Drug Policy:

Kadcyla™ (ado-trastuzumab emtansine)

I. PURPOSE

To define and describe the accepted indications for Kadcyla (ado-trastuzumab emtansine) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When available, generic alternatives are preferred over brand-name drugs.

B. HER-2 Positive Breast Cancer

1. Metastatic HER-2 positive breast cancer: Kadcyla (ado-trastuzumab emtansine) may be used as a single agent for members who have experienced disease progression after prior therapy with [trastuzumab,+,pertuzumab] +/- chemotherapy, e.g., a taxane.

2. For adjuvant therapy of members with stages I-III HER-2 positive breast cancer: Kadcyla (ado-trastuzumab emtansine) is the preferred drug, used as a single agent in members with stage I-III HER-2 positive breast cancer, who have undergone neoadjuvant therapy, and have residual disease in the breast and/or axillary nodes after surgery. See table below:

<table>
<thead>
<tr>
<th>Disease characteristics</th>
<th>Neoadjuvant Preferred Rx</th>
<th>Adjuvant Preferred Rx</th>
<th>Adjuvant Preferred Rx</th>
<th>Adjuvant Preferred Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No Residual Disease after Neoadjuvant Therapy</td>
<td>Residual Disease present after Neoadjuvant Therapy</td>
<td>No Neoadjuvant Therapy given</td>
</tr>
<tr>
<td>NODE negative or Stage I disease</td>
<td>Trastuzumab + Chemo</td>
<td>Additional Trastuzumab; Additional Chemo if not completed pre-op</td>
<td>Kadcyla</td>
<td>Trastuzumab + Chemo then additional Trastuzumab</td>
</tr>
<tr>
<td>NODE positive or Stage II or III disease</td>
<td>Trastuzumab + Pertuzumab + Chemotherapy</td>
<td>Additional Trastuzumab + Pertuzumab; Additional Chemo if not completed pre-op</td>
<td>Kadcyla</td>
<td>Trastuzumab + Pertuzumab + Chemotherapy, then additional Trastuzumab + Pertuzumab</td>
</tr>
</tbody>
</table>

III. EXCLUSION CRITERIA

A. Concurrent use with trastuzumab, lapatinib, pertuzumab, Enhertu, or other chemotherapy; endocrine therapy may continue concurrently with Kadcyla if indicated.

B. Disease progression while taking Kadcyla (ado-trastuzumab emtansine).

C. Dosing exceeds single dose limit of Kadcyla (ado-trastuzumab emtansine) 3.6 mg/kg.

D. Dosing exceeds maximum duration of 14 cycles for adjuvant (curative-intent) treatment.

E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department
B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS
A. None

VII. REFERENCES