

DISEASE BURDEN

In 2022, 39 million people globally were living with HIV and 1.3 million people became newly infected, most of which occurred in LMICs.




CLINICAL RELEVANCE

Lenacapavir is a first-in-class capsid inhibitor, approved for treatment of multi-drug resistant HIV infection in adults. It is studied for HIV PrEP as a subcutaneous injection every 6 months and has a promising safety profile. Results are expected by September 2024.



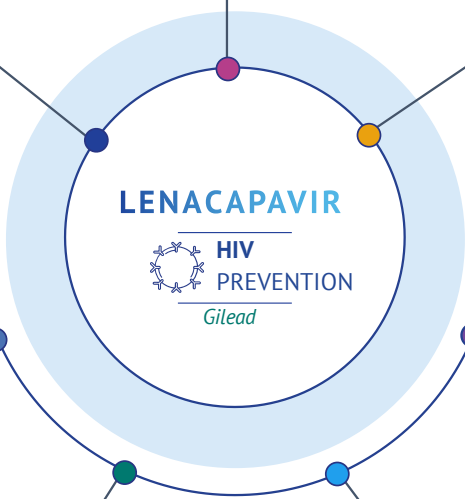

INTELLECTUAL PROPERTY LANDSCAPE

Lenacapavir primary patents have been filed or granted in several LMICs and are expected to expire between 2034 and 2037. Gilead also holds secondary patents that may provide exclusivity until 2038 in many LMICs.




SERVICE DELIVERY ENABLERS

Lenacapavir for PrEP would not require companion drugs. While it may have advantages in terms of adherence, health system requirements might be higher compared to once-daily oral PrEP options such as TDF/FTC. However, the upcoming access to long-acting cabotegravir for PrEP in LMICs will likely pave the way for successful lenacapavir implementation, if proven safe and effective.


REGULATORY

While lenacapavir for PrEP is not approved regulatory authorities yet, the formulation appears to be the same as the approved treatment.



MANUFACTURING

Assuming the formulation is the same as the approved treatment: A spray-drying process is adopted for oral formulation. Injectable product is a standard solution, terminally sterilised. Standard excipients are used. The injectable formulation contains a specialised syringe along with vials. Shelf life is 2 years at room temperature for tablets and injectable product.



MARKET

This medicine is still in the R&D pipeline and therefore little is known about its potential positioning in treatment protocols, pricing, and overall access plans.

