

MSAC application 1829

**Anti-Müllerian hormone testing for
identification of Polycystic Ovarian
Morphology, to support the
diagnosis of Polyendocrine
Metabolic Ovarian Syndrome (PMOS)**

Application for MBS eligible service or health technology

HPP Application number:

HPP200380

Application title:

Anti-Müllerian hormone for identifying Polycystic Ovarian Morphology, to support the diagnosis of Polyendocrine Metabolic Ovarian Syndrome

Submitting organisation:

ROCHE DIAGNOSTICS AUSTRALIA PTY LIMITED

Submitting organisation ABN:

29003001205

Application description

Succinct description of the medical condition/s:

Polyendocrine metabolic ovarian syndrome (PMOS, previously referred to as polycystic ovarian syndrome or PCOS) is a condition that affects up to 10% of reproductive-aged women. PMOS increases cardiovascular and metabolic disease risk, leading to increased mortality and morbidity unless managed over a patient's life. PMOS can also impact fertility and reproductive health, and may also have negative psychological health effects. It is a serious, and life-long condition for which a range of multidisciplinary medical and lifestyle interventions can be considered to reduce risk and improve overall quality of life. The importance of effective approaches to diagnose and support people with PMOS was highlighted in the development of the 2023 International evidence-based guidelines, produced by Monash University and endorsed by the National Health and Medical Research Council as Australian Clinical Guidelines.

Succinct description of the service or health technology:

Anti-Müllerian Hormone (AMH) is produced by ovarian follicles, and can be detected in serum (blood) samples using high-quality IVD assays. In PMOS, AMH levels can be higher than expected for a person's age, because of a high number of small, maturing ovarian follicles, called polycystic ovarian morphology. PCOM can also be detected by transvaginal ultrasound. In the 2023 updated guidelines, AMH testing

has been included as an alternative to ultrasound, and this application is for MBS funding for AMH testing as a less invasive and less costly alternative to ultrasound.

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

Applicant organisation name:

ROCHE DIAGNOSTICS AUSTRALIA PTY LIMITED

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?

New

Please select any relevant MBS items.

MBS item number	Selected reason type
55065	Other

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Clinical biochemistry

PICO sets

Application PICO sets:

PICO set name
Anti-Müllerian hormone for identifying Polycystic Ovarian Morphology

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

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

What additional purpose(s) could the health technology be used for, other than the purposes listed above for this PICO set?

Purpose category:

Prognosis

Purpose description:

To provide information about prognosis (staging/re-staging)

Rationale:

AMH provides prognostic information about a woman's ovarian reserve (the potential quantity of remaining eggs) and her response to fertility treatments like IVF. The clinical evidence for this application only supports PCOM identification.

Population

Describe the population in which the proposed health technology is intended to be used:

People who are

- Suspected of having PMOS due to clinical symptoms of oligo-anovulation or hyperandrogenism; and
- Do not have biochemical hyperandrogenism if clinical oligo-anovulation is present; and
- Require PCOM identification for PCOS diagnosis.

Intervention

Name of the proposed health technology:

Anti-Müllerian hormone for identifying Polycystic Ovarian Morphology, to aid in the diagnosis of Polyendocrine Metabolic Endocrine Syndrome

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:

Nomination of comparators for AMH testing for the classification of PCOM was informed by the recommended modalities for the diagnosis of PCOS outlined in the International Evidence-based Guideline for the assessment and management of polycystic ovary syndrome 2023. Based on the recommendations made in this clinical practice guideline, several comparators are nominated.

Transvaginal ultrasound - provides high-resolution visualisation of the ovaries, allowing for accurate identification of follicle number per ovary (FNPO), ovarian volume, and stromal characteristics. It is recommended when feasible and acceptable to the patient.

Transabdominal - Used when transvaginal assessment is not feasible or acceptable (e.g. in adolescents or those who decline TVUS). It offers a non-invasive alternative for evaluating ovarian morphology, although with lower resolution and reduced accuracy for FNPO and ovarian volume compared to transvaginal imaging.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

For the purposes of this assessment, the outcome from AMH testing is establishing PCOM for the purposes of diagnosing PMOS; this outcome is non-inferior to the outcome of ultrasound diagnosis which is currently eligible for MBS reimbursement. AMH testing would be an alternative to ultrasound, with the expectation that a

patient would only have one of these diagnostic investigations (in line with the Australian clinical guidelines). AMH testing is likely to be cost-minimising in comparison to ultrasound.

Proposed MBS items

Please provide at least one proposed item with their descriptor and associated costs, for each population / intervention:

Proposed item:

AAAAA

Category number:

6 - Pathology services

Category description:

P2 – Chemical

Proposed item descriptor:

Quantification of Anti-Mullerian hormone to determine polycystic ovarian morphology for the diagnosis of polyendocrine metabolic ovarian syndrome

Proposed MBS fee:

\$58.50

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

\$58.50

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

Proposed MBS fee is benchmarked to Item 66829, as a similar chemical pathology test which is related to the use of ultrasound for diagnosis.

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Where available, AMH testing is self-funded with varying private fees set by current providers. Example private fee for AMH testing is \$95, as part of fertility / IVF-related testing.

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)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

AMH testing can be used instead of ultrasound to determine polycystic ovarian morphology. Detecting PCOM, combined with other clinical signs and symptoms, can aid clinicians in making a diagnosis of polyendocrine metabolic ovarian syndrome. AMH testing provides non-inferior health outcomes to ultrasound and is likely to be cost-saving in comparison.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

Prevalence - up to 10% of reproductive-age women, equivalent to approximately 494,000

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

Year 1 estimated uptake (%):

10

Year 2 estimated uptake (%):

20

Year 3 estimated uptake (%):

30

Year 4 estimated uptake (%):

40

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

19,701

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service:

Royal College of Pathologists Australia

Entities who request the health technology/service:

Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)

Endocrine Society of Australia

Royal Australian College of General Practitioners (RACGP)

Entity who may be impacted by the health technology/service:

Royal Australian and New Zealand College of Radiologists

Patient and consumer advocacy organisation relevant to the proposed service/health technology:

Jean Hailes for Women's Health

Entity who produces similar products:

Abbott Laboratories

Beckman Coulter

Siemens

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?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
181221	Clinical chemistry hormone IVDs

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes