Medicare Negotiations for Lower Drug Prices Explained: Stelara

Thanks to President Biden and Democrats in Congress, Medicare is currently 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 Stelara, a drug used to treat psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis, manufactured by Johnson & Johnson. Stelara has made billions of dollars in revenue, and big drug companies like Johnson & Johnson are eager to protect their sky-high profits by blocking the Medicare Negotiation so they can continue to charge patients unaffordable prices.

Tens of Thousands of Medicare Beneficiaries Rely on Stelara.

- <u>20,000</u> Medicare Part D beneficiaries rely on Stelara as of 2022 <u><1 percent of Medicare Part D</u> enrollees.
- Beneficiaries who are not enrolled in the Extra Help program pay an average of <u>\$2,058</u> annually for Stelara.

Stelara Costs Taxpayers Billions.

• Stelara has cost Medicare <u>nearly \$7.6 billion</u> as of 2022 – an average of \$117,131 per beneficiary taking Stelara.

Johnson & Johnson Price Gouges Americans for Stelara.

- Stelara costs significantly more in the U.S. than in other high-income countries. For example, Johnson & Johnson charges U.S. customers <u>around 2x</u> more than customers in Germany, and 7.5x more to U.S. customers than to customers in Australia.
- Stelara has increased in price by <u>184</u> percent since its launch in <u>2009</u>.



Johnson & Johnson Rakes In Profits While Rewarding Shareholders and Lobbying.

- Stelara has generated <u>over \$64.3 billion</u> in global revenue since its launch.
- Johnson & Johnson has spent <u>\$78.2 billion</u> on stock buybacks for their investors since launching Stelara.
- Johnson & Johnson has spent <u>\$93.9 million</u> on lobbying since launching Stelara.

Table 1: Stelara By The Numbers.

Stelara Quick Facts		
Years on U.S. Market Since Approval	15	
Stelara List Price Increase Since Launch	184 percent	
Global Revenue Since Stelara's Launch	\$64.3 billion	
Lobbying Since Stelara's Launch	\$93.9 million	
Stock Buybacks Since Stelara's Launch	\$78.2 billion	

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

State	Average Out-of-Pocket Costs for Stelara By State	Difference From National Average*	Rurality
Nebraska	<u>\$4,466</u>	2.17 times higher	<u>27 percent</u> of residents live in rural areas
Mississippi	<u>\$3,875</u>	1.88 times higher	53.7 percent of residents live in rural areas
Kansas	<u>\$3.513</u>	1.71 times higher	27.7 percent of residents live in rural areas

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

*Medicare Part D beneficiaries not in the Extra Help program pay an average of <u>\$2,058</u> annually for Stelara

Johnson & Johnson Has A Long History of Jacking Up Prices and Exploiting Patents for Stelara:

Pharmaphorum: Lawsuit Claims J&J Illegally Delayed Stelara Biosimilars. "A lawsuit in the US is accusing Johnson & Johnson of unlawfully delaying the onset of biosimilar competition to its immunology blockbuster Stelara beyond its US patent expiry date. The complaint filed by CareFirst BlueCross BlueShield, one of the largest not-for-profit health plans in the US, alleges that J&J acquired a method-of-use patent 'by fraud' to extend patent protection for Stelara (ustekinumab) beyond the expiry date of 25th September 2023. [...] According to court documents, other allegations include that J&J and its Janssen Biotech unit



misrepresented facts to the patent examiner, and acquired a biosimilar drugmaker – Momenta Pharma – in 2020 to block the entry of competitors. [...] Stelara was first launched in 2009 as a treatment for psoriasis and has since picked up additional indications in psoriatic arthritis, Crohn's disease, and ulcerative colitis, building its annual sales to almost \$10 billion in 2022 – about 10% of J&J's total revenues. Around two-thirds (\$6.4 billion) of that total comes from the US market. If the lawsuit is successful, it could allow lower-priced biosimilars of Stelara to launch during 2024, potentially saving around a billion dollars in overpayments for US health systems, says the complaint." [Pharmaphorum, 1/1/24]

- Reuters: Stelara Patent Deal Puts J&J Back On Path To \$57 Billion 2025 Revenue Forecast. "Johnson & Johnson's (JNJ.N), opens new tab legal settlement with Amgen Inc (AMGN.O), opens new tab to delay a biosimilar version of its blockbuster psoriasis treatment Stelara until January 2025 could make the drug a larger contributor to J&J's 2024 and 2025 sales than Wall Street is forecasting. Stelara, introduced in 2009, has been J&J's top-selling drug since 2019, with sales reaching \$9.7 billion in 2022. Its patents begin to expire this year, opening the door to a cheaper biosimilar entering the market, and raising expectations that the company would need to lower the \$13,000 per month price of Stelara. [...] But legal agreements under which rival drugmakers delay market entry to escape lengthy patent litigation have held back their launches, keeping prices high. Analysts currently expect J&J to bring in \$54.5 billion in 2025 pharmaceutical sales on average, and for Stelara sales to fall from \$9.9 billion this year to \$7.5 billion in 2024 after a key U.S. patent expires in September, according to Refinitiv data. Two analysts have estimated \$5.4 billion for Stelara in 2025." [Reuters, <u>6/5/23</u>]
- <u>Reuters</u>: J&J Sues Amgen Over Plan To Sell Drug Similar To Blockbuster Stelara. "Johnson & Johnson's (JNJ.N), opens new tab Janssen unit has sued Amgen Inc (AMGN.O), opens new tab over its plan to market a drug for ulcerative colitis and other conditions similar to J&J's top-selling Stelara, saying it would infringe two patents in a lawsuit made public on Wednesday. Stelara accounted for \$9.1 billion of J&J's \$52 billion in global drug sales last year. Sales for the first nine months of this year were \$7.3 billion, up 7.9% over the same period last year." [Reuters, 11/30/22]

Additional Resources

- <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