Breast Cancer – Metastatic Disease

Note: Consider Clinical Trials as treatment options for eligible patients.

EVALUATION FOR METASTASIS

- Biopsy to confirm metastatic disease, histology, ER/PR and HER2 status
- Bone scan
- CT with contrast, PET/CT, or MRI to encompass chest, abdomen and pelvis
  - If imaging does not include PET/CT, obtain radionuclide bone scan
- CBC with differential and chemistries including renal and liver enzymes
- Consider tumor markers as an adjunctive test for monitoring response to therapy
- Assessment of symptoms and metastatic sites for clinical scenarios requiring individualized therapy
- Genetic counseling referral if indicated
- Lifestyle risk assessment

Is there a clinical scenario requiring individualized care present?

No

Yes

Multidisciplinary team discussion to determine appropriate sequencing of treatment options
- Surgical and Radiation Oncology consult as indicated (see Principles of Radiation)
- Systemic therapy
  - HR-positive/HER2-negative, see Page 2
  - HR-positive/HER2-positive, see Page 3
  - HR-negative/HER2-positive, see Page 4
  - HR-negative/HER2-negative (triple negative breast cancer), see Page 5

TREATMENT

- Molecular analysis for PIK3CA mutation
- Consider testing for ESR1 mutations

HR-positive/HER2-negative

See Page 2

HR-positive/HER2-positive

See Page 3

HR-negative/HER2-positive

See Page 4

HR-negative/HER2-negative (triple negative breast cancer)

Molecular biomarker analysis

See Page 5

ER = estrogen receptor
HER = human epidermal growth factor receptor
HR = hormone receptor
PR = progesterone receptor

Note: Patients with bone metastases and life expectancy > 12 weeks should receive a bisphosphonate if creatinine clearance ≥ 30 mL/minute or denosumab after dental evaluation, in addition to other anti-cancer therapy.

1 If bone scan shows substantial lesions in weight-bearing areas that are not included in the CTs, then additional views are indicated to rule-out impending fractures
2 See Genetic Counseling algorithm
3 See Physical Activity, Nutrition, and Tobacco Cessation algorithms; ongoing reassessment of lifestyle risks should be a part of routine clinical practice
4 Review MD Anderson approved breast biomarkers
5 HER2-positive by either immunohistochemistry 3+ or FISH, (HER2/CEP17 ratio ≥ 2 or HER2 copy number ≥ 6)

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Department of Clinical Effectiveness V1
Approved by Executive Committee of the Medical Staff on 02/15/2022
Breast Cancer – Metastatic Disease

Note: Consider Clinical Trials as treatment options for eligible patients.

**PRESENTATION**

**TREATMENT**

**EVALUATION**

Postmenopausal patients²,³:

First line therapy
- Aromatase inhibitor (AI) with palbociclib, ribociclib or abemaciclib
- If prior endocrine therapy (including adjuvant), can consider fulvestrant plus CDK4/6 inhibitor
- For select patients², consider endocrine therapy only

Second line therapy (or within one year of completing adjuvant endocrine therapy with aromatase inhibitor)
- If fulvestrant not given previously:
  - If PIK3CA mutation present, fulvestrant with alpelisib
  - If PIK3CA mutation is not present, consider fulvestrant with CDK4/6 inhibitor if not previously given or exemestane with or without everolimus
- If germline mutation (e.g., BRCA 1 or 2, palbB2), olaparib or talazoparib
- For select patients², consider endocrine therapy only

Third or subsequent lines of therapy (other endocrine or biological treatments)
- Exemestane with or without everolimus if not previously given
- Abemaciclib if no previous CDK4/6 inhibitor
- Consider olaparib or talazoparib for patients with germline BRCA mutation
- Tamoxifen • Estrogens (estradiol) • Progestins (megestrol acetate)

CDK = cyclin-dependent kinase

**Note:** Patients with bone metastases and life expectancy > 12 weeks should receive a bisphosphonate if creatinine clearance ≥ 30 mL/minute or denosumab after dental evaluation, in addition to other anti-cancer therapy.

² See Appendix B: Recurrent or Metastatic Breast Cancer Systemic Therapy Treatment Options
³ Status post surgical bilateral oophorectomy (BSO), clinically suppressed on gonadotropin analogues, > 2 years without clinical menses if stopped early due to chemotherapy, or naturally ceased menses for 2 years without clinical menses if stopped early due to chemotherapy.
⁴ If premenopausal, add ovarian function suppression or ablation
⁵ Select patients include patients at high risk for morbidity from biological options, low burden and low grade disease, clinically sensitive to endocrine therapy, etc
⁶ Consider breast surgery for patients with limited responding metastatic disease who have an intact primary

HR-positive/HER2-negative

- Provide supportive care with symptom management as indicated
- Monitor identified target lesions after every 2-3 cycles (months) of treatment by physical exam and/or imaging, as indicated
- Continue current treatment until progressive disease or unacceptable toxicity, then consider alternate endocrine therapy³,⁵
- If progressive or unacceptable toxicity and no further endocrine options consider systemic chemotherapy until progressive disease or abemaciclib if no previous CDK4/6 inhibitor³,⁵

If failure to respond to multiple systemic regimens or deterioration of Zubrod/Eastern Cooperative Oncology Group (ECOG) performance status² to ≥ 3, consider supportive care alone

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EVALUATION

Provide supportive care with symptom management as indicated
- Monitor identified target lesions after every 2-3 cycles (months) of treatment by physical exam and/or imaging, as indicated
- Continue current treatment until progressive disease or unacceptable toxicity, then consider alternate anti-HER2 therapy (with or without endocrine therapy)\textsuperscript{1,9}
- If progressive or unacceptable toxicity and no other anti-HER2 therapy or endocrine options are available, consider chemotherapy or other systemic therapy until progressive disease\textsuperscript{1,9}

If failure to respond to multiple anti-HER2 therapies and/or endocrine systemic regimens or deterioration of Zubrod/Eastern Cooperative Oncology Group (ECOG) performance status\textsuperscript{10} to ≥ 3, consider supportive care alone

PRESENTATION

TREATMENT\textsuperscript{1}

Postmenopausal patients\textsuperscript{3,4}:
- **First line therapy\textsuperscript{5}**
  - If no prior trastuzumab\textsuperscript{6} or > 1 year since adjuvant trastuzumab:
    - Paclitaxel (or docetaxel) plus trastuzumab and pertuzumab\textsuperscript{7}
    - Aromatase-inhibitor (AI) with trastuzumab or lapatinib or trastuzumab plus lapatinib
  - If ≤ 12 months from adjuvant trastuzumab or if prior (neo) adjuvant pertuzumab:
    - Ado-trastuzumab emtansine or consider alternate HER2 directed therapies\textsuperscript{1}
- **Second line therapy\textsuperscript{5}**
  - Fam-trastuzumab deruxtecan-nxki
  - Ado-trastuzumab emtansine, if not previously given
- **Third or subsequent lines of therapy\textsuperscript{5,8}**
  - Tucatinib plus trastuzumab and capcitabine
  - Capecitabine plus lapatinib or trastuzumab
  - Neratinib plus capcitabine
  - Margituximab-cmkb plus chemotherapy (capcitabine, vinorelbine, gemcitabine or eribulin)
  - Trastuzumab plus a taxane, with or without carboplatin
  - Trastuzumab plus lapatinib
  - Trastuzumab plus chemotherapy (vinorelbine, gemcitabine, capecitabine or eribulin)
  - Trastuzumab plus pertuzumab (if pertuzumab not previously given)
  - Other endocrine therapy not previously used (tamoxifen, estrogens, progestins or androgens)

Note: Patients with bone metastases and life expectancy > 12 weeks should receive a bisphosphonate if creatinine clearance ≥ 30 mL/minute or denosumab after dental evaluation, in addition to other anti-cancer therapy.

1 See Appendix B: Recurrent or Metastatic Breast Cancer Systemic Therapy Treatment Options
2 HER2-positive by either immunohistochemistry 3+ or FISHHER2/CEP17 ratio ≥ 2 or HER2 copy number ≥ 6
3 Status post surgical bilateral oophorectomy (BSO), clinically suppressed on gonadotropin analogues, > 2 years without clinical menses if stopped early due to chemotherapy, or naturally ceased menses for 1 year. For patients after hysterectomy or < 55 years old, consider verifying with estrogen, luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels. If definite BSO with hysterectomy, verification with hormone levels is not indicated.
4 If premenopausal, add ovarian function suppression or ablation
5 In patients with central nervous system metastases, tucatinib-containing regimens are preferred
6 Obtain cardiac evaluation at baseline and as clinically indicated
7 After 4-6 months with no progression or unacceptable toxicity, chemotherapy may be discontinued with continuation of trastuzumab and pertuzumab with endocrine therapy
8 Endocrine therapy may be used for maintenance of response if toxicity prompts discontinuation of anti-HER2 therapy. Endocrine therapy alone may also be used for third and subsequent lines therapy, although anti-HER2 regimens are preferred.
9 Consider breast surgery for patients with limited responding metastatic disease who have an intact primary
10 See Appendix C: Zubrod/ECOG Performance Status

Note: Consider Clinical Trials as treatment options for eligible patients.

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Note: Consider Clinical Trials as treatment options for eligible patients.

**PRESENTATION**

**First line therapy**
- If no prior trastuzumab or > 1 year since adjuvant trastuzumab:
  - Paclitaxel (or docetaxel) plus trastuzumab and pertuzumab
- If < 6 – 12 months from adjuvant trastuzumab or if prior (neo) adjuvant pertuzumab:
  - Ado-trastuzumab emtansine or consider alternate HER2 directed therapies

**Second line therapy**
- Fam-trastuzumab deruxtecan-nxki
- Ado-trastuzumab emtansine, if not previously given

**Third or subsequent lines of therapy**
- Tucatinib plus trastuzumab and capecitabine
- Capecitabine plus lapatinib or trastuzumab
- Neratinib plus capecitabine
- Margetuximab-cmkb plus chemotherapy (capecitabine, vinorelbine, gemcitabine or eribulin)
- Trastuzumab plus a taxane, with or without carboplatin
- Trastuzumab plus lapatinib
- Trastuzumab plus chemotherapy (vinorelbine, gemcitabine, capecitabine or eribulin)
- Trastuzumab plus pertuzumab (if pertuzumab not previously given)

**TREATMENT**

- Provide supportive care with symptom management as indicated
- Monitor identified target lesions after every 2-3 cycles (months) of treatment by physical exam and/or imaging, as indicated
- Continue current treatment until progressive disease or unacceptable toxicity, then consider alternate anti-HER2 therapy
- If progressive or unacceptable toxicity and no other anti-HER2 therapy options are available, consider chemotherapy until progressive disease
- Consider breast surgery for patients with limited responding metastatic disease who have an intact primary

**EVALUATION**

- If failure to respond to multiple anti-HER2 therapies or deterioration of Zubrod/Eastern Cooperative Oncology Group (ECOG) performance status to ≥ 3, consider supportive care alone

Note: Patients with bone metastases and life expectancy > 12 weeks should receive a bisphosphonate if creatinine clearance ≥ 30 mL/minute or denosumab after dental evaluation, in addition to other anti-cancer therapy.

---

1 See Appendix B: Recurrent or Metastatic Breast Cancer Systemic Therapy Treatment Options
2 HER2-positive by either immunohistochemistry 3+ or FISH, (HER2/CEP17 ratio ≥ 2 or HER2 copy number ≥ 6)
3 In patients with central nervous system metastases, tucatinib-containing regimens are preferred
4 Obtain cardiac evaluation at baseline and as clinically indicated
5 After 4-6 months with no progression or unacceptable toxicity, chemotherapy may be discontinued with continuation of trastuzumab and pertuzumab
6 Consider breast surgery for patients with limited responding metastatic disease who have an intact primary
7 See Appendix C: Zubrod/ECOG Performance Status

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Breast Cancer – Metastatic Disease

Note: Patients with bone metastases and life expectancy > 12 weeks should receive a bisphosphonate if creatinine clearance ≥ 30 mL/minute or denosumab after dental evaluation, in addition to other anti-cancer therapy

1 See Appendix B: Recurrent or Metastatic Breast Cancer Systemic Therapy Treatment Options
2 PD-L1 expression is evaluated with PD-L1 IHC (immunohistochemical assay) 22C3 and considered to be present if Combined Positive Score (CPS) is ≥ 10
3 Consider breast surgery for patients with limited responding metastatic disease who have an intact primary

**PRESENTATION**

HR-negative/HER2-negative (triple negative breast cancer)

**TREATMENT**

**First line therapy**
If PD-L1 expression is present:
- Pembrolizumab plus chemotherapy (albumin-bound paclitaxel, paclitaxel, or gemcitabine and carboplatin)
If PD-L1 expression is absent:
- For chemotherapy options, see Appendix B
- Single-agent therapy is preferred, except for patients with impending visceral crisis or very symptomatic disease
  - Gemcitabine/carboplatin is an option if recent progression on a taxane
- Combination chemotherapy is also preferred for patients with oligometastases

**Second line therapy**
- For chemotherapy options not used in first line therapy, see Appendix B
- If germline mutation (e.g., BRCA 1 or 2, palbB2), olaparib or talazoparib

**Third or subsequent lines of therapy**
- Sacituzumab govitecan-hziy preferred
- For other chemotherapy options not used in first or second line therapy, see Appendix B

**EVALUATION**

- Provide supportive care with symptom management as indicated
- Monitor identified target lesions after every 2-3 cycles (months) of treatment by physical exam and/or imaging, as indicated
- Continue current treatment until progressive disease or unacceptable toxicity, then consider alternate chemotherapy or targeted therapy
- If progressive or unacceptable toxicity and no further systemic therapy options remain, consider supportive care alone

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### APPENDIX A: Clinical Scenarios Requiring Individualized Therapy

- Oligometastases\(^1\) or Stage IV NED\(^2\)
- Brain metastases
- Leptomeningeal disease
- Choroid metastases
- Cord compression
- Plexopathy/radiculopathy
- Extensive local-regional disease
- Pathologic fracture
- Impending pathologic fracture
- Pleural effusion\(^3\)
- Pericardial effusion\(^3\)
- Superior vena cava syndrome
- Biliary obstruction
- Ureteral obstruction
- Pregnancy

\(^1\) Oligometastases includes selected patients with up to 5 metastatic lesions in the same or different organ sites. These patients may be considered for definitive treatment with curative intent.

\(^2\) Stage IV NED is considered to include patients with up to 5 metastatic lesions in the same or different organ sites who have been treated with surgical or other ablative therapy. These patients may be considered for definitive treatment with curative intent.

\(^3\) If patient is symptomatic, a multidisciplinary team discussion is required.
Breast Cancer – Metastatic Disease

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APPENDIX B: Recurrent or Metastatic Breast Cancer Systemic Therapy Treatment Options

<table>
<thead>
<tr>
<th>Chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred single agents:</strong></td>
</tr>
<tr>
<td>Anthracyclines</td>
</tr>
<tr>
<td>Doxorubicin</td>
</tr>
<tr>
<td>Pegylated liposomal doxorubicin</td>
</tr>
<tr>
<td><strong>Other single agents:</strong></td>
</tr>
<tr>
<td>Cyclophosphamide</td>
</tr>
<tr>
<td>Cisplatin</td>
</tr>
</tbody>
</table>

| Combination chemotherapy regimens: |
| FAC/CAF (cyclophosphamide, doxorubicin, and fluorouracil) | EC (epirubicin and cyclophosphamide) | | Docetaxel and capecitabine |
| FEC (fluorouracil, epirubicin, and cyclophosphamide) | CMF (cyclophosphamide, methotrexate, and fluorouracil) | Gemcitabine and paclitaxel |
| AC (doxorubicin and cyclophosphamide) | Gemcitabine and carboplatin | | Ixabepilone/capecitabine |

<table>
<thead>
<tr>
<th>HER2 Based Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First-line regimens for HER2-positive disease:</strong> (patients with trastuzumab naïve disease or those who recurred &gt; 12 months after adjuvant trastuzumab)</td>
</tr>
<tr>
<td>Pertuzumab plus trastuzumab and plus paclitaxel</td>
</tr>
<tr>
<td>Pertuzumab trastuzumab and docetaxel</td>
</tr>
</tbody>
</table>

| Other options (not considered preferred first options): |
| Trastuzumab with docetaxel |
| Trastuzumab with paclitaxel with or without carboplatin |
| Trastuzumab with vinorelbine |
| Trastuzumab with capecitabine |
| Trastuzumab plus pertuzumab (if pertuzumab not previously given) |

| Regimens for trastuzumab-exposed HER2-positive disease: |
| Ado-trastuzumab emtansine for recurrence ≤ 12 months after adjuvant trastuzumab |
| Fam-trastuzumab deruxtecan-nxki |
| Trastuzumab plus lapatinib without cytotoxic therapy |
| Trastuzumab plus chemotherapy (capecitabine, vinorelbine, gemcitabine or eribulin) |
| Margeluximab-cmkb plus chemotherapy (capecitabine, vinorelbine, gemcitabine or eribulin) |
| Lapatinib plus capecitabine |
| Trastuzumab plus pertuzumab plus capecitabine |
| Neratinib plus capecitabine |
| Tucatinib plus trastuzumab plus capecitabine |

1. Dose-dense AC is not indicated for treatment of metastatic breast cancer
2. After maximal benefit achieved with chemotherapy, consider continuous anti-HER2 therapy alone, if ER or PR positive, in combination with appropriate endocrine therapy (does not apply to ado-trastuzumab emtansine)

Continued on next page
### APPENDIX B: Recurrent or Metastatic Breast Cancer Systemic Therapy Treatment Options - continued

#### Endocrine Based Therapies

- **Aromatase inhibitors (AI)**
  - AI with or without CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib)
  - Anastrozole
  - Letrozole
  - Exemestane
  - Exemestane plus everolimus
- **Tamoxifen**

- Fulvestrant
  - Fulvestrant with alpelisib for PIK3CA mutation
  - Fulvestrant with or without CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib)
  - Fulvestrant with AI
- **Abemaciclib single agent**
- **Progestin (megestrol acetate)**
- **Estrogen (estradiol)**

#### Other Therapies

**HR-negative/HER2-negative (triple negative breast cancer) with PDL1 expression:**
- Pembrolizumab plus chemotherapy (albumin-bound paclitaxel, paclitaxel, or gemcitabine and carboplatin)

**BRCA-positive directed therapies:**
- Olaparib
- Talazoparib

**Molecularly targeted agents along with NTRK fusion-directed:**
- Larotrectinib and Entrectinib plus MSI-H/dMMR-positive

**Total Mutation Burden-High (TMB-H: ≥ 10 muts/mb):**
- Pembrolizumab

**Bone-directed therapies:**
- Pamidronate disodium
- Zoledronic acid
- Denosumab
- Strontium-89
- Samarium Sm 153 lexidronam
APPENDIX C: Zubrod/ECOG Performance Status

<table>
<thead>
<tr>
<th>Description</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully active, able to carry on all pre-disease performance without restriction</td>
<td>0</td>
</tr>
<tr>
<td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g., light house work, office)</td>
<td>1</td>
</tr>
<tr>
<td>Ambulatory and capable of self care but unable to perform any work activities; up and about &gt; 50% of waking hours</td>
<td>2</td>
</tr>
<tr>
<td>Capable of only limited self care, confined to bed or chair &gt; 50% of waking hours</td>
<td>3</td>
</tr>
<tr>
<td>Completely disabled, cannot carry on any self care, totally confined to bed or chair</td>
<td>4</td>
</tr>
<tr>
<td>Dead</td>
<td>5</td>
</tr>
</tbody>
</table>

ECOG = Eastern Cooperative Oncology Group
Breast Cancer – Metastatic Disease

PRINCIPLES OF BREAST ONCOLOGIC SURGERY

Stage IV disease

- Traditionally, surgical management of the primary and regional nodes are not recommended in the setting of stage IV disease
- In selected patients with oligometastatic disease, excellent response to systemic therapy and acceptable performance status, surgery and/or radiotherapy of the primary tumor, nodal involvement, and all oligometastatic sites is recommended
- Radiation therapy and/or palliative mastectomy may be considered in patients with advanced local progression, symptomatic fungating and/or bleeding tumors not responsive to systemic therapy

Oligometastatic Disease

- For patients with oligometastatic disease who have undergone definitive surgery, conventional treatment with whole breast or chest wall and undissected draining lymphatics, to include the internal mammary nodes (IMN), supraclavicular (SCV), and level III axilla is recommended. Include level I/II axilla if axillary lymph node dissection (ALND) not performed.
- Additional treatment of the oligometastatic disease site, (e.g., bone, lung, liver) with radiation therapy or enrollment in a trial for randomization to treatment is also recommended. Trial radiation doses may be reasonable for patients being considered for definitive treatment off trial.
- Consultation to other radiation services based on oligometastatic disease site may be warranted as follows:
  - Brain with < 10 metastatic lesions: CNS Radiation Oncology
  - Spine with limited (1-2) vertebral body involvement: CNS Radiation Oncology for stereotactic treatment
  - Skull base: Head and Neck Radiation Oncology
  - Lung metastases: Thoracic Radiation Oncology
  - Liver metastases: Gastrointestinal Radiation Oncology
  - Limited bone metastases: Breast Radiation Oncology

Widely Metastatic Disease

- Consultation to other radiation services for non-oligometastatic disease should be considered for the following:
  - Brain with ≥ 10 metastatic lesions, diffuse spine disease or leptomeningeal disease (LMD): Breast Radiation Oncology
  - Diffuse bone disease, including spine or bone disease causing pain or at risk of fracture: Radiation Oncology Bone Metastatic Clinic or Breast Radiation Oncology
  - Bleeding and/or painful and/or fungating primary mass: Breast Radiation Oncology

PRINCIPLES OF RADIATION

Oligometastatic Disease

- For patients with oligometastatic disease who have undergone definitive surgery, conventional treatment with whole breast or chest wall and undissected draining lymphatics, to include the internal mammary nodes (IMN), supraclavicular (SCV), and level III axilla is recommended. Include level I/II axilla if axillary lymph node dissection (ALND) not performed.
- Additional treatment of the oligometastatic disease site, (e.g., bone, lung, liver) with radiation therapy or enrollment in a trial for randomization to treatment is also recommended. Trial radiation doses may be reasonable for patients being considered for definitive treatment off trial.
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  - Spine with limited (1-2) vertebral body involvement: CNS Radiation Oncology for stereotactic treatment
  - Skull base: Head and Neck Radiation Oncology
  - Lung metastases: Thoracic Radiation Oncology
  - Liver metastases: Gastrointestinal Radiation Oncology
  - Limited bone metastases: Breast Radiation Oncology

Widely Metastatic Disease

- Consultation to other radiation services for non-oligometastatic disease should be considered for the following:
  - Brain with ≥ 10 metastatic lesions, diffuse spine disease or leptomeningeal disease (LMD): Breast Radiation Oncology
  - Diffuse bone disease, including spine or bone disease causing pain or at risk of fracture: Radiation Oncology Bone Metastatic Clinic or Breast Radiation Oncology
  - Bleeding and/or painful and/or fungating primary mass: Breast Radiation Oncology
Breast Cancer – Metastatic Disease

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SUGGESTED READINGS


Continued on next page
SUGGESTED READINGS - continued


*Continued on next page*
SUGGESTED READINGS - continued


Continued on next page
SUGGESTED READINGS - continued


This practice algorithm is based on majority expert opinion of the Breast Center Faculty at the University of Texas MD Anderson Cancer Center. It was developed using a multidisciplinary approach that included input from the following:

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Core Development Team
Clinical Effectiveness Development Team

Continued on next page
Development Credits - continued

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