NOTE: Consider clinical trials as treatment options for eligible patients.

INITIAL EVALUATION

- Pathology review
- Bilateral diagnostic mammography
- History and Physical
- CBC, platelets, liver function tests (total bilirubin, alkaline phosphatase, SGPT, LDH), creatinine
- CXR
- Baseline ultrasound of breast and regional nodal basins with FNA of suspicious nodes
- Clinical Stage II and III: Optional bone scan CT of abdomen

CLINICAL STAGING

- Breast conservation therapy with sentinel lymph node dissection
- Total mastectomy with sentinel lymph node dissection with or without reconstruction

LOCAL TREATMENT

- Breast conservation therapy with axillary dissection
- Total mastectomy with axillary lymph node dissection with or without reconstruction
- Consider neoadjuvant chemotherapy (see page 2)

1 There are special circumstances in which these guidelines do not apply. These include, but are not limited to:
- Sarcoma of the breast
- Male breast cancer
- Special histologies (i.e., tubular, medullary, pure papillary, or colloid)
- Cancer during pregnancy

2 Pathology Review to include:
- Tumor size
- Nuclear grade
- Lymph node status
- HER2
- Margin status
- Extracapsular extension (focal less than 2 mm or gross greater than 2 mm)
- Vascular/lymphatic invasion
- Size of metastasis
- Ki67
- Patients with lupus and scleroderma
- Lymphoma of the breast
- Patients with limited life expectancy
- Cancer during pregnancy

3 Surgeons with an established record of lymphatic mapping experience for breast cancer (a minimum of 20 cases with an identification rate of 85% and a false negative rate of 5%) may consider sentinel lymph node dissection as the initial and primary means of evaluating nodal status for selected patients who are clinically node negative.

4 For patients with stage II disease requiring post-mastectomy radiation, consider delayed reconstruction. For patients with stage III disease, delayed reconstruction is preferred

5 Candidates for breast conservation therapy:
- unicentric disease
- tumor to breast size ratio allows for acceptable cosmetic result
- margins greater than or equal to 2 mm,
- resolution of any skin edema
- no evidence of diffuse calcification on mammogram
- No contraindication to radiotherapy

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Department of Clinical Effectiveness V11
NOTE: Consider clinical trials as treatment options for eligible patients.

PATHOLOGICAL STAGING

POST-SURGERY

Meets Z0011 criteria? Yes

Tumor less than or equal to 0.5 cm

Completion Axillary Lymph Node Dissection (ALND)

No further axillary treatment

Yes

No adjuvant therapy or
Consider hormonal therapy if tumor is hormone receptor positive
Consider trastuzumab-based chemotherapy if HER2 positive

Tumor greater than 0.5 to 1 cm

Tumor greater than 1 cm

ADJUVANT THERAPY FOLLOWING SURGERY AS LOCAL TREATMENT
(See Appendix A)

No adjuvant therapy or
Consider hormonal therapy if tumor is hormone receptor positive
Consider trastuzumab-based chemotherapy if HER2 positive

Completion Axillary Lymph Node Dissection (ALND)

No further axillary treatment

Adjuvant chemotherapy with weekly paclitaxel times 12 followed by FAC3 times 4 (other NCCN approved regimens acceptable)
Trastuzumab-based chemotherapy if HER2 positive
Adjuvant hormonal therapy if tumor is hormone receptor positive

Adjuvant chemotherapy with weekly paclitaxel times 12 followed by FAC3 times 4 (other NCCN approved regimens acceptable)
Trastuzumab-based chemotherapy if HER2 positive
Adjuvant hormonal therapy if tumor is hormone receptor positive

If giving chemotherapy, use trastuzumab-based regimen for HER2 positive disease
Adjuvant hormonal therapy if tumor is hormone receptor positive (consider Oncotype Testing for node negative and ER positive)

Tumor less than or equal to 0.5 cm

Adjuvant chemotherapy with weekly paclitaxel times 12 followed by FAC3 times 4 (other NCCN approved regimens acceptable)
Trastuzumab-based chemotherapy if HER2 positive
Adjuvant hormonal therapy if tumor is hormone receptor positive

See Page 4 For Radiotherapy Options

Adjuvant chemotherapy with weekly paclitaxel times 12 followed by FAC3 times 4 (other NCCN approved regimens acceptable)
Trastuzumab-based chemotherapy if HER2 positive
Adjuvant hormonal therapy if tumor is hormone receptor positive

Positive Nodes?

Yes

No

Tumor less than or equal to 0.5 cm

Completion Axillary Lymph Node Dissection (ALND)

No further axillary treatment

Tumor greater than 0.5 to 1 cm

Tumor greater than 1 cm

1 There are special circumstances in which these guidelines do not apply. These include, but are not limited to:
- Sarcoma of the breast
- Patients with lupus and scleroderma
- Special histologies (i.e., tubular, medullary, pure papillary, or colloid)
- Male breast cancer
- Lymphoma of the breast
- Patients with limited life expectancy
- Cancer during pregnancy

2 Z0011 criteria: Clinical T1 or T2, N0, M0, lumpectomy and sentinel lymph node dissection, and tumor positive sentinel node planned for whole breast irradiation and systemic therapy.

3 Cardiac evaluation at baseline, during and after treatment and as clinically indicated

4 Endocrine therapy for all patients with ER positive and/or PR positive tumors (endocrine therapy is not indicated in patients with ER negative and PR negative tumors):
- Premenopausal women: Tamoxifen 5 years
- Postmenopausal women: aromatase inhibitors for 5 years

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Department of Clinical Effectiveness V11
Breast Cancer – Invasive

This practice algorithm has been specifically developed for M. D. Anderson using a multidisciplinary approach and taking into consideration circumstances particular to M. D. Anderson, including the following: M. D. Anderson’s specific patient population; M. D. Anderson’s services and structure; and M. D. Anderson’s clinical information. Moreover, this algorithm is not intended to replace the independent medical or professional judgment of physicians or other health care providers. This algorithm should not be used to treat pregnant women.

**NOTE:** Consider clinical trials as treatment options for eligible patients.

### CLINICAL STAGE/PRESENTATION

<table>
<thead>
<tr>
<th>Stage II or Stage III (including inflammatory breast cancer)</th>
<th>LOCAL TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumors too large for breast conservation</td>
<td></td>
</tr>
<tr>
<td>Recommend preoperative systemic chemotherapy^3</td>
<td></td>
</tr>
<tr>
<td>OR Chemotherapy and Endocrine therapy as clinically indicated</td>
<td></td>
</tr>
<tr>
<td>• If candidate for breast conservation therapy^3, place radio-opaque markers for tumors less than or equal to 2 cm unless tumor marked by calcification prior to systemic therapy</td>
<td></td>
</tr>
</tbody>
</table>

**HER2 positive?**

| Yes | **Herceptin**
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Paclitaxel and Trastuzumab followed by FEC (75 mg/m²) and Trastuzumab^4</td>
</tr>
<tr>
<td></td>
<td>HER2 positive chemotherapy options from NCCN</td>
</tr>
</tbody>
</table>

| No  | **Weekly Paclitaxel**
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>times 12, followed by FAC^4 times 4</td>
</tr>
<tr>
<td></td>
<td>HER2 negative chemotherapy options from NCCN</td>
</tr>
</tbody>
</table>

**Assess tumor size within 6-8 weeks and at completion of systemic treatment with physical exam, and additional imaging with mammogram and/or ultrasound**

**Breast conservation therapy candidate^5?**

| Yes | **Total mastectomy with nodal treatment as determined by initial nodal status:**
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Clinically node negative at diagnosis, proceed with sentinel node biopsy^6 followed by axillary node dissection if sentinel node is positive</td>
</tr>
<tr>
<td></td>
<td>• If clinically node positive, proceed with axillary node dissection</td>
</tr>
<tr>
<td></td>
<td>• Total mastectomy with or without reconstruction^7 or breast conservation^8</td>
</tr>
</tbody>
</table>

| No  | See Pathological Findings on Page 4 |

---

^1 There are special circumstances in which these guidelines do not apply. These include, but are not limited to:
- Sarcoma of the breast
- Male breast cancer
- Patients with lupus and scleroderma
- Patients with limited life expectancy
- Cancer during pregnancy

^2 If tumor meets criteria for breast conservation therapy^3, then consider page 2 for local treatment first.

^3 For postmenopausal patients with ER-positive disease, aromatase inhibitors may be an option.

^4 For patients with stage II disease requiring post-mastectomy radiation, consider delayed reconstruction. For patients with stage III disease, delayed reconstruction is preferred.

^5 Candidates for breast conservation therapy:
- unincinetic disease
- resolution of any skin edema
- tumor to breast size ratio allows for acceptable cosmetic result
- no evidence of diffuse calcification on mammogram
- margins greater than or equal to 2 mm,
- No contraindication to radiotherapy
- Consider reconstruction^7

^6 Surgeons with an established record of lymphatic mapping experience for breast cancer (a minimum of 20 cases with an identification rate of 85% and a false negative rate of 5%) may consider sentinel lymph node dissection as the initial and primary means of evaluating nodal status for selected patients who are clinically node negative.

^7 For patients with stage II disease requiring post-mastectomy radiation, consider delayed reconstruction. For patients with stage III disease, delayed reconstruction is preferred.
NOTE: Consider clinical trials as treatment options for eligible patients.

Breast Cancer – Invasive

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PATHOLOGICAL FINDINGS

Stage II disease, except T3N0, with 0-3 involved lymph node(s)

Stage III disease or T3N0 or 4 or more involved lymph nodes; residual tumor greater than 5 cm

TREATMENT

Whole breast radiotherapy for breast conservation therapy with or without regional lymphatics.
Discuss chest wall radiotherapy with or without regional lymphatics for patients with total mastectomy and any positive lymph nodes.
Chest wall radiotherapy for greater than 4 nodes, consider radiotherapy for 1-3 nodes.

Post mastectomy radiotherapy to chest wall and regional lymphatics.
Whole breast radiotherapy with regional lymphatics for breast conservation therapy.

SURVEILLANCE

Endocrine therapy for ER and/or PR positive sequential after chemotherapy and local therapy.
Consider hormone therapy if less than 0.5 cm and hormone positive.
Trastuzumab to complete one year if HER2-positive.

Physical exam every 3-6 months for 3 years, then every 6-12 months for the next 2 years, then annually after year 5.
Annual gynecologic exam.
Annual assessment of bone density.
If on Aromatase Inhibitors. Encourage age appropriate cancer and general health guidelines.

From local treatment

Previous Breast Conservation Therapy

Previous Mastectomy

Physical exam every 3-6 months for 3 years, then every 6-12 months for the next 2 years, then annually after year 5.
Mammogram of treated breast at 6 months, then annually.
Annual gynecologic exam, if receiving tamoxifen.
Assess bone health.
Encourage age appropriate cancer/general health screening.

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- Patients with lupus and scleroderma
- Special histologies (i.e., tubular, medullary, pure papillary, or colloid)
- Male breast cancer
- Lymphoma of the breast
- Patients with limited life expectancy
- Cancer during pregnancy

2 Radiotherapy for BCT and post-mastectomy radiation, are generally delivered at completion of chemotherapy. For early stage node negative patients, radiotherapy may be delivered before or after chemotherapy.

3 Endocrine therapy for all patients with ER positive and/or PR positive tumors (endocrine therapy is not indicated in patients with ER negative and PR negative tumors):
- Premenopausal women: Tamoxifen 5 years
- Women with chemotherapy induced menopause: Tamoxifen until postmenopausal status biochemically confirmed, then at least 1 year to complete, aromatase inhibitors for 5 years.
- Postmenopausal women: aromatase inhibitors for 5 years

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NOTE: Consider clinical trials as treatment options for eligible patients.

EVALUATION FOR METASTASIS

- Biopsy as clinically indicated to confirm metastatic disease:
  - Bone Scan
  - CT or MRI of abdomen
  - CXR
  - ER/PR
  - HER2
  - Creatinine, CA15-3
  - Consider PET/CT scan

TREATMENT FOR METASTASIS

- ER or PR positive and bone or soft tissue metastasis only or
  - Limited visceral disease
- ER or PR negative or
  - ER and/or PR positive and extensive visceral disease or
  - Symptomatic disease

Aromatase inhibitor
- Prior endocrine therapy:
  1. If prior tamoxifen, give aromatase inhibitors
  2. If prior aromatase inhibitors:
     a. Tamoxifen
     b. Steroidal aromatase inhibitors
     c. Fulvestrant
     d. Progestins
     e. Estrogens
     f. Androgen
- Chemotherapy until progressive disease or maximum benefit:
  1. FAC if no prior anthracyclines
  2. Taxane
  3. Capecitabine
  4. Ixabepilone
  5. Vinorelbine
  6. Gemcitabine
  7. Eribulin
  8. Paclitaxel with Bevacizumab

- Chemotherapy plus trastuzumab if no prior trastuzumab
  - If prior trastuzumab, consider capcitabine plus lapatinib
  - Trastuzumab plus anastrozole or letrozole if ER and/or PR positive
  - Letrozole plus lapatinib

- Disease response or clinical benefit?
  Yes → Continue current treatment until progressive disease then consider alternate endocrine therapy
  No → Palliative care

Failure to respond to 3 sequential regimens or Zubrod status greater than or equal to 3, discontinue chemotherapy

- Progressive disease?
  Yes → Continue treatment until progressive disease, maximum benefit, or unacceptable side effects
  No → Endocrine therapy if ER and/or PR positive or Additional chemotherapy with or without HER2 targeted therapy

NOTE: all patients with bone metastases should also be treated with denosumab or a bisphosphonate, if life expectancy is longer than 12 weeks and creatinine clearance is 30 or greater.

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- Sarcoma of the breast
- Patients with lupus and scleroderma
- Special histologies (i.e., tubular, medullary, pure papillary, or colloid)
- Male breast cancer
- Lymphoma of the breast
- Patients with limited life expectancy
- Cancer during pregnancy

2 See Appendix B for scenarios requiring individualized therapy.

3 Consider breast surgery for patients with responding metastatic disease who have an intact primary.

4 This regimen is under review by the Food and Drug Administration for label modification.

ER = Estrogen Receptor  FISH = Fluorescence In Situ Hybridization  HER2 = Human Epidermal Growth Factor Receptor 2  PR = Progesterone Receptor  LHRH = Luteinizing Hormone-Releasing Hormone

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NOTE: Consider clinical trials as treatment options for eligible patients.

EVALUATION FOR RECURRENCE

Local regional recurrence without distant metastasis

Biopsy to confirm recurrence with:
- Bone Scan
- CT or MRI of abdomen
- CXR
- ER/PR
- HER2
- Creatinine
- CA15-3
- Test for markers
- Circulating tumor cells
- If intact breast, bilateral diagnostic mammogram
- Ultrasound of affected sites including regional nodal basin
- Consider PET/CT scan

Previous breast radiotherapy?

Yes

Breast intact?

Yes

Resectable?

Yes

Surgical resection with margin assessment

Endocrine therapy or HER2-directed therapy with or without chemotherapy

Resectable?

Yes

Radiotherapy to chest wall and regional lymphatics, if no previous radiation

Persistent disease?

Yes

Surveillance and endocrine therapy if hormone receptor positive

Consider chemotherapy

No

Resectable?

No

Radiotherapy to chest wall and regional lymphatics (if not DCIS alone)

Consider additional systemic therapy

No

Resectable?

Yes

Consider systemic therapy

No

Previous chest wall radiotherapy?

Yes

Consider neoadjuvant chemotherapy or endocrine therapy prior to WLE

No

Wide local excision (WLE) with margin assessment

Consider systemic therapy

Surveillance and hormonal treatment if estrogen receptor positive

No

Invasive histology?

Yes

Total mastectomy with lymph node surgery (consider sentinel lymph node surgery if clinically node negative)

No

Breast conservation therapy with margin assessment, or

Total mastectomy; lymph node surgery; radiotherapy

No

Surveillance and endocrine therapy if hormone receptor positive

Yes

Consider systemic therapy

No

Consider systemic therapy
APPENDIX A – Recommended Chemotherapy Regimens

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Drugs</th>
<th>Doses</th>
<th>Schedule</th>
<th>Frequency</th>
<th>Cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adjuvant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pac – FAC</td>
<td>Paclitaxel</td>
<td>80 mg/m2 IV over 1 hour</td>
<td>Weekly</td>
<td>every 7 days</td>
<td>12 weeks</td>
</tr>
<tr>
<td>(total 24 weeks)</td>
<td>followed by 5-Fluorouracil</td>
<td>500 mg/m2 IV</td>
<td>Days 1* or bolus Days 1</td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Doxorubicin</td>
<td>50 mg/m2 IV Continuous Infusion</td>
<td>48-96 hours</td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Cyclophosphamide</td>
<td>500 mg/m2 IV</td>
<td></td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td><strong>Trastuzumab-Based</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Adjuvant</td>
<td>Doxorubicin</td>
<td>60 mg/m2 IV</td>
<td>Day 1</td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Cyclophosphamide</td>
<td>600 mg/m2 IV</td>
<td>Day 1</td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>followed by Paclitaxel</td>
<td>80 mg/m2 IV over 1 hour</td>
<td>Weekly</td>
<td>every 7 days</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Trastuzumab</td>
<td>4 mg/kg IV followed by 2 mg/kg IV</td>
<td>Weekly</td>
<td>every 7 days</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>followed by Trastuzumab</td>
<td>2 mg/kg IV or 6 mg/kg IV</td>
<td>Weekly or</td>
<td>every 7 days</td>
<td>Complete 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Day 1</td>
<td>every 21 days</td>
<td></td>
</tr>
<tr>
<td><strong>Trastuzumab</strong></td>
<td>Paclitaxel</td>
<td>80 mg/m2 IV over 1 hour</td>
<td>Weekly</td>
<td>every 7 days</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Neoadjuvant</td>
<td>Trastuzumab</td>
<td>4 mg/kg IV followed by 2 mg/kg IV</td>
<td>Weekly</td>
<td>every 7 days</td>
<td>12 weeks</td>
</tr>
<tr>
<td>PH - FEC(75)H</td>
<td>followed by Fluorouracil</td>
<td>500 mg/m2 IV</td>
<td>Day 1</td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Epirubicin</td>
<td>75 mg/m2 IV</td>
<td>Day 1</td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Cyclophosphamide</td>
<td>500 mg/m2 IV</td>
<td>Day 1</td>
<td>every 21 days</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Trastuzumab</td>
<td>2 mg/kg IV</td>
<td>Weekly</td>
<td>every 7 days</td>
<td>1 year</td>
</tr>
</tbody>
</table>

* If doxorubicin is given as a continuous infusion, the 5-fluorouracil is given on day 1 and at the end of the infusion. For example, if doxorubicin is given over 72 hours, then the 5-fluorouracil is given on day 1 and 4.

** Cardiac monitoring at baseline, 3,6 and 9 months.
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### APPENDIX A – Chemotherapy Regimens

**Adjuvant/Neoadjuvant non-Trastuzumab Chemotherapy regimens:**
- FAC/CAF (fluorouracil/doxorubicin/cyclophosphamide or fluorouracil/doxorubicin/cyclophosphamide)
- FEC/CEF (cyclophosphamide/epirubicin/fluorouracil)
- AC (doxorubicin/cyclophosphamide) with/without sequential paclitaxel
- EC (epirubicin/cyclophosphamide)
- TAC (docetaxel/doxorubicin/cyclophosphamide) with filgrastim support
- Doxorubicin followed by CMF (cyclophosphamide/methotrexate/fluorouracil)
- Epirubicin followed by CMF (cyclophosphamide/methotrexate/fluorouracil)
- CMF (cyclophosphamide/methotrexate/fluorouracil)
- AC for 4 cycles (doxorubicin/cyclophosphamide) followed by sequential paclitaxel times 4, every 2 weeks with filgrastim support
- Doxorubicin followed by paclitaxel followed by cyclophosphamide every 2 weeks with filgrastim support
- Docetaxel/cyclophosphamide
- FEC (fluorouracil/epirubicin/cyclophosphamide) followed by docetaxel

**Adjuvant/Neoadjuvant Trastuzumab Chemotherapy regimens:**
- AC (doxorubicin/cyclophosphamide) followed by paclitaxel plus trastuzumab
- Docetaxel plus trastuzumab followed by FEC (fluorouracil/epirubicin/cyclophosphamide)
- TCH (docetaxel/carboplatin/trastuzumab)
- Chemotherapy followed by trastuzumab sequentially
- AC (doxorubicin/cyclophosphamide) followed by docetaxel plus trastuzumab
- Paclitaxel plus trastuzumab followed by FEC (fluorouracil/epirubicin/cyclophosphamide) plus trastuzumab

### APPENDIX B - Clinical Scenarios Requiring Individualized Therapy:

#### Brain metastases
- Cord compression
- Ureteral obstruction
- Leptomeningeval disease
- Impending pathologic fracture
- Impending pathologic fracture
- Pathologic fracture
- Extensive local-regional disease
- Pleural effusion

**NOTE:** Oligometastases – selected patients with isolated metastatic breast cancer may be considered for definitive treatment.

**Cord compression**
- Pericardial effusion
- Plexopathy/radiculopathy
- Biliary obstruction
- Superior vena cava syndrome
- Stage IV NED
- Oligometastasis
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SUGGESTED READINGS:


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SUGGESTED READINGS - Continued:


43. Hortobagyi GN. (2002). Integration of docetaxel into adjuvant breast cancer treatment regimens. Oncology,16(6 Suppl 6),27-33.


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SUGGESTED READINGS - Continued:

SUGGESTED READINGS – Chemotherapy Regimens for Metastatic Breast Cancer and in Combination with Transtuzumab

This practice consensus algorithm is based on majority expert opinion of the Breast Center Faculty at the University of Texas M.D. Anderson Cancer Center. It was developed using a multidisciplinary approach that included input from the following medical oncologists, radiation oncologists, and surgical oncologists.

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