Prostate Cancer Genetic Testing Criteria

Criteria for Mainstream Medicare Funded Testing

- ❑ Metastatic castration-resistant prostate cancer, tumour testing with reflex to germline if tumour testing inconclusive (MBS Item # 73303) OR
- ❑ Metastatic castration-resistant prostate cancer, for patients where testing of tumour tissue is not clinically feasible (MBS Item # 73304)

If not eligible on above criteria, do not order mainstream genetic testing. Consider referral to the Adult Genetics Unit for the following patients:

Genetic testing will be offered by the Adult Genetics Unit for the following patients:

- Male with prostate cancer and a Manchester score ≥15 or CanRisk score ≥ 10%
- Male with prostate cancer with intraductal/ductal histopathology
- Male with prostate cancer from a population where a founder pathogenic variant of high prevalence exists (i.e. Ashkenazi Jewish)
- Male with prostate cancer and evidence of DNA mismatch repair deficiency by immunohistochemical staining or microsatellite instability studies in tumour tissue
- Male with prostate cancer where a pathogenic variant has been detected on tumour testing

Genetic testing may be offered by the Adult Genetics Unit for the following patients:

- Male with prostate cancer and a family history suggestive of a well characterised familial cancer predisposition syndrome (i.e. premenopausal breast cancer and/or ovarian cancer)

Adult Genetics Unit
Tel: (08) 7074 2697
Fax: (08) 8429 6112
Email: adultgenetics@sa.gov.au

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Prostate Cancer
Mainstream Genetic Testing Checklist

Patient name:
DOB:
UR:
EMR Visit:

(or patient label)

- ❑ Patient's family history taken and documented
- ❑ Provide patient with genetic testing information leaflets
- ❑ Discuss genetic testing with patient (somatic and/or germline)
- ❑ Complete Consent to Genetic Testing form
- ❑ Provide patient with completed SA Pathology request form
  - Copy of histopathology report with lab number
    [for somatic (tumour) testing under MBS item #73303 only]
  - 4mL blood in EDTA tube [both MBS items #73303 & 73304]
  - Cc: Responsible Consultant
  - Cc: Adult Genetics Unit, Royal Adelaide Hospital
- ❑ Place a copy of consent form and this checklist in patient notes (Paper or scan to EMR)
- ❑ Ensure patient follow-up appointment in 3 months to discuss results (date of appointment _ _ / _ _ / _ _)

MO Signature: _____ Date _ _ / _ _ / _ _

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Government of South Australia
SA Health

Consent to Mainstream Cancer Genetic Testing

PATIENT LABEL (if available)

Name of person to be tested		**DOB**
Hospital		**UR**
Sample to be collected	☐ Tumour Tissue (somatic) ☐ Blood (germline) ☐ Other (_____)	

I consent to a genetic test for _____

The gene(s)/gene panel being tested is _____

I understand that:

1. The meaning of the result is based on what is known now. This could change in the future.
2. There are limitations to genetic testing:
   - We do not know all the genes that cause cancers.
   - Genetic variants may be found that cannot be interpreted. These are called variants of unknown significance or VUS. A VUS cannot be used to guide clinical care.
3. Rarely, there may be a technical problem with a genetic test. Further sample(s) may be needed.
4. Test results may have implications for both my treatment/cancer risks AND for my family members.

I am aware that:

1. Samples will be stored after testing for at least the period required by laboratory guidelines.
2. I can change my mind about testing at any point before a report is issued.

I consent to the genetic testing described above.
I have had the chance to ask questions and I am satisfied with the answers I have been given.

I give permission for this genetic test result to be retained confidentially by the Adult Genetics Unit and/or given to health care services looking after other members of my family: ☐ Yes ☐ No

Patient signature:..... Date:.....

If I am unable to receive my genetic test result, I nominate the following individual(s) to receive it on my behalf:

Name and Contact Information:.....

Person obtaining consent:..... Signature: .....

Position and specialty of person obtaining consent:.....

Responsible Consultant (please print in capitals): .....

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PATHOLOGY REQUEST FORM

Genetic Testing (V1 Nov 2022)

SA PATHOLOGY

AFFIX BARCODE HERE

PERSON BEING TESTED *(all samples must include at least two patient identifiers)*

Family Name	Date of Birth	Sex	Ethnicity *(if known)*	Your Ref
Given Name(s)	Medicare No.			Telephone
Address: *(Number, Street)*	Suburb			Postcode

Patient Status at the time of the service or when the specimen was collected:
☐ a private patient in a private hospital or approved day hospital facility
☐ a private patient in a private recognised hospital
☐ a public patient in a recognised hospital
☐ an outpatient public of in a recognised hospital

Medicare Assignment "Section 20A of the Health Insurance Act 1973"
I offer to assign my right to benefits to the approved pathology practitioner who will render the requested pathology service(s) and any eligible pathologist determinable services(s) established as necessary by the practitioner.

Patient Signature & Date _____

Your doctor has recommended that you use SA Pathology. You are free to choose your own pathology provider. However, if your doctor has specified a particular pathologist on clinical grounds a Medicare rebate will only be payable if that pathologist performs the service. You should discuss this with your doctor.

REQUESTING DOCTOR DETAILS

Requesting Clinician:

Responsible Consultant & provider number:

COPY REPORTS TO

Adult Genetics Unit
Royal Adelaide Hospital

CLINICAL SETTING

✕ Diagnostic test	☐ Predictive test	✕ Affected
☐ Carrier Test	☐ Prenatal *(please tick one)*	☐ Unaffected *(please tick one)*

TEST TYPE *(please tick)*

☐ Common mutation screen ✕ Full gene mutation analysis ☐ Known familial mutation(s)

CLINICAL NOTES

This is a <u>Medicare Funded</u> Mainstream Genetic Test (MBS item number 73303)

Consent Obtained and Documented by ordering clinician ☐ YES ☐ NO
MBS Criteria ☐ Metastatic castrate resistant prostate cancer (with tumour tissue available for testing)

TESTS REQUESTED

	EDTA	BUCCAL SWAB	OTHER

Tumour testing at SA Pathology (Molecular Lab, Frome Road) for:

1. **BRCA1 and BRCA2 gene sequencing from tumour block, histopathology report # _____**
   Please include a copy of the pathology report.
   Sample requirements: 10 x 4um dewaxed sections with H&E and tumour % estimate; minimum of 15% tumour required.

If tumour testing is inconclusive, please reflex to germline testing under the same service item
4ml blood in EDTA tube for:

2. **Genetic testing: BRCA1 and BRCA2 gene analysis (sequencing and del/dup studies)**

Doctor's Signature & Date

I have verified FULL NAME, DOB and URN on the sample label and request form verbally with the patient and/or checking the patient's ID band.

Collector's Signature: Specimen Collected: / / : Hrs

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Consumer Information Sheet

Information about Genetic Testing and Cancer

This leaflet was written for people who are thinking about having a genetic test following a cancer diagnosis. This leaflet does not replace a discussion with your managing specialist. If you have any questions or concerns after reading this leaflet, please discuss them with your managing specialist or contact the Adult Genetics Unit.

What are genes?

The human body is made up of millions of cells. Each cell contains DNA. DNA spells out the genetic instructions (genes) the cells need. Some genes tell cells how to grow, divide and work properly. Some genes help keep DNA healthy. Other genes tell worn-out cells when to self-destruct (die). These genes work together to control cell growth.

What is cancer?

The DNA in our cells is continually damaged by the things we are exposed to in our environment, for example UV light or cigarette smoke, and the process of aging. This DNA damage is usually repaired but the repair process is not perfect. This means that damage can build up in our DNA. If a cell has too much DNA damage it normally dies.

Cancer occurs when abnormal cells do not die and start to grow in an uncontrolled way. These abnormal cells can damage or invade the nearby tissues or spread to other parts of the body; this is called a cancer.

What is familial cancer?

Rarely, a person is born with a genetic error (called a variant or mutation) in a cell growth-control gene or a DNA-repair gene. These genetic errors increase the chance of developing a cancer. Usually, the genetic error has been inherited from the person's mother or father. If a genetic error is inherited, other blood relatives may also have an increased chance of developing cancer. This is called familial or hereditary cancer.

What is a genetic test?

A genetic test involves collecting a sample, usually blood. Genetic material (DNA) is extracted from the sample and analysed looking for genetic errors or variants.

- Everyone's genes have differences or variants, this makes us each unique.
- Most genetic variants are harmless and do not cause problems.
- Some genetic variants change how a gene works and **do** cause a problem, like an increased risk of developing a cancer.
- The names for a variant that causes a medical problem include a disease-causing variant, mutation, genetic error or genetic fault.
- Most genetic tests analyse a number of genes that are all known to cause a particular health problem, like an increased risk of cancer. This is called a gene panel test.
- Genetic testing is part of the standard care for patients with certain types of cancer. This genetic testing is not research based or part of a clinical trial.

Endorsed by the SA Cancer Clinical Network

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Consumer Information Sheet

Why have a genetic test?

There are many reasons a doctor may suggest having a genetic test in the setting of a cancer diagnosis, including:

- To help identify the best treatments for some types of cancer.
- To understand the chance of developing another cancer.
- To help family members understand their cancer risks.
- To help family members manage and reduce their cancer risks through early cancer screening tests and other management options.

What are the possible outcomes of a genetic test?

1. No genetic variants are found. This is the most common result and is called a negative or uninformative test. This may mean that the cancer did not have an inherited genetic cause or that an inherited genetic cause cannot be found using the currently testing technology.
2. A genetic variant that explains the cancer is found. This is a less common result. This may influence cancer treatments. It also means that other family members may have the variant and can choose to have their own genetic test.
3. A variant that is not understood is found. This is an uncommon result and is called a variant of unknown significance or VUS. A VUS is neither good nor bad; its meaning is just not known yet. Sometimes more testing can help to understand the meaning of a VUS, or the meaning may become clearer overtime. A VUS cannot be used to influence cancer treatments or offer testing to other relatives.
4. An unexpected variant is found. This is a rare result called an incidental finding. It occurs when a genetic variant that causes a different medical problem is found.

What do I tell my family about genetic testing?

A genetic variant found in you may be relevant for your blood relatives. Genetic variants can occur in both sexes and both sexes can pass a genetic variant down to their children. Telling your family members about a genetic variant can be difficult but may help them understand and manage or reduce their cancer risks.

What about genetic tests and insurance?

A genetic test result is part of a person's health history. In Australia, premiums for private health insurance do **not** depend on health history. Previously, other types of insurance like income protection and life insurance could have been impacted by genetic testing. However, the laws have recently changed and there is now more protection from genetic discrimination by insurance companies. A genetic test should not impact insurance for a person with a cancer.

Where can I get more information or support?

- **Watch Our Video** (scan the QR code or use the link) https://t2m.io/zr5HM4O0
- NSW Centre for Genetics Education https://www.genetics.edu.au/
- Inherited Cancers Australia https://www.inheritedcancers.org.au/
- Adult Genetics Unit, Royal Adelaide Hospital Tel: 08 7074 2697

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Government of South Australia
SA Health

Consumer Information Sheet

Information for people considering genetic testing of their tumour

This leaflet is for people who are thinking about having genetic testing done on their tumour or cancer tissue. It is intended to help people understand and make decisions about this testing. It does not replace a discussion with your managing specialist. If you have any further questions or concerns after reading this leaflet, ask your managing specialist or contact the Adult Genetics Unit.

Genes and Genetic Testing

Genes are the instructions the body uses to grow, develop and work. Genes are written in DNA. Genetic testing involves collecting a sample (blood, hair, tumour tissue), extracting DNA from the sample, and testing the DNA to look for changes in the genes.

Somatic Genetic Changes

A cancer forms when certain genetic changes develop in a cell. The genetic changes allow the cancer cells to grow and spread abnormally. This type of change is called a “somatic genetic change”

- Somatic genetic changes develop as you age; you are not born with these changes.
- Somatic genetic changes are only found in certain cells in the body, like tumour or cancer cells.
- Somatic genetic changes cannot be passed on to children.
- To find somatic genetic changes, testing is done on a sample of tumour or cancer, often from a biopsy or surgery.

Somatic (Tumour) Genetic Testing

This is usually done in consultation with a cancer specialist (i.e. your oncologist), as part of your clinical care, or possibly as part of research or a clinical trial.

- Tumour testing looks for somatic genetic changes in tumour or cancer cells.
- Tumour testing can sometimes help make decisions about the best treatment for a cancer.

Germline Genetic Changes

We are all born with genetic changes that are in all the cells of our body. This type of change is called a “germline genetic change”.

- Germline genetic changes make us each unique.
- Germline genetic changes are usually passed down from a parent, and can be passed down to a child (inherited).

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Consumer Information Sheet

Germline Genetic Changes and Health

- Most germline genetic changes are harmless and do **not** affect your health, they are called normal variants.
- Some germline genetic changes can affect your health or cause a health problem.
- Germline genetic changes that cause a health problem are called disease-causing variants, mutations, or genetic faults/errors.

The Overlap Between Somatic and Germline Changes

- Germline and somatic (tumour) genetic testing sometimes overlap.
- Because germline genetic changes are present in all the cells of the body, they are also present in the cells of a cancer or tumour.
- This means tumour genetic testing can sometimes find germline genetic changes that are important for both the person with cancer **and** for other family members.
- This sort of genetic test result is uncommon and often unexpected.

Emotions, Family and Tumour Genetic Testing

Genetic test results can have emotional impacts for both the person having the test and their family. If you are having any sort of genetic test, think about:

- How you might feel receiving the results, including unexpected results.
- How you will share the results with your family members, if required.
- How to be open with, and supportive and respectful of other family members' responses to a genetic test result.

More Information

If you have questions or worries about a genetic test, you can talk to your specialist. In some situations, your specialist may refer you to a Clinical Genetics Service.

Other places to get information:
Seattle Children's Hospital leaflet (Somatic and Germline Cancer Testing)
www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe2960.pdf
Centre for Genetics Education
http://www.genetics.edu.au/

If you have further questions or concerns, you can speak to your cancer specialist or contact:

The Adult Genetics Unit
Royal Adelaide Hospital (8F401.52, MDP 63)
Port Road, ADELAIDE, SA 5000
Telephone: 08 7074 2697 Fax: 08 8429 6112

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