**Clinical Relevance**
Lenacapavir is a first-in-class capsid inhibitor, studied for HIV PEP as a sub-cutaneous injection every 6 months. Initial results from the PURPOSE 1 study indicated full protection from HIV acquisition in young women and adolescent girls. Further data on safety and efficacy in other populations are expected soon.

**Service Delivery Enablers**
Lenacapavir for PEP 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 PEP options such as TDF/FTC. However, the ongoing access to long-acting cabotegravir for PEP 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 the tablets and the injectable product.

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**Disease Burden**
In 2022, 39 million people globally were living with HIV and 1.5 million people became newly infected, most of which occurred in LMICs.

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**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.

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**Regulatory**
While lenacapavir for PEP is not approved by regulatory authorities yet, the formulation appears to be the same as the approved injectable treatment. Bioequivalence studies are necessary for oral solid formulations. B investigational new drug (IND) applications and Investigational Product (IP) files have been submitted to regulatory agencies in multiple countries. There is a possibility of biodistribution for injectable products.