National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

SUMMARY OF INHERITED (GERMLINE) BRCA TESTING PROCESS FOR MEDICAL ONCOLOGISTS

Background

Germline BRCA (refers to BRCA 1 & BRCA 2) testing may now be requested by medical oncologists, to allow determination of likely response to the parp inhibitor talazoparib

Eligible patients

- Have a diagnosis of
    - HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy or be considered unsuitable for endocrine-based therapy
- Have no known contraindication to the use of talazoparib therapy
- Patients who have previously undergone full germline BRCA mutation screening* without detection of a pathogenic or likely pathogenic germline variant will not benefit from additional germline analysis

*Predictive BRCA testing is only used to exclude specific familial variants and is not equivalent to full BRCA mutation screening

Patient information and consent

The indication for testing is to determine likely response to talazoparib therapy.
Written consent must be provided for genetic testing and is incorporated in the test request form.
Information materials to assist discussion are available on the NCCP website here[2].

Test request

A test request form is available from the testing laboratory for germline BRCA testing which includes details of sample and transport requirements and incorporates written patient consent.

Results

Results are sent to the ordering consultant by email. Note that this testing is limited to the germline BRCA gene and that a hereditary predisposition to breast cancer can occur in other genes.
Possible outcomes are as follows:

	Results	Talazoparib treatment	Offer genetics referral
1.	Germline BRCA mutation identified	Eligible	Yes
2.	Germline 'variant of uncertain (or unknown) significance' (VUS) identified	Not eligible	Yes
3.	No germline BRCA mutation identified	Not eligible	If a strong family history

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With the patient's agreement, a referral should be made to Cancer Genetics Services, to discuss the implications of the results for the patient and their family.

Cancer Genetics Services
• Cancer Genetics Service, St James's Hospital, Dublin 8 Tel 01 410 3759

1. See https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/sactguidance/brca%20testing%20for%20parp%20inhibitors.html **for test request/consent form, patient information materials & treatment regimen**

2. All public and voluntary hospitals and some private hospital emails are connected securely to healthmail. To check if a particular institution is healthmail connected, please go to: http://www.ehealthireland.ie/Access-to-Information/Healthmail-/ Note that personal email accounts or those related to academic postings are not connected to healthmail and should not be used for return of results.