

DISEASE BURDEN



In 2023, 39.9 million people globally were living with HIV, 1.3 million people became newly infected, and 630,000 people died of HIV, most of which occurred in LMICs.



CLINICAL RELEVANCE



Cabotegravir together with rilpivirine is the only approved long-acting HIV treatment regimen. The combination is approved as a monthly or every-two-month intramuscular injections for virologically suppressed adults without prior HIV treatment failure. It is efficacious and improves adherence, supporting viral suppression. Challenges include risk of resistance and considerations related to co-infections with TB and HBV. The CARES study in sub-Saharan Africa found this regimen non-inferior to standard of care, supporting its potential for roll-out in LMICs. This long-acting injectable regimen is currently not included in the WHO guide lines.



SERVICE DELIVERY ENABLERS

Cabotegravir and rilpivirine are administered by trained professionals as two separate intramuscular injections. Rilpivirine has a cold chain requirement, potentially posing a challenge for effective roll-out in some resource limited settings. Transitioning to long-acting HIV treatment may provide benefits for adherence, but health system requirements may be higher than a daily oral regimen at primary healthcare or community levels.



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 for rilpivirine, and without refrigeration for cabotegravir.



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TREATMENT ViiV Healthcare

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.

MARKET



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