COLOMBIA

LENACAPAVIR ACCESS SNAPSHOT

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Lenacapavir is a highly effective, long-acting HIV prevention option administered only twice a year. It could be a game-changing tool, but only if it reaches the people who need it.

This comes at a critical moment: Latin America is one of the few regions where new HIV infections continue to rise[1], and Colombia has seen an overall increase in reported HIV notifications in recent years, with over 15,000 cases reported in 2024[2]. These trends are a stark reminder that existing prevention options are still not reaching everyone who needs them, particularly gay men and other men who have sex with men, transgender people, sex workers, migrants and other populations facing heightened exposure to HIV and barriers to health services. Yet access to lenacapavir is currently being determined by the decisions of a single company – Gilead - rather than by public health needs. High prices, patent barriers, exclusion from generic licensing agreements and limited supply risk keeping this highly effective prevention tool out of reach for most people who could benefit from it. These barriers can — and must — be addressed through concrete public interest action.

1. REGULATORY STATUS

The first access barrier in Colombia is that lenacapavir does not have regulatory approval in the country. As of June 2026, there was no public indication that Gilead had submitted — or planned to submit in the short term — an application to Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA), the national medicines regulatory agency.

Before national registration, lenacapavir could potentially be imported through Colombia's "vital unavailable medicines" pathway, mainly for personal or compassionate use[3]. This is an exceptional route, not a pathway for broad public sector rollout. For wider access, Colombia could potentially procure lenacapavir through the Pan American Health Organization (PAHO) Strategic Fund, but only if the product becomes available through that mechanism. PAHO has indicated that it is working to negotiate affordable pricing and pooled procurement for new technologies such as lenacapavir[4], but no PAHO-Gilead agreement on price or supply has been announced.

Even if lenacapavir is approved or exceptionally imported, people will not benefit unless it is supplied at an affordable price and in sufficient quantities.

3. INVIMA. Medicamentos Vitales No Disponibles. Available at: https://www.invima.gov.co/productos-vigilados/medicamentos-y-productos-biologicos/medicamentos-vitales-no-disponibles

4. PAHO. Alliance for the Elimination of HIV in the Americas. Available at: https://www.paho.org/en/alliance-elimination-hiv-americas

2. PRICE AND AFFORDABILITY

Price is likely to be a major barrier to access.

Gilead holds the monopoly on lenacapavir and is currently the only company marketing it worldwide. In the United States, lenacapavir is listed at around USD 28,000 per person per year[5], but there is no publicly available information on the price Gilead intends to charge in Colombia or whether formal price negotiations have begun. Colombia is also excluded from global access arrangements expected to make generic versions available in certain countries for around USD 40 per person per year. This gap between the US list price and the announced generic price shows the impact of monopoly pricing and the importance of ensuring affordable access also outside these arrangements.

PRICE POINT	ANNUAL PRICE PER PERSON	PEOPLE REACHED
Gilead's US list price[5]	USD 28,000	1
Announced price for licensed generics	USD 40	700

5. UNAIDS. UNAIDS urges Gilead to drop price of new HIV prevention shot. 18 June 2025. Available at: https://www.unaids.org/en/resources/press-centre/pressreleaseandstatementarchive/2025/june/20250618_lenacapavir

3. SUPPLY AND AVAILABILITY

Patents can limit medicine supply and keep prices high by restricting generic competition.

Because Gilead holds patents on lenacapavir, generic manufacturers generally need a license to produce and supply generic versions in countries where those patents apply. Gilead has signed voluntary licensing agreements with selected manufacturers to supply generic lenacapavir in 120 countries[6]. However, Colombia is excluded from these licenses[7].

Gilead holds two layers of granted compound-level patent protection on lenacapavir in Colombia. The first could remain in force until 2034 and the second until 2037[8]. The later compound patent may be vulnerable to invalidation if lenacapavir was already disclosed in the earlier broader (Markush) patent. Unless the patents are invalidated or overridden, Colombia will remain dependent on Gilead as the only supplier until they expire.

Colombia has legal tools to address this situation. Patents that may not meet the applicable legal requirements can be challenged and invalidated. The government can also issue a compulsory license, including on public interest grounds, allowing generic production or importation without Gilead's authorization.

6. Gilead Sciences. Gilead Signs Royalty-Free Voluntary Licensing Agreements with Six Generic Manufacturers to Increase Access to Lenacapavir for HIV Prevention in High-Incidence, Resource-Limited Countries. 2 October 2024. Available at: https://www.gilead.com/news/news-details/2024/gilead-signs-royalty-free-voluntary-licensing-agreements-with-six-generic-manufacturers-to-increase-access-to-lenacapavir-for-hiv-prevention-in-high-incidence-resource-limited-countries

7. Médecins Sans Frontières Access Campaign. Gilead's voluntary license on lenacapavir: key limitations of the license and recommendations to improve access. 3 July 2025. Available at: https://msfaccess.org/gileads-voluntary-license-lenacapavir-key-limitations-license-and-recommendations-improve-access

8. Superintendencia de Industria y Comercio (SIC), Colombia. Oficina Virtual de Propiedad Industrial — SIPI. Search patent applications CO15199357 and CO2019001379. Available at: https://sipi.sic.gov.co/sipi/Extra/

9. Ministerio de Salud y Protección Social, Colombia. Informe de Gestión 2025. 2025, pp. 143–145. Available at: https://www.minsalud.gov.co/; Ministerio de Salud y Protección Social, Colombia. Licencia obligatoria para Dolutegravir. Dirección de Medicamento y Tecnologías en Salud, July 2025.

10. Ministerio de Salud y Protección Social, Colombia. Resolución No. 453 de 2026: Por medio de la cual se declara la existencia de razones de interés público para someter las patentes de unos Antivirales de Acción Directa - AAD para el tratamiento de la Hepatitis C a licencia obligatoria. 16 March 2026. Available at: https://www.minsalud.gov.co/Normatividad_Nuevo/Resolucion%20No%20453%20de%202026.pdf

Colombia's experience with compulsory licensing

In 2024, Colombia issued its first compulsory license for a medicine, allowing government procurement of generic dolutegravir for HIV treatment. The price fell by approximately 96%, meaning that, for roughly the previous cost of treating one person, the government could treat about 25 people. Colombia imported more than 819,000 bottles of the fixed-dose combination dolutegravir/tenofovir/lamivudine, with supply expected to cover approximately 50,000 people through 2026. The Ministry of Health estimated savings of more than COP 303 billion—approximately USD 73 million[9].

In March 2026, Colombia also declared public-interest grounds for compulsory licensing patents covering sofosbuvir/velpatasvir and sofosbuvir/velpatasvir/voxilaprevir for hepatitis C[10], demonstrating its continued willingness to use public interest safeguards to expand access to essential medicines.

3. SUPPLY AND AVAILABILITY

Gilead has also filed other patent applications related to lenacapavir, including a standalone oral medication not included in the existing voluntary licenses for the production of generics. While these applications are not expected to block generic versions of the currently approved regimen - including the injectable formulation and the oral formulation needed for regimen initiation - they should be monitored to prevent new patent barriers from delaying access to future lenacapavir-based regimens.

In Colombia, one relevant application that includes a modified version of lenacapavir (prodrug) is still pending[11]. A formal pre-grant opposition may be filed within 60 days after publication of the patent application. After that period, third parties may still submit observations to the patent office, although the office is not formally required to take them into account during examination[12].

Colombia's patent law also permits parallel importation of Gilead's originator product or an authorized generic. However, its practical use depends on the availability of a source able to export the product. Current originator supply is scarce and largely allocated through global public health programs limiting its commercial availability, while Gilead's voluntary licenses and anti-diversion provisions restrict licensed manufacturers and their distribution channels from supplying excluded countries such as Colombia.

Data exclusivity may create an additional barrier even if the patents are invalidated or overridden. Colombia provides five years of exclusivity for test data submitted for approval of a new chemical entity, during which INVIMA is prevented from relying on the originator's data to approve a generic product.

If data exclusivity is granted, Colombian law includes a public-interest exception under which data exclusivity does not apply when necessary to protect the public[13]. Any strategy involving generic lenacapavir should therefore assess whether this exception must also be invoked to avoid data exclusivity delaying regulatory approval.

However, for these measures to be effective, generic versions of lenacapavir must be available for supply in Colombia. Colombia is currently excluded from Gilead's voluntary licenses and cannot purchase lenacapavir from the six authorized generic manufacturers, which are also prohibited from supplying excluded countries even where no patent barriers exist. Moreover, current supply commitments aim to reach around 3 million people through 2028[14], while the global need for PrEP exceeds 20 million[15]. Therefore, even if Colombia is included in the licenses, supply may remain insufficient to meet the country's needs.

Regardless of any licensing agreement with Gilead, Colombia should support the development of additional sources of lenacapavir to ensure a secure and sustainable supply at affordable prices. The country's patent law includes research and Bolar exceptions that allow manufacturers to conduct research and undertake the activities needed to obtain regulatory approval while patents remain in force.

Finally, because lenacapavir is a long-acting injectable, generic manufacturers may need to provide additional product-specific evidence beyond the usual requirements. INVIMA should therefore engage early with potential manufacturers and clarify the requirements for approving generic versions of lenacapavir.

11. Superintendencia de Industria y Comercio (SIC), Colombia. Oficina Virtual de Propiedad Industrial — SIPI. Search patent application CO2024006742, corresponding to PCT/US2022/051734 / WO2023102239. Available at: https://sipi.sic.gov.co/sipi/Extra/

12. Andean Community. Decision 486 — Common Industrial Property Regime, Articles 42–43.

13. INVIMA. Decreto número 2085 de 2002 — Reglamentación de información para registro sanitario de nuevas entidades químicas en medicamentos. Available at: https://www.invima.gov.co/biblioteca/decreto_2085_2002_2pdf

14. The Global Fund. Global Fund and U.S. Expand Commitment to Long-Acting HIV Prevention as Country Rollout of Lenacapavir Accelerates. 14 April 2026. Available at: https://www.theglobalfund.org/en/updates/2026/2026-04-14-us-global-fund-expand-commitment-long-acting-hiv-prevention-country-rollout-lenacapavir-accelerates/

15. UNAIDS. 2025 Global AIDS Update: AIDS, crisis and the power to transform. Geneva: UNAIDS; 2025. Available at: https://www.unaids.org/sites/default/files/2025-07/2025-global-aids-update-JC3153_en.pdf

3. SUPPLY AND AVAILABILITY

LEGAL TOOL PRE-GRANT OPPOSITION AND THIRD-PARTY OBSERVATIONS

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
A formal opposition may be filed to submit arguments and evidence for consideration during examination. After the opposition period, third parties may still submit observations, although the patent office is not required to consider them. This can help prevent the grant of patents that do not meet patentability requirements.	Articles 42–43 of Andean Community Decision 486	Any interested person or organization.	A formal opposition may be filed within 60 days after publication of the patent application. Third-party observations may be submitted after this period.	Official fees and legal or technical costs depend on the action taken.

LEGAL TOOL POST-GRANT OPPOSITION (JUDICIAL INVALIDITY ACTION)

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
A procedure seeking the invalidation of all or part of a granted patent that should not have been granted, for example lack of novelty or inventive step.	Articles 75–79 of Andean Community Decision 486	Any person or organization. A lawyer is required.	At any time for absolute nullity; within five years of the patent grant for relative nullity.	Official fees and legal or technical costs depend on the case.

LEGAL TOOL RESEARCH EXCEPTION

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Allows acts involving a patented invention for experimental purposes related to scientific research or experimentation.	Article 53(b)–(c) of Andean Community Decision 486	Researchers, manufacturers and other persons or organizations conducting experimental activities.	While the patent remains in force.	No license or re-muneration to patent holder (royalties) are required; ordinary research costs apply.

LEGAL TOOL COMPULSORY LICENSE ON PUBLIC INTEREST GROUNDS

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Government authorization to produce or import a generic version of a patented product without the patent holder's consent.	Article 65 of Andean Community Decision 486 and Colombia's national compulsory licensing procedures.	The Ministry of Health declares that public interest grounds exist, and the Superintendence of Industry and Commerce grants the license. Civil society and other actors may advocate for government action.	At any time while the patent remains in force.	Royalties must be paid to the patent holder.

LEGAL TOOL BOLAR EXCEPTION

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Allows activities involving a patented invention to generate the information, data and test results required for regulatory approval. This can accelerate generic entry once the patents expire or are otherwise overcome.	Article 3 of Decree 729 of 2012	Generic manufacturers and other persons or organizations preparing a regulatory submission.	While the patent remains in force.	No license or royalties are required; development, testing and regulatory costs apply.

3. SUPPLY AND AVAILABILITY

LEGAL TOOL PARALLEL IMPORTATION

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Allows the importation of the originator product or an authorized generic that was lawfully placed on another market by the patent holder or with its consent.	Article 54 of Andean Community Decision 486	An authorized importer or public purchaser, subject to Colombian regulatory, procurement and import requirements.	While a lawful source of supply is available.	Product, transport, importation and regulatory costs. No patent royalty is required.

LEGAL TOOL PUBLIC-INTEREST EXCEPTION TO DATA EXCLUSIVITY

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
Allows data exclusivity not to apply when necessary to protect the public, potentially preventing it from delaying the approval of generics.	Article 4(c) of Decree 2085 of 2002	The Colombian Ministry of Health must determine that applying the exception is necessary to protect the public.	During the period of data exclusivity.	No direct costs.

4. PRIORITY ACTIONS TO SECURE SUSTAINABLE ACCESS

Access to lenacapavir in Colombia will depend on overcoming several interconnected barriers: lack of regulatory approval, an unaffordable price, patent-based monopoly and limited supply. To help overcome these barriers:

People who could benefit from lenacapavir cannot continue waiting while access depends on a single company's commercial decisions on pricing, licensing and supply. Colombia should act now to ensure this prevention option is affordable and available at scale through the health system, in line with people's needs.

We cannot allow history to repeat itself: people's health and access to HIV prevention must take precedence over commercial interests and pharmaceutical company profits.

GILEAD SHOULD

- Submit lenacapavir for regulatory approval in Colombia without delay.
- Offer Colombia a transparent and affordable price that allows large-scale access through the health system.
- Expand its voluntary licenses to all countries, including Colombia, or, at a minimum, allow licensees to supply countries where no patent barriers exist or where patent barriers have been overcome through legal mechanisms.
- Increase the number and geographic diversity of licensed manufacturers, including Colombian manufacturers, to expand global supply.

THE COLOMBIAN GOVERNMENT SHOULD:

- Conduct transparent price negotiations with Gilead and disclose proposed prices, supply volumes, delivery timelines and other terms needed to assess whether any agreement is compatible with public health needs.
- Have the relevant government bodies assess lenacapavir patent applications and granted patents and, where they do not meet patentability requirements, take action to prevent their grant or seek their invalidation.
- Apply rigorous pharmaceutical patent examination guidelines and, where necessary, revise them to prevent the grant of excessively broad claims, such as Markush claims, and claims covering modifications of known products, such as prodrugs, that do not meet patentability requirements.
- Issue compulsory licenses to enable the production, importation and supply of affordable generic lenacapavir.
- Apply the public interest exception to data exclusivity, if needed to enable timely approval of generic lenacapavir.
- Encourage and support potential Colombian manufacturers in using the research and Bolar exceptions to conduct research, develop generic lenacapavir and prepare regulatory submissions while patents remain in force.
- Provide early regulatory guidance for generic lenacapavir approval.
- Use public procurement to create predictable demand for generic lenacapavir and support sustainable, geographically diverse production in Colombia, across the region and internationally.

COMMUNITIES AND CIVIL SOCIETY ORGANIZATIONS SHOULD CONTINUE TO:

- Demand transparency on regulatory submissions, prices, supply commitments, licensing terms and government negotiations with Gilead.
- Contribute to the analysis of lenacapavir patents and, where appropriate, initiate or support patent oppositions.
- Advocate for the use of compulsory licensing and other public-interest measures to facilitate affordable, sustainable supply of lenacapavir.
- Hold Gilead and the government accountable for ensuring affordable, sufficient and sustainable access for everyone who could benefit from lenacapavir.