

ZANUBRUTINIB (BRUKINSA) 80MG CAPSULE

Chronic Lymphocytic Leukemia

- As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, or unmutated IGHV).
- 2. As monotherapy for the treatment of adult patients with relapsed or refractory CLL / SLL who have received at least one prior systemic therapy.

Renewal Criteria:

• Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

- 1. Patients must have a good performance status and no evidence of prolymphocytic leukemia or Richter's transformation.
- 2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.
- Approval period: 1 year.

Waldenström Macroglobulinemia

For the treatment of adult patients with relapsed or refractory Waldenström macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.

Renewal Criteria:

• Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

- 1. Patients must meet at least one criterion for treatment as per International Workshop on WM (IWWM) consensus panel.
- 2. Patients must have a good performance status and no evidence of disease transformation.
- 3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

• Approval period: 1 year.

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