

CLINICAL RELEVANCE



Cabotegravir with rilpivirine is the only injectable long-acting regimen approved for HIV so far. This combination is safe and efficacious for HIV treatment, despite some challenges for use in LMICs. Recent implementation data indicate initial success in LMIC settings and in adolescents, paving the way to broader adoption. The injectable cabotegravir and rilpivirine regimen for HIV treatment is not currently listed in WHO guidelines.

DISEASE BURDEN



In 2022, 39.0 million people globally were living with HIV and 1.3 million people became newly infected, most of which occurred in LMICs.

INTELLECTUAL PROPERTY LANDSCAPE



Primary patents on cabotegravir have been granted in many LMICs and are expected to expire in 2026. Secondary patents on the long-acting parenteral composition as well as intermediates and processes are expected to expire in 2031. MPP holds a licence with ViiV Healthcare for the use of cabotegravir for HIV PrEP. Rilpivirine primary patent has expired except in a few countries where the term has been extended until 2026-2027. Secondary patents on formulation are present in many LMICs and are expected to expire in 2027.

SERVICE DELIVERY ENABLERS



Cabotegravir is used in combination with rilpivirine as a long-acting injectable for the treatment of HIV. Rilpivirine has a cold chain requirement, limiting its potential for impact in LMICs. Transitioning to long-acting HIV treatment has adherence benefits, but the health system requirements may be higher than a daily oral regimen at primary healthcare or community levels.

CABOTEGRAVIR + RILPIVIRINE LONG-ACTING

HIV
TREATMENT

ViiV & Janssen

REGULATORY



The product is approved by stringent regulatory authorities. Potential sublicensees could potentially receive tentative approval from the USFDA for quality assurance. Pharmacokinetics (PK)-based bioequivalence studies will be required. Bioequivalence studies will be complex and long since it is a long-acting injectable. Biowaiver is not possible.

MANUFACTURING



The product requires sterile long-acting injectable nanosuspension formulation with specific requirements in terms of technology and manufacturing equipment. There are no anticipated challenges with respect to excipients. There is a requirement for special packaging for the medical device. Due to complex manufacturing technology, there are special manufacturing facilities requirements. Shelf life is three years with refrigeration.

MARKET



Cabotegravir and rilpivirine long-acting combination for HIV treatment has been registered in very few LMICs. Implementation trials are ongoing. Access plans are not yet known.