RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Ibrance is a prescription medicine that is used along with aromatase inhibitor or fulvestrant (Faslodex) for the treatment of males and postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as the first hormone-based therapy for their metastatic disease.(1)

Regulatory Status
FDA-approved indication: Ibrance is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: (1)
- letrozole as initial endocrine based therapy in postmenopausal women, or
- fulvestrant in women with disease progression following endocrine therapy

Off Label Use: (2)
The National Comprehensive Cancer Network (NCCN) recommend the use of Ibrance in males with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer and for well-differentiated/ dedifferentiated liposarcoma (WD-DDLS) per the NCCN guidelines. Also Ibrance can be used with fulvestrant (Faslodex) for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as seen in the PALOMA3 study which showed that palbociclib with fulvestrant resulted in longer progression-free survival and a relatively higher quality of life than fulvestrant alone in patients with advanced hormone-receptor–positive breast cancer that had progressed during prior endocrine therapy.

The safety and effectiveness of Ibrance have not been established in pediatric patients (1).

Summary
Ibrance is a prescription medicine that is used along with aromatase inhibitor or fulvestrant (Faslodex) for the treatment of males and postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as the first hormone-based therapy for their metastatic disease (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Ibrance
while maintaining optimal therapeutic outcomes.

References