



DISEASE BURDEN

Chronic Lymphocytic Leukaemia (CLL) is the most common type of leukaemia in Western countries, making up about 25% to 30% of all leukaemia cases. In some countries of Central Sub-Saharan Africa, the death rate from CLL is rising rapidly.



INTELLECTUAL PROPERTY LANDSCAPE

Ibrutinib primary patent expires in 2026 and it has been granted in few LMICs, including India. Secondary patents with expiry dates ranging between 2031 and 2036 covering formulations, methods of treatment or crystalline forms are present in many LMICs.



SERVICE DELIVERY ENABLERS

CLINICAL RELEVANCE

Ibrutinib treatment, when used as the first

option for CLL patients, continues to provide

better survival and delays cancer progression compared to chemotherapy for up to eight years.

CLL is a relatively rare condition in LMICs. Access to diagnosis is still challenging. Blood count capacity is widely available, but more sophisticated tests required for the diagnosis are scarcely available or affordable in the majority of LMICs.



ONCOLOGY
CHRONIC LYMPHOCYTIC
LEUKEMIA

Janssen



Product approved by stringent regulatory authorities.
Potential sublicensees of ibrutinib can rely on
mechanisms adopt standard registration procedures
like USFDA Paragraph III, Swissmedic MAGHP, EUM4all. Bioequivalence studies are necessary.
Biowaivers will not be an option.



MANUFACTURING

Standard manufacturing process for oral formulation. No challenges with respect to excipients or final packaging. Probable occupational exposure band category 3, manufacturing precautions may be required. Shelf life is 3 years at room temperature for tablets and capsules and 2 years at 2-25 degrees for oral suspension.

MARKET

Ibrutinib appears to be more expensive than standard chemotherapy drugs such as bendamustine and fludarabine. It is scarcely available and affordable in public domain in LMICs.



