

NCCN Guidelines for Breast Cancer V.1.2019 – Follow-Up on 03/11/19

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	ABSTAIN	ABSENT
<p>BINV-18 External submission from Genentech, Inc. based on the Food and Drug Administration (FDA) approval of companion diagnostic to aid in identifying triple-negative breast cancer (TNBC) patients eligible for treatment with atezolizumab plus albumin-bound paclitaxel.</p> <p>Request including determination of tumor PD-L1 status to ensue appropriate patient selection for treatment with atezolizumab plus albumin-bound paclitaxel.</p>	<p>Based upon review of the data in the noted references and the FDA approval, the panel consensus was to include the following bullet in the workup for recurrent/stage IV breast cancer.</p> <p>“For triple negative breast cancer (TNBC), assess PD-L1 biomarker status on tumor-infiltrating immune cells to identify patients most likely to benefit from atezolizumab plus albumin-bound paclitaxel.”</p> <p>See Submission for References.</p>	21	0	1	7
<p>BINV-Q External submission from Genentech, Inc. based on FDA approval of atezolizumab in combination with albumin-bound paclitaxel for the treatment of patients with PD-L1-positive metastatic TNBC.</p> <p>Request inclusion of atezolizumab + nab-paclitaxel (option for patients with PD-L1-positive TNBC as an option under HER2-negative preferred regimens).</p>	<p>Based upon review of the data in the noted references and the FDA approval, the panel consensus was to add atezolizumab + albumin-bound paclitaxel (option for patients with PD-L1-positive TNBC) to the list of HER2-negative preferred regimens with the following footnote: “Patients with TNBC, assess PD-L1 biomarker status on tumor-infiltrating immune cells to identify patients most likely to benefit from atezolizumab plus albumin-bound paclitaxel.”</p> <p>See Submission for References.</p>	21	0	1	7
<p>BINV-L, BINV-P, and BINV-Q External submission from Genentech, Inc. based on FDA approval of trastuzumab and hyaluronidase-oysk</p>	<p>Based upon review of the data in the noted references and the FDA approval, the panel consensus was to add the following footnote on pages that include trastuzumab: Trastuzumab and hyaluronidase-oysk injection for subcutaneous use may be substituted for trastuzumab. It has different dosage and administration instructions compared to intravenous trastuzumab. Do not</p>	19	0	3	7

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<p>subcutaneous (sc) injection in HER2-positive adjuvant and metastatic breast cancer.</p> <p>Request to consider FDA approval of trastuzumab and hyaluronidase-oysk sc injection in HER2-positive adjuvant and metastatic breast cancer and the supporting pivotal trial publications for inclusion into the guidelines.</p>	<p>substitute trastuzumab and hyaluronidase-oysk for or with ado-trastuzumab emtansine.</p> <p>See Submission for References.</p>				
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