

Item 6.3 Application 1230: HER2 ISH testing for access to trastuzumab for NEOADJUVANT breast cancer.

Decision: MSAC advised the Minister that it supports amending the current item descriptor for MBS item 73332, which currently states:

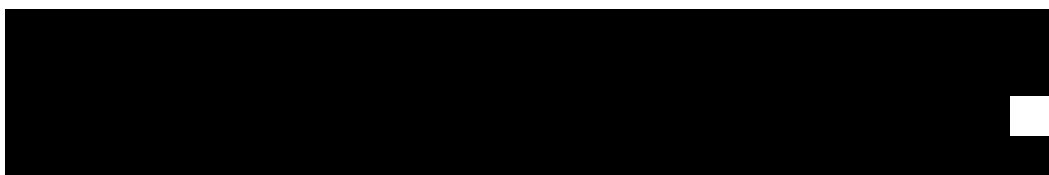
MBS Item 73332 SERVICES	Category 6 – PATHOLOGY
An in situ hybridization (ISH) test of tumour tissue from a patient with breast cancer <u>(other than in the neoadjuvant setting)</u> requested by, or on behalf of, a specialist or consultant physician to determine if the requirements relating to human epidermal growth factor receptor 2 (HER2) gene mutation status for access to trastuzumab under the Pharmaceutical Benefits Scheme (PBS) or the Herceptin Program are fulfilled.	
Fee: \$317.50 Benefit: 75% = \$238.15 85% = \$269.90.	

by removing “(other than in the neoadjuvant setting)”, so that the item descriptor would read as follows:

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In addition to this, MSAC supported a further modification to this item, to enable this test to become a pathologist-determinable service, noting that this would require further investigation by the Department.

Consideration: MSAC noted that HER2 in situ hybridisation (ISH) testing of tumour tissue from a patient with breast cancer for HER2 was added to the MBS to help determine eligibility for government-subsidised trastuzumab (Herceptin®) on 1 May 2012. MSAC additionally noted that the Government has reimbursed trastuzumab (on the Herceptin program) since 2001 for HER2 positive metastatic breast cancer and on the Pharmaceutical Benefits Scheme (PBS) since 2006 for treatment of HER2 positive early breast cancer in the adjuvant setting.



MSAC further noted that at, its July 2012 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended PBS listing for neoadjuvant trastuzumab in these patients. [REDACTED]

MSAC noted that, in the neoadjuvant setting, testing is on a core biopsy sample taken from the patient, rather than on a surgical resected specimen. False negatives are more likely when testing core biopsies than surgical resections, so MSAC expected some repeat testing of patients initially testing negative once the surgically resected specimen becomes available.

Economic: MSAC noted that the present fee (as at 1 May 2012 amended Medicare Benefits Schedule) for ISH testing of HER2 is \$317.50, and considered that this would also be suitable for the extended use.

MSAC considered that the additional use of ISH testing for HER2 as a result of the extended listing would be small. The sponsor's original estimate of 725 in the first year of listing is no longer relevant because it included patients with stage II disease. The submission's estimate of zero additional tests for patients with stage III disease is based on the argument that all such patients are already receiving testing on core biopsy samples and re-testing if negative because all have subsidised access to trastuzumab via the Herceptin Program and subsidised access to testing via the MBS.

However, this is inconsistent with the view of the Medical Oncology Group of Australia that some patients are currently missing out. Stage III disease represents 12.6% of the 2006 and 2007 incidence of breast cancer from the Victorian Cancer Registry, and 85% of these are expected to test negative for HER2. When these percentages are applied to the submission's projected overall incidence of 14,288 breast cancer patients, together with the estimate from the submission that 80% of these patients will have their disease resected (i.e., excluding borderline inoperable patients), the maximum number of additional tests in the first year of listing is 1189. The true estimate will fall within this range of zero to 1189.

MSAC's Advice to the Minister:

After considering the strength of the available evidence in relation to the safety, effectiveness and cost effectiveness, MSAC advised the Minister that it supported the extension of the MBS listing of in situ hybridisation (ISH) testing of tumour tissue from a patient with breast cancer to include its use to support the PBAC-recommended extension of the PBS listing of trastuzumab to include trastuzumab use in the neoadjuvant setting.