ACTION:
☒ New Policy
☐ Revising Policy Number
☐ Superseding Policy Number
☐ Archiving Policy Number
☐ Retiring Policy Number

Effective Date: 06/02/2017

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement. Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

POLICY:

For US Family Health Plan see TRICARE Policy Manual 6010.57-M, February 1, 2008, Pathology and Laboratory: Chapter 6, Section 1.1

For Advantage MD:
Local Coverage Determinations (LCDs) do not exist at this time. (Accessed April 3, 2017) Medicare does not have a National Coverage Determination (NCD) for breast cancer biomarker tests.

I. When benefits are provided under the member’s contract, JHHC considers the following, ASCO recommended biomarker tests medically necessary to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer:
   A. Estrogen receptor
   B. Progesterone receptor
   C. HER2 receptor
   D. Oncotype DX
   E. EndoPredict
   F. PAM50
   G. Breast Cancer Index
   H. Urokinase plasminogen activator/plasminogen activator inhibitor type 1

II. Unless specific benefits are provided under the member’s contract, JHHC considers all other biomarker tests to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer experimental and investigational, as they do not meet Technology Evaluation Criteria (TEC) #2-5.
BACKGROUND:

Biomarkers are substances found in the blood, urine, or tumors of a person with cancer that can help predict how cancer will respond to certain treatments (Weigel, 2010). Estrogen receptor (ER), progesterone receptor (PR), and HER2 are examples of common biomarkers used for breast cancer. To help predict the recurrence of breast cancer in patients who are ER/PR-positive or HER2-negative, the American Society of Clinical Oncology recommends one of the following tests: Oncotype DX, EndoPredict, Breast Cancer Index, and PAM50. These tests estimate recurrence risk in patients through genetic analysis following a tumor biopsy (ASCO, 2017).

CODING INFORMATION:

*CPT Copyright 2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.*

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member’s specific benefit plan determines coverage and referral requirements. All inpatient admissions require pre-authorization.

**PRE-AUTHORIZATION REQUIRED**

*Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits*

<table>
<thead>
<tr>
<th>Employer Health Programs (EHP)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>See Specific Summary Plan Description (SPD)</strong></td>
</tr>
</tbody>
</table>

| Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply policy criteria |

| US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria |

| Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria |

<table>
<thead>
<tr>
<th>CPT ® CODES</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>81519</td>
<td>Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score</td>
</tr>
</tbody>
</table>
HCPCS CODES | DESCRIPTION
--- | ---
S3854 | Gene expression profiling panel for use in the management of breast cancer treatment

**NO PRE-AUTHORIZATION REQUIRED**

*Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits*

CPT® CODES | DESCRIPTION
--- | ---
85415 | Fibrinolytic factors and inhibitors; plasminogen activator
88360 | Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual
88361 | Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology
88377 | Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure

ICD10 CODES ARE FOR INFORMATIONAL PURPOSES ONLY

ICD10 CODES | DESCRIPTION
--- | ---
C50.011-C50.929 | Malignant neoplasm of breast
C77.3 | Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes

REVENUE CODES

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
</tr>
</thead>
</table>
| 0310 | Laboratory Pathology-General; Hospital; outpatient

**REFERENCE STATEMENT:**

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.
REFERENCES:


