External request:
Submission from Novartis (05/24/19) to consider data to support the use of alpelisib in combination with fulvestrant for the treatment of hormone receptor-positive (HR+)/human epidermal growth factor receptor-2-negative (HER2-negative) advanced or metastatic breast cancer with a PIK3CA mutation following progression on or after an endocrine-based regimen.

Based on the data in the noted reference and discussion, the panel consensus was to include fulvestrant + alpelisib (for PIK3CA mutated tumors) as a preferred systemic therapy option for HR-positive/HER2-negative recurrent or stage IV (M1) breast cancer following progression on or after an endocrine-based regimen.

The panel consensus supported a category 1 recommendation.

Reference: