**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.

**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.

**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. The upcoming access to long-acting cabotegravir for PrEP in LMICs will likely pave the way for a successful lenacapavir implementation, if proven safe and effective.

**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 sterilized. Standard excipients are used. The injectable formulation contains a specialized syringe along with vials. Shelf life is two years at room temperature for tablets and injectable product.

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

**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.

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**PRIORITY LIST**