

MSAC application 1824

**Genetic testing for the detection of
germline variants in cancer
predisposition genes in people with
prostate cancer and their relatives**

Application for MBS eligible service or health technology

HPP Application number:

HPP200411

Application title:

Genetic testing for the detection of germline variants in cancer predisposition genes in people with prostate cancer and their relatives

Submitting organisation:

Cancer Australia and Genomics Australia

Application description

Succinct description of the medical condition/s:

Prostate cancer is the most commonly diagnosed cancer in Australia with 28,868 new cases estimated in 2025. This cancer develops when genetic differences cause the cells in the prostate gland to grow uncontrollably. These genetic differences may be inherited or acquired, and an estimated 17.2% of patients with prostate cancer carry an inherited pathogenic or likely pathogenic variant in a cancer predisposition gene that may have contributed to the cancer developing.

Succinct description of the service or health technology:

This application proposes extending eligibility for existing MBS-funded germline testing for variants in BRCA1, BRCA2 and other cancer predisposition genes in patients with breast, ovarian, fallopian tube and primary peritoneal cancer (MBS item 73296) to include those with prostate cancer and their relatives (MBS item 73297).

Redacted.

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:

Cancer Australia and Genomics Australia

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 medical condition under the existing item(s)

Justification for amendment:Amendment to add prostate cancer. **Redacted.****Relevant MBS items****Please select any relevant MBS items.**

MBS item number	Selected reason type
73296	Expansion or amendment to existing item
73297	Expansion or amendment to existing item

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Molecular diagnostic tests

Please select the type of molecular diagnostics health technology:

Multigene/biomarker panel assay

Specify the number of genes/biomarkers in the panel assay:

12

Is it possible to vary or select the genes/biomarkers requested within the panel?

Yes

PICO sets

Application PICO set 1:

PICO set name
Cascade testing for the detection of germline P/LP variants in cancer predisposition genes, in the biological relatives of prostate cancer patients in whom a germline P/LP variant in a cancer predisposition gene has been identified

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.

Purpose category:

Predisposition

Purpose description:

To identify a hereditary predisposition to disease(s) or condition(s) in affected or at risk but currently unaffected patients

Purpose category:

Prognosis

Purpose description:

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

Purpose category:

Targeted testing

Purpose description:

To test currently unaffected or asymptomatic individual(s) identified as at increased risk for the condition. For example: cascade testing

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

Purpose category:

Value of knowing

Purpose description:

Tests may also provide additional non-health value to patients or to their family members and carers, and discussion of these outcomes could supplement an assessment of the clinical utility of the technology.

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

People who have a biological relative with prostate cancer in whom a P/LP variant has been identified in one or more of the genes encompassed by MBS item 73296.

Select the most applicable Medical condition terminology (SNOMED CT):

Carrier of heritable cancer

Intervention**Name of the proposed health technology:**

Cascade testing for known germline gene variants, including copy number variation, in genes encompassed by item 73296

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:

No cascade testing (cancer surveillance is based on family history).

Outcomes

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

Germline P/LP variants in BRCA1/2 and other cancer-associated genes are associated with a substantially increased risk of developing various cancer types, depending on the gene. These include breast, ovarian, prostate, pancreatic, colorectal and uterine cancer and other Lynch syndrome cancers (Nyberg et al., 2020; Page et al., 2019).

Cascade testing enables identification of relatives who carry a germline variant and are therefore candidates for tailored surveillance plans, and risk-reducing interventions reflecting the level of risk. Those planning a family can consider reproductive strategies such as in vitro fertilisation and pre-implantation genetic testing to reduce the risk of their future children having the variant.

In relation to prostate cancer, eviQ recommends surveillance from the age of 40 for individuals carrying a BRCA2 germline variant, and consideration for those with a BRCA1 germline variant of PSA testing from age 40 (Diagnostic Evaluation, 2026; RACGP). Detection of a pathogenic variant in BRCA1, BRCA2, PALB2, ATM, MLH1, MSH2, MSH6, PMS2 or EPCAM also confers an increased risk of pancreatic cancer, and those with a family history that includes pancreatic cancer would be eligible for the Australian-wide APRISE pancreatic cancer screening study.

In relation to breast cancer, individuals may consider risk-reducing medication or bilateral risk-reducing mastectomy, as well as earlier and enhanced breast cancer surveillance using magnetic resonance imaging (MRI). In relation to ovarian cancer, the results of cascade testing can inform eligibility and the timing of risk-reducing salpingo-oophorectomy (eviQ). These changes in management are already established for germline variants in cancer predisposition genes that have been detected in association with a relative having breast, ovarian, fallopian tube or primary peritoneal cancer under MBS item 73296.

Those with a mismatch repair gene P/LP variant would be recommended to follow the cancer risk management recommendations in eviQ, including screening for colorectal cancer, with surgical intervention recommended to reduce the risk of uterine and tubo-ovarian cancer. Additional recommendations are gene-specific and risk-specific and are outlined in the eviQ guidelines. These changes in management are already established clinical practice in Australia for germline variants in cancer predisposition genes that have been detected in association with a relative having ovarian, fallopian tube or primary peritoneal cancer under MBS item 73296 or Lynch syndrome under MBS item 73354.

Earlier and more intensive surveillance in identified carriers has been shown to shift cancer detection toward earlier stages, when disease burden is lower and treatments are more likely to be curative. This stage shift is associated with improved cancer-specific survival and reduced need for intensive systemic therapies, although it may increase the number of surveillance investigations performed over a lifetime. The IMPACT trial has shown that PSA-based surveillance in BRCA2 carriers without a prior diagnosis of cancer is associated with higher detection rates of clinically

significant disease and at an early stage facilitating timely intervention with curative intent. This validates that the strategy of using PSA testing in this group does not result in overdiagnosis (Bancroft et al., 2026).

Cascade testing concentrates surveillance resources on those at highest risk, improving efficiency compared with age-based surveillance, but also increases short-term utilisation of diagnostic services such as imaging, biopsies, and specialist consultations (Bancroft et al., 2026).

Knowledge of germline status may also prompt changes in modifiable lifestyle factors recommended in eviQ, such as smoking cessation, alcohol reduction, physical activity and weight management, which may contribute to overall cancer risk reduction.

Proposed MBS items

This application proposes simplifying the descriptor for MBS item 73297: the proposed rewording will encompass cascade testing in the biological relatives of prostate cancer patients as proposed in this application, while also linking more directly to affected individual testing under 73296 to futureproof for any future expansions to that testing.

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

Proposed item:

73297

Category number:

6

Category description:

Pathology services - Genetics

Proposed item descriptor:

Characterisation of known germline gene variants, including copy number variation, in genes encompassed by item 73296, requested by a specialist or consultant physician, for a patient:

- a) who has a biological relative with a pathogenic or likely pathogenic variant identified in one or more of those genes; and
- b) who has not previously received a service to which item 73295, 73296 or 73302 applies.

Once per variant

Proposed MBS fee:

\$400.00

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

\$400.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

The proposed MBS fee is the same as the current MBS fee for MBS item 73297 (as of March 2026: Fee \$400.00 Benefit: 75% = \$300.00 85% = \$340.00). Gap fee is unlikely to be charged.

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

State-based funding or self-funded by patients or referral/testing not offered.

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:

The proposed germline genetic testing of known variants in BRCA1/2 and other cancer predisposition genes is likely to have non-inferior safety and superior effectiveness in the biological relatives of patients with prostate cancer, compared to no cascade testing.

Safety is likely to be non-inferior because it introduces minimal additional physical or clinical risk beyond standard care. Germline testing typically requires the collection of a biological sample, most commonly a minimally invasive or non-invasive sample such as blood or a buccal swab. These collection methods are routinely used in clinical practice and are associated with minimal risk to individuals.

The effectiveness of cascade testing for cancer predisposition genes is likely to be superior. Identifying at-risk family members enables consideration of earlier and enhanced surveillance and risk-reducing interventions. Individuals carrying P/LP variants in high-penetrance genes such as BRCA1/2 may be candidates for enhanced

breast surveillance with MRI, prompted to be aware of physical changes in the chest area, or recommended PSA testing at an earlier age (eviQ; eviQ; RACGP). They may also be eligible for risk-reducing medications, risk-reducing bilateral mastectomy and risk-reducing salpingo-oophorectomy, to lower their risks of breast and ovarian cancer (eviQ). Results may then influence clinical management, including treatment selection, eligibility for targeted therapies, and the intensity of ongoing monitoring.

Estimated utilisation

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

As detailed above for PICO set 1, approximately 1,872 patients with prostate cancer would be expected to undertake germline genetic testing in the first year. Where the patient tests positive for a germline P/LP variant, their biological relatives are proposed to become eligible for cascade testing. However given the combined uncertainty around the diagnostic yield amongst affected individuals, the number of relatives each affected individual has and the uptake rate of cascade testing amongst biological relatives, an alternative approach to estimate the number of cascade tests is used below that does not rely on uncertain estimates of the total size of the cascade testing population.

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

Year 1 estimated uptake (%):

N/A

Year 2 estimated uptake (%):

N/A

Year 3 estimated uptake (%):

N/A

Year 4 estimated uptake (%):

N/A

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

606

Optionally, provide details:

This application proposes expanding MBS items 73296 and 73297 to add prostate cancer patients and their relatives, although these are existing MBS items that

already provide equivalent testing for patients with breast, ovarian, fallopian tube and primary peritoneal cancer (73296), and their relatives (73297). MBS item utilisation data (Services Australia, 2026) show that the number of 73297 cascade tests per 73296 affected individual test is relatively consistent at 0.3-0.6 cascade tests per affected individual test. There is a decreasing trend in this rate over time, with 0.324 cascade tests per affected individual test in the 2025-26 financial year to-date. Clinical expert opinion is that this declining rate is likely to reflect the broadening of the testing criteria (particularly for access to PARP inhibitor in breast cancer) and that many relatives are tested outside the MBS (e.g. familial cancer centres in some public hospitals). Given the rate is decreasing over time, the current rate of 0.324 therefore represents a conservative estimate of the future number of cascade tests.

Applying this 0.324 rate to the 1,872 affected individual tests estimated for PICO set 1, results in an estimated 606 cascade tests per year.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Once per variant

Optionally, provide details:

More than one cascade test per patient is possible because equivalent testing for other types of cancer is currently permitted once per variant under MBS item 73297, and this application does not propose changing the frequency restriction. Permitting testing once per variant is clinically appropriate because two P/LP variants in different genes are present in some families and these may be identified at different times.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Once per variant

Optionally, provide details:

More than one cascade test per patient is possible because equivalent testing for other types of cancer is currently permitted once per variant under MBS item 73297, and this application does not propose changing the frequency restriction. Permitting testing once per variant is clinically appropriate because two P/LP variants in

different genes are present in some families and these may be identified at different times.

Application PICO set 2:

PICO set name
Testing prostate cancer patients who are at >10% risk of having a variant, for germline variants in BRCA1, BRCA2 and other cancer predisposition genes

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

Purpose category:

Predisposition

Purpose description:

To identify a hereditary predisposition to disease(s) or condition(s) in affected or at risk but currently unaffected patients

Purpose category:

Prognosis

Purpose description:

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

Population

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

Expansion beyond the currently indicated populations with breast, ovarian, fallopian tube or primary peritoneal cancer to include patients with prostate cancer for whom clinical and family history criteria indicate greater than 10% risk of having a germline P/LP variant in a cancer predisposition gene.

Existing MBS-funded testing for the identification of germline variants in cancer predisposition genes in people with breast, ovarian, fallopian tube or primary peritoneal cancer (MBS item 73296) includes the requirement that clinical and family history criteria place the patient at greater than 10% risk of having a P/LP variant. This application proposes expanding the eligible population to include patients with prostate cancer, while retaining the 10% risk criterion to ensure that this testing remains targeted to patients who have a high risk of carrying a relevant variant. The proposed amendment will therefore enable equity of access for prostate cancer patients to equivalent testing to that already provided for patients with breast, ovarian, fallopian tube and primary peritoneal cancer who are at the same level of risk of having a germline variant.

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

Malignant tumour of prostate

Intervention

Name of the proposed health technology:

Genetic testing for germline variants in BRCA1, BRCA2 and other relevant cancer predisposition genes.

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:

No germline genetic testing for patients with prostate cancer for whom clinical and family history criteria indicate a greater than 10% risk of having a germline P/LP variant in a cancer predisposition gene.

Outcomes

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

Most importantly, the benefits of germline testing extend beyond the affected individual, as determination of germline status enables cascade testing in biological relatives.

In the patient themselves, testing for germline variants in cancer predisposition genes will allow a diagnosis of heritable prostate cancer, and can help inform their prognosis, treatment choices, the frequency and/or intensity of follow-up for disease progression, and surveillance for other malignancies associated with the specific variant. Germline genetic test results are included with other factors (family history, personal risk factors) in models such as CanRisk to estimate cancer risks associated with inherited pathogenic variants in the individual and their family members.

Positive results can significantly alter clinical recommendations for patients with prostate cancer, depending on the gene identified (Shore et al., 2024). This may include changes to treatment recommendations, follow-up (increasing/reducing frequency of clinical follow-up, choice of follow-up imaging) and a lower threshold for further investigation and treatment where disease progression is suspected or more likely. Advice may be provided regarding risk of other cancers with surveillance where indicated. Those with a positive result should be offered a referral to a familial cancer service or genetic counsellor to facilitate cascade testing for relatives (Shore et al., 2024; Xu et al., 2025).

The change in prostate cancer management following identification of a P/LP germline variant involves a shift toward more intensive and personalised treatment and monitoring strategies (Reiter & Hassler, 2024). This includes earlier escalation to definitive local therapy, avoidance of prolonged active surveillance in higher-risk carriers, and the use of genomically targeted systemic therapies in advanced disease in the event of disease progression (Reiter & Hassler, 2024). These changes mitigate the higher risk of aggressive disease and early progression associated with certain germline variants, particularly BRCA2. BRCA1/2 positive individuals with prostate cancer have a poorer prognosis so are more likely to undergo radical prostatectomy (Teppala et al., 2025).

Negative germline results can support better risk stratification (McHugh et al., 2025) and shared decision-making between the patient and their treating team, and

support less invasive approaches to managing early prostate cancer. In patients with prostate cancer, negative results can inform current or future treatments, provide reassurance (Shore et al., 2024), and potentially reduce unnecessary interventions (Shore et al., 2025).

Germline testing also informs the patient about their risk of other cancers and risk of passing on a variant to future children, informs decisions about surveillance for other cancer types, and supports shared decision-making about cancer risk management and reproductive interventions (Allen et al., 2025). Incorporation of personalised risk information may enhance patient engagement and adherence to preventive behaviours.

Germline testing-informed management may change short-term use of health services, including increased PSA testing, advanced imaging techniques and genetic counselling. However, any increases associated with identification of a P/LP variant may be partially offset by reductions in downstream costs associated with delayed diagnosis and more advanced disease stage at presentation and need for more extensive and/or costly treatments (including targeted therapies), ineffective treatments, or advanced disease complications. (Reiter & Hassler, 2024). Reductions in usage may also be seen for patients with negative results due to less intensive monitoring and/or less invasive treatment.

Amending the current MBS-funded testing to include patients with prostate cancer (or at high risk of prostate/other cancers due to a known P/LP variant in the family, see PICO set 2), is unlikely to introduce harms not already considered. Potential harms include overtreatment, treatment-related morbidity, and psychological distress associated with genetic risk information - underscoring the importance of shared decision-making and access to genetic counselling (Reiter & Hassler, 2024). However, in the PROCLAIM trial, most patients (452/485, 93.2%) reported reduced/unchanged concerns about their diagnosis, treatment and follow-up after receiving test results (Shore et al., 2025).

Proposed MBS items

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

Proposed item:

73296

Category number:

6

Category description:

Pathology services - Genetics

Proposed item descriptor:

Characterisation of germline gene variants, including copy number variation where appropriate, requested by a specialist or consultant physician:

(a) in predisposition genes for breast, ovarian, fallopian tube, primary peritoneal or prostate cancer,

which must include at least:

- i. BRCA1 and BRCA2 genes; and
- ii. one or more other relevant genes; and

(b) in a patient:

- i. with breast, ovarian, fallopian tube, primary peritoneal or prostate cancer; and
- ii. for whom clinical and family history criteria place the patient at greater than 10% risk of having a pathogenic or likely pathogenic variant associated with breast, ovarian, fallopian tube, primary peritoneal or prostate cancer

Once per cancer diagnosis

Proposed MBS fee:

\$1,200.00

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

\$1,200.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

The proposed MBS fee is the same as the current fee for MBS item 73296 (as of March 2026: Fee: \$1,200.00 Benefit: 75% = \$900.00 85% = \$1,095.50). Gap fee is unlikely to be charged.

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:

The proposed germline genetic testing of BRCA1/2 and other cancer-associated genes is likely to have non-inferior safety and superior effectiveness in patients with prostate cancer for whom clinical and family history indicate a greater than 10% risk of having a germline P/LP variant in a cancer predisposition gene, compared to not offering germline genetic testing in this cohort.

Effectiveness in prostate cancer patients is likely to be superior. For patients with prostate cancer, germline testing results may influence their follow-up intensity, treatment decisions, and/or later eligibility for targeted therapies. A key utility of this testing arises from improved health outcomes in biological relatives, who receive cascade testing as a consequence of patients with prostate cancer having received germline testing.

Safety is likely to be non-inferior, because extension of the current MBS items to include offering testing to patients with prostate cancer raises no new safety concerns. The testing process itself does not alter or delay standard prostate cancer diagnostic pathways. Potential non-physical risks, such as psychological distress, anxiety, or concerns about genetic discrimination, are well recognised in genetic testing programs. However, these risks are mitigated through existing clinical safeguards, including pre-test and post-test genetic counselling, informed consent processes, and privacy protections. Such measures are routinely embedded in clinical genetics services and are considered part of standard best practice.

Estimated utilisation

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

Approximately 5,199 individuals per year would become eligible for testing.

This figure is calculated from the 28,868 prostate cancer diagnoses in Australia projected for 2025 (AIHW, 2025), removing the proportion with a prostate cancer subtype other than adenocarcinoma (4%), and those with metastatic disease at presentation (4.3%). To restrict testing to those at high risk of having a germline P/LP variant, this population of prostate cancer patients is then multiplied by the

proportion (28%) of cases who based on NCCN criteria alone (e.g. early stage disease, ancestry, family

history) would benefit from genetic testing to assist their management (Korn et al., 2025), and the proportion of these who would meet the 10% risk threshold for MBS-funded testing (70%, expert opinion).

Of prostate cancer cases in Australia, 96% are adenocarcinoma (AIHW, 2025).

Prostate cancer subtypes other than adenocarcinoma (4%) are removed because clinical expert opinion is that patients with other subtypes of prostate cancer are in practice not offered gene panel testing.

Prostate cancer patients presenting with metastatic castration-resistant disease (4.3% metastatic at presentation, calculated from figures in (AIHW, 2025)) are already eligible for MBS-funded somatic and germline BRCA testing for PARP inhibitor access via MBS items 73303 and 73304, therefore are removed as they are not incremental in this application.

The proportion of prostate cancer diagnoses meeting NCCN criteria was informed by a US population-based study using the SEER Prostate Cancer Specialized Database, which found that 28% of the study cohort met NCCN guideline recommendations for germline genetic testing based on clinicopathologic features and family cancer history (Korn et al., 2025). This 28% represents only those patients at an early stage, with high-risk disease, and a family history of cancer; those with a previous diagnosis of breast cancer were excluded as they are already for MBS-funded testing. These are the patients who would benefit from genetic testing to assist their management.

These patients who meet the NCCN criteria will have their risk of having a germline P/LP variant assessed according to CanRisk (or equivalent) to determine eligibility in relation to the 10% risk threshold for MBS-funded testing. This is done at intake in the Familial Cancer Clinic assessment, because treating teams do not have sufficient time or information to do a CanRisk (or equivalent) assessment to determine whether the 10% threshold has been met. Clinical expert opinion is that 70% of these patients would meet the threshold of >10% risk of having a germline P/LP variant.

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

Year 1 estimated uptake(%):

36

Year 2 estimated uptake(%):

36

Year 3 estimated uptake(%):

36

Year 4 estimated uptake(%):

36

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

1872

Optionally, provide details:

Of these approximately 5,199 patients per year, an estimated 36% would take up germline genetic testing, resulting in an estimated 1,872 tests per year.

Uptake rates depend on whether the treating specialist recommends testing and makes a referral, and whether the patient agrees to a referral, attends a genetics service and then has the sample collected. Clinical expert opinion estimates each of these factors as follows:

- 40% referral rate, because referral requires the clinician to identify and accept the utility of testing, and capture the family history and other relevant information. This testing may not be perceived as being of immediate relevance to the cancer diagnosis so clinicians and patients may delay germline testing until their disease reaches metastatic stage.
- 90% patient acceptance of the genetics referral and attendance, given this testing may be perceived as non-urgent. There may also be delays in obtaining an appointment.
- 100% testing uptake following counselling appointment.

Multiplying the 5,199 eligible patients by these estimates informed by clinical expert opinion results in an estimated 1,872 tests per year, equating to an uptake rate of 36%. Australian clinical expert opinion is that this rate appears reasonable, and a fair reflection of expert experience of rates of uptake in other cancers where the result does not influence immediate access to systemic therapies but is mostly for prognostic value for the individual and familial risk.

This 36% uptake rate also appears reasonable in comparison to uptake rates reported in the literature including in a study of US Medicare-funded germline

testing uptake in patients with early prostate cancer meeting NCCN criteria (Korn et al., 2025). Although the US Medicare population is typically older (>65 years), the test purposes are the same and the maximum uptake rate of 14.1% across the study sites, and the average uptake of 2.38%, indicate lower clinician and/or patient uptake for predominantly non-treatment-oriented testing.

This clinical scenario can be contrasted with published studies reporting much higher (often around 70%) uptake rates for germline testing in a mainstreaming setting. Uptake estimates in that setting have low applicability to the testing proposed in this application. With mainstreaming, treating clinicians request genetic testing for immediate access to a PARP inhibitor or surgical decision-making. Patients are more likely to be influenced by their treating doctor to accept given it is to clarify immediate treatment options and their specialist can action the request straight away; genetic services are only involved where the test is positive to address other potential cancer risks and the familial implications. In contrast, germline testing for a predominantly familial predisposition purpose may be a secondary consideration for patients in the midst of a new cancer diagnosis, requires a referral to a genetics service, with potentially lengthy delays in obtaining an appointment – these are all likely contribute to a drop-off in referrals, interest and attendance.

Clinical expert opinion is that there will not be a prevalent pool of patients who would seek germline gene panel testing upon expansion to prostate cancer as proposed in this application, because prevalent patients rarely re-present, unless there is new information or a treatment implication. Prevalent prostate cancer patients are therefore not included in these utilisation estimates.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Once per cancer diagnosis

Optionally, provide details:

Testing once per cancer diagnosis is permitted under the existing MBS item (73296).

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Once per cancer diagnosis

Optionally, provide details:

Testing once per cancer diagnosis is permitted under the existing MBS item (73296).

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:

Human Genetics Society of Australasia

The Royal College of Pathologists of Australasia

Entity who requests the health technology/service:

Australian College of Rural and Remote Medicine Ltd

Royal Australasian College of Surgeons

The Royal Australasian College of Physicians

The Royal Australian College of General Practitioners Limited

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

Allied Health Professions Australia Ltd

Cancer Nurses Society of Australia (Incorporated)

Medical Oncology Group of Australia

The Royal Australian and New Zealand College of Radiologists Limited

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

Inherited Cancers Australia Ltd

The trustee for Prostate Cancer Foundation of Australia

Entity who produce similar products relevant to the proposed service/health technology:

The Royal College of Pathologists of Australasia

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)?

No

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?

Class III

Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?

No

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No

Is the therapeutic good in the process of being considered by the TGA?

No

Please provide details of when you intend to lodge an ARTG inclusion application, or provide a rationale if you do not intend to lodge an ARTG inclusion application:

Not applicable