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CLIENT NOTICE

Notification Date: 20 January 2026

Technical Notice for Her2 by Immunohistochemistry Reporting in Breast Carcinoma

South Bend Medical Foundation has recently updated the reporting terminology for Her2 by Immunohistochemistry for invasive primary and metastatic breast carcinoma cases to reflect updated terminology provided by the CAP regarding the DESTINY-Breast 04 and 06 trials. Cases that are negative for Hercept IHC are now being split into 3 categories as below regarding the amount of membrane staining as recommended by CAP, with an included educational comment.

***Please note that negative cases prior to the October 2025 change that were not reported using the below terminology did not distinguish between cases with no membrane staining versus cases with membrane staining in less than or equal to 10% of tumor cells (HER2 ultralow). Please contact SBMF if there is a case with the previous reporting terminology that you would like to have re-evaluated using the updated reporting terminology.

NEGATIVE (Score 0/absent membrane staining)

No membrane staining detected

NEGATIVE (Score 0+/with membrane staining)

Membrane staining that is incomplete and is faint / barely perceptible and in less than or equal to 10% of tumor cells

NEGATIVE (Score 1+)

Incomplete membrane staining that is faint / barely perceptible and in greater than 10% of tumor cells

In the DESTINY-Breast 04 and 06 trials, "HER2 low" was considered IHC Score 1+ or 2+ / ISH negative, and "HER2 ultralow" was HER2 IHC Score of 0 (pattern 0+) with membrane staining that is incomplete and faint / barely perceptible in less than or equal to 10% of tumor cells. Breast cancers with these staining patterns may be eligible for treatment with trastuzumab-deruxtecan in the metastatic setting (but those with no staining, IHC 0, are currently excluded).

For positive cases (Score 3+), clustered heterogeneity will now also be reported per the CAP guidelines if there are discrete, separate populations of tumor with different staining patterns, where at least one population of 3+ staining comprises greater than 10% of the tumor cells.

If you have further questions, please contact Dr. Gerig, Chief Medical Officer, at 574-204-4360.

SOUTH BEND MEDICAL FOUNDATION

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