In response to the FDA approval of neratinib + capecitabine for recurrent or stage IV (M1) HER2-positive breast cancer, the panel reassessed the inclusion of neratinib + capecitabine as a category 2B, other recommended regimen for this indication.

External request: Submission from Puma Biotechnology, Inc., to consider revising neratinib + capecitabine to a category 2A option for recurrent or stage IV (M1) HER2-positive breast cancer based on the FDA approval.

The panel consensus supported the continued listing of neratinib + capecitabine under "other recommended regimens" for recurrent or stage IV (M1) HER2-positive breast cancer with a change in category from a category 2B to a category 2A.