



Breast Cancer

乳癌診療指引

一、參與討論同仁

主席	洪進昇部長 (乳房外科)	
附設醫院	洪進昇部長 (乳房外科)	王文科主任 (乳房外科)
	何昱萱醫師 (乳房外科)	黃振僑醫師 (乳房外科)
	林寰澤醫師 (血液腫瘤科)	呂隆昇主任 (放射腫瘤科)
	郭婉君個管師 (癌症中心)	楊喬茹個管師 (癌症中心)
	陳芯怡個管師 (乳房外科)	
萬芳醫院	張家峯主任 (血液腫瘤科)	劉育辰個管師 (癌症中心)
雙和醫院	趙祖怡教授 (血液腫瘤科)	蘇智銘主任 (乳房外科)
	陳欣韻個管師 (癌症中心)	吳雪綺個管師 (乳房外科)
	魏綺萱個管師 (乳房外科)	

二、討論日期：114 年 11 月 07 日

三、校稿人員：趙祖怡教授 / 廖立民醫師 / 陳欣韻個管師

114 年版與上一版差異：

113 年版	114 年修訂版
Consensus Guidelines for Breast Cancer Management -1: No changes.	『 Consensus Guidelines for Breast Cancer Management -1 』 Added Note: 13. For abdominal examination, complete either abdominal ultrasound (US) or chest-abdomen CT. If a whole-body assessment (e.g., PET/CT) has already been performed, repetition is not required.
Consensus Guidelines for Breast Cancer Management -1: No changes.	『 Consensus Guidelines for Breast Cancer Management -1 』 No changes.
Consensus Guidelines for Breast Cancer Management -2: No changes.	『 Consensus Guidelines for Breast Cancer Management -2 』 No changes.
『 Consensus Guidelines for Breast Cancer Management -3 』 Adjuvant Therapy Updates: HR(+), HER2(−) high-risk breast cancer (註 12) considered adjuvant abemaciclib for 2 years Notes Added:12. high-risk : breast cancer (with ≥ 4 positive lymph nodes, or 1–3 positive lymph nodes with one or more of the following: Grade 3 disease, Ki67 $\geq 20\%$,tumor size ≥ 5 cm 。	『 Consensus Guidelines for Breast Cancer Management -3 』 Updates and Notes on Adjuvant Therapy: For HR(+), HER2(−) early-stage breast cancer with intermediate to high risk, adjuvant TS-1 for one year (Note 13) or ribociclib for three years (Note 14) may be considered.
『 Consensus Guidelines for Breast Cancer Management -4 』 Adjuvant Therapy Updates: 3.HR(+), HER2(−) high-risk breast cancer (註 12) considered adjuvant abemaciclib for 2 years Notes Added:11. high-risk : breast cancer (with ≥ 4 positive lymph nodes, or 1–3 positive lymph nodes with one or more of the following: Grade 3 disease, Ki67 $\geq 20\%$,tumor size ≥ 5 cm 。	『 Consensus Guidelines for Breast Cancer Management -4 』 Updates and Notes on Adjuvant Therapy:New Recommendation: For HR(+), HER2(−) early-stage breast cancer with intermediate to high risk, adjuvant TS-1 for one year (Note 12) or ribociclib for three years (Note 13) may be considered.

113 年版

《 Consensus Guidelines for Breast Cancer Management -5》 No changes.

《 Consensus Guidelines for Breast Cancer Management -6 》 No changes.

《 Consensus Guidelines for Breast Cancer Management -7》 No changes.

《 Consensus Guidelines for Breast Cancer Management -8 》

Adjuvant Therapy: Added

2. 1. For high-risk(4) : Adjuvant pembrolizumab (if pembrolizumab containing regimen was given preoperatively)

《 Consensus Guidelines for Breast Cancer Management -8 》

Adjuvant Therapy: Added

1. Adjuvant capecitabine (6–8cycles) and or
2. Adjuvant olaparib for 1 year if germline BRCA1/2 mutation and or
3. Adjuvant pembrolizumab (if pembrolizumab containing regimen was given preoperatively)

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《 Consensus Guidelines for Breast Cancer Management -5》 No changes.

《 Consensus Guidelines for Breast Cancer Management -6 》

Added: For patients undergoing treatment for Stage IV disease, those with HER2(+) may receive anti-HER2 therapy including ADCs. Additionally, patients with gBRCA or PALB2 mutations may be treated with PARP inhibitors.

《 Consensus Guidelines for Breast Cancer Management -7》 No changes.

《 Consensus Guidelines for Breast Cancer Management -8 》

Added: Timing for BRCA Testing

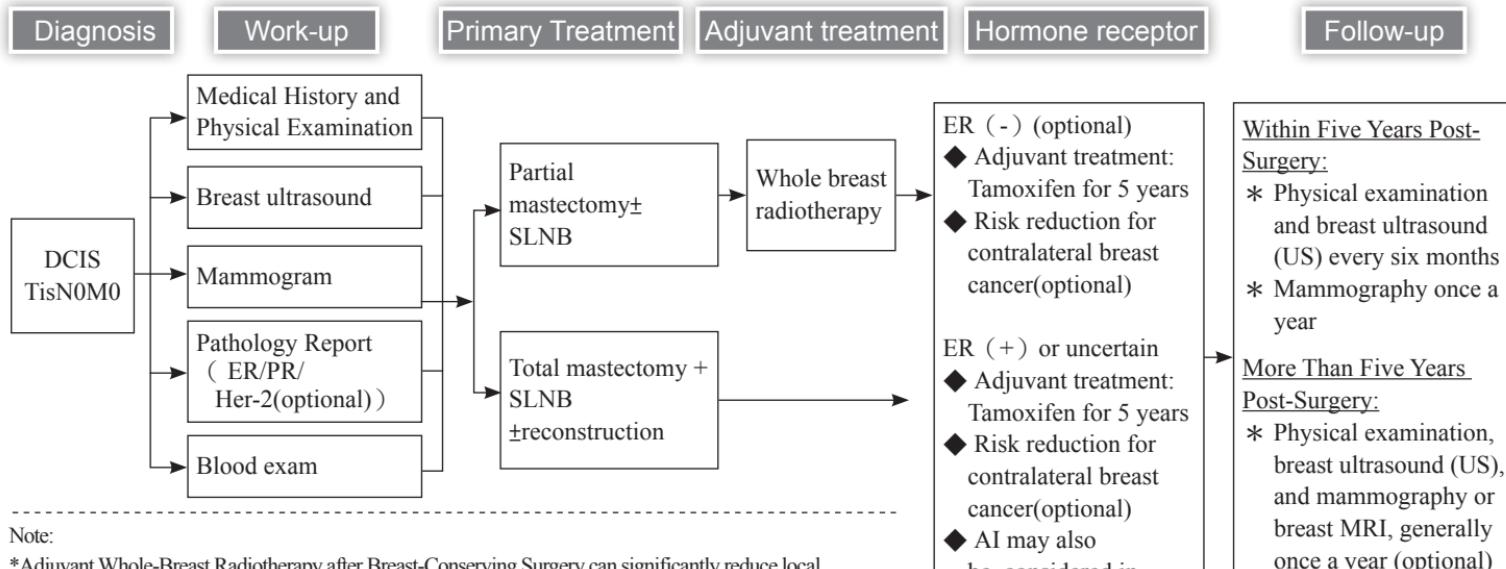
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《 Consensus Guidelines for Breast Cancer Management -8 》

Notes Added:

4. High-risk criteria include stage II-III TNBC. The use of adjuvant pembrolizumab (category 2A) may be individualized

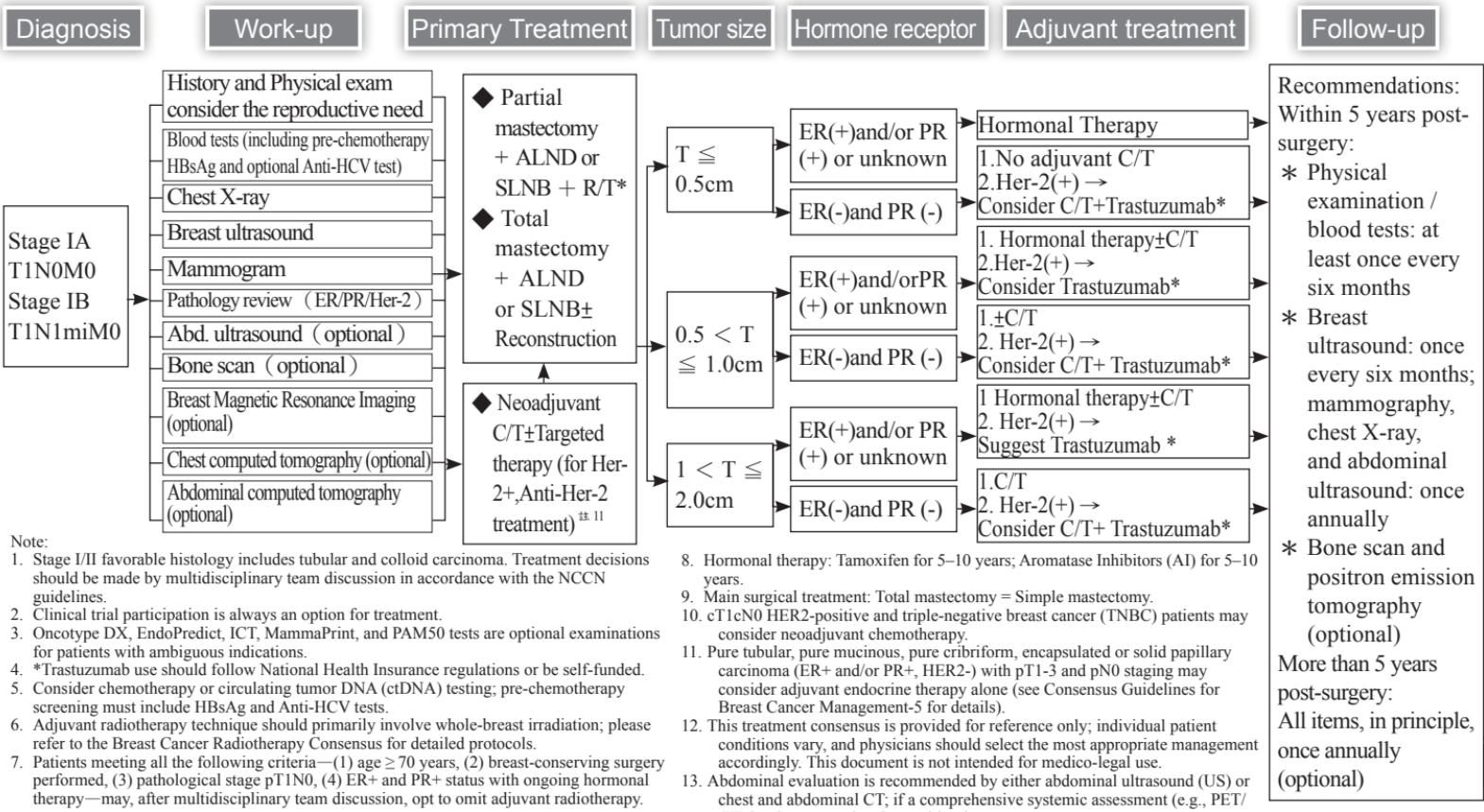


Note:

*Adjuvant Whole-Breast Radiotherapy after Breast-Conserving Surgery can significantly reduce local recurrence by up to 50%. If the patient, in consultation with the breast cancer care team through a shared decision-making (SDM) process, agrees that the case is low-risk for recurrence, some patients may opt for lumpectomy alone. Risk factors for local recurrence include palpable tumors, larger tumor size, high grade, close tumor margins, and younger age.

- The standard dose of tamoxifen is 20 mg/day for five years. Low-dose* tamoxifen (5 mg/day for three years) may be considered only if patients experience side effects at the standard dose or are unwilling/unable to take the standard dose.
- Encapsulated or solid papillary carcinoma has been classified under DCIS.
- This treatment consensus is provided for reference only. As individual patient conditions vary, physicians should select the most appropriate management on a case-by-case basis. It is not intended for use in medical litigation.

《Consensus on Guidelines for Diagnosis and Treatment of Breast Cancer -2》



Note:

1. Stage I/II favorable histology includes tubular and colloid carcinoma. Treatment decisions should be made by multidisciplinary team discussion in accordance with the NCCN guidelines.
2. Clinical trial participation is always an option for treatment.
3. Oncotype DX, EndoPredict, ICT, MammaPrint, and PAM50 tests are optional examinations for patients with ambiguous indications.
4. *Trastuzumab use should follow National Health Insurance regulations or be self-funded.
5. Consider chemotherapy or circulating tumor DNA (ctDNA) testing; pre-chemotherapy screening must include HBsAg and Anti-HCV tests.
6. Adjuvant radiotherapy technique should primarily involve whole-breast irradiation; please refer to the Breast Cancer Radiotherapy Consensus for detailed protocols.
7. Patients meeting all the following criteria—(1) age ≥ 70 years, (2) breast-conserving surgery performed, (3) pathological stage pT1N0, (4) ER+ and PR+ status with ongoing hormonal therapy—may, after multidisciplinary team discussion, opt to omit adjuvant radiotherapy.
8. Hormonal therapy: Tamoxifen for 5–10 years; Aromatase Inhibitors (AI) for 5–10 years.
9. Main surgical treatment: Total mastectomy = Simple mastectomy.
10. cT1cN0 HER2-positive and triple-negative breast cancer (TNBC) patients may consider neoadjuvant chemotherapy.
11. Pure tubular, pure mucinous, pure cribriform, encapsulated or solid papillary carcinoma (ER+ and/or PR+, HER2-) with pT1-3 and pN0 staging may consider adjuvant endocrine therapy alone (see Consensus Guidelines for Breast Cancer Management-5 for details).
12. This treatment consensus is provided for reference only; individual patient conditions vary, and physicians should select the most appropriate management accordingly. This document is not intended for medico-legal use.
13. Abdominal evaluation is recommended by either abdominal ultrasound (US) or chest and abdominal CT; if a comprehensive systemic assessment (e.g., PET/CT) has been completed, repetition is not necessary.

《Consensus on Guidelines for Diagnosis and Treatment of Breast Cancer -3》

Diagnosis

Work-up

Primary Treatment

Adjuvant treatment

Hormone receptor

Follow-up

Stage II
IIA: T0 N1
M0, T1 N1
M0, T2 N0
M0
IIB: T2 N1
M0, T3 N0
M0

- Medical history and physical examination, with consideration of reproductive needs
- Blood tests (including pre-chemotherapy HBsAg and optional Anti-HCV test)
- Chest X-ray
- Breast ultrasound
- Mammogram
- Pathology Report (including ER/PR/Her-2)
- Abd. ultrasound (optional)
- Bone scan (optional)
- Breast Magnetic Resonance Imaging (optional)
- Chest computed tomography (optional)
- Abdominal computed tomography (optional)

If unresectable or resectable, assess the feasibility of breast-conserving surgery (neoadjuvant therapy may be considered)

Neoadjuvant C/T +Targeted therapy (for Her-2 +, Anti-Her-2 treatment)

Post-mastectomy radiotherapy (PMRT) indications:

1. Tumor > 5cm
2. N2 or N1 without axillary dissection
3. Strongly consider PMRT in N1 cases*
4. Positive margins
5. ECE (+)

- ◆ Partial mastectomy + ALND or SLNB + R/T*
- ◆ Total mastectomy + ALND or SLNB± reconstruction± R/T*

1. C/T
2. Her-2 (+)
→ Consider Trastuzumab* (± Pertuzumab) or TDM-1 (non- PCR) 註 4
3. HR(+), HER2(-)
a. high-risk considered adjuvant abemaciclib for 2 years (註 12)
b. intermediate-high risk consider adjuvant TS-1 for 1 year (註 13) or ribociclib for 3 years(註 14)

- ◆ Adjuvant H/T: ER (+) and/or PR (+) or unknown
- ◆ PNo H/T ER (-) and PR (-)

Recommendations:
Within 5 years post-surgery:

* Physical examination / blood tests: at least once every six months

* Breast ultrasound: once every six months; mammography, chest X-ray, and abdominal ultrasound: once annually

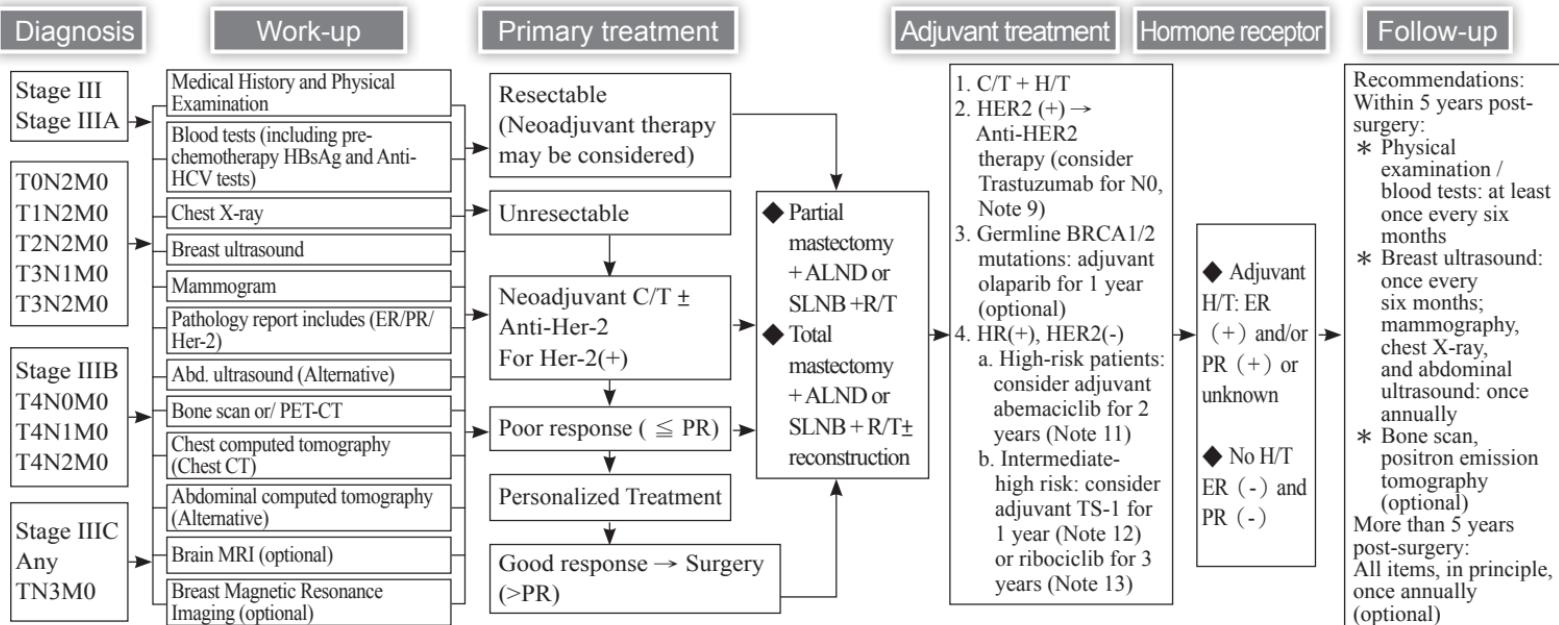
* Bone scan and positron emission tomography (optional)

More than 5 years post-surgery:
All items, in principle, once annually (optional)

Note:

1. Stage I/II favorable histology includes tubular and colloid carcinoma. Treatment decisions should refer to the NCCN guideline and be determined through multidisciplinary team discussion.
2. Clinical trial participation is always an option for treatment.
3. Oncotype, MammaPrint, PAM50 test, or EndoPredict are optional assays for ER(+) HER2(-) N1 patients with ambiguous risk.
4. Anti-HER2 therapy is administered according to National Health Insurance regulations or self-pay. For N+ patients: consider adjuvant chemotherapy combined with Trastuzumab and Pertuzumab (category 1).
5. Consider chemotherapy or circulating tumor DNA (ctDNA) testing (pre-chemotherapy screening should include HBsAg and optional Anti-HCV testing).
6. *For N1 patients with low risk of recurrence, after shared decision-making between patient and medical team, adjuvant radiotherapy may be omitted following total mastectomy. Low-risk criteria include all of the following: age ≥ 40 years, T1 tumor, single lymph node involvement, no lymphovascular invasion, HER2/Neu negative.
7. Main surgical treatment: Total mastectomy = Simple mastectomy.
8. For triple-negative breast cancer (TNBC) following standard neoadjuvant or adjuvant therapy: consider Capecitabine maintenance therapy (self-pay).
9. Stage II/III TNBC: neoadjuvant chemotherapy combined with immunotherapy can be considered as treatment.
10. Pure tubular, pure mucinous, pure cribriform, encapsulated or solid papillary carcinoma (ER+ and/or PR+, HER2-, pT1-3, and pN0): adjuvant endocrine therapy only may be considered (see Consensus Guidelines for Breast Cancer Management-5 for details).
11. This treatment consensus is provided for reference only. Individual patient conditions vary, and physicians should select the most appropriate management accordingly. This document is not intended for medical litigation purposes.
12. High-risk breast cancer is defined as having ≥ 4 positive lymph nodes, or 1–3 positive lymph nodes with one or more of the following: Grade 3 disease, Ki-67 ≥ 20%, tumor size ≥ 5 cm.
13. (TS-1 for 1 year): Indications include N+ status, tumor >3 cm, Grade 3, tumor 2–3 cm with Grade 2, Ki-67 ≥ 30%, or residual disease after neoadjuvant chemotherapy; combined with hormone therapy for 1 year.
14. (Ribociclib for 3 years): Indicated for any N+ patient; for N0 patients, criteria include Grade 3, or Grade 2 plus Ki-67 ≥ 20%, or high genomic risk score (e.g., Oncotype RS ≥ 26); used in combination with hormone therapy.

《Consensus on Guidelines for Diagnosis and Treatment of Breast Cancer -4》

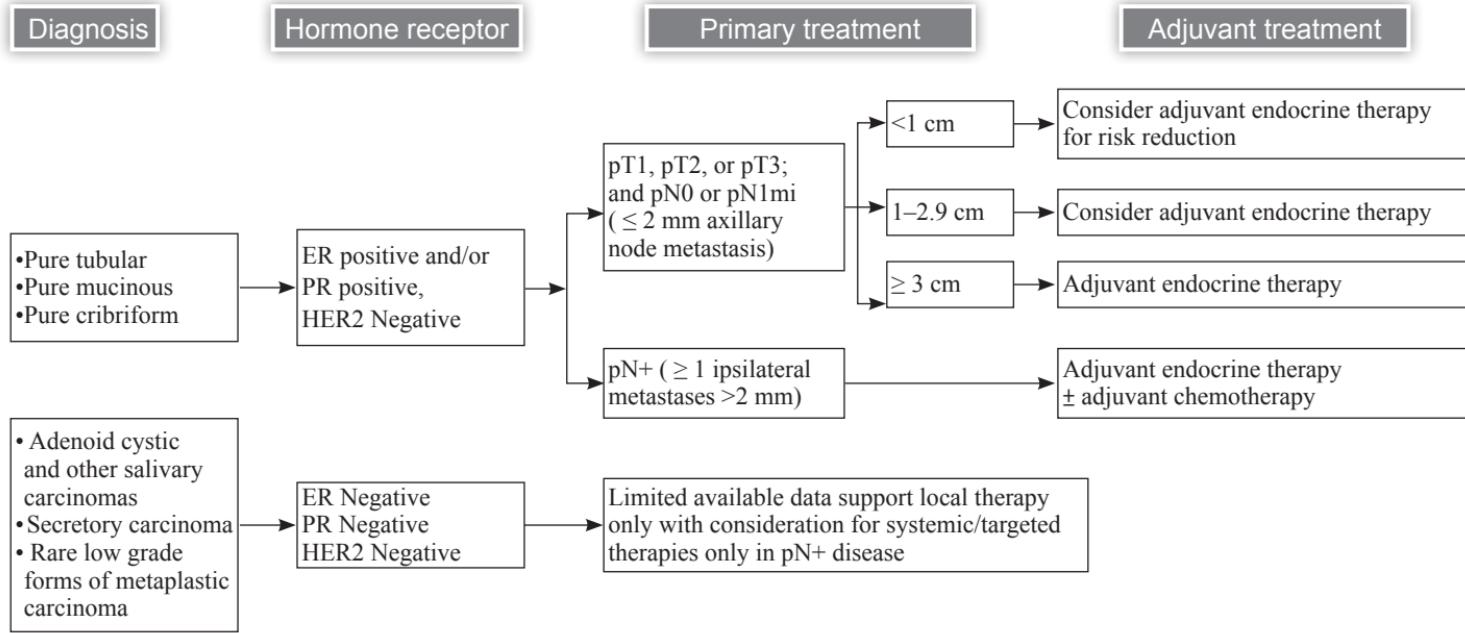


Note:

1. Stage I/II favorable histology includes tubular and colloid carcinoma. Refer to the NCCN guideline and determine treatment approach through multidisciplinary team discussion.
2. Clinical trial participation is always an option for treatment.
3. For radiotherapy (RT), refer to the consensus on breast cancer radiation therapy.
4. Abdominal ultrasound or abdominal CT can be used as alternatives.
5. Main treatment: Total mastectomy = Simple mastectomy.
6. For triple-negative breast cancer (TNBC) following standard neoadjuvant/adjuvant therapy: consider Capecitabine maintenance therapy (self-pay).
7. Response criteria: Complete Response (CR), Partial Response (PR), No Change (NC; stable disease, SD), Progressive Disease (PD).

8. For high-risk TNBC, neoadjuvant and adjuvant immunotherapy can be considered.
9. Anti-HER2 treatment should follow National Health Insurance (NHI) regulations or be self-paid. For node-positive (N+) patients: consider adjuvant chemotherapy plus Trastuzumab and Pertuzumab (category I recommendation).
10. This treatment consensus is provided for reference only. Due to individual patient differences, physicians should select the most appropriate management. This document is not intended for medical litigation purposes.
11. High-risk definition: breast cancer with ≥ 4 positive lymph nodes, or 1–3 positive lymph nodes with one or more of the following: Grade 3 disease, Ki-67 ≥ 20%, tumor size ≥ 5 cm.
12. TS-1 (1 year): indicated for N+ patients with tumor >3 cm and Grade 3, or tumor 2–3 cm with Grade 2, Ki-67 ≥ 30%, or residual disease after neoadjuvant chemotherapy; combined with hormone therapy (HT) for 1 year; self-pay.
13. Ribociclib (3 years): indicated for any N+ patient; for N0 patients, requires Grade 3, or Grade 2 plus Ki-67 ≥ 20%, or high genomic score (e.g., Oncotype DX Recurrence Score ≥ 26); used in combination with HT; self-pay.

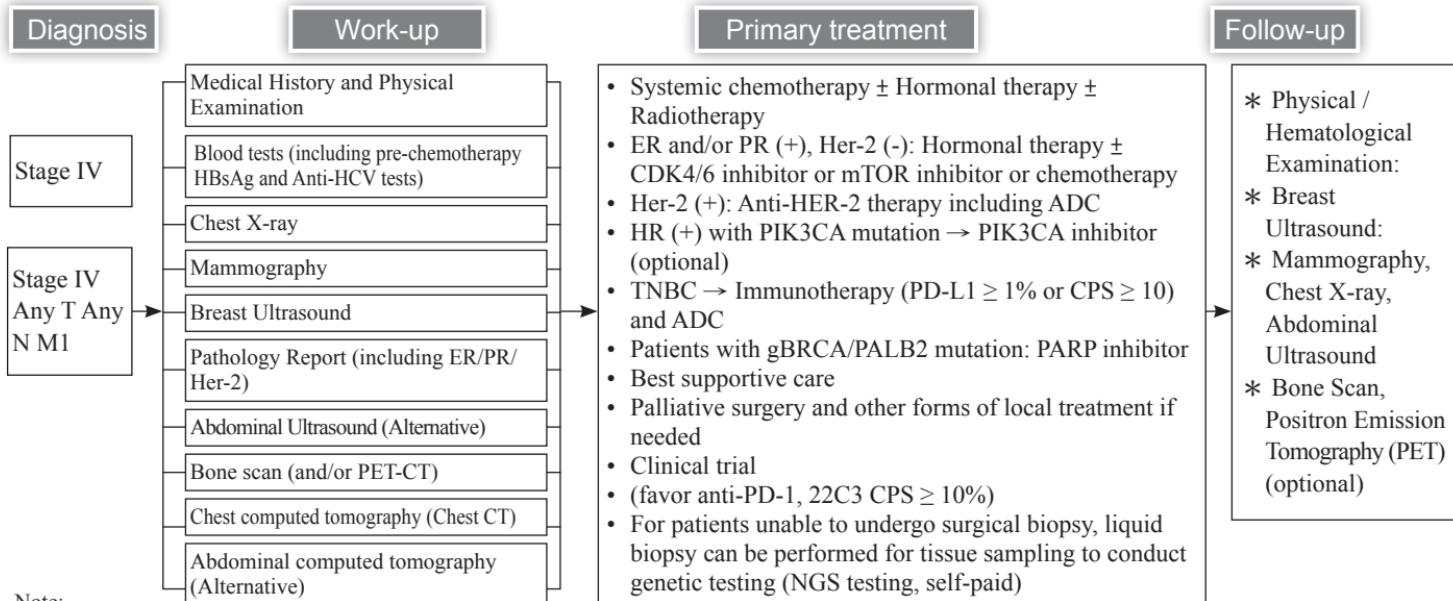
《Consensus on Guidelines for Diagnosis and Treatment of Breast Cancer -5》



附註：

1. There are rare subtypes of metaplastic carcinoma (eg, low-grade adenosquamous and low-grade fibromatosis-like carcinoma) that are considered to have a favorable prognosis without adjuvant systemic therapies.
2. To be associated with favorable prognosis, the favorable histologic type should not be high grade, should be pure ($>90\%$ as classified on the surgical excision, not core biopsy alone), and should be HER2 negative. If atypical pathologic or clinical features are present, consider treating as ductal/NST.
3. This treatment consensus is only for reference. Since each person's situation is different, each physician chooses the most appropriate treatment method and is not intended to be used for medical litigation.

《Consensus on Guidelines for Diagnosis and Treatment of Breast Cancer -6》



Note:

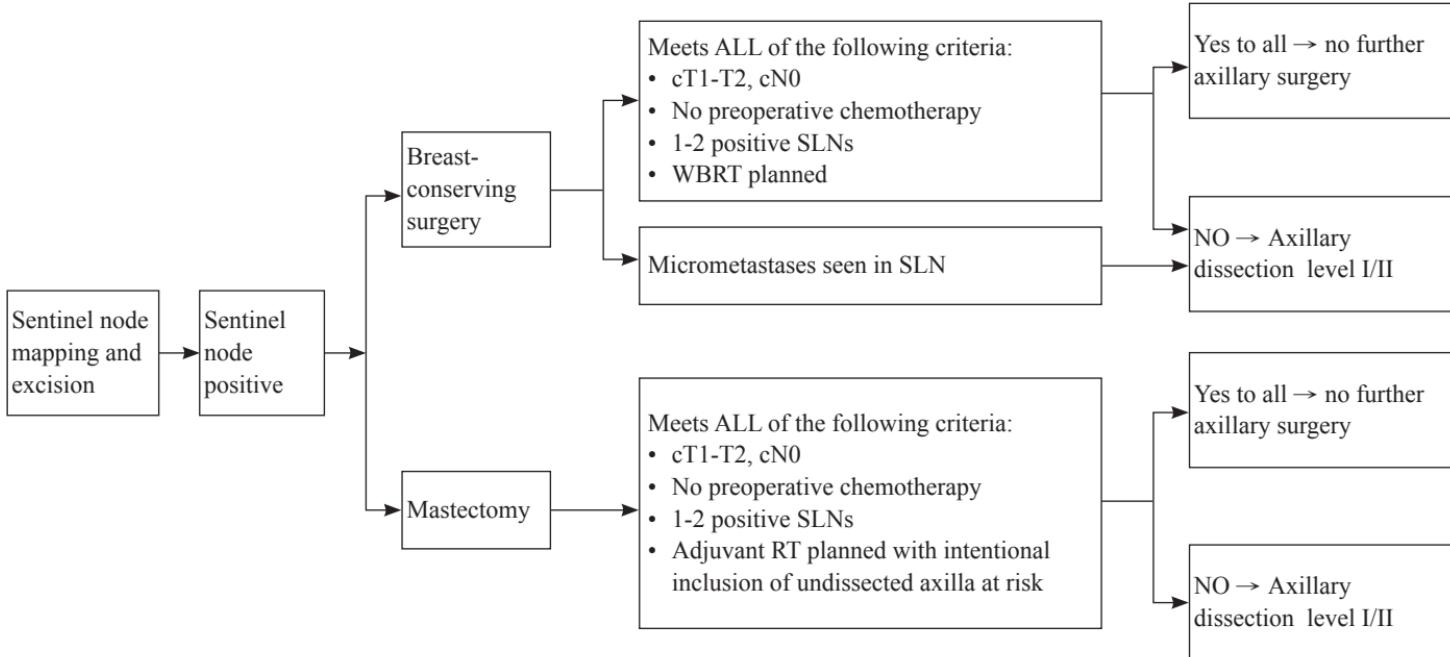
1. Stage I & II favorable histology includes tubular and colloid carcinoma. Treatment decisions should be made by multidisciplinary team discussion in accordance with the NCCN guidelines.
2. Clinical trial participation is always an option for treatment.
3. Abdominal ultrasound or abdominal CT can be used as alternatives.
4. Anti-HER2 therapy should be administered according to National Health Insurance (NHI) regulations or on a self-pay basis.
5. CPS: combined positive score
6. Anti-HER2 therapy for HER2-positive metastatic breast cancer should be used according to NHI regulations or on a self-pay basis.
7. This treatment consensus is provided for reference only. Due to individual patient differences, each physician should select the most appropriate management approach. This document is not intended for use in medical litigation.

Cell Type

Primary treatment

Primary treatment

Adjuvant treatment

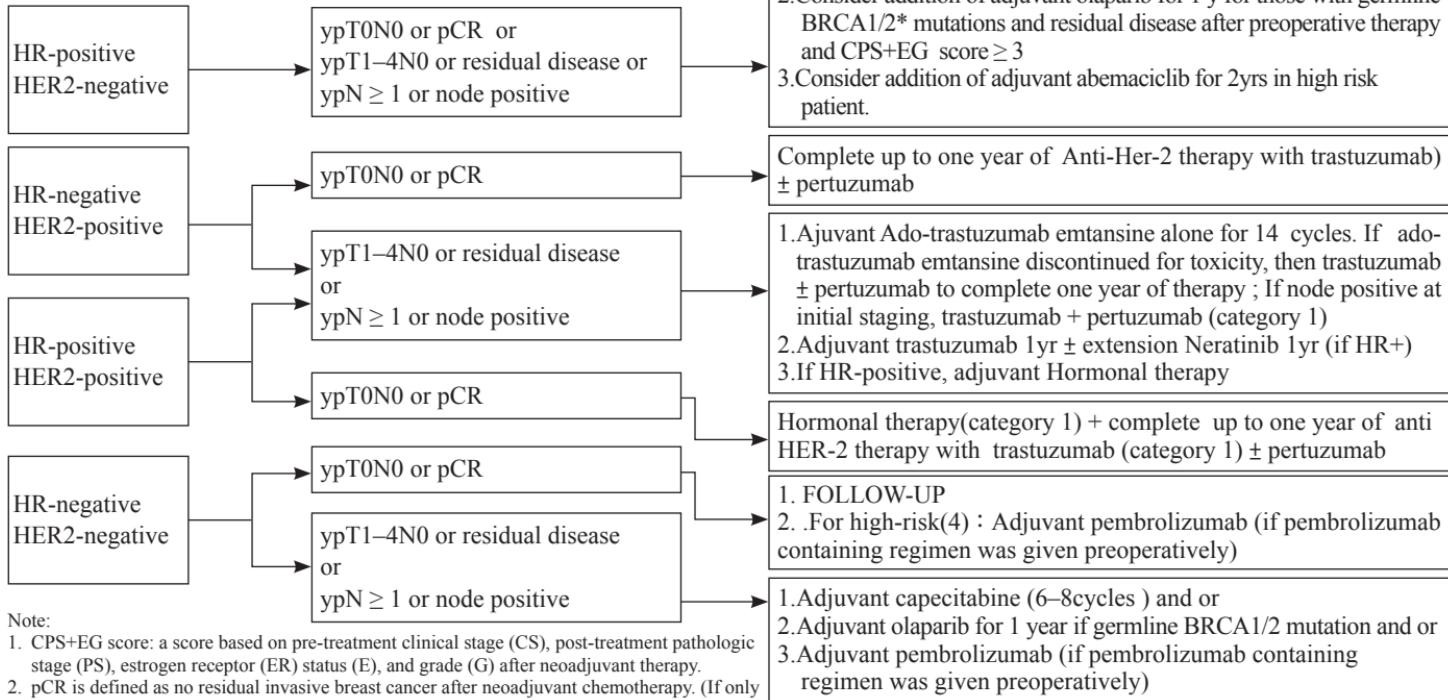


Note:

This treatment consensus is only for reference. Since each person's situation is different, each physician chooses the most appropriate treatment method and is not intended to be used for medical litigation.

《Consensus on Guidelines for Diagnosis and Treatment of Breast Cancer -8》

After complete course of neoadjuvant chemotherapy



Note:

1. CPS+EG score: a score based on pre-treatment clinical stage (CS), post-treatment pathologic stage (PS), estrogen receptor (ER) status (E), and grade (G) after neoadjuvant therapy.
2. pCR is defined as no residual invasive breast cancer after neoadjuvant chemotherapy. (If only residual carcinoma in situ remains, it is still considered pCR.)
3. This treatment consensus is provided for reference only. Due to individual patient differences, each physician should select the most appropriate management approach. This document is not intended for use in medical litigation.
4. High-risk criteria include stage II-III triple-negative breast cancer (TNBC). The use of adjuvant pembrolizumab (category 2A) may be individualized.

* For timing of BRCA testing, please refer to the following page.

Timing for BRCA Testing:

I. Individuals with a Personal History of Breast Cancer (meeting any of the following criteria)

- ◎ Age at Diagnosis
 - Diagnosis age \leq 50 years
- ◎ Any age but meeting the following treatment indications or pathological features:

【Treatment Indications】

- Assessment of PARP inhibitor for systemic therapy decision-making in metastatic breast cancer
- Evaluation of postoperative adjuvant Olaparib use in high-risk, HER2-negative early breast cancer

【Pathology / Histology】

- Triple-negative breast cancer (TNBC)
- Multiple primary breast cancers (synchronous or metachronous)
- Lobular breast cancer with personal or family history of diffuse gastric cancer
- Male breast cancer

II. Any Age with Family History (Meeting Any of the Following Criteria)

- ◎ At least one first- or second-degree relative meets any of the following:
 - Breast cancer with age at diagnosis \leq 50 years
 - Male breast cancer
 - Ovarian cancer
 - Pancreatic cancer
 - Prostate cancer: metastatic, or classified as high-risk/extremely high-risk group
- ◎ A cumulative total of \geq 3 cases of breast cancer and/or prostate cancer (any grade) on the same side of the family (paternal or maternal), including the individual concerned

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【Consensus on Breast Cancer Radiotherapy】

A. Whole breast radiotherapy

CT should be the standard to define target volume and critical organs

Indications: invasive cancers or carcinoma in situ after breast conserving surgery

Target volume: ipsilateral breast in entirety

Dose : 50 GyE (25 fractions) or 50.4 GyE (28 fractions), or 40 GyE (15 fractions) or 42.5 GyE (16 fractions), or 28 GyE in 5 fractions (once-a-week, for selected patients meeting all of the following criteria: age over 50 years, tumor size less than 3 cm, complete surgical resection with negative margins and no residual tumor, no lymph node metastasis, a radiotherapy plan that does not require a tumor bed boost to the primary site, and a treatment plan that does not include chemotherapy.)

Boost irradiation: lumpectomy cavity with adequate margins

Boost Dose: 10 GyE (5 fractions) to 16 GyE (8 fractions)

Techniques: Radiation is delivered in tangential fields, intensity modulated radiotherapy, volumetric modulated arc therapy, tomotherapy, and proton beam therapy. Image guidance and cardiopulmonary sparing techniques are optional. Boost dose can be delivered sequentially or concomitantly. Dose/fractionation for concomitant boost should be converted from standard boost irradiation based on biologically equivalent dose concept if proton beam therapy is planned.

B. Chest wall radiotherapy

CT should be the standard to define target volume and critical organs

Indications: invasive cancers with \geq T3 diseases after mastectomy; clinical or pathological nodal positive disease; involved or close (<1mm) surgical margins

Target volume: ipsilateral chest wall, surgical scar and its margins

Dose: 50 GyE (25 fractions) or 50.4 GyE (28 fractions), or 40 GyE (15 fractions) or 42.5 GyE (16 fractions) if no further breast reconstruction

Boost irradiation: surgical scar and its margins

Boost Dose: 10 GyE (5 fractions) to 16 GyE (8 fractions)

Techniques: Radiation is delivered in tangential fields, intensity modulated radiotherapy, volumetric modulated arc therapy, tomotherapy, and proton beam therapy. Image guidance and cardiopulmonary sparing techniques are optional. Boost dose can be delivered sequentially or concomitantly. Dose/fractionation for concomitant boost should be converted from standard boost irradiation based on biologically equivalent dose concept if proton beam therapy is planned.

C. Regional nodal irradiation

CT should be the standard to define target volume and critical organs

Indications: invasive cancers with \geq T3 diseases after mastectomy; clinical or pathological nodal positive disease

Target volume: ipsilateral axillary basin, subclavicular and supraclavicular fossa. May include internal mammary chain (IMC) when IMC lymph nodes are clinically involved or when such plans do not violate normal tissue constraints.

Dose: 50 GyE (25 fractions) or 50.4 GyE (28 fractions). Or 40 GyE (15 fractions) or 42.5 GyE (16 fractions) if no further breast reconstruction

Boost irradiation: grossly involved or enlarged lymph nodes that have not been surgically addressed

Boost Dose: 10 GyE (5 fractions) to 16 GyE (8 fractions)

Techniques: Radiation is delivered in tangential fields, intensity modulated radiotherapy, volumetric modulated arc therapy, tomotherapy or proton beam therapy. Image guidance and cardiopulmonary sparing techniques are optional. Dose/fractionation for concomitant boost should be converted from standard boost irradiation based on biologically equivalent dose concept if proton beam therapy is planned.

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