Imbruvica® (ibrutinib)

FDA INDICATIONS AND USAGE

- Mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) in patients who have received at least one prior therapy.
- Chronic lymphocytic leukemia 17p deletion.

APPROVAL CRITERIA

1. Patients with a diagnosis of mantle cell lymphoma (MCL) who have trialed at least one prior therapy; **OR**
2. Patients with a diagnosis of chronic lymphocytic leukemia (CLL) who do not have 17p deletion who have trialed at least one prior therapy; **OR**
3. Patients with a diagnosis of deletion 17p chronic lymphocytic leukemia (CLL).

DENIAL CRITERIA:

1. Renewal authorizations will not be approved if the patient has had more than three therapy interruptions due to adverse reactions/toxicities.
2. Pregnancy

CAUTIONS:

- Imbruvica should be avoided in patients taking strong CYP3A inhibitors and inducers (see package insert for complete information).
- If Imbruvica must be taken concomitantly with a moderate CYP3A inhibitor, please refer to package insert for dose reduction guidance of Imbruvica.

DURATION OF APPROVAL:

- Approval may be granted up to 1 year

QUANTITY LIMIT:

- MCL – four 140mg capsules (560mg) per day
- CLL – three 140mg capsules (420mg) per day

REFERENCES / FOOTNOTES:

1. Imbruvica® [package insert]. Sunnyvale, CA; Pharmacyclics, Inc., July 2014.