Protocol for Genomic Testing of Patients with a Diagnosis of Breast Cancer

NHS Greater Manchester Cancer Alliance

Diagnostic MDM

Is the individual with breast cancer under 31 years of age?

Yes → Refer to regional clinical genetics team: St Mary's Hospital MFT (include copy of the histopathology report) → The patient will be seen within 2 weeks

No

Does the individual with breast cancer (including high grade DCIS) meet one of the following criteria?

- Breast cancer <40 years, OR
- HER2 positive breast cancer, age 31-35 years, OR
- Bilateral breast cancer, both < 60 years, OR
- Triple negative breast cancer < 60 years, OR
- Male/assigned male at birth and breast cancer at any age, OR
- High grade non-mucinous ovarian cancer at any age, OR
- Breast cancer <45 years and a first degree relative (FDR) with breast cancer < 45 years, OR
- Ashkenazi Jewish ancestry, OR
- 1 or more grandparents from Westray (Orkney) or Whalsay (Shetland)

Surgical clinic

Yes

Patient is eligible for germline mutation testing

BCN to provide and discuss patient information leaflet and complete consent form[2]

Surgical team to take blood sample and request germline testing using Genetic Testing Referral Form (use clinical indication code **R208**).[3]
For patients aged 31-35 years, with triple positive disease, use clinical indication codes **R208 AND R216**, so that TP53 mutations are also tested for.[3]

No

Manchester Score[1] ≥15

Yes

No

Unusual cancer diagnoses in family:

- 2 or more FDR with ovarian cancer
- sarcoma ≤45yo
- diffuse gastric cancer
- thyroid cancer <40yo
- bowel cancer/polyps <50yo
- endometrial cancer <50yo

GLH

The test result will be available within 6 weeks

POSITIVE germline mutation test

VUS (Variant of Unknown Significance)

NEGATIVE germline mutation test

Yes

No

Referral

Refer to regional clinical genetics team (St Mary's Hospital MFT). If TP53 mutation, do **not** start radiotherapy

Referral to Regional Laboratory Hub in 5 years to allow review of VUS[4]

If the patient is 31-35 years, with a triple positive breast cancer and a negative test, e-mail the clinical genetics team with the patient's full cancer family history for further advice[4]

Refer to regional clinical genetics team (St Mary's Hospital MFT)

No need for onward referral

[1]See Manchester Score document guidance on calculation, [2]See Patient Information and Consent Form, [3]See Genetic Test Referral Form and FAQs for further instructions, [4]See FAQs for further information about 5 year VUS review referral and TP53 testing

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Important notes

Ensuring your referral is appropriate and can be processed by the regional Genomic Laboratory Hub:

- Local breast services can only request germline mutation blood tests for patients with breast cancer. Individuals with no personal history of breast cancer must not be tested via this pathway and must proceed through the standard family history pathway.
- Please follow the algorithm and do not request a germline mutation blood test for patients who do not meet the eligibility criteria.
- If a patient has an unusual family history of cancer, please contact the regional clinical genetics team at St Mary's Hospital (MFT) for advice.
- Please ensure the request form is completed legibly. It is **particularly important to add a legible e-mail address**, so the regional Genomic Laboratory Hub can make timely contact, once the patient's germline mutation test results are available.

Other resources

Please access the resources that have been produced to support this algorithm:

- Please read the Greater Manchester Cancer Breast Cancer Genetic Testing FAQ document for further advice and guidance about germline mutation testing. This document provides useful information about germline mutation testing that will ensure you are meeting the national guidelines and are using this pathway correctly.
- The Greater Manchester consent form, FAOs document, Manchester Score guidance and information videos can be found on the Greater Manchester Cancer website:
- Genetic Testing – Greater Manchester Cancer (gmcancer.org.uk)