blue of california

vemurafenib (ZELBORAF)

Diagnoses Considered for Coverage:

- Malignant melanoma with BRAF V600 gene mutation – unresectable or metastatic
- Erdheim-Chester disease
- Non-small cell lung cancer (NSCLC)
- Hairy cell leukemia
- Differentiated thyroid gland carcinoma (follicular, Hurthle cell, papillary)-metastatic or recurrent
- Histiocytic neoplasms: Langerhans Cell Histiocytosis, and Erdheim-Chester disease
- CNS low-grade gliomas, anaplastic gliomas and glioblastoma

Coverage Criteria:

1. **For diagnosis of malignant melanoma:**
   - Provider attestation that patient has BRAF V600 activating mutation (e.g. V600E or V600K), **and**
   - One of the following:
     - ***For recurrent, unresectable, or metastatic disease:*** Being used as a single agent or in combination with Cotellic with or without Tecentriq, or
     - ***For adjuvant treatment:*** Being used in combination with Cotellic and patient has intolerance or contraindication with a Tafinlar and Mekinist combination regimen, **and**
   - Dose does not exceed 1920 mg per day.

2. **For diagnosis of histiocytic neoplasms: Langerhans Cell Histiocytosis, and Erdheim-Chester disease:**
   - Provider attestation of positive BRAF V600E mutation, **and**
   - Being used as single agent therapy, **and**
   - Dose does not exceed 1920 mg per day.

3. **For diagnosis of non-small cell lung cancer:**
   - Being used for recurrent, advanced, metastatic disease, **and**
   - Provider attestation of positive BRAF V600E mutation, **and**
   - Being used as single agent therapy, **and**
   - Patient has intolerance or contraindication to Tafinlar and Mekinist combination regimen, **and**
   - Dose does not exceed 1920 mg per day.

4. **For diagnosis of hairy cell leukemia:**
   - One of the following:
     - Being used in combination with obinutuzumab (Gazyva) for initial treatment, or
     - Being used as a single agent or in combination with rituximab for progressive, relapsed, or refractory disease, **and**
   - Dose does not exceed 1920 mg per day.

5. **For diagnosis of advanced differentiated (follicular, Hurthle cell, and papillary) thyroid cancer:**
   - Inadequate response, intolerable side effect, or contraindication to Lenvima (lenvatinib) or Nexavar (sorafenib), **and**
   - Provider attestation of positive BRAF mutation, **and**
   - Dose does not exceed 1920 mg per day.

6. **For CNS low-grade gliomas, anaplastic gliomas and glioblastoma:**
   - Provider attestation of positive BRAF V600E mutation, **and**
   - Being used in combination with Cotellic, **and**
   - Dose does not exceed 1920 mg per day.

Coverage Duration: one year

References:

1. Prescribing Information. Zelboraf. Genentech Inc. 2020