<table>
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<th>Guideline Page and Request</th>
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| BINV-5, BINV-13, and BINV-15, External request: Submission from Puma Biotechnology, Inc. Request inclusion of neratinib in the treatment algorithm (as opposed to the footnote) as extended adjuvant treatment following treatment with adjuvant trastuzumab-based therapy per FDA indication in the following:  
  - Systemic Adjuvant Treatment – Hormone Receptor-Positive (HR+) – HER2-Positive Disease (BINV-5)  
  - Preoperative Systemic Therapy: Adjuvant Therapy (BINV-13)  
  - Preoperative Systemic Therapy for Inoperable or Locally Advanced Breast Cancer (Non-Inflammatory) (BINV-15).  
  - Preferred and Other Adjuvant Regimens to follow trastuzumab-based regimens (BINV-K; Page 1 and pages 4,5). | Based on a review of data and discussion, the panel consensus was to not make changes to the current recommendations. See Submission for references. | 0 12 0 16 |
| BINV-N External request: Submission from Novartis Pharmaceuticals Corporation. Request for the Panel to consider ribociclib in combination with NSA/I/tamoxifen with ovarian suppression or ablation as the preferred first-line treatment option for premenopausal HR+/HER2-negative advanced breast cancer in those with no prior endocrine therapy within 1 year. | Based on a review of data and discussion, the panel consensus supported the inclusion of ribociclib in combination with tamoxifen as a preferred option for first-line therapy with ovarian suppression or ablation for premenopausal patients with HR+, HER2- metastatic breast cancer. This is a category 1 recommendation. See Submission for References. | 12 0 0 16 |
| BINV-O Internal request to remove the following chemotherapy regimens for recurrent or stage IV (M1) disease:  
  - CAF/FAC (cyclophosphamide/doxorubicin/fluorouracil)  
  - FEC (fluorouracil/epirubicin/cyclophosphamide) | The panel consensus supported the removal of the noted combination regimens as treatment options for patients with recurrent or stage IV (M1) disease. | 12 0 0 16 |