MEXICO

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 Mexico recorded 15,789 new HIV diagnoses in 2024 alone[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 Mexico is that the long-acting injectable formulation of lenacapavir does not have regulatory approval in the country. According to available information, Gilead submitted an application to Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), the national regulatory agency, in March 2026 for the oral formulation of lenacapavir. However, there is no confirmation that an application has been submitted for the injectable formulation used for long-acting HIV prevention.

Before national registration, lenacapavir could potentially be imported into Mexico through an exceptional import pathway, including for personal use, donation, or special treatment purposes, subject to prior authorization from COFEPRIS[3]. This is an exceptional route, not a pathway for broad rollout. Mexico could also import lenacapavir through the Pan American Health Organization (PAHO) or another international organization even without national registration[4]. PAHO has indicated that it is working to negotiate affordable pricing and pooled procurement for new technologies such as lenacapavir[5], but no PAHO-Gilead agreement on price or supply has been announced.

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

1. UNAIDS. Latin America — Regional profile — 2025 Global AIDS Update. 2025. Available at: https://www.unaids.org/sites/default/files/2025-07/2025-global-aids-update-latam.pdf

2. Secretaría de Salud, Dirección General de Epidemiología, México. Informe Histórico VIH Día Mundial 2025. Sistema de Vigilancia Epidemiológica de VIH, 2025. Available at: https://www.gob.mx/cms/uploads/attachment/file/1040435/InformeHist_rico_VIH_DVEET_DIA_MUNDIAL2025.pdf

3. Mexico. Reglamento de Insumos para la Salud, Article 196. Available at: https://salud.gob.mx/unidades/cdi/nom/compi/ris.html

4. Secretaría de Salud, México. Acuerdo por el que se reconocen como equivalentes los requisitos establecidos en los artículos 167, 170, 177, 177 Bis 2, 179 y 180 del Reglamento de Insumos para la Salud... así como los criterios para la importación de insumos para la atención de enfermedades emergentes, desatendidas o en casos de emergencia nacional. Diario Oficial de la Federación, 11 June 2025. Available at: https://sidof.segob.gob.mx/notas/5759832

5. 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

6. 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

7. Unitaid. Unitaid, CHAI, and Wits RHI enter into a landmark agreement with Dr. Reddy's to make HIV prevention tool lenacapavir affordable in LMICs. 24 September 2025. Available at: https://unitaid.org/news-blog/lenacapavir-for-hiv-prevention/

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[6], but there is no publicly available information on the price Gilead intends to charge in Mexico or whether formal price negotiations have begun. Mexico is also excluded from global access arrangements expected to make generic versions available in certain countries for around USD 40 per person per year[7]. 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	USD 28,000	1
Announced price for licensed generics	USD 40	700

3. SUPPLY AND AVAILABILITY

8. 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

9. 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

10. Instituto Mexicano de la Propiedad Industrial (IMPI), México. SIGA — Sistema de Información de la Gaceta de la Propiedad Industrial. Search patent applications MX2015011478 and MX2018012905. Available at: https://siga.impi.gob.mx/

11. Instituto Mexicano de la Propiedad Industrial (IMPI), México. SIGA — Sistema de Información de la Gaceta de la Propiedad Industrial. Search patent application MX2024006396A, corresponding to PCT/US2022/051734 / WO2023102239. Available at: https://siga.impi.gob.mx/

12. World Intellectual Property Organization (WIPO). Third Party Observations. PCT System. Available at: https://www.wipo.int/en/web/pct-system/faqs/third_party_observations

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[8]. However, Mexico is excluded from these licenses[9].

Gilead holds two layers of granted compound-level patent protection on lenacapavir in Mexico. The first could remain in force until 2034 and the second until 2037[10]. 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, Mexico will remain dependent on Gilead as the only supplier until they expire.

Mexico 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 utility grounds, allowing generic production or importation without Gilead's authorization.

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 Mexico, one relevant patent application that includes a modified version of lenacapavir (prodrug) is still pending[11]. Third parties may submit information to IMPI, the national patent office, within two months after publication of a patent application. IMPI may consider that information as technical support during substantive examination, but is not required to decide on it. After that period, there does not appear to be a clearly defined formal pre-grant opposition mechanism, although indirect mechanisms may still be available, including informal submissions to IMPI and, where the application is still within the applicable international phase deadline, third-party observations through the PCT system before 28 months from the priority date[12].

Data exclusivity may create an additional barrier even if the patents are invalidated or overridden. Mexico provides five years of exclusivity for test data submitted for approval of a new pharmaceutical

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product, during which COFEPRIS may be prevented from relying on the originator's data to approve a generic product[13]. Mexico does not appear to have a clearly defined procedure for applying a public-interest exception to data exclusivity. Any strategy involving generic lenacapavir should therefore assess whether COFEPRIS could authorize generic registration on public health grounds despite an applicable exclusivity period.

However, for these measures to be effective, generic versions of lenacapavir must be available for supply in Mexico. Mexico 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 Mexico is included in the licenses, supply may remain insufficient to meet the country's needs.

Regardless of any licensing agreement with Gilead, Mexico should support the development of additional sources of lenacapavir to ensure a secure and sustainable supply at affordable prices. The country possesses robust manufacturing capacity, and its patent framework includes research and Bolar exemptions. These mechanisms allow generic manufacturers to conduct research and undertake the testing needed to secure regulatory approval while patents remain in force. While Mexico's patent linkage system normally blocks the market approval of generics while a patent is active[16], overcoming these barriers through patent invalidation or a compulsory license would clear this hurdle, allowing for immediate generic entry.

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

13. Mexico. Reglamento de Insumos para la Salud, Articles 167 and 167 Bis, as amended by Decreto por el que se reforman y adicionan diversas disposiciones del Reglamento de Insumos para la Salud. Diario Oficial de la Federación, 24 April 2026. Available at: https://sidof.segob.gob.mx/notas/5785957

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

16. Mexico, Article 167 Bis of the Regulations for Health-Related Consumable Goods (Reglamento de Insumos para la Salud – RIS).

LEGAL TOOL **PRE-GRANT OPPOSITION (THIRD-PARTY OBSERVATIONS)**

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
A submission of documents and information to IMPI to support patent examination before it is granted. IMPI may consider the information but is not required to do so. It can help prevent the grant of a patent that does not meet patentability requirements.	Article 109 of the Federal Law for the Protection of Industrial Property	Any person or organization. A lawyer is not required.	Within two months from the publication of the patent application.	There is no fee. Translation costs may apply.

LEGAL TOOL **POST-GRANT OPPOSITION (ADMINISTRATIVE LEVEL)**

WHAT IT IS & WHAT IT CAN DO	LEGAL BASIS	WHO CAN USE IT	WHEN	COST
A proceeding before IMPI seeking the invalidation of all or part of a granted patent that does not meet the patentability criteria. IMPI's decision may subsequently be challenged before the Federal Court of Administrative Justice.	Articles 154 and 328–342 of the Federal Law for the Protection of Industrial Property	IMPI may initiate the proceeding on its own initiative or following a request by a person or organization able to demonstrate legal interest (lawyer required). Any person may also submit information asking IMPI to consider initiating the proceeding ex officio (lawyer not required).	At any time after the patent has been granted.	An official IMPI filing fee applies. Additional legal, technical, expert and translation costs depend on the case.

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LEGAL TOOL COMPULSORY LICENSE (PUBLIC UTILITY)

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 medicine without the patent holder's consent for public utility reasons (emergency, national security or serious disease declared to be of priority attention).	Article 153 of the Federal Law for the Protection of Industrial Property	Following a declaration by the General Health Council, pharmaceutical companies may request a license before IMPI. The Ministry of Health sets the conditions and royalties.	While the qualifying declaration and public health need remain in force.	An official filing fee applies. Fair and reasonable remuneration (royalties) must be paid to the patent holder, and additional legal and 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 purely experimental scientific or technological research, testing or teaching involving a patented invention.	Article 57(I) of the Federal Law for the Protection of Industrial Property	Researchers and other persons or organizations conducting qualifying experimental activities.	While the patent remains in force.	No license or royalties are required; ordinary research costs apply.

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 57(II) of the Federal Law for the Protection of Industrial Property	Generic manufacturers and other persons or organizations preparing a regulatory submission.	While the patent remains in force.	No license or royalties are required; ordinary development, testing and regulatory costs apply.

4. PRIORITY ACTIONS TO SECURE SUSTAINABLE ACCESS

Access to lenacapavir in Mexico 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.
Mexico 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 the long-acting injectable formulation of lenacapavir for regulatory approval in Mexico without delay.
- Offer Mexico a transparent and affordable price that allows large-scale access through the health system.
- Expand its voluntary licenses to include all middle-income countries, including Mexico, 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 Mexican manufacturers, to expand global supply.

THE MEXICAN 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.
- Clarify and accelerate the regulatory and importation pathways for lenacapavir, including procurement through the PAHO Strategic Fund where appropriate.
- 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 on public-utility grounds to enable the production, importation and supply of affordable generic lenacapavir.
- Assess whether data exclusivity could delay approval of generic lenacapavir and what administrative or legal measures would be needed to prevent it from becoming an additional access barrier.
- Encourage and support potential Mexican 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 Mexico, across the region and internationally.

COMMUNITIES AND CIVIL SOCIETY ORGANIZATIONS SHOULD:

- 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 on public-utility grounds 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.