Medicare Negotiations for Lower Drug Prices Explained: Entresto

Thanks to the Biden-Harris administration and Democrats in Congress, Medicare has been negotiating lower prices for the first 10 drugs selected for the Negotiation Program, and will negotiate lower prices for more drugs each year. By 2030, up to 80 drugs will have lower negotiated prices. One of the first ten drugs <u>selected for negotiation</u> is Entresto, a drug used to treat heart failure, manufactured by Novartis. Entresto has made billions of dollars in revenue, and big drug companies like Novartis are eager to protect their sky-high profits by blocking the Medicare Negotiation so they can continue to charge patients unaffordable prices.

Hundreds of Thousands of Medicare Beneficiaries Rely on Entresto.

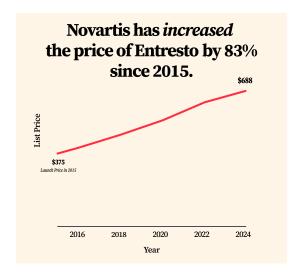
- <u>521,000</u> Medicare Part D beneficiaries rely on Entresto as of 2022 <u>around 1 percent of</u> Medicare Part D enrollees.
- Beneficiaries who are not enrolled in the Extra Help program pay an average of \$357 annually for Entresto.

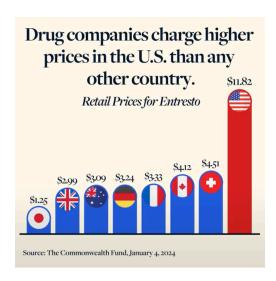
Entresto Costs Taxpayers Billions.

 Entresto has cost Medicare just under \$7 billion as of 2022 – an average of \$4,780 per beneficiary taking Entresto.

Novartis Price Gouges Americans for Entresto.

- Entresto costs significantly more in the U.S. than in other high-income countries. For example, Novartis charges U.S. customers nearly 3x more than customers in Switzerland, and 9.5x more to U.S. customers than to customers in Japan.
- According to Analysource, Entresto has increased in price by 83 percent since its launch in <u>2015</u> 4.3x <u>faster</u> than inflation for prescription drugs and 2.4x <u>faster</u> than inflation overall during the same time frame.





Novartis Rakes In Profits While Rewarding Shareholders and Lobbying.

- Entresto has generated nearly \$24 billion in global revenue since its launch.
- Novartis has spent <u>\$48.2 billion</u> on stock buybacks for their investors since launching Entresto.
- Novartis has spent <u>nearly \$64 million</u> on lobbying since launching Entresto.

Table 1: Entresto By The Numbers.

Entresto Quick Facts			
Years on U.S. Market Since Approval	10		
Entresto List Price Increase Since Launch	83 percent		
Global Revenue Since Entresto's Launch	\$24 billion		
Lobbying Since Entresto's Launch	\$64 million		
Stock Buybacks Since Entresto's Launch	\$48.2 billion		

Entresto Is Disproportionately Taken by Black Medicare Enrollees. Relative to their proportion in the population enrolled in Medicare Part D, the <u>proportion</u> of Black enrollees taking Entresto is 1.68 times higher – 18 percent, compared to <u>11 percent overall</u>. Black Americans are <u>30 percent more likely</u> to die from heart disease and <u>30 percent more likely</u> to have high blood pressure than their white counterparts. Black Medicare beneficiaries have <u>more than twice</u> the emergency care rates for heart failure than their white counterparts.

Entresto Is Most Expensive In Rural States Like North Dakota. The ten drugs selected for price negotiation by Medicare, with few exceptions, are most expensive in heavily rural states. Entresto costs Medicare Part D beneficiaries residing in North Dakota, South Dakota, and Wyoming the most out-of-pocket.

Table 2: States with the Highest Out-of-Pocket Costs for Medicare Part D Enrollees Taking Entresto

State	Average Out-of-Pocket Costs for Entresto By State	Difference From National Average*	Rurality
North Dakota	\$656	1.84 times higher	39 percent of residents live in rural areas
South Dakota	\$601	1.68 times higher	42.8 percent of residents live in rural areas

Wyoming	\$589	1.65 times higher	38 percent of residents live in rural
			areas

^{*}Medicare Part D beneficiaries not in the Extra Help program pay an average of \$357 annually for Entresto

Novartis Has A Long History of Jacking Up Prices and Exploiting Patents for Entresto:

- Fierce Pharma: After Series Of Patent Lawsuits, Novartis Doubles Down In Entresto Defense With FDA Complaint. "Two weeks ago, Novartis CEO Vas Narasimhan referred to the initial wave of drug pricing effects tied to the Inflation Reduction Act (IRA) as 'manageable.' What the company appears to be finding unmanageable, however, is potential near-term generic competition to its heart failure blockbuster Entresto. On Wednesday afternoon in federal court in Washington, D.C., the Swiss company filed a lawsuit against the FDA, claiming that the U.S. regulator's approval of a generic version of Entresto is unlawful. The complaint comes a week after the FDA approved an Entresto generic from MSN Laboratories. The agency also rejected a Novartis-orchestrated Citizen Petition, which asked it to block the entry of generic versions of Entresto. The petition, which was submitted in September 2022, had asked the agency to deny the approval of any Entresto generic until Feb. 16 of this year. It also petitioned to prevent the FDA from approving any Entresto generics that would violate Novartis patents due to expire in 2033 and 2036. [...] Novartis is seeking to preserve U.S. exclusivity for Entresto as long as possible. The company owns a series of patents on the drug, with some expiring in 2025, 2026 and 2027, according to FDA records. In 2026, government-negotiated prices Entresto will kick in. Those prices are set to be published Sept. 1 of this year." [Fierce Pharma, 8/1/24]
- Fierce Pharma: Aiming To Block Entresto Generics, Novartis Sues Mylan, Alembic And Others For Patent Infringement. "In its latest effort to defend against forthcoming Entresto copycats, Novartis is taking to U.S. federal court to allege infringement against several generics players. [...] It's not Novartis's first attempt to defend Entresto. Last December, the company filed a lawsuit against Torrent Pharma, alleging patent infringement when Torrent submitted its generic application. The company argued that if Torrent were to move forward with production, it would be doing so knowing its actions constitute patent infringement, which would be 'substantially and irreparably' damaging to Novartis. Meanwhile, last month, the company petitioned the FDA to not approve generics of the drug until the end of its three-year exclusivity period that lasts until February 2024. That move followed a similar but unsuccessful appeal last November. Last year, Entresto garnered nearly \$3.55 billion in global sales. The company has maintained that the drug could deliver peak sales of \$5 billion." [Fierce Pharma, 10/26/22]

• Pharmaceutical Technology: Novartis Plans Appeal To Ward Off Entresto Generics. "Swiss-based Novartis announced that the US District Court for the District of Delaware has invalidated the patent covering its cardiac drug Entresto, which expires on 15 July 2025 with the associated paediatric exclusivity. The company said it will now appeal to the US Court of Appeals for the Federal Circuit (CAFC) to further pursue the efforts to validate the combination patent around Entresto. [...] Novartis has also been involved in patent infringement litigation with multiple abbreviated new drug application (ANDA) filers over Entresto, since October 2019. As a result, the company has settled with some manufacturers to launch Entresto generics at a certain date. Novartis reaffirmed that it would counteract any breach of its intellectual property rights relating to Entresto, the combination treatment, and the multiple patents covering additional innovations. Adding that later litigation may be carried out on any commercial launch of a generic Entresto product prior to the outcome of Novartis' appeal, or ongoing infringement litigations involving other patents." [Pharmaceutical Technology, 7/10/23]

Additional Resources

- <u>Protect Our Care</u>: NEW REPORT: Big Drug Companies Continue to Put Profits Over People
- Protect Our Care: NEW REPORT: In 2023, Greedy Drug Companies Raked in \$684 Billion and Spent \$106 Billion Rewarding Shareholders
- <u>Protect Our Care</u>: Big Drug Companies Continue To Bring In Hundreds of Billions While Americans Struggle To Afford Skyrocketing Prices
- <u>Protect Our Care</u>: Fact Sheet: American Seniors Will Save As Medicare Negotiates Lower Drug Costs
- <u>Protect Our Care</u>: Big Drug Companies Are in Court to Stop Medicare Negotiation and Protect Their Sky-High Profits
- <u>Protect Our Care</u>: FACT SHEET: How Medicare's New Drug Price Negotiation Power Will Advance Health Equity
- <u>Protect Our Care</u>: By the Numbers: The Ten Costly Drugs That Are Now Eligible to Have Lower Prices Negotiated by Medicare