

MBC Clinical Practice Guidelines Update

Selected updates relevant to HR+, HER2- MBC: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer

Updates from Version 8.2026 (October 8, 2026)

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These guidelines describe some uses of medical products that are not approved by the FDA, and the safety and effectiveness of any unapproved use(s) have not been established.

For more information, please see full US prescribing information linked on [Slide 17](#).

HR+, HER2- MBC Treatment

NCCN Guidelines® in Breast Cancer

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General Considerations for Therapy Selection for HR+ Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease

Ovarian function assessment: (see [Slide 13](#))

- Assess serum estradiol prior to therapy initiation.
- If premenopausal or perimenopausal,
 - Ovarian suppression/ablation/resection plus anti-estrogen therapy is more effective than endocrine therapy alone.
 - Start ovarian function suppression (OFS) with or prior to initiation of endocrine therapy

Choice of endocrine therapy:

- Depends on prior adjuvant endocrine agent and disease-free interval (see [Slide 5](#))
- Must balance benefit with additional side effects.

Endocrine + CDK4/6 inhibitor therapy:

- Endocrine therapy + CDK4/6 inhibitor is preferred over chemotherapy, even for extensive visceral involvement
- Chemotherapy recommended only if true visceral crisis
- If frail or extensive comorbidity, consider single agent aromatase inhibitor (AI).

Management of toxicity (particularly early in initiation of these therapies) is essential.

Duration of initial response to endocrine therapy can guide likelihood of benefit of continued endocrine therapy as later line therapy.

Note: All NCCN recommendations are category 2A unless otherwise indicated. For definitions of NCCN categories of evidence, see [Slide 15](#).

NCCN recognizes the importance of clinical trials and encourages participation when applicable and available. Trials should be designed to maximize inclusiveness and broad representative enrollment.

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Suggested Systemic Therapy for ER+ and/or PR+ Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease^a

FIRST-LINE THERAPY OPTIONS

Preferred Regimens

- Aromatase inhibitor + CDK4/6 inhibitor^b
 - Aromatase inhibitor + ribociclib (NCCN Category 1)^c
 - Aromatase inhibitor + abemaciclib
 - Aromatase inhibitor + palbociclib

If disease progression on adjuvant endocrine therapy or relapse within 12 months of adjuvant endocrine therapy completion, consider:

- For tumors with *PIK3CA* activating mutations:
 - Fulvestrant/Inavolisib/Palbociclib, see [Slide 8](#)
- Fulvestrant^d + CDK4/6 inhibitor^b
 - Fulvestrant + ribociclib (NCCN Category 1)^e
 - Fulvestrant + abemaciclib (NCCN Category 1)^e
 - Fulvestrant + palbociclib

Useful in Certain Circumstances

- If *ESR1* mutation is detected during AI + CDK4/6 inhibitor therapy (NCCN Category 2B):^f
 - Consider switching to camizestrant + continuing the same CDK4/6 inhibitor (NCCN Category 2B), see [Slide 9](#)

^a HER2- and postmenopausal or premenopausal receiving ovarian ablation or suppression. Baseline assessment of bone density recommended for patients receiving an aromatase inhibitor who are at risk of osteoporosis (eg, age >65, family history, chronic steroids).

^b There is controversy on the choice of CDK4/6 inhibitor as there are no randomized comparisons between the agents and there are some differences in the study populations in the phase 3 randomized studies.

^c In phase 3 randomized controlled trials, ribociclib + endocrine therapy have shown OS benefit in the first-line setting.

^d Consider for disease progression on adjuvant endocrine therapy or with early disease relapse within 12 months of adjuvant endocrine therapy completion.

^e In phase 3 randomized controlled trials, fulvestrant + abemaciclib or ribociclib has shown OS benefit in the first-line setting.

^f If *ESR1* mutation is detected (category 2B) in a patient on an AI + CDK4/6 inhibitor for at least 6 months, in the absence of radiologic progression, could consider switching to camizestrant and continue the same CDK4/6 inhibitor (category 2B)

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Suggested Systemic Therapy for ER+ and/or PR+ Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease^a

SECOND- AND/OR SUBSEQUENT-LINE THERAPY OPTIONS	
Preferred Regimens	Useful in Certain Circumstances
- Fulvestrant + CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) if CDK4/6 inhibitor not previously used (NCCN Category 1)^{b,c} - For tumors without a <i>PIK3CA</i> mutation following progression on or after treatment with at least one line of endocrine therapy: Fulvestrant/Gedatolisib ± Palbociclib (NCCN Category 1) - For tumors with <i>PIK3CA</i> or <i>AKT1</i> activating mutations or <i>PTEN</i> inactivating mutations and genomic changes (eg, deletions), see Slide 8^d - Everolimus + endocrine therapy (exemestane, fulvestrant, tamoxifen)^{e,f}	- Megestrol acetate - Estradiol - Abemaciclib^g - Targeted therapy, see Slide 10, and emerging biomarker options, see Slide 11

^a HER2- and postmenopausal or premenopausal receiving ovarian ablation or suppression. Baseline assessment of bone density recommended for patients receiving an aromatase inhibitor who are at risk of osteoporosis (eg, age >65, family history, chronic steroids).

^b In phase 3 randomized controlled trials, fulvestrant in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, and ribociclib) has shown OS benefit in the second-line setting.

^c If there is disease progression while on palbociclib, there are limited phase II data to support the use of ribociclib in the second-line setting.

^d If there is progression while on a PI3K inhibitor, there are limited data to support another line of therapy with a PI3K-pathway inhibitor-containing regimen.

^e If there is disease progression while on an everolimus-containing regimen, there are no data to support an additional line of therapy with another everolimus regimen.

^f A combination of everolimus with exemestane can be considered for patients who meet the eligibility criteria for BOLERO-2 (progressed within 12 mo or on non-steroidal aromatase inhibitor).

^g Indicated after progression on prior endocrine therapy and prior chemotherapy in the metastatic setting.

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Suggested Systemic Therapy for ER+ and/or PR+ Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease^a

OTHER RECOMMENDED REGIMENS FOR FIRST AND/OR SUBSEQUENT LINES OF THERAPY

- For HER2-negative disease and *ESR1* mutated tumors and after a prior line of endocrine therapy ± CDK4/6 inhibitor therapy (in adjuvant or metastatic setting), see [Slide 9](#) for options.
- Fulvestrant + aromatase inhibitor (anastrozole, letrozole) (NCCN Category 1)^b
- Fulvestrant
- Anastrozole
- Letrozole
- Tamoxifen
- Exemestane

^a HER2- and postmenopausal or premenopausal receiving ovarian ablation or suppression. Baseline assessment of bone density recommended for patients receiving an aromatase inhibitor who are at risk of osteoporosis (eg, age >65, family history, chronic steroids).

^b A single study (S0226) in patients with HR-positive breast cancer and no prior chemotherapy, biologic therapy, or endocrine therapy for metastatic disease demonstrated that the addition of anastrozole to fulvestrant resulted in prolongation of time to progression and OS. Subset analysis suggested that patients without prior adjuvant tamoxifen and >10 years since diagnosis experienced the greatest benefit. Two studies with similar design (FACT and SOFEA) demonstrated no advantage in time to progression with the addition of fulvestrant to anastrozole.

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Targeted Therapies and Associated Biomarker Testing for Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease (1 of 3)

BIOMARKERS ASSOCIATED WITH FDA-APPROVED THERAPIES					
Breast Cancer Subtype	Biomarker	Detection ^a	FDA-Approved Agents	NCCN Category of Evidence	NCCN Category of Preference
HR-positive/ HER2-negative	<i>PIK3CA</i> activating mutation	NGS, PCR	Inavolisib + palbociclib + fulvestrant ^c	Category 1	Preferred
HR-positive/ HER2-negative	<i>PIK3CA</i> activating mutation	NGS, PCR	Alpelisib + fulvestrant	Category 1	Preferred
HR-positive/ HER2-negative	PIK3CA or AKT1 activating mutations or PTEN ^b inactivating mutations and genomic changes (eg, deletions)	NGS, PCR	Capivasertib + fulvestrant ^d	Category 1	Preferred

^a Some plasma-based ctDNA assays include a measure of TF, which can aid in identification of low ctDNA content. Samples with low TF, especially <1% or negative, should be interpreted with caution. Tests have varying sensitivities at low TF. Additional sampling from current tumor sample or future plasma can be considered.

^b Tissue biopsy is preferred to ctDNA at detecting homozygous copy loss of *PTEN* or TMB.

^c Consider for disease progression on adjuvant endocrine therapy or with early disease relapse within 12 months of adjuvant endocrine therapy completion.

^d In adult patients with *PIK3CA* or *AKT1* activating mutations, or for *PTEN* inactivating mutations and genomic changes (eg, deletion) after disease progression or recurrence after a prior line of endocrine therapy + CDK4/6 inhibitor.

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Targeted Therapies and Associated Biomarker Testing for Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease (2 of 3)

BIOMARKERS ASSOCIATED WITH FDA-APPROVED THERAPIES					
Breast Cancer Subtype	Biomarker	Detection ^a	FDA-Approved Agents	NCCN Category of Evidence	NCCN Category of Preference
HR-positive/ HER2-negative	<i>ESR1</i> mutation ^b	NGS, PCR	Elacestrant ^c	Category 2A	Other recommended
			Imlunestrant ^d		
			Vepdegestrant ^e		
			Imlunestrant + Abemaciclib ^f		
HR-positive/ HER2-negative	<i>ESR1</i> mutation detected during AI + CDK4/6 inhibitor therapy ^g	NGS, PCR ^g	Camizestrant + continue the same CDK4/6 inhibitor ^g	Category 2B	Useful in Certain Circumstances

Highlighted content updated in Version 8.2026

^a Some plasma-based ctDNA assays include a measure of tumor fraction (TF), which can aid in identification of low ctDNA content. Samples with low TF, especially <1% or negative, should be interpreted with caution. Tests have varying sensitivities at low TF. Additional sampling from current tumor sample or future plasma can be considered.

^b Assess for *ESR1* mutations at progression following prior lines of endocrine therapy (ctDNA preferred). If *ESR1* negative and TF is low, consider reflex testing with tissue-based NGS assay.

^c For disease progression during or after a prior line of aromatase inhibitor plus CDK4/6 inhibitor therapy in the adjuvant or metastatic setting.

^d For disease progression during or after a prior line of aromatase inhibitor with or without CDK4/6 inhibitor therapy in the adjuvant or metastatic setting.

^e For disease progression after at least one line of endocrine therapy + CDK4/6 inhibitor in the metastatic setting.

^f The combination of imlunestrant + abemaciclib has been approved in those with *ESR1* mutations. The EMBER-3 trial (Jhaveri KL, et al. N Engl J Med 2025;392:1189-1202) included patients with and without *ESR1* mutations and also those who had not received a prior CDK4/6 inhibitor. Study compared the combination of imlunestrant + abemaciclib to imlunestrant alone; but did not compare to standard treatment containing endocrine therapy plus CDK4/6 inhibitor.

^g If *ESR1* mutation is detected (category 2B) in a patient on an AI + CDK4/6 inhibitor for at least 6 months, in the absence of radiologic progression, could consider switching to camizestrant and continue the same CDK4/6 inhibitor (category 2B) (see [Slide 5](#))

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Targeted Therapies and Associated Biomarker Testing for Recurrent Unresectable (Local or Regional) or Stage IV (M1) Disease (3 of 3)

BIOMARKERS ASSOCIATED WITH FDA-APPROVED THERAPIES					
Breast Cancer Subtype	Biomarker	Detection ^a	FDA-Approved Agents	NCCN Category of Evidence	NCCN Category of Preference
Any	Germline <i>BRCA1</i> or <i>BRCA2</i> PVs	Germline sequencing	Olaparib Talazoparib	Category 1	Preferred
Any	Germline <i>PALB2</i> PVs	Germline sequencing	Olaparib ^c	Category 2A	Other recommended
Any	<i>NTRK1/2/3</i> gene fusion	FISH, NGS, PCR	Larotrectinib Entrectinib Repotrectinib	Category 2A	Useful in certain circumstances
Any	MSI-H/dMMR	IHC, NGS, PCR	Pembrolizumab Dostarlimab-gxly	Category 2A	
Any	TMB-H ^b (≥10 mut/Mb)	NGS	Pembrolizumab	Category 2A	
Any	<i>RET</i> gene fusion	NGS	Selpercatinib	Category 2A	

^a Some plasma-based ctDNA assays include a measure of TF, which can aid in identification of low ctDNA content. Samples with low TF, especially <1% or negative, should be interpreted with caution. Tests have varying sensitivities at low TF. Additional sampling from current tumor sample or future plasma can be considered.

^b Tissue biopsy is preferred to ctDNA at detecting homozygous copy loss of *PTEN* or TMB.

^c This regimen is not FDA approved for this indication. Tung NM, Robson ME, Venz S, et al. TBCRC 048: phase II study of olaparib for metastatic breast cancer and mutations in homologous recombination-related genes. J Clin Oncol 2020;38:4274-4282.

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Emerging Biomarkers and Novel Therapies for Patients with Stage IV (M1) Disease

Breast Cancer Subtype	Emerging Biomarker	Detection ^a	Potential Targeted Therapy ^b	NCCN Category of Evidence	NCCN Category of Preference
ER+/HER2- ER-/HER2-	<i>HER2 (ERBB2)</i> activating Mutations	NGS, PCR	Fulvestrant/Neratinib + Trastuzumab	Category 2A	Useful in certain circumstances • If ER+/HER2-, in patients who have already received CDK4/6 inhibitor therapy.
			Tucatinib + Trastuzumab ± Fulvestrant		
			Neratinib ± Fulvestrant	Category 2B	
Any	Somatic <i>BRCA1/2</i> mutations	NGS	Olaparib	Category 2B	Useful in certain circumstances
Any	<i>FGFR1-3</i> fusion/ mutation	NGS	Erdafitinib	Category 2B	Useful in certain circumstances

^a Some plasma-based ctDNA assays include a measure of TF, which can aid in identification of low ctDNA content. Samples with low TF, especially <1% or negative, should be interpreted with caution. Tests have varying sensitivities at low TF. Additional sampling from current tumor sample or future plasma can be considered.

^b At the present time, the data for the emerging biomarkers for the potential targeted agents noted in the table are promising but limited.

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Appendix

Definition of Menopause

Definition of Menopause

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- Menopause is the permanent cessation of menses and includes a profound and permanent decrease in ovarian estrogen synthesis.
- Determination of menopausal status may be required to guide selection of endocrine therapy for breast cancer.
- Menopause is usually a clinical diagnosis made after ≥ 12 months of amenorrhea. Natural menopause is experienced between ages 42–58 years.
- Breast cancer treatments may affect ovarian function and menses.
 - In those who are premenopausal at the beginning of chemotherapy and who develop chemotherapy-induced amenorrhea, ovarian function may still be intact despite amenorrhea or may resume over time. The likelihood of ovarian function resuming after chemotherapy is higher among those aged < 40 years.
 - Tamoxifen may cause amenorrhea without inducing menopause in premenopausal individuals.
 - Ovarian function suppression induces amenorrhea and reduces ovarian estrogen synthesis without causing permanent menopause.
- Twelve months of amenorrhea alone is insufficient to diagnose menopause with chemotherapy-induced amenorrhea or with tamoxifen $\pm$ ovarian suppression. FSH and estradiol levels are used to support the diagnosis of menopause; however, clear criteria to guide interpretation of FSH and estradiol in this population is lacking.
 - Tamoxifen may alter FSH levels, limiting its utility in determination of menopausal status.
 - FSH and estradiol should be repeated serially to ensure menopausal status in patients with breast cancer with chemotherapy-induced amenorrhea.
- Evidence-based criteria for the diagnosis of menopause in patients with breast cancer are lacking. Clinical trials in breast cancer have utilized a variety of definitions of menopause. Reasonable criteria for determining menopause in patients with breast cancer include any of the following:
 - Prior bilateral oophorectomy
 - Age ≥ 60 years
 - Age < 60 with amenorrhea for ≥ 12 months in the absence of prior chemotherapy, receipt of tamoxifen, toremifene, or ovarian suppression and estradiol and FSH in the postmenopausal range
 - Age < 60 years: chemotherapy-induced amenorrhea for ≥ 12 months with FSH and estradiol in post-menopausal range on serial assessments
 - Age < 60 years: on tamoxifen with FSH and estradiol level in postmenopausal range
- Menopausal status cannot be determined in those receiving ovarian function suppression

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Appendix

NCCN Categories of Evidence and Preference

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NCCN Categories of Evidence and Consensus	
Category 1	Based upon high-level evidence (≥1 randomized phase 3 trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus (≥50%, but <85% support of the Panel) that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

All recommendations are category 2A unless otherwise indicated.

NCCN Categories of Preference	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, Affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for selected patient populations (defined with recommendation).

All recommendations are considered appropriate.

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Appendix

Prescribing Information

Direct Links to Prescribing Information

- [AFINITOR \(everolimus\) USPI](#)
- [Anastrozole USPI](#)
- [AROMASIN \(exemestane\) USPI](#)
- [AUGTYRO \(repotrectinib\) USPI](#)
- [BALVERSA \(erdafitinib\) USPI](#)
- [ETCAMAH \(camizestrant\) USPI](#)
- [Fulvestrant USPI](#)
- [HERCEPTIN \(trastuzumab\) USPI](#)
- [IBRANCE \(palbociclib\) USPI](#)
- [INLURIYO \(imlunestrant\) USPI](#)
- [ITOVEBI \(inavolisib\) USPI](#)
- [JEMPERLI \(dostarlimab-gxly\) USPI](#)
- [KEYTRUDA \(pembrolizumab\) USPI](#)
- [KISQALI \(ribociclib\) USPI](#)
- [Letrozole USPI](#)
- [LYNPARZA \(olaparib\) USPI](#)
- [Megestrol acetate USPI](#)
- [NERLYNX \(neratinib\) USPI](#)
- [ORSERDU \(elacestrant\) USPI](#)
- [PIQRAY \(alpelisib\) USPI](#)
- [RETEVMO \(selpercatinib\) USPI](#)
- [REVTORPYK \(gedatolisib\) USPI](#)
- [ROZLYTREK \(entrectinib\) USPI](#)
- [TALZENNA \(talazoparib\) USPI](#)
- [Tamoxifen citrate USPI](#)
- [TRUQAP \(capivasertib\) USPI](#)
- [TUKYSA \(tucatinib\) USPI](#)
- [VEPPANU \(vepdegestrant\) USPI](#)
- [VERZENIO \(abemaciclib\) USPI](#)
- [VITRAKVI \(larotrectinib\) USPI](#)