Pembrolizumab (Keytruda®)

<table>
<thead>
<tr>
<th>Iowa Medicaid Program:</th>
<th>Prior Authorization</th>
<th>Effective Date:</th>
<th>4/30/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision Number:</td>
<td>1</td>
<td>Last Review Date:</td>
<td>1/15/2016</td>
</tr>
<tr>
<td>Reviewed By:</td>
<td>Medicaid Clinical Advisory Committee</td>
<td>Next Review Date:</td>
<td>1/2017</td>
</tr>
<tr>
<td>Approved By:</td>
<td>Medicaid Medical Director</td>
<td>Approved Date:</td>
<td>4/27/2016</td>
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Pembrolizumab is an injectable anti-PD-1 humanized monoclonal antibody antineoplastic, U.S. Food and Drug Administration (FDA) has approved as Keytruda® (pembrolizumab) with unresectable, metastatic melanoma if BRAF V600 mutation positive, a BRAF inhibitor. It has also been approved for the treatment of advanced metastatic non small cell lung cancer (NSMCLC) that has failed traditional chemotherapy AND is positive for PD L1 receptor based on the PD L1 IHC 22C3 pharmDx test.

Criteria: **ALL OF THE FOLLOWING** must be met:
1. The member must have unresectable or metastatic melanoma or a NSCLC which has progressed or failed to respond to traditional chemotherapy.
2. For metastatic melanoma, the BRAF V600 inhibitor must be positive.
3. Members with metastatic NSCLC must have tumors which test positive for the PD-1 ligand.
4. The member is not pregnant. Nursing should be discontinued during treatment.
5. Female patients of reproductive potential must be advised of potential hazard to a fetus. Advise females of reproductive potential to use highly effective contraception during treatment and for 4 months after the last dose of Keytruda®.
6. If hypophysitis is present, the member must be on appropriate physiologic replacement endocrine therapy.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. Should additional information from these trials fail to support ongoing FDA approval, the Medical director has authority to discontinue authorizing use of pembrolizumab (Keytruda®) immediately on receipt of this information pending further investigation.

**Codes:**
- HCPCS Codes:
  - J9999
  - J3590
  - J3490
  - C9399
  (for use only on Medicare hospital outpatient claims)

**References Used:**
- Merck Sharp & Dohme Corp., Keytruda® product information [www.keytruda.com](http://www.keytruda.com) (8/14)
References Used (cont):
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Change History:

<table>
<thead>
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<th>Change Date</th>
<th>Changed By</th>
<th>Description of Change</th>
<th>New Version Number</th>
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<tr>
<td>1/15/16</td>
<td>CAC</td>
<td>Removed dosing information. Removed reference to ipilimumab (Yervoy). Added information on non-small cell lung cancer (NSMCLC).</td>
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C. David Smith, MD