

HM848 : Deliverable 2
Evaluation of FDA Approved drug : Xyrem
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1. Brand Name and Chemical Composition

- Xyrem is the brand name for the drug sodium oxybate. [1]

2. Product Indications

- Xyrem is approved for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness in narcolepsy. [1]

3. Patient Population

- Xyrem is indicated for patients 7 years of age and older with narcolepsy. [1]

4. Initial U.S. Approval Date

- Xyrem was initially approved for sale in the United States on July 17, 2002. [2]

5. Manufacturer

- Xyrem is manufactured by Jazz Pharmaceuticals, Inc. [1]

6. Formulation

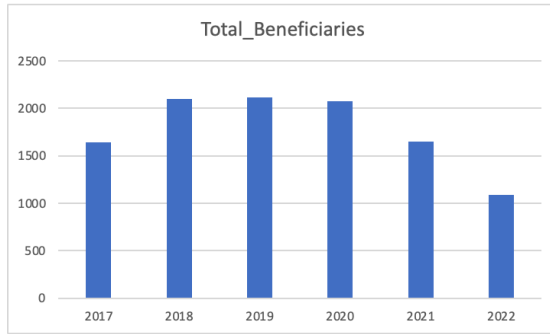
- The formulation for Xyrem is an oral solution in a concentration of 0.5 g per mL (0.5 g/mL of sodium oxybate equivalent to 0.413 g/mL of oxybate). [1]

7. Medicare Coverage

- Xyrem is covered under Medicare Part D, which is optional and only provided through private insurance companies approved by the federal government. Part D, however is offered to everyone who qualifies for Medicare. [3]

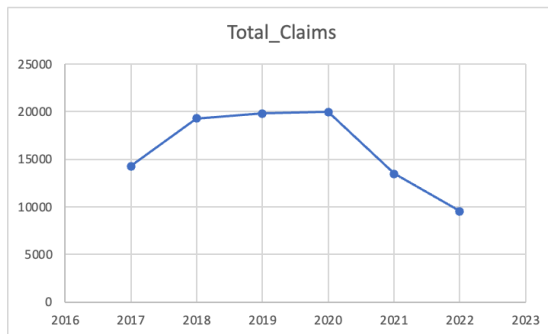
8. Medicare Beneficiaries

- In 2017, there were 1,643 Medicare beneficiaries using Xyrem. [3]
- In 2021, there were 1,647 Medicare beneficiaries using Xyrem. [3]



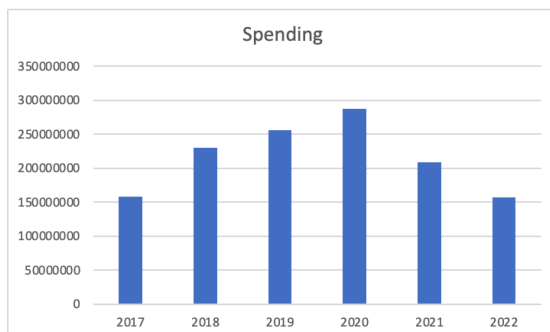
9. Medicare Claims

- In 2017, there were 14,288 claims for Xyrem under Medicare. [3]
- In 2021, there were 13,490 claims for Xyrem under Medicare. [3]



10. Medicare Spending

- Medicare spending on Xyrem was \$157,483,988 in 2017. [3]
- Medicare spending on Xyrem was \$208,290,136 in 2021. [3]



11. Average Reimbursement Price

(Formula used : Average Reimbursement Price per Dosage Unit = Total Spending / Total Dosage Units)

- The average reimbursement price per dosage unit of Xyrem was \$23.73 in 2017.
[Calculated from 3]
- The average reimbursement price per dosage unit of Xyrem was \$33.43 in 2021.
[Calculated from 3]

Year	Total_Spending	Total_Dosage_Units	Avg_Reimbursement_Price_per_Dosage_Unit
2017	\$157,483,988	6,622,470	\$23.73
2018	\$230,188,815.8	8,963,460	\$25.68
2019	\$255,629,021.3	9,216,991	\$27.70
2020	\$287,143,623.6	9,286,650	\$30.91
2021	\$208,290,136.4	6,231,330	\$33.43
2022	\$156,545,926.3	4,428,990	\$35.35

But if we consider the average reimbursement price for the drug as a whole

Using the formula : Average Reimbursement Price = Total Spending / Total Claims, we get the following information:

Year	Total_Spending	Total_Claims	Avg_Reimbursement_Price
2017	\$157,483,988	14,288	\$10,822.12
2018	\$230,188,815.8	19,304	\$11,238.17
2019	\$255,629,021.3	19,824	\$12,086.86
2020	\$287,143,623.6	19,996	\$13,621.61
2021	\$208,290,136.4	13,490	\$14,398.72
2022	\$156,545,926.3	9,548	\$16,929.69

12. Manufacturer Revenue

- Jazz Pharmaceuticals' revenue specifically for Xyrem in 2022 was \$1,020.5 million.



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Xyrem (sodium oxybate) oral solution:

- Xyrem net product sales decreased 19% to \$1,020.5 million in 2022 and decreased 14% to \$247.5 million in 4Q22 compared to the same periods in 2021, reflecting the continued adoption of Xywav by patients with narcolepsy.

Sources:

[1] Xyrem Label. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021196s030lbl.pdf

[2] FDA Orange Book.
https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021196

[3] Medicare Part D Dashboard.
<https://data.cms.gov/drug-spending/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug>