# Eligibility for Medicare funded testing using item 73295 and item 73296. Who is eligible and when should you test?

The executive summary is:

- use item 73296 **at diagnosis** if the patient meets the 10% likelihood criteria (includes **all triple negative** breast cancer, breast cancer ≤ age 40, male breast cancer or if there is Ashkenazi heritage)
- use item 73295 **after surgery** in ER positive HER2 negative patients who have **4 or more positive lymph nodes** who will be having adjuvant chemotherapy and who would be **considered suitable for Olaparib** if BRCA positive
- use item 73295 in ER positive HER2 negative patients **post neoadjuvant chemotherapy and after surgery** if there is **residual disease** and **considered suitable for Olaparib** if BRCA positive
- use item 73295 in ER positive HER2 negative patients during neoadjuvant chemotherapy and before surgery **after discussion and agreement at an MDT** that the patient has high risk disease (at least grade 3 or 1 node or >2cm) AND would be suitable for Olaparib AND is likely to have residual disease post chemotherapy AND it is unlikely that a result would be available in a timely manner (12 weeks) if testing were to be delayed until post surgery.
- **Do NOT use item 73295** if the patient is not suitable for either chemotherapy or Olaparib.

The best way to think about these item numbers is that **item 73296** relates to the **diagnosis** and **item 73295** relates to **treatment**.

**Item 73296.**

This item number was introduced in November 2017. At that time, a 10% likelihood of a BRCA1 or BRCA2 gene mutation was needed to meet testing criteria, calculated using a quantitative algorithm. That is, it was a personal likelihood.

In November 2023, the criteria were updated. Key changes were that a 'quantitative algorithm' was no longer required. Instead, the 10% risk was calculated using clinical and family history criteria. The following groups have a clinical risk of ≥10%, according to research. **Note: this is independent of family history and the patient's current age:**

- Diagnosis of invasive breast cancer **at or before age 40**
- **Metastatic** breast cancer at any age
- **Triple negative** breast cancer at any age
- **Ashkenazi heritage and diagnosis of breast cancer**
- **Male breast cancer** at any age

(See Table of who has >10% clinical likelihood for the list and references). If the link doesn't open, you'll find it on the eviQ website (www.eviQ.org.au) under the Cancer Genetics >> Adult >> Genetic Testing for Heritable Pathogenic Variants >> BRCA1, BRCA2 and PALB2 >>Probability of a heritable pathogenic variant).

In addition, the 10% criteria were expanded beyond just BRCA1 and BRCA2 to include other genes "associated with breast, ovarian, fallopian tube or primary peritoneal cancer". That is, while you can still use the Manchester score and bulk bill testing under item 73296 if the patient scores more than 15 points, you can also use a more sophisticated model such as CanRisk (www.CanRisk.org ). CanRisk includes the risk prediction model BOADICEA. BOADICEA takes into account the size and blend of the family, the age at which the cancers occurred and the age at which people died. The estimate includes moderate and high risk genes: ATM, BARD1, BRCA1, BRCA2, BRIP1, CHEK2, PALB2, RAD51C and RAD51D. This model is very useful for estimating the residual likelihood in a patient who may have had testing (self-funded or via a public familial cancer clinic) prior to November 2017, especially if only BRCA1 and BRCA2 were tested.

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**Item 73295**

This item was introduced in February 2017 to determine eligibility relating to BRCA status for access to Olaparib, initially for use in ovarian cancer. The item, along with the PBS eligibility was updated on July 1, 2024 to include Triple negative breast cancer as well as hormone receptor positive, HER2-negative, early breast cancer with one or more high-risk characteristics.

The actual wording of the item is quite vague. As a result, I emailed AskMBS for clarification in July 2024 and asked a colleague to do same more recently (September 2024). The answers were quite clear – this is a "companion" test and if the patient will not meet the PBS criteria, the test should not be billed under item 73295. The second answer also came with a fairly strongly worded reminder that it is the ordering doctor's responsibility to ensure that the patient meets the criteria (and that there are consequences for over billing).

That means **you can't test ALL patients just because they are ER positive and HER2 negative, even if they have a high risk feature** (grade 3, one node or >20mm). For example, it would be difficult to justify the use of item 73295 in the following patients with ER positive, HER2 negative breast cancer, as they are unlikely to receive chemotherapy:

- Frail 80 year old one node involved with multiple comorbidities
- 50 year old with grade 3 cancer that was a 5mm tumour, no nodes involved and no LVI or other concerning features.
- 55 year old with 25mm tumour that was grade 1, strongly ER and PR positive, node negative low Ki67 and no LVI or other concerning features.

**If surgery is done first**: you know whether they will meet the PBS criteria (4 or more positive nodes) and you have the weeks of recovery and the weeks chemotherapy to get your genetic testing done.

**If neoadjuvant chemo is given**: it is usually because of triple negative disease, large tumours or nodal involvement. Triple negative breast cancer can be tested under item 73296 at diagnosis. In the other cases, it would be reasonable to use what you know from the biopsy (grade 3, ER+/HER2-) and imaging (size, nodes) to make an assessment, ideally via an MDT, as to whether this particular patient should be considered for PBS Olaparib if there was residual disease post neoadjuvant chemotherapy. Then, if you would not be able to obtain the genetic test result within 12 weeks of surgery, you may be able to justify ordering genetic testing under item 73295 without already having a pathology report to confirm that your patient meets the PBS criteria.

Lastly, **please don't "waste" the patient's rebate** by only ordering BRCA1 and BRCA2. Please use a full breast cancer risk panel (the absolute minimum should be ATM, BRCA1, BRCA2, CHEK2, PALB2, RAD51C and RAD51D. Most panels include BARD1, BRIP1, CDH1 and the Lynch syndrome genes (MLH1, MSH2, MSH6 and PMS2) as well as PTEN, STK11 and TP53). Also don't forget that patients may elect to self-funded their genetic testing (cost $450 to $575 for a breast and ovarian cancer risk panel of 18 or 20 genes with the laboratories I use).

A great deal of care was taken in the production of this document. However, I am not a Medicare specialist and this is my interpretation only. Use AskMBS if you have your own questions.

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