ibrutinib (IMBRUVICA)

Diagnoses Considered for Coverage:

- Chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL)
- Graft Vs Host Disease (GVHD)
- Waldenstrom's macroglobulinemia
- B-cell lymphomas (e.g. see below)
  - Mantle cell lymphoma (MCL),
  - Marginal zone lymphoma (e.g. Extra-Nodal MZL, Splenic MZL, Nodal MZL),
  - Diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, HIV-related non-germinal center diffuse large B-cell lymphoma, and monomorphic post-transplant lymphoproliferative disorders (PTLD),
- Hairy cell leukemia
- Primary CNS lymphoma

Coverage Criteria:

2. **For B-CELL LYMPHOMAS:**
   - ***For 140 mg tablet request:*** Patient is unable to take the 140 mg capsule, **and**
   - Dose not to exceed 560 mg per day, **and**
   - One of the following:
     - Diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, HIV-related non-germinal center diffuse large B-cell lymphoma, and monomorphic post-transplant lymphoproliferative disorders (PTLD), and all of the following:
       - Being used as a single agent, and
       - Being used for second-line or subsequent therapy

       OR
     - **For marginal zone lymphoma (e.g. Nodal MZL, extra-nodal MZL, Splenic MZL, and all of the following:**
       - Being used as a single agent for second-line or subsequent therapy, and
       - Patient is unable to receive treatment with Brukinsa (zanubrutinib) or Calquence (acalabrutinib).

       OR
     - **For mantle cell lymphoma (MCL), and one of the following:**
       - One of the following:
         - Being used as single agent therapy or in combination with venetoclax (Venclexta) or rituximab for second line and subsequent therapy, **and**

- Patient is unable to receive treatment with Brukinsa (zanubrutinib) or Calquence (acalabrutinib).

OR

- Being used for aggressive induction therapy, and
  - Being used as a component of TRIANGLE regimen, or
  - Being used in combination with rituximab as pre-treatment to limit the number of cycles of RHyperCVAD

OR

- Being used in combination with rituximab for maintenance following high dose therapy/autologous stem cell rescue or aggressive induction therapy.

3. **For chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL):**
   - ***For 140 mg tablet request:*** Patient is unable to take the 140 mg capsule, **and**
   - Dose not to exceed 420 mg per day, **and**
   - Being used as a single agent.

4. **For Waldenstrom's macroglobulinemia:**
   - ***For 140 mg tablet request:*** Patient is unable to take the 140 mg capsule, **and**
   - Dose not to exceed 420 mg per day, **and**
   - One of the following:
     - Being used as single agent therapy or
     - Being used in combination with rituximab

5. **For Graft Vs Host Disease (GVHD):**
   - ***For 140 mg tablet request:*** Patient is unable to take the 140 mg capsule, **and**
   - Dose not to exceed 420 mg per day, **and**
   - Inadequate response to at least one prior drug (i.e. systemic corticosteroids, immunosuppressants [e.g. cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus, sirolimus]) for GVHD.

6. **For hairy cell leukemia:**
   - ***For 140 mg tablet request:*** Patient is unable to take the 140 mg capsule, **and**
   - Dose not to exceed 420 mg per day, **and**
   - Being used as a single agent, **and**
   - Disease progression despite treatment for relapsed or refractory disease.

7. **For primary CNS Lymphoma:**
   - ***For 140 mg tablet request***: Patient unable to take 140 mg capsule, **and**
   - Dose does not exceed 840 mg per day, **and**

- One of the following:
  - Being used as single agent therapy, or
  - Being used in combination with a rituximab-based regimen for relapsed or refractory disease.

Coverage Duration: one year

Effective Date: 02/28/2024