PRIORITY LIST

LENACAPAVIR
HIV PREVENTION
Gilead

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 sub-cutaneous injection every 6 months and has a promising safety profile.

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 a successful lenacapavir implementation, if proven safe and effective.

REGULATORY
While lenacapavir for PrEP is not approved by 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 two 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.

PRIORITY LIST

LENACAPAVIR
HIV TREATMENT
Gilead

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, already approved for the treatment of multi-drug resistant HIV infection in adults as a subcutaneous injection every 6 months in combination with other daily ARVs. It has a promising safety profile studied as: a weekly oral HIV treatment in combination with islatravir, a daily oral regimen with bictegravir, a sub-cutaneous injections in association with monoclonal antibodies every 6 months.

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

SERVICE DELIVERY ENABLERS
Lenacapavir's possible companion drugs are still under study. A six-monthly injectable regimen could aid adherence but may conflict with efforts to simplify and decentralize HIV treatment due to healthcare workers' requirements for injections.

REGULATORY
Product approved by stringent regulatory authorities. Potential sublicensees of lenacapavir could rely on mechanisms like USFDA Paragraph III through PEPFAR (if included), Swissmedic MAGHP or EU-M4all or WHO Prequalification (if included) for quality assurance. Bioequivalence studies are necessary for oral solid formulations. Biowaivers will not be an option for oral solid formulations. There is a possibility of biowaiver for injectable products.

MANUFACTURING
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 specialised syringe along with vials. Shelf life is two years at room temperature for tablets and injectable product.

MARKET
While lenacapavir is currently approved by some major regulatory authorities for heavily treatment-experienced adults, it is not yet registered (and is therefore not available) in any LMICs. Access plans for lenacapavir in LMICs are not yet known.