

# Genomic Testing For Breast Cancer

Genomics is rapidly becoming an integral part of cancer care and its clinical significance continues to increase. Now that next generation sequencing panel testing is available in the NHS for cancer patients, genomics will transition into a central pillar of routine cancer treatment and prevention.

Genome UK has outlined a strategy to embed genomics into routine care over the coming years. Part of this strategy is to ensure we can deliver equitable access to genomic testing in cancer care, ensuring better outcomes for our patients.

## What is Genomic Testing?

When people inherit changes in their genes at birth, they can be at increased risk of developing a cancer in their lifetime. The genes we look at for Breast, Ovarian and Prostate cancers usually work to protect the body from a cancer forming by repairing DNA damage in cells. If these genes have a change in them, they stop working well at repairing DNA damage, genetic mutations accumulate within the cells and put the person at higher risk of getting a cancer in their lifetime.

If a person develops a cancer at a particularly young age, or has multiple incidences of cancer in their family, or the cancer has certain 'traits' (ie 'Triple negative breast cancer'), then it's more likely that this cancer could be caused by a genetic change.

'Mainstreaming Genomics' allows cancer teams to directly order genomic tests for patients who meet standardised criteria set out by the National Genomic Test Directory. The model has been piloted in a number of tumour sites including ovarian and colorectal cancers and has resulted in reduced waiting times, cost savings and improved outcomes for patients. The test for breast cancer sequences and analyses genes listed in the test directory's R208 panel: *BRCA1*, *BRCA2*, *PALB2*, *CHEK2*, *ATM*, *RAD51C* & *RAD51D*. It is usually delivered as a blood test.

## Why are we implementing this?

The NHS Long Term Plan has set the goal that 75% of cancers will be diagnosed at an early stage by 2028. One of the ways this ambition can be reached is through the targeted screening and personalised surveillance plans of those at risk from developing cancers. The insight from genomic testing can impact treatment options, identify risk of recurrence, or indicate that a person's cancer has developed from a hereditary gene, meaning implications for family screening, testing and preventative intervention.

## Genomics mainstreaming clinic set-up: Step-by-step guide

### Mainstreaming

This is a simple blood test that can be ordered by the Breast Cancer Team instead of being outsourced/referred onto the separate clinical genetics team. This speeds up results, reduces the number of healthcare professionals the patient has to interact with and hospital appointments they have to navigate during a stressful time, and ensures they access relevant treatment in a timely manner based on their results.

## Clinic Set Up Requirements

Although this can be added to the Breast CNS's portfolio of activity, to ensure a sustainable model, it is recommended that the service is set-up as a separate clinic to enable tracking of genomics-related activity within the MDT, for clinical governance, budgeting, and auditing.

The initial consultation should be booked as a "new appointment" and can have a duration of 30-45 minutes plus an additional 15 minutes for administrative tasks associated with the appointment. Face-to-face or remote appointments are appropriate. If conducted remotely, a follow-up appointment will need to be booked to allow for signing consent and blood sampling. The first consultation can include:

- Drawing a detailed family pedigree
- Taking informed consent (*unless the patient requires more time to consider*).
- Filling in the genetics request form
- Taking a blood sample (*unless the patient requires more time to consider*).
- Send away for genetic testing.

The subsequent consultation(s) can be booked as follow-ups and can have a duration of 20 minutes plus an additional 10 minutes (30 min total) for administrative tasks associated with the appointment. Face-to-face or virtual/telephone appointments are appropriate.

- Discussing the results with the patient
- Referring the patient to the clinical genetics department for future management

### Step-by-step set up recommendations:

To ensure you have the appropriate infrastructure and processes in place it is recommended that you start by:

1. Familiarise yourself with national policy in relation to Genomics within the NHS:
  - a. [NHS England » NHS Genomic Medicine Service](#)
  - b. [NHS England » Accelerating genomic medicine in the NHS](#)
  - c. [NHS Long Term Plan » The NHS Long Term Plan](#) (see page 76).
2. Ensure you have completed the relevant training to feel confident and competent:
  - a. Educational modules.
  - b. Familiarise with test request forms.
  - c. Familiarise with Record of Discussion form.
  - d. Understand test result pathways: positive, negative and variant of uncertain significance.
  - e. Ensure there is an up-to-date patient information leaflet.
3. Identify a mentor within your team and contact your nearest regional genetic laboratory, including the genetic counselling team for support and guidance.
4. Contact clinical **and** non-clinical managers to establish procedure within the Trust to set-up a new service – you may need to develop a business case.
5. You might need to consider:
  - a. contacting IT (appointment letter description or to obtain clinic-code)

- b. find out if there is a service/clinic request form that needs to be filled in
- c. Decide how you would like to see your patients (phone or face-to-face)
- d. It is recommended that you specify the length, and type of appointments.
- e. Who will manage sample collection and documentation?
- f. Who will collect results from the lab? Consider a ***generic email address*** and provide a second contact.