to existing item
72830	Expansion or amendment to existing item
72836	Expansion or amendment to existing item
72838	Expansion or amendment to existing item

What is the type of service or health technology?
Investigative

Please select the type of investigative health technology:
Histopathology and cytology

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	N/A

N/A

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:
Other

Purpose description:

Supporting documentation

Document type	File name(s)
Application PICO set documents	Placental Complexity_v0.3.pdf
Reference list	Discussion paper_Increasing stillbirth autopsies_final (002).pdf; Extract from Ratified Minutes - MSAC Executive May 2023 - Agenda Item 5.1.docx; Management of Stillbirth_ACOG.pdf; NW-Stillbirth-Guideline-FINAL-V4-March-2021(4).pdf; Section-5-Stillbirth-Investigations-V3.2-121219.pdf

Population

Describe the population in which the proposed health technology is intended to be used:
The placenta of women who have experienced a still birth or fetal loss

Search and select the most applicable Medical condition terminology (SNOMED CT):
Birth

Intervention

Name of the proposed health technology:
Gross and microscopic examination of the placenta, umbilical cord, and fetal membranes by a trained pathologist in the investigation and evaluation of possible causes of perinatal death.

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:
There is no comparator

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
Due to lack of funding, many stillbirth/neonatal autopsies are currently not conducted, and placental examinations are being delayed or not performed by pathologists with appropriate expertise with many women who have experienced a pregnancy or perinatal loss going to their follow-up obstetric appointments hoping for, yet not receiving, answers as to the cause of their baby's death.

Proposed MBS items

Proposed Item AAAAA

MBS item number:
72823

Please search and select the proposed category:
PATHOLOGY SERVICES

Please search and select the proposed group:
TISSUE PATHOLOGY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:
Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 separately identified specimen (Item is subject to rule 13)

Proposed MBS fee:
$97.15

Indicate the overall cost per patient of providing the proposed health technology:
$97.15

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Based on current Level 4 examinations

Proposed Item BBBBB

MBS item number:
72830

Please search and select the proposed category:
PATHOLOGY SERVICES

Please search and select the proposed group:
TISSUE PATHOLOGY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:
Complexity Level 5: Placenta - livebirth at any gestation where placental examination is clinically indicated according to clinical practice guidelines.

Proposed MBS fee:
$274.15

Indicate the overall cost per patient of providing the proposed health technology:
$274.15

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Based on current Level 5 complexity

Proposed Item CCCCC

MBS item number:
72830

Please search and select the proposed category:
PATHOLOGY SERVICES

Please search and select the proposed group:
TISSUE PATHOLOGY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:
Complexity level 5: Placenta - second trimester pregnancy loss (greater than 12 weeks) delivered before 20 weeks gestation (i.e. non-registered baby), with delivered placenta (excluding D&C) samples)

Proposed MBS fee:
$274.15

Indicate the overall cost per patient of providing the proposed health technology:
$274.15

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Based on current Level 5 complexity

Proposed Item DDDDD

MBS item number:
72836

Please search and select the proposed category:
PATHOLOGY SERVICES

Please search and select the proposed group:
TISSUE PATHOLOGY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:
Placenta -all stillbirths of a registered baby delivered at or after 20 weeks gestation.

Proposed MBS fee:
$417.20

Indicate the overall cost per patient of providing the proposed health technology:
$417.20

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
Based on current level 6 complexity

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
The majority of placentas examined from public hospital births in Australia are billed based on MBS Item 72823 (Complexity Level 4 biopsy, fee $97.15, 85% benefit $82.60). This fee is based on a single specimen from a gastrointestinal biopsy with a relative time unit (RTU) of 5 minutes.

Please provide a cost break down attachment:

Document type	File name(s)
Cost breakdown attachment	Fees are based on the time.docx

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?
Superior

Please state what the overall claim is, and provide a rationale:
Gross and microscopic examination of the placenta, umbilical cord, and fetal membranes by a trained

pathologist is the single most useful aspect of the evaluation of stillbirth and neonatal death and is an essential component of the evaluation
(Grade of recommendation 1A – Strong recommendation, high-quality evidence).
The three investigations most likely to give useful information in the event of a stillbirth or miscarriage are:
1) post-mortem 24.7% - 84.5%
2) placental histology 69.5% to 95.7%
3) fetal chromosomal analysis 11.7% to 29.0%. with 1) and 2) offered and ideally performed by a suitable trained pathologist in all cases.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
The % uptake question just doesn't work for most applications - its better to have an estimated number of utilisation
In 2020, there were 3,004 registered perinatal deaths (stillbirths plus neonatal deaths), 2,801 (93%) of which had a stated autopsy status (2,136 stillbirths and 665 neonatal deaths). Table 1 describes the number of deaths where autopsy status was stated, and an autopsy was performed.
There is a lack of accurate data describing fetal loss at the different gestational ages, coupled with difficulties integrating public and private hospital data across jurisdictions. More accurate real-world data obtained from South Australia, summarising placental examinations conducted in private (23%) and public (77%) hospitals, which may be used to extrapolate and estimate the number of placental examinations performed in other jurisdictions that do not collect such granular private/public data. It should be noted that South Australia tend to perform a higher number of autopsies compared to other states; however, the proportion of births (including live and stillbirths) requiring placental examination is likely to be similar across jurisdictions.
The number of births that had a placental examination in South Australia (not specifically associated with perinatal death/stillbirth), was approximately 3,500 examinations per year with numbers increasing in 2021 and 2022 due to concerns around the unknown effects of COVID on pregnancy. Using an approximate number of 20,000 births as the denominator, approximately 17% of pregnancies therefore required a placental examination for clinical indications including prematurity, growth problems, infections or fetal abnormalities.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):
100

Year 2 estimated uptake(%):
100

Year 3 estimated uptake(%):
100

Year 3 estimated uptake(%):
100

Estimate the number of patients who will utilise the proposed technology for the first full year:
See below

Optionally, provide details:
Estimates for the number of examinations for each of the complexity levels are as follows:
Level 4: this figure is difficult to estimate as data of this granularity is not routinely collected. However,

the number will be less than the number of Level 4 examinations currently conducted, due to movement of examinations to Level 5 and Level 6. A rough estimate may be approximately 10-20% of the total number of births in Australia – 30-60,000 per year; however, the majority of these would be delivered in the public sector and not impact on MBS item usage.
Level 5: pre-term births would represent approximately 20% of all births ~ 60,000 births. Of these, approximately 40% would be in the private sector, and as such use an MBS item number, and 60% would be in the public sector.
Level 6: Data obtained in the Department of Health and Aged Care's 2022 Discussion paper indicated that there were 2,128 > 20 weeks still births in Australia in 2021, which would be expected to remain relatively steady over time.

Will the technology be needed more than once per patient?
No, once only

Provide references to support these calculations.

Document type	**File name(s)**
Estimated utilisation references	Estimated prevalence.docx

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

Professional body name:
Pathology Australia

Professional body name:
Public Pathology Australia

Professional body name:
The Royal College of Pathologists of Australasia

List all appropriate professional bodies / organisations representing the group(s) of health professionals who request the health technology/service:

Professional body name:
Perinatal Society of Australia & New Zealand

Professional body name:
Royal Australasian College of General Practitioners

Professional body name:
Royal Australian and New Zealand College of Obstetricians and Gynaecologists

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

Professional body name:
N/A

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

Number of organisations listed: 3

Professional body name:
Still Aware

Number of organisations listed: 3

Professional body name:
Stillbirth Foundation Australia

Number of organisations listed: 3

Professional body name:
The Centre of Research Excellence in Stillbirth

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?
No