

Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1777 – Review of MBS items for clinically indicated gross and histologic examination of placentas in perinatal deaths

Applicant: The Royal College of Pathologists of Australasia

Date of MSAC consideration: 1-2 August 2024

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting an increase to the Medicare Benefits Schedule (MBS) complexity level (and fee) of placental tissue examinations was received from the Royal College of Pathologists of Australasia (RCPA) by the Department of Health and Aged Care.

Part 3 of the *Health Insurance (Pathology Services Table) Regulations 2020* (PST) specifies complexity levels for the examination of different tissue specimen types. Placental tissue examinations are claimed under MBS item 72823. This MBS item is used for all tissue examinations listed as level 4 complexity. The RCPA proposed that all placental tissue examinations be increased from level 4 complexity to levels 5 or 6.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported increasing the complexity levels of the Pathology Services Table (PST) items for clinically indicated gross and histologic placental examination. MSAC considered there remained a strong clinical need for placental examination, as it provides important causal and prognostic information when clinically indicated. MSAC considered there was an unmet need for appropriately resourced placental examination given Australia's stillbirth rate is substantially higher than comparable countries, and the current complexity level does not reflect the time and resources required. MSAC acknowledged that perinatal death includes stillbirths through to post-natal deaths, and hence considered that the complexity level of placental examination for stillbirths should also apply to neonatal deaths that occur several days after birth to allow time for appropriate clinical management. MSAC advised that placental examination following stillbirth or early neonatal death (up to 7 days after birth) should be increased from level 4 to level 6 complexity, while placental examination following all other live births for which placental examination is clinically indicated or from 12 to 20 weeks gestation (excluding dilatation and curettage samples) should be increased from level 4 to level 5 complexity. MSAC advised the financial cost to the MBS of increasing the complexity level of placental examination was acceptable.

Consumer summary

This is an application from the Royal College of Pathologists of Australasia requesting an increase to the complexity of placental examinations from complexity level 4 to complexity level 5 or 6 on the Pathology Services Table (PST). The PST lists pathology services that are eligible for Medicare Benefits Schedule (MBS) rebate. Increasing the complexity level would also mean an increase to the MBS rebate for the services.

A placental examination is where a doctor specifically trained in pathology (pathologist), performs a detailed look at the placenta following birth of a baby. The placenta is an organ that develops throughout pregnancy, connecting the baby to the mother. It provides the baby with oxygen and nutrients, while also removing waste products. The pathologist performing the placental examination will check its size, shape and weight, along with the condition of the placental tissue and umbilical cord. Additionally, a number of other tests and microscopic evaluation(s) will be used to create a detailed report. The placental examination can inform doctors about signs of infection, abnormalities and/or missing pieces that may provide information about potential health issues for both the parent and/or baby.

Placental examinations are important in identifying underlying issues associated with live births, stillbirths and where the death of a baby occurs within a relatively short period of time after birth. The results of a placental examination help guide clinical management and improve outcomes for both the parent and baby, as well as provide information for management of subsequent pregnancies.

Most placental examinations are claimed under MBS item 72823 at complexity level 4 as per the PST. However, the applicant has claimed this complexity level (and fee) does not adequately compensate for the time and expertise required to perform a detailed placental examination. Due to the current complexity level (and fee), the applicant has proposed that many placental examinations are being delayed and/or not performed by pathologists with appropriate expertise.

MSAC acknowledged that there is a clinical and unmet need for appropriately funded placental examinations.

MSAC supported increasing the placental examination complexity from level 4 to level 5 (for second trimester [12 to 20 weeks gestation] losses and all live births) or level 6 (for stillbirths and death of a baby occurring within 24 hours after birth [very early neonatal death]). MSAC considered this would better reflect the time and expertise needed to perform placental examinations. Additionally, MSAC recommended the proposed wording for placental tissue examination of very early neonatal deaths should be expanded to include early neonatal deaths up until 7 days (rather than 24 hours) after birth.

There was some uncertainty about estimated utilisation and uptake, but MSAC considered there was a low level of uncertainty overall as two different approaches to the financials produced similar results in terms of net financial impact.

MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC supported increasing the complexity level and fee of placental tissue examinations. Additionally, MSAC recommended that placental tissue examinations for very early neonatal deaths should be expanded to include early neonatal deaths up until 7 days at complexity level 6 on the PST. MSAC acknowledged there was a clinical and unmet need, and that the proposed amended complexity levels are appropriate and reflective of the time and complexity of the placental examinations.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this application by the Royal College of Pathologists of Australasia (RCPA) requested to amend the complexity level (and as a result, the fee) of the placental tissue examinations listed in [Part 3 of the Health Insurance \(Pathology Services Table\) Regulations 2020](#), made under the Health Insurance Act 1973 (hereafter referred to as the PST). Placental tissue examinations are currently claimed under MBS item 72823, as are all tissue examinations listed as level 4 complexity (if one, separately identified specimen is involved). The RCPA proposed that all placental tissue examinations be increased from level 4 complexity to levels 5 or 6, to allow them to be claimed under MBS items 72830 and 72836). MSAC noted this application contained no proposed changes to any MBS items. Additionally, MSAC noted it has not previously considered the complexity level and fee of placental tissue examination.

MSAC noted that a recommendation to increase the complexity of placental tissue examinations was made by the Pathology Clinical Committee to the MBS Review Taskforce in 2017. The RCPA then submitted a further request to the Department in February 2023 to review the complexity level(s) for items relevant to placental tissue examinations on the PST. MSAC noted that the MSAC Executive considered the proposal in May 2023 and recommended that the request bypass both PASC/ESC and progress directly to MSAC. MSAC noted the MSAC Executive requested the application specifically quantify the financial impact on the MBS based on real-world estimates.

MSAC acknowledged that there is a high clinical need for this service, as histopathological examination of the placenta following a pregnancy affected by medical complications, pregnancy loss or neonatal death may provide insight into causation. Additionally, MSAC considered placental examinations may also provide information relevant to the management of the current infant and/or subsequent pregnancies.

MSAC noted there is an unmet need, as stillbirths have been identified as an unaddressed global public health problem. The 2020 [National Stillbirth Action and Implementation Plan](#) notes that, in 2016, Australia's late gestation (28 weeks or more) stillbirth rate was estimated to be 35% higher than countries with the lowest rates. MSAC noted that the rates of stillbirth in Australia are higher for certain groups including First Nations individuals, some migrant and refugee groups and individuals living in rural and remote areas. MSAC further noted that people who experience one stillbirth have an increased risk of stillbirth in subsequent pregnancies. MSAC therefore considered that high-quality and specialised placental examinations are vital to address this unmet clinical need, which is in alignment with the strategy of the National Stillbirth Action and Implementation Plan to reduce the stillbirth rate.

MSAC considered that the current funding is no longer commensurate with the duration and increased complexity of placental examinations which has evolved over time, that are performed by highly trained pathologists.

MSAC noted that this application bypassed PASC/ESC and as a result, a formal PICO was not defined for this assessment. MSAC noted the three populations proposed in the assessment report:

- Population 1: stillbirth of a baby delivered at or after 20 weeks' gestation or a very early neonatal death occurring within 24 hours
- Population 2: second trimester pregnancy occurring at greater than 12 weeks and delivered before 20 weeks' gestation (excluding dilatation and curettage samples)
- Population 3: live birth at any gestation (note: this excludes very early neonatal death as captured in Population 1).

MSAC considered the comparator to be the existing, unchanged complexity levels for placental examination. MSAC noted that the proposed change to the complexity level and fee of placental histopathology is not expected to impact the clinical pathway. The clinical indications for the service remain the same and no downstream impacts are anticipated. The criteria for placental examination are documented in Australian clinical practice guidelines. MSAC noted that there is some inconsistency between guidelines with regards to the indications for placental examination and considered that this may lead to inconsistent rates of referral to pathology between settings or jurisdictions.

MSAC noted the public consultation feedback was broadly supportive of the application for increasing the complexity level for items relevant to placental tissue examinations on the PST. Australian Pathology strongly supported better alignment between rebates and labour costs involved in conducting examinations. Additionally, Australian Pathology emphasised the need for the re-establishment of a clinical committee that reviewed histological examination complexity levels to ensure they remained aligned with contemporary pathology practice. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) also strongly agreed with the proposed complexity and fees. Public Pathology Australia also strongly agreed with the need to increase the complexity level. However, it suggested that complexity levels for twin and triplet placentas should be assigned complexity level 6 (given the work involved and length of the report); second trimester pregnancy loss placentas should come under complexity level 6 (rather than the proposed level 5); and stillbirth placentas should come under complexity level 7 (rather than the proposed level 6).

MSAC noted that the application proposed an increase to the complexity levels (and associated fees) of the placental tissue examinations listed in the PST from complexity level 4 to level 5 or 6. MSAC noted that MBS General Note 10.26 states “The fee for any item listed in the MBS is that which is regarded as being reasonable on average for that service having regard to usual and reasonable variations in the time involved in performing the service on different occasions and to reasonable ranges of complexity and technical difficulty encountered.” MSAC noted the proposed changes to placental tissue examinations from complexity level 4 to level 5 or 6 would increase the fee from \$97.15 (for level 4) to \$274.15 (level 5) or \$417.20 (level 6), respectively. MSAC noted that the proposed complexity level increase is based on the time taken to complete a placental examination. MSAC noted that the majority of placental tissue examinations are currently claimed under MBS item 72823 (complexity level 4), which was based on a single gastrointestinal biopsy specimen with a corresponding time value of 5 minutes (one block of labour). MSAC noted the applicant’s statement that the average examination time for one placenta, including gross examination and measurements, sampling for ancillary studies, dissection, tissue processing, staining, microscopy and reporting, would require a minimum of 30 minutes, with this increasing to 45-60 minutes in complex cases associated with a neonatal death or stillbirth. For each placenta, this equates to at least 5–6 blocks of tissue or more in the case of complex cases. MSAC considered this time requirement to be in alignment with expert clinical advice obtained during assessment of the current application. Additionally, MSAC considered that the time requirements also aligned with the macroscopic and microscopy examinations of the placenta outlined in the [RCPA standard protocol](#) and the exemplar placental histopathology [request form](#) provided in the clinical guidelines developed by the Centre of Research Excellence in Stillbirth (Stillbirth CRE) and Perinatal Society of Australia and New Zealand (PSANZ), respectively. MSAC considered the increased times for placental tissue examinations justified the need for increase in complexity level and fee – commensurate of the time and expert training required to perform these examinations.

MSAC noted that the assessment report proposed new items and revised wording to the placental histopathology and related examinations currently on the PST (Table 4). MSAC noted that the ‘products of conception’ specimen types had been further defined following input from

RCPA and included revised wording by the Department to 'Products of conception, termination of pregnancy less than 12 weeks'; and 'Products of conception first trimester (<12 weeks) pregnancy, or second trimester (<20weeks) with D&C tissue only'. MSAC noted that these specimen types were not proposed to change in complexity level, remaining at complexity level 3 and 4 respectively. MSAC considered that the terminology 'products of conception' is a clinically factual term and is not a new concept that has been introduced as part of the change. MSAC recommended that consultation occur to advise if this terminology remains appropriate, or is outdated and requires revision.

Additionally, MSAC noted that although 'Fetus with dissection' was related to placental tissue examinations in the PST, this specimen type was not proposed to change in complexity level – nor required any wording updates to the descriptor.

MSAC noted that the reference to “registered” or “non-registered” baby was removed to avoid causing offence. MSAC considered that all deliveries at or after 20 weeks' gestation – including stillborn babies – are registered as births in Australia. MSAC noted that the proposed complexity level descriptors for placental histopathology included reference to gestational age, based upon advice from the MSAC Executive in May 2023. This advice was predicated on the concern that absence of gestational age in the descriptors may result in use beyond their indication to examine tissue from early pregnancy loss and result in leakage. MSAC considered the concerns raised by the MSAC Executive and agreed that the proposed complexity level descriptors should refer to gestational age. Additionally, MSAC noted that the proposed wording “loss” was removed as some clinicians may not consider terminations to be “pregnancy loss”.

MSAC noted that the assessment report recommended that very early neonatal death (occurring within 24 hours of birth) may require complexity level 6 placental tissue examinations. This resulted in the proposed specimen type descriptor: “Placenta – live birth at any gestation associated with very early neonatal death within 24 hours of birth”. MSAC acknowledged the importance of placental examinations in very early neonatal death occurring within 24 hours of birth. However, MSAC recommended that this descriptor should be expanded from very early neonatal death (occurring within 24 hours of birth) to early neonatal deaths (occurring within 7 days of birth) at the higher complexity level 6 fee. MSAC noted that this aligned with the [PSANZ guideline](#) that state “...ideally all placentas should be retained for a few days after birth to allow for subsequent retrieval should an infant deteriorate”.

The proposed amendments to the complexity levels for placental histopathology and related examinations on the PST based on MSAC advice is presented in Table 1. MSAC noted that the proposed complexity descriptors contain more detail compared to those currently included within the PST. However, MSAC considered that these more detailed descriptors provide greater clarity around the correct use and would assist in preventing leakage due to more stringent descriptors.

Table 1: Proposed amendments to the current complexity levels and specimen type descriptors for placental histopathology and related examinations on the PST based on MSAC advice

Specimen Type	Complexity Level
Fetus with dissection	6*
Placenta – not third trimester	4
Placenta – third trimester, abnormal pregnancy or delivery	4
Placenta – stillbirth of a baby delivered at or after 20 weeks gestation	6
Placenta – second trimester pregnancy at 12 weeks gestation and delivered before 20 weeks' gestation (excluding D&C samples)	5
Placenta – live birth at any gestation	5
Placenta – live birth at any gestation associated with very early neonatal death within 24 hours 7 days of birth	6
Products of conception, spontaneous or missed abortion first trimester (<12 weeks) pregnancy, or second trimester (<20 weeks) with D&C tissue only	4*
Products of conception, termination of pregnancy less than 12 weeks	3*

D&C = dilatation and curettage; MBS = Medicare Benefits Schedule.

Note: Red text (additions) and black strikethrough (deletions) indicate amendments to the current PST proposed by the assessment report agreed by MSAC. Blue text (additions) and blue strikethrough (deletions) indicates MSAC recommendations to that proposed in the assessment report. * indicates items that have not been proposed to change in complexity.

MSAC noted that a systematic evaluation of the evidence base for placental histopathology and an evaluation of the comparative safety and effectiveness was not in scope for this assessment. MSAC considered that a change in the designated complexity level (and fee) associated with the service is not expected to impact on safety or effectiveness, unless the current reimbursement (which may be considered inadequate for the time and effort involved) for the service lowers the quantity or quality of the placental examinations taking place. MSAC noted from expert feedback that some specialised pathology laboratories do not perform placental histology because the complexity level (and fee) is considered inadequate for the time and effort involved.

MSAC noted that an economic evaluation was not in scope for this application as per advice from the MSAC Executive in May 2023. MSAC noted that the [2024 Stillbirth CRE and PSANZ guideline](#) states that placental examination by a perinatal pathologist is one of the most cost-effective tests for stillbirth investigation that can provide causal and prognostic information. The guideline states that pathological placental changes have been reported in 23–96% of stillbirths and recommended that histopathology of the placenta and umbilical cord should be undertaken for all perinatal deaths. MSAC considered the Stillbirth CRE and PSANZ guideline reaffirms the clinical need for placental tissue examinations.

MSAC noted that the estimated financial cost to the MBS was based on available epidemiological data and evidence based on real-world estimates. The epidemiological approach used data from the National Perinatal Mortality Data Collection (NPMDC), National Perinatal Data Collection (NPDC) from the Australian Institute of Health and Welfare (AIHW), Australian Bureau of Statistics (ABS), and published studies identified in a targeted literature search. MSAC noted the real-world data, provided by the applicant, comprised of placental pathology service utilisation data from **redacted** from July 2018 to March 2024, including whether the examination was funded publicly or privately. MSAC noted the real-world data did not include details of the birth (for example, live birth, stillbirth, week of gestation, indication/reason for referral). MSAC noted that almost all placental examinations of the available real-world data were undertaken at a single laboratory. MSAC noted that both the epidemiological and real-world data yielded similar estimates, with a lower overall financial impact (by approximately 14%) estimated using the real-world data. MSAC

considered the financial impact calculated by the epidemiological data was more accurate than the real-world data, given the real-world data for the least uncertain population data set (population 1 perinatal deaths) was lower. compared to epidemiological data.

MSAC noted the estimated utilisation for each population as obtained from epidemiological data. Estimated utilisation for population 1 (stillbirths and very early neonatal deaths occurring within 24 hours of birth) was captured as part of registration of births and deaths from the NPMDC, AIHW and NPDC. MSAC noted the number of perinatal deaths remained stable (approximately 3,000 per year) between 2014 and 2021. MSAC noted the projected data to 2024 and noted that the trend is flat with minimal change in annual numbers. MSAC noted that the total number of stillbirths related to private patients, and therefore eligible for MBS funding, was calculated based on the total proportion of births that occur in a private hospital. Based on these data, the estimated financial cost to the MBS of the proposed complexity level 6 placental examinations, using the 75% benefit for MBS item 72836 (Examination of complexity level 6 biopsy material; \$312.90), is \$189,225 in Year 1 to \$193,352 in Year 6. MSAC noted that this was estimated at less than 5% of the total cost to the MBS from all three populations. However, MSAC noted that the financial estimates for this population did not include very early neonatal deaths occurring within 24 hours of birth being expanded to early neonatal deaths occurring up to 7 days as per MSAC's recommendation. MSAC considered that although the actual cost due to this recommendation was uncertain, it was likely to be of minimal impact.

MSAC noted that the number of eligible services for second trimester pregnancy loss (population 2) was estimated using hospital separations with a primary diagnosis of spontaneous abortion from epidemiological data. MSAC noted that in 2021, there were 10,722 hospitalisations due to spontaneous abortion. MSAC noted the number of eligible services following a live birth (population 3) was estimated using the proxy of admission to a special care nursery (SCN) or neonatal intensive care unit (NICU). These admissions cover premature births and births complicated by abnormal gestation or fetal development. MSAC noted the AIHW reports that, in 2021, 17% of live births were admitted to SCN or NICU, resulting in 53,670 babies. MSAC noted the number of people who give birth and the number of babies born between 2011 and 2021 have both remained steady. Therefore, MSAC noted that for the financial analysis for populations 2 and 3, the number of eligible services per year is assumed to remain stable over the 6-year period. Based on this, MSAC noted the estimated financial cost to the MBS for the proposed complexity level 5 placental examinations (populations 2 and 3), using the 75% benefit for MBS item 72830 (Examination of complexity level 5 biopsy material; \$205.65), is approximately \$3.4 million per year. MSAC considered the financial estimates for these populations were appropriate.

MSAC noted that population 3 was estimated to comprise more than 80% of the estimated total financial cost to the MBS for the combined three populations and was viewed as the main source of uncertainty. MSAC considered that this uncertainty was somewhat reduced given similar service volume estimates were obtained from both an epidemiological approach and via extrapolation from real-world data.

MSAC noted that the combined financial impact to the MBS of the proposed change in complexity level from 4 to level 6 (population 1) and level 5 (populations 2 and 3), taking into consideration the cost offset of reduced level 4 claims, was approximately \$2.3 million in Year 6. MSAC noted that the proposed complexity change would increase the financial viability of placental histopathology and could increase the number of services and service providers. MSAC noted the sensitivity analysis in the assessment report indicated that if this led to an increased uptake of 10% per year over the 6-year analysis, then the estimated total cost to the MBS would increase from approximately \$2.3 million to \$4.1 million in Year 6. MSAC considered that growth in services for populations 1 and 2 would be limited, and population 3 was considered the most

likely source of any growth in services as the indications are broader and the volume is higher and could be influenced by factors such as increased capacity and awareness.

MSAC noted that in the case of a multiple birth where individual placentas would be recognised as “separately identified” specimens, a single item can be billed under the higher fee MBS item 72824 for “...examination of 2–4 separately identified specimens”. However, MSAC noted that, in its pre-MSAC response, the applicant stated that this may be a non-issue once at level 5 or 6, as both would be considered 1+ samples (with no option for 2 or more). MSAC agreed with the applicant’s interpretation and considered that this would not be an issue if the proposed changes to the complexity level were implemented.

MSAC noted that multiple births had not been factored in the financial analysis and would slightly decrease the net financial impact to the MBS, as the slightly higher fee for complexity level 4 multiple births items would further offset the costs. MSAC considered that the impact would not be overly significant given that, according to the AIHW, the number of multiple births in Australia each year is small and has remained relatively stable at around 2–3% of all births.

Overall, MSAC supported the proposed complexity level increase to the relevant specimen types on the PST. MSAC acknowledged the high clinical and unmet need, and noted the increased time and expertise required to perform placental examinations. MSAC agreed that the current fee structure is not commensurate with the time and complexity to perform placental tissue examinations by specialist pathologists. MSAC supported the proposed wording updates to the ‘Products of Conception’ specimen types on the PST as recommended by both the applicant and Department. Additionally, MSAC supported that complexity level 6 placental tissue examinations be expanded to include early neonatal deaths occurring within 7 days, as opposed to limiting to very early neonatal deaths occurring within 24 hours.

4. Background

MSAC has not previously considered the complexity level (and fee) of placental tissue examination.

The Pathology Clinical Committee (PCC) (Tissue (Anatomical) Pathology/Cytology) [report](#) to the Medicare Benefits Schedule Review Taskforce, recommended in May 2017, that:

- the examination of the placenta when clinically necessary (i.e. in an abnormal gestation), in the absence of fetal demise, should be increased from level 4 to level 5 complexity, and
- that examination of the placenta of a stillborn baby (when no examination of the fetus/baby is conducted) be increased to level 6.

The recommendations were made on the basis that the fee for level 4 complexity was not commensurate with the time required for and complexity involved in these examinations.

In February 2023, the RCPA wrote to the department requesting an increase to the complexity level of placental examination. In May 2023, the Medical Services Advisory Committee (MSAC) Executive advised that the request should progress directly to MSAC with the RCPA as the applicant, highlighting the financial impact to the MBS based on real-world estimates. The application therefore bypassed consideration by the PICO Advisory Sub-committee and the Evaluation Sub-committee.

The department undertook targeted consultation and responses are herein referred to as ‘Expert 1,’ ‘Expert 2’ and Expert 3.’

5. Prerequisites to implementation of any funding advice

The requested complexity level change is for a medical service already delivered by pathologists. There would be no change to medical practice or associated quality assurance requirements.

6. Proposal for public funding

Placental tissue examinations are currently claimed under MBS item 72823 (complexity level 4). This MBS item is one of 12 tissue histopathology items for examination of biopsy materials of different complexity levels (see Table 2 for MBS items relating to complexity levels 3 to 6). Complexity levels for specimen types are not prescribed by the MBS items but are specified in the PST 'Complexity levels for tissue pathology items'. Placental histopathology is specified as level 4 complexity in this table and is distinguished from products of conception and examination of a fetus (see Table 3).

Table 2 Excerpt of existing MBS items for tissue histopathology complexity levels 3 to 6 relevant to this application

Category 6 – PATHOLOGY SERVICES	
MBS item 72816	Examination of complexity level 3 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) Fee: \$86.35 Benefit: 75% = \$64.80 85% = \$73.40
MBS item 72823	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) Fee: \$97.15 Benefit: 75% = \$72.90 85% = \$82.60
MBS item 72824	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 – 2-4 separately identified specimens (Item is subject to rule 13) Fee: \$141.35 Benefit: 75% = \$106.05 85% = \$120.15
MBS item 72825	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 – 5-7 separately identified specimens (Item is subject to rule 13) Fee: \$180.25 Benefit: 75% = \$135.20 85% = \$153.25
MBS item 72830	Examination of complexity level 5 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 or more separately identified specimens (Item is subject to rule 13) Fee: \$274.15 Benefit: 75% = \$205.65 85% = \$233.05
MBS item 72836	Examination of complexity level 6 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 or more separately identified specimens (Item is subject to rule 13) Fee: \$417.20 Benefit: 75% = \$312.90 85% = \$354.65

Source: [MBS online website](#) (accessed 16 May 2024). Grey shading indicates MBS item(s) that were not in scope for assessment.

The MBS item currently claimable for placental histopathology (MBS item 72823) specifies that the service must be rendered for one separately identified specimen. For a multiple birth resulting in multiple placentas, the assessment evaluated all level 4 examinations as using the single sample item 72823 (separate service required for each placenta), and multiple sample items were not in scope for the assessment. However, for multiple placenta births, item 72824 provides higher funding than 72823 for the examination of 2 - 4 separately identified specimens, at a fee of \$141.35 (item 72825 allows for 5 – 7 specimens at a fee of \$180.25). MBS Note PN.0.33 (Rules for the Interpretation of the PST), specifically rule 13. (4) and 13. (5),¹ would also be relevant in the case of a multiple birth where individual placentas would be recognised as ‘separately identified’ specimens. In the event more than one histopathology examination is rendered on these specimens for a single patient episode, only one item, that with the highest fee, can be billed. This prevents 72823 being billed multiple times in the case of a multiple birth, when item 72824 might be more appropriate.

Table 3 Current complexity levels for placental histopathology and related examinations on the MBS Pathology Services Table

Specimen Type	Complexity Level
Fetus with dissection	6
Placenta – not third trimester	4
Placenta – third trimester, abnormal pregnancy or delivery	4
Products of conception, spontaneous or missed abortion	4
Products of conception, termination of pregnancy	3

Source: *Health Insurance (Pathology Services Table) Regulations 2020*, available at: [Federal Register of Legislation](https://www.federalregister.gov/). Grey shading indicates specimen types not proposed to change complexity level.

No changes to the MBS items for tissue histopathology were proposed by the applicant. The proposal was to increase the complexity levels specified in the PST for placental histopathology to levels 5 or 6. The changes proposed in the application are presented in Table 4, including revised wording as described below. These changes would increase the fee for placental examinations from \$97.15 (level 4) to \$274.15 (level 5) or \$417.20 (level 6) for applicable services.

The MSAC Executive expressed concern over the potential overuse of placental tissue items to examine non specific products of conception. The applicant proposed revised wording (with proposed amendments by the department) that could be appropriate to manage the boundary between examination of a placenta (complexity level 5 or 6) versus products of conception.

There are some pregnancy terminations that occur after 12 weeks, including when there are suspected genetic or developmental issues with the fetus where a placental examination may be relevant. The proposed wording “pregnancy loss” may be potentially problematic, as some clinicians may not consider termination of pregnancy to be “pregnancy loss”. To address this, the department proposed that “loss” could be removed.

The intention is that products of conception from terminations less than 12 weeks would remain eligible under the lower complexity item (level 3), whereas placental examination following second trimester terminations – especially performed for underlying clinical reasons at greater than 12 weeks, would be eligible under the higher complexity item (level 4).

¹ Medicare Benefits Schedule – Note PN.0.33: <https://www9.health.gov.au/mbs/fullDisplay.cfm?type=note&qt=NoteID&q=PN.0.33>

Reference to the term “registered baby” or “non-registered baby” may also cause offence, therefore the department has suggested removing the term from the updated item descriptors proposed by the RCPA.

‘Fetus with dissection’ was not proposed to change wording or complexity level.

The application form proposed level 6 complexity only for stillbirths (and level 5 complexity for all live births). However, input from the applicant during the assessment included that there is a continuum from intrauterine death or intrapartum death leading to a stillbirth (with or without attempted resuscitation) and very early neonatal death of a liveborn infant, and that placental examination is equally important for all. Additional information provided by the applicant during the assessment asserted that level 6 complexity should apply also to placentas where there is a neonatal death. Very early neonatal death (within 24 hours of birth) may indicate the requirement for a complexity level 6 placenta examination, as opposed to level 5 for all other live births. For example, this may be the case when a neonate was not stillborn but was kept alive in the Neonatal Intensive Care Unit (NICU) following birth to enable appropriate management and counselling to occur. To accommodate this advice from the applicant, the intervention was revised to include a proportion of live births (those associated with very early neonatal death within 24 hours of birth) at complexity level 6. This resulted in proposing to add a specimen type to the PST: “Placenta – live birth at any gestation associated with very early neonatal death within 24 hours of birth”.

Table 4 Proposed complexity levels for placental histopathology and update to products of conception on the MBS Pathology Services Table

Specimen Type	Complexity Level
Fetus with dissection	6
Placenta – stillbirth of a registered baby delivered at or after 20 weeks gestation	6
Placenta – second trimester pregnancy loss at (greater than 12 weeks gestation) and delivered before 20 weeks’ gestation (i.e., non-registered baby), with delivered placenta (excluding D&C samples)	5
Placenta – live birth at any gestation where placental examination is clinically indicated according to clinical practice guidelines	5
<u>Placenta – live birth at any gestation associated with very early neonatal death within 24 hours of birth</u>	6
Products of conception first trimester (<12 weeks) pregnancy loss, or second trimester loss (<20 weeks) with D&C sample tissue only	4
Products of conception, termination of pregnancy <u>less than 12 weeks</u>	3

D&C = dilatation and curettage; MBS = Medicare Benefits Schedule.

Note: Grey shading indicates specimen types not proposed to change complexity level.

Source: developed by assessment group based on the application form. Strikethrough and underline indicate changes proposed by the department during the assessment.

Following advice from the MSAC Executive, the proposed complexity level descriptors for placental histopathology include reference to gestational age, based on the MSAC Executive’s concern that they could be used beyond their indication to examine tissue from early pregnancy loss. This differs from the PCC recommendation and that of Expert 1, who both preferred to remove specification of gestational age in the descriptor.

As with all MBS services in an antenatal setting, the patient is the mother (or pregnant person) until the birth of the baby. People who are deceased, including stillborn infants, are ineligible to

access Medicare services and in this setting pathology tests on the placenta are ordered under the mother's name and will be retained on the mother's record to inform future antenatal care.

The complexity descriptors proposed by the applicant are more detailed than those currently included within the PST, in contrast to the recommendations of the PCC that retained sparse wording ('placenta, abnormal pregnancy or delivery' (level 5) and 'placenta, stillbirth' (level 6)).

Justification of the complexity and associated fee

The requested fee increase was based on the time taken to complete a placental examination. The currently claimed MBS pathology item, 72823 (complexity level 4), was based on a single gastrointestinal biopsy specimen with a corresponding time value of 5 minutes. Whereas the application stated that the average examination time for one placenta, including gross examination and measurements, sampling for ancillary studies, dissection, tissue processing, staining, microscopy and reporting, was estimated to be a minimum of 30 minutes. In complex cases associated with a neonatal death or stillbirth, the time taken for placental examination is 45-60 minutes.

The applicant provided a brief description of the standard protocol for investigation of the placenta:

- Placenta received fresh and is swabbed for infection and sampled for genetic studies if clinically indicated. An urgent cord section may be performed to look for evidence of fetal response to infection, which is used to determine antibiotic use in neonates if there is a high risk of sepsis.
- Macroscopic examination is undertaken on both fresh and fixed whole placenta, taking an average 10-15 minutes including photography of any significant abnormalities.
- The placenta is fixed for 24 hours.
- A minimum of five tissue blocks are examined or an average of six blocks per placenta.
- Microscopic examination including reporting takes a minimum 10 minutes per placenta for live births, 20 minutes per placenta for an intrauterine fetal death.

The RCPA manual for placental examination provides greater detail². The number of specimens per examination is usually one (one placenta), except for multiple births (e.g. twins).

While it is not an MBS requirement, guidelines recommend that the service should be performed by a perinatal pathologist, defined as follows³:

“Pathologist with specialist professional training in examining tissues of pregnancy (placenta, embryo, foetal tissue) to identify cause of death during the perinatal period. Perinatal pathologists are also trained in performing autopsies to investigate causes of neonate death.”

Additional justification for the fee was provided by two clinical experts.

Expert 2 noted that placental weights and measurements are required to be conducted fresh to allow comparison with internationally recognised gestational tables. However, fresh handling is time-consuming, particularly given the large sample size – often associated with significant volumes of blood – requiring greater care and clean up. The need for photography also

² [Placenta single gestation - RCPA manual](#)

³ Centre of Research Excellence in Stillbirth & Perinatal Society of Australia and New Zealand (PSANZ) (2024). Care Around Stillbirth and Neonatal Death Clinical Practice Guideline.

distinguishes examination of the placenta from a biopsy specimen. Finally, each placenta has at least 5-6 blocks or more if grossly abnormal (compared to one for a single gastrointestinal biopsy), and interpretation is often complex, particularly for intrauterine death cases (requested level 6 complexity), as there is also an expectation of clinical correlation.

Expert 3 provided details of reporting time for placental specimens compared to endoscopic biopsies (Table 5).

Table 5 Estimated time for examination of placenta specimens compared to endoscopic biopsies

Time element	Placenta	Endoscopic biopsy
Pathologist reporting time	10-15 mins	1-2 mins
Specimen cut-up time	10-15 mins	1-2 mins
Scientific labour time	20 minutes	4 minutes
Equivalent block labour	4-5 blocks	1 block

Source: Adapted from correspondence from Expert 3

7. Population

Three populations are proposed and align with the applicant's advice:

1. Stillbirth of a baby delivered at or after 20 weeks' gestation or a very early neonatal death occurring within 24 hours
2. Second trimester pregnancy occurring at greater than 12 weeks and delivered before 20 weeks' gestation (excluding dilatation and curettage [D&C] samples)
3. Live birth at any gestation (*note: this excludes very early neonatal death as captured in Population 1*)

Perinatal death in Australia is defined as (and encompasses both):

- Stillbirth (fetal death): birth following the death of an unborn baby of 20 or more completed weeks of gestation or of 400 g or more birthweight.
- Neonatal death: a live born baby who dies within 28 days of life (regardless of gestation or weight at birth)⁴. Neonatal deaths are further subdivided by the World Health Organization (WHO) into:
 - (i) very early neonatal death (0 to <24 hours);
 - (ii) early neonatal death (>24 hours to <7 days); and
 - (iii) late neonatal deaths (>7 days to <28 days)⁵.

Australian law defines a fetal death as a pregnancy loss from 20 weeks' gestational age (when the perinatal period commences) until delivery. All deliveries at or after 20 weeks' gestation, including stillborn babies, are registered as births in Australia. Pregnancy losses prior to 20 weeks' gestation usually cannot be registered, though this is dependent on the state or territory jurisdiction involved. Pregnancy loss prior to 20 weeks is termed a miscarriage; a loss between 12 to <20 weeks' gestation is a late miscarriage.

⁴ Centre of Research Excellence in Stillbirth & Perinatal Society of Australia and New Zealand (PSANZ) (2024). Care Around Stillbirth and Neonatal Death Clinical Practice Guideline.

⁵ Neonatal death: Case definition & guidelines for data collection, analysis, and presentation of immunization safety data, Vaccine, Volume 34, Issue 49, 2016. <https://doi.org/10.1016/j.vaccine.2016.03.040>.

Criteria for placental examination are documented in Australian clinical practice guidelines^{4,6,7,8}. The criteria specified by the Perinatal Society of Australia and New Zealand (PSANZ) are listed in Table 6. There is some inconsistency between guidelines; for example, South Australian Perinatal Practice Guidelines (2019) appear to have broader criteria including:

- poor obstetric history
- history of >2 miscarriages
- drug or alcohol misuse
- meconium-stained liquor.

This may lead to inconsistent rates of referral to pathology between settings or jurisdictions.

The 2024 PSANZ guideline notes that placental examination by a perinatal pathologist is one of the most cost-effective tests for stillbirth investigation that can provide causal and prognostic information. The guideline states that pathological placental changes have been reported in 23% to 96% of stillbirths. Therefore, histopathology of the placenta and umbilical cord is recommended for all perinatal deaths. Guidelines frequently recommend that placentas are retained for a few days after birth to enable examination should the baby's condition deteriorate.

⁶ The Royal College of Pathologists of Australasia (RCPA) (2023) RCPA Best Practice Guideline For Perinatal Death Investigations. First Edition, Version 1.5.

⁷ Agency for Clinical Innovation, NSW Health (2014) Maternity - Indications for Placental Histological Examination. Guideline GL2014_006.

⁸ Department of Health and Wellbeing, Government of South Australia (2019) Histopathology Management of the Placenta. Version 2.

Table 6 Indications for placental examination by a pathologist

Group	Indications for placental examination
Maternal indications:	Systemic disorders such as an active autoimmune disease, uncontrolled diabetes, or other significant maternal disease that has affected the pregnancy Moderate or severe pre-eclampsia Intrapartum fever or infection Suspected chorioamnionitis Unexplained bleeding in the third trimester Excessive bleeding (more than 500 mL) Placental abruption Severe maternal trauma Amniotic Fluid Index abnormalities
Fetal and neonatal indications:	Admission to neonatal intensive care Failure to respond to resuscitation Spontaneous or iatrogenic preterm birth Fetal compromise including growth restriction Severe cardiorespiratory depression at birth Signs consistent with congenital infection Severe growth restriction Diagnosis of hydrops fetalis Suspected severe anaemia Suspected or known major congenital abnormalities Death
Placental indications:	Physical abnormality Abnormal placental size or weight for gestational age (small or large) Suspected vasa praevia Umbilical cord lesions Abnormal cord length

Source: Centre of Research Excellence in Stillbirth & Perinatal Society of Australia and New Zealand (PSANZ) (2024). Care Around Stillbirth and Neonatal Death Clinical Practice Guideline. Available at: <https://learn.stillbirthcre.org.au/>

The proposed change to complexity level (and fee) of placental histopathology is not expected to impact the clinical pathway. The clinical indications for the service remain the same and no downstream impacts are anticipated.

RCPA Best Practice Guidelines (2023) state that no lower or upper limit on gestational age, or gestational birthweight, should be applied to perinatal investigations. This is consistent with the PCC recommendations, although does not align with the proposed complexity descriptors.

8. Comparator

A formal PICO was not defined for this assessment, but the comparator was assumed to be the existing, unchanged MBS items for histopathology (with associated item complexity guidance for placenta specimen types).

Expert 2 noted that some specialised pathology laboratories do not perform placental histology because the complexity level (and fee) is considered inadequate for the time and effort involved.

9. Summary of public consultation input

Consultation input was welcomed from three (3) professional organisations.

The organisations who submitted input were:

- Australian Pathology (AP)
- Public Pathology Australia (PPA)
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)

The consultation feedback received was mostly supportive of the application.

Benefits

- Families would benefit from understanding the cause of their child's death, and treating clinicians would be better able to counsel patients.
- Clinicians could advise of any consequential health interventions that may be associated with the child's cause of death, and this information could assist in informed reproductive choices and future pregnancy management.
- Placental examination is important in routine obstetric care where a wide range of conditions have specific placental manifestations.
- Public funding will improve the uptake of perinatal autopsy and placental examination, and will enable a better understanding of the causes of pregnancy loss and poor perinatal outcomes including prematurity and growth restriction.

No disadvantages were identified by the Organisations providing consultation Feedback.

Additional Comments

In the past, the government maintained a clinical committee which reviewed histological examination complexity levels to ensure they remained aligned with contemporary pathology practice, and feedback from AP is that it should be re-established.

Feedback from PPA noted that as the majority of cases are referred from the public hospital system, there should be clarity that MBS can be used for all placenta histopathology, including referrals from the public hospital system.

Other services identified to be delivered alongside the testing include a meeting with the patients' health care provider to discuss the results, post-test counselling and management of subsequent pregnancies (obstetric services).

10. Characteristics of the evidence base

A systematic evaluation of the evidence base for placental histopathology was not in scope for this fit-for-purpose DCAR.

11. Comparative safety

An assessment of the comparative safety of placental histopathology was not in scope for this fit-for-purpose DCAR. A change in the designated complexity level (and fee) associated with the service is not expected to impact on safety.

12. Comparative effectiveness

An assessment of the comparative effectiveness of placental histopathology was not in scope for this fit-for-purpose DCAR. A change in the designated complexity level (and fee) associated with the service is not expected to impact on effectiveness, unless the current reimbursement (which may be considered inadequate for the time and effort involved) for the service lowers the quantity or quality of the placental examinations taking place.

13. Economic evaluation

An economic evaluation was not undertaken for this fit-for-purpose DCAR.

14. Financial/budgetary impacts

The MSAC Executive noted that relevant epidemiological data are available and requested this assessment focus on estimating the financial cost to the MBS, also including evidence based on real-world estimates.

Using epidemiological data

An epidemiological approach was used to estimate the financial impact to the MBS of increasing the complexity level in the PST to levels 5 or 6 for placental histopathology, depending on gestational age and birth outcome. The financial implications to the MBS of the proposed change in complexity level from 4 to 6 for Population 1 (stillbirths and very early neonatal death within 24 hours of birth) are summarised in Table 7. The financial implications to the MBS of the proposed change in complexity level from 4 to 5 for Population 2 (second trimester losses) and Population 3 (live births) are summarised in Table 8.

The key sources of data were from the Australian Institute of Health and Welfare (AIHW): the National Perinatal Data Collection (NPDC), and the National Perinatal Mortality Data Collection (NPMDC). The NPDC provides the annual number of births nationally (and by state and territory) and the trend over time. The NPMDC provides annual perinatal mortality data (stillbirth and neonatal death), both nationally and by state and territory.

Intrapartum stillbirth (fetal death occurring during labour and birth) and neonatal death within the first 24 hours after birth are often considered together as, in many cases, the process leading to the death is a continuum that may result in death before or after the birth occurs. For this reason, although the proposed PST descriptor referred to stillbirths, both intrapartum stillbirth and very early (within 24 hours) neonatal death were included to provide a conservative estimate of the total number of examinations for Population 1 (level 6 complexity). Multiple births have higher rates of perinatal mortality and are accounted for in the NPMDC data, but the MBS restriction on claiming for a single item per patient episode in the event of two or more placentas being examined from a multiple birth is not incorporated into the utilisation estimates. Therefore, the population may be marginally overestimated.

Based on linear regression from historical data, the number of perinatal deaths increased slowly over the 6-year forecast period, due to a small increase over time in the number of stillbirths and a very small decrease in very early neonatal deaths. The total cost of the proposed level 6 complexity services to the MBS was partially offset by the reduced use of level 4 complexity services.

Table 7 Net financial impact to the MBS of increasing the complexity level of placental examinations for Population 1 – stillbirths and very early neonatal death within 24 hours of birth – from level 4 to 6, using epidemiological data

Parameter	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	FY 2030–31
Estimated use and cost of the proposed health technology						
Number of stillbirths	2,277	2,290	2,302	2,314	2,326	2,338
Number of very early neonatal deaths ^a	104	102	101	99	97	96
Total number of placental examinations for Population 1	2,382	2,392	2,402	2,413	2,423	2,434
Number of private placental examinations for Population 1 ^b	605	607	610	613	615	618
Cost to MBS of proposed level 6 services (75% benefit) ^c	\$189,225	\$190,051	\$190,876	\$191,702	\$192,527	\$193,352
Change in use and cost of other health technologies						
Cost to MBS of level 4 services (75% benefit) ^d	-\$44,086	-\$44,278	-\$44,471	-\$44,663	-\$44,855	-\$45,048
Net financial impact to MBS of increasing from complexity level 4 to 6 (75% benefit)	\$145,139	\$145,772	\$146,406	\$147,039	\$147,672	\$148,305

FY = financial year; MBS = Medicare Benefits Schedule.

a Calculated by multiplying the proportion of neonatal deaths that occur within 24 hours (16%) by the number of all neonatal deaths.

b Calculated by multiplying the total number of placental examinations for Population 1 by the proportion of patients giving birth in a private hospital (25.4%). Assumes one placental examination per stillbirth/neonatal death.

c Calculated using 75% benefit (\$312.90) for examination of complexity level 6 biopsy material (MBS item 72836).

d Calculated using 75% benefit (\$72.90) for examination of complexity level 4 biopsy material (MBS item 72823).

Source: DCAR Tables 18 and 23.

The AIHW does not report statistics for pregnancy loss, nor prenatal data prior to 20 weeks' gestation. Therefore, hospital separations with a primary diagnosis of spontaneous abortion (ICD-10 codes O03.0 to O03.9) were used as an approximate measure in the absence of more specific data. In 2021, there were 10,722 hospitalisations due to spontaneous abortion. Although this would include some early miscarriages (prior to 12 weeks' gestation), it was assumed that essentially all late miscarriages would be captured as hospitalisations (or if not, would not be available for placental examination). Furthermore, it was assumed that all late hospital miscarriages would be indicated for, and undergo, placental histopathology.

Indications for placental histology, including following a live birth, are listed in Table 6. These include fetal, maternal and placental indications and although they cover a broad range of conditions and outcomes, admission to a special care nursery (SCN) or NICU following birth is considered a suitable proxy. These admissions cover premature births and births complicated by abnormal gestation or fetal development. The AIHW reports that in 2021, 17% of live births were admitted to SCN or NICU, equating to 53,670 babies.

The number of women who give birth and the number of babies born have both remained steady between 2011 and 2021 and therefore no trend analysis was included for Populations 2 and 3 (proposed level 5 complexity.)

A large proportion of the estimated net cost to the MBS was associated with live births (83%) and this was partially offset by a reduction in level 4 services.

Table 8 Net financial impact to the MBS of increasing the complexity level of placental examinations for Populations 2 and 3 – second trimester losses and live births – from level 4 to 5, using epidemiological data

Parameter	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	FY 2030–31
Estimated use and cost of the proposed health technology						
Population 2: Second trimester pregnancy losses with delivered placenta						
Number of hospital separations with primary diagnosis of SAB	10,722	10,722	10,722	10,722	10,722	10,722
Number of private placental examinations for Population 2 ^a	2,723	2,723	2,723	2,723	2,723	2,723
Cost to MBS of proposed level 5 services (75% benefit) ^b	\$559,902	\$559,902	\$559,902	\$559,902	\$559,902	\$559,902
Population 3: Live births (Proposed Level 5 complexity)						
Number of live births admitted to SCN or NICU ^d	53,670	53,670	53,670	53,670	53,670	53,670
Number of private placental examinations for Population 3 ^a	13,628	13,628	13,628	13,628	13,628	13,628
Cost to MBS of proposed level 5 services (75% benefit) ^b	\$2,802,638	\$2,802,638	\$2,802,638	\$2,802,638	\$2,802,638	\$2,802,638
Total for Populations 2 & 3						
Total cost to MBS of proposed level 5 services (75% benefit)	\$3,362,540	\$3,362,540	\$3,362,540	\$3,362,540	\$3,362,540	\$3,362,540
Change in use and cost of other health technologies						
Cost to MBS of level 4 services (75% benefit) ^c	-\$1,191,973	-\$1,191,973	-\$1,191,973	-\$1,191,973	-\$1,191,973	-\$1,191,973
Net financial impact to MBS of increasing from complexity level 4 to 5	\$2,170,568	\$2,170,568	\$2,170,568	\$2,170,568	\$2,170,568	\$2,170,568

FY = financial year; MBS = Medicare Benefits Schedule; NICU = neonatal intensive care unit; SAB = spontaneous abortion; SCN = special care nursery.

a Calculated by multiplying the total number of placental examinations for the population by the proportion of patients giving birth in a private hospital (25.4%). Assumes one placental examination per hospital separation.

b Calculated using 75% benefit (\$205.65) for examination of complexity level 5 biopsy material (MBS item 72830).

c Calculated using 75% benefit (\$72.90) for examination of complexity level 4 biopsy material (MBS item 72823).

Source: DCAR Tables 19 and 24.

The combined financial implication to the MBS of the proposed change in complexity level from 4 to 6 for Population 1, and 4 to 5 in Populations 2 and 3 are summarised in Table 9. Increasing the complexity of level 4 services to level 5 for Populations 2 and 3 was estimated to have the largest net financial impact to the MBS.

Table 9 Net financial impact to the MBS of increasing the complexity of level 4 services to level 5 (Populations 2 and 3) or level 6 (Population 1), using epidemiological data

Parameter	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	FY 2030–31
Estimated use and cost of the proposed health technology						
Cost of services to the MBS (75% benefit) ^a	\$3,551,766	\$3,552,591	\$3,553,416	\$3,554,242	\$3,555,067	\$3,555,893
Change in use and cost of other health technologies						
Cost of level 4 service to the MBS (75% benefit) ^b	-\$1,236,059	-\$1,236,251	-\$1,236,443	-\$1,236,636	-\$1,236,828	-\$1,237,020
Net financial impact to the MBS of increasing level 4 to 5 or 6 to the MBS	\$2,315,707	\$2,316,340	\$2,316,973	\$2,317,606	\$2,318,239	\$2,318,872

FY = financial year; MBS = Medicare Benefits Schedule.

a Calculated by adding the cost of level 5 services with the cost of level 6 services.

b Calculated using 75% benefit (\$72.90) for examination of complexity level 4 biopsy material (MBS item 72823). Source: Table 7 and Table 8.

Using real-world data

In addition to epidemiological data, the applicant provided placental pathology service utilisation data from **redacted** from July 2018 to March 2024, including whether the examination was funded publicly or privately. **redacted**. The **redacted** data did not include details of the birth (for example, live birth, stillbirth, week of gestation, indication/reason for referral).

redacted. In response to a request from the assessment group for further details, the applicant sourced additional data from this laboratory, which provided the indication for placental histology and gestational age for the year 2021. These data were less certain because details were not always provided on the request form, not readily searchable from the data files, and there may have been more than one indication per placenta.

The additional data analysis provided by the **redacted** enabled an estimate of the actual number of examinations in 2021 for Population 1 in **redacted**. This was derived from the indications of fetal loss, stillbirth, miscarriage, intrauterine death, and intrauterine fetal demise at gestations of 20 weeks or more. The **redacted** stillbirths identified in these data were fewer than the **redacted** stillbirths recorded by the AIHW in **redacted** for that year and may represent actual uptake of the service being lower than guideline recommendations for histopathological examination of all placentas following stillbirth. Alternatively, it may reflect the limitations of the data available or lack of parental consent for placental examination, particularly when they perceive cause of death to be apparent.

The estimated number of complexity level 6 placental examinations for Population 1 was extrapolated from the **redacted** data (Table 10) and resulted in a lower net cost to the MBS (26% lower in the 2030–31 financial year) than the estimates derived from AIHW data (Table 7).

Table 10 Net financial impact to the MBS of increasing the complexity level of placental examinations for Population 1 – stillbirths and very early neonatal death within 24 hours of birth – from level 4 to 6, using real-world data

Parameter	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	FY 2030–31
Estimated use and cost of the proposed health technology						
Number of placental examinations for stillbirths ^a in redacted	redacted	redacted	redacted	redacted	redacted	redacted
Number of placental examinations for Population 1 in Australia (extrapolated)	1,955	1,955	1,955	1,955	1,955	1,955
Number of private placental examinations for Population 1 ^b	455	455	455	455	455	455
Cost to MBS of proposed level 6 services (75% benefit) ^c	\$142,416	\$142,416	\$142,416	\$142,416	\$142,416	\$142,416
Change in use and cost of other health technologies						
Cost to MBS of level 4 services (75% benefit) ^d	-\$33,180	-\$33,180	-\$33,180	-\$33,180	-\$33,180	-\$33,180
Net financial impact to MBS of increasing from complexity level 4 to 6	\$109,236	\$109,236	\$109,236	\$109,236	\$109,236	\$109,236

MBS = Medicare Benefits Schedule; **redacted**

a Assumed to also include placental examinations for very early neonatal deaths.

b Calculated by multiplying total number of placental examinations for Population 1 by proportion of privately funded placental examinations in **redacted** (23.3%).

c Calculated using 75% benefit (\$312.90) for examination of complexity level 6 biopsy material (MBS item 72836).

d Calculated using 75% benefit (\$72.90) for examination of complexity level 4 biopsy material (MBS item 72823).

Source: DCAR Tables 21 and 26

From the data provided by **redacted**, there were **redacted** placental examinations that were coded with a gestational age between 12 and <20 weeks and with an indication of fetal loss, stillbirth, miscarriage, intrauterine death or intrauterine fetal demise. This was considered a lower estimate of this population based on **redacted** data; an upper estimate was all **redacted** examinations of placentas recorded with a gestational age of 12 to <20 weeks.

The remaining placental examinations (i.e., total number of placental examinations by **redacted** in 2021 minus the number of placental examinations for stillbirths and 12 to <20 weeks pregnancy losses in 2021) were used to estimate the uptake for Population 3, live births. Of the total proposed level 5 complexity placental examinations (i.e., Population 2 and 3), **redacted**% were estimated to be live births using **redacted** data, compared to 83% using AIHW data.

The estimated number of complexity level 5 placental examinations for Populations 2 and 3 were extrapolated from the **redacted** data (Table 11) and resulted in a lower net cost to the MBS (13% lower in 2030–31) than the estimates derived from AIHW data (Table 8).

Table 11 Net financial impact to the MBS of increasing the complexity level of placental examinations for Populations 2 and 3 – second trimester losses and live births – from level 4 to 5, using real-world data

Parameter	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	FY 2030–31
Estimated use and cost of the proposed health technology						
Population 2: Second trimester losses with delivered placenta						
Number of placental examinations for 2nd trimester PL in redacted	redacted	redacted	redacted	redacted	redacted	redacted
Number of placental examinations in Population 2 in Australia (extrapolated)	1,048	1,048	1,048	1,048	1,048	1,048
Number of private placental examinations for Population 2 ^a	244	244	244	244	244	244
Cost to MBS of proposed level 5 services (75% benefit) ^b	\$50,170	\$50,170	\$50,170	\$50,170	\$50,170	\$50,170
Population 3: Live births						
Number of placental examinations following live birth in redacted	redacted	redacted	redacted	redacted	redacted	redacted
Number of placental examinations in Population 3 in Australia (extrapolated)	60,072	60,072	60,072	60,072	60,072	60,072
Number of private placental examinations for Population 3 ^a	13,982	13,982	13,982	13,982	13,982	13,982
Cost to MBS of level 5 services (75% benefit) ^b	\$2,875,432	\$2,875,432	\$2,875,432	\$2,875,432	\$2,875,432	\$2,875,432
Total for Populations 2 & 3						
Total cost to MBS of proposed level 5 services (75% benefit)	\$2,925,602	\$2,925,602	\$2,925,602	\$2,925,602	\$2,925,602	\$2,925,602
Change in use and cost of other health technologies						
Cost to MBS of level 4 services (75% benefit) ^c	-\$1,037,084	-\$1,037,084	-\$1,037,084	-\$1,037,084	-\$1,037,084	-\$1,037,084
Net financial impact to MBS of increasing from complexity level 4 to 5	\$1,888,518	\$1,888,518	\$1,888,518	\$1,888,518	\$1,888,518	\$1,888,518

MBS = Medicare Benefits Schedule; PL = pregnancy loss; **redacted**.

a Calculated by multiplying number of placental examinations for second trimester pregnancy loss by proportion of privately funded placental examinations in **redacted** (23.3%).

b Calculated using 75% benefit (\$205.65) for examination of complexity level 5 biopsy material (MBS item 72830).

c Calculated using 75% benefit (\$72.90) for examination of complexity level 4 biopsy material (MBS item 72823).

Source: DCAR Tables 22 and 27

The combined financial implications to the MBS of the proposed change in complexity levels for histopathological placental examination for all three populations based on real-world data are summarised in Table 12. As seen in the financial estimates from the epidemiological data, increasing the complexity of level 4 services to level 5 for Populations 2 and 3 was estimated to have the largest net financial impact to the MBS.

Table 12 Net financial impact to the MBS of increasing the complexity of level 4 services to level 5 (Populations 2 and 3) or level 6 (Population 1), using real-world data

Parameter	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	FY 2030–31
Estimated use and cost of the proposed health technology						
Cost of services to the MBS (75% benefit) ^a	\$3,068,018	\$3,068,018	\$3,068,018	\$3,068,018	\$3,068,018	\$3,068,018
Change in use and cost of other health technologies						
Cost of level 4 service to the MBS (75% benefit) ^b	-\$1,070,265	-\$1,070,265	-\$1,070,265	-\$1,070,265	-\$1,070,265	-\$1,070,265
Net financial impact to the MBS of increasing level 4 to 5 or 6 to the MBS	\$1,997,753	\$1,997,753	\$1,997,753	\$1,997,753	\$1,997,753	\$1,997,753

FY = financial year; MBS = Medicare Benefits Schedule.

a Calculated by adding the cost of level 5 services with the cost of level 6 services.

b Calculated using 75% benefit (\$72.90) for examination of complexity level 4 biopsy material (MBS item 72823).

Source: Table 10 and Table 11.

Uncertainty in the financial estimates

To reduce uncertainty in the financial estimates, the analyses have been conducted using both an epidemiological approach and a real-world data approach with data provided by **redacted**. Given that the approaches yielded similar estimates, with a lower overall financial impact estimated using the real-world data, the need for additional uncertainty analyses was reduced.

One additional uncertainty analysis was conducted. Although the birth rate and stillbirth rate have remained relatively stable in Australia and are assumed to remain stable over the 6-year period of the analyses, the proposed changes to complexity level 4 placental histopathology services may increase the number of service providers if it is more financially viable to perform. A 10% increase in uptake of services per year was applied to the financial analyses (Table 13). While this is unlikely to occur in Populations 1 and 2, it is possible that there could be growth in Population 3 given the indications for placental examination in live births are broader, more varied, and could be influenced by factors such as increased capacity and awareness.

Table 13 Net financial impact to the MBS if service volume increases 10% per year – epidemiological approach

Parameter	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	FY 2030–31
Population 1: stillbirth >20 weeks' gestation and very early neonatal death within 24 hours of birth (Complexity Level 6)						
Net financial impact to MBS of increasing complexity from level 4 to 6 (75% benefit)	\$158,957	\$174,853	\$192,338	\$211,572	\$232,729	\$256,002
Populations 2 & 3: second trimester pregnancy loss and live births (Complexity Level 5)						
Net financial impact to MBS of increasing complexity from level 4 to 5 (75% benefit)	\$2,387,624	\$2,626,387	\$2,889,025	\$3,177,928	\$3,495,721	\$3,845,293
All three populations						
Total net financial impact to the MBS (75% benefit)	\$2,546,581	\$2,801,239	\$3,081,363	\$3,389,499	\$3,728,449	\$4,101,294

MBS = Medicare Benefits Schedule.

Source: Compiled by the assessment group using data from DCAR Table 30, assuming number of private placental examinations increases 10% per year.

Note that the assessment was conducted under the assumption that placental examinations would use the single sample MBS item (72823 at level 4, 72830 at level 5, and 72836 at level 6), and did not incorporate late policy advice that for births with multiple placentas multiple specimen items (at higher fees) would be used.

15. Other relevant information

Nil.

16. Committee-in-confidence information

Clinical Experts

The names and affiliations of the clinical experts who provided information following consultation by the department are listed in Table 14.

Table 14 Clinical experts who provided information for this application

Expert	Name	Affiliation
Expert 1	Redacted	Redacted
Expert 2	The applicant's clinical experts	The Royal College of Pathologists of Australasia (RCPA)
Expert 3	Redacted	Redacted

17. Applicant comments on MSAC's Public Summary Document

The College's Working Party would like to express their delight in MSAC approving the revision of fees associated with MBS items for clinically indicated gross and histologic examination of placentas in perinatal deaths, and would like to take this opportunity to thank the Department for its assistance throughout the assessment process.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)