



Creon[®] (pancrelipase)¹

Version 3.0



¹ Image source: <https://www.mountainside-medical.com/products/creon-dr-pancrelipase-capsules-6000-usp>

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Document version history

Version	Date	Description
v1.0	8/13/2025	Original Release
v1.5	9/24/2025	Updated table numbers and references
v2.0	10/9/2025	Added new survey comments
v3.0	10/27/2025	30 day supply data added. 75 th and 95 th percentile data for cost per enrollee, and out of pocket costs added. Formatting changes.

Review summary

Therapeutic alternatives^{2,3,4}

Creon® (*pancrelipase*) has the following therapeutic alternatives: **Pancreaze, Pertyze, Viokace,** and **Zenpep.**

Proprietary name	Non-proprietary name	Manufacturer	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
Creon⁵	<i>pancrelipase</i>	Abbvie Inc.				No
Pancreaze⁶	<i>pancrelipase</i>	Vivus, Inc.				No
Pertyze⁷	<i>pancrelipase</i>	Digestive Care, Inc.				No
Viokace⁸	<i>pancrelipase</i>	Viokace, LLC				No
Zenpep⁹	<i>pancrelipase</i>	Zenpep, LLC				No

Price history^{10,11}

Creon rose at an **average annual rate of 6.0 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
 - Pancreaze: **13.1** percent
 - Pertyze: **3.5** percent
 - Viokace: **6.3** percent
 - Zenpep: **3.3** percent

² [Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations](#)

³ Definitions of patents and exclusivity based on the U.S. Food & Drug Administration.

[https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What is the difference between patents a](https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What%20is%20the%20difference%20between%20patents%20a)

⁴ <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices>

⁵ No patent or exclusivity information was listed for Creon in the U.S. Food & Drug Administration Purple Book Database

⁶ No patent or exclusivity information was listed for Pancreaze in the U.S. Food & Drug Administration Purple Book Database

⁷ No patent or exclusivity information was listed for Pertyze in the U.S. Food & Drug Administration Purple Book Database

⁸ No patent or exclusivity information was listed for Viokace in the U.S. Food & Drug Administration Purple Book Database

⁹ No patent or exclusivity information was listed for Zenpep in the U.S. Food & Drug Administration Purple Book Database

¹⁰ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

¹¹ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

Additionally, the average annual rate of Creon **exceeded inflation in 2019, 2020, 2021, 2023, and 2024**. Pharmacy acquisition costs (AAAC) for **Medicaid also increased by 13.6 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions¹²

Based on data received from healthcare carriers, Creon in 2023 had the **gross spend of \$2,674 per claim**, while the **spend net of discount was \$2,130 per claim**. Price concessions per claim were reported to be **\$545**.

Cost to the payers¹³

Table 1 2023 APAC gross annual payer total expenditure, utilization, and cost per enrollee

Proprietary name	Total expenditure	Utilization	Cost per enrollee	Cost per enrollee, median
Creon	\$32,874,312	18,427	\$10,280	\$1,292
Pancreaze	\$456,954	339	\$5,573	\$955
Pertzze	\$25,567	21	\$8,522	\$2,368
Viokace	\$70,729	49	\$3,723	\$557
Zenpep	\$10,504,953	3,669	\$14,631	\$1,934

Cost to enrollees¹⁴

Table 2 2023 APAC gross annual enrollee out-of-pocket (OOP) cost

Proprietary name	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Creon	\$451	\$25	\$90	\$8
Pancreaze	\$600	\$80	\$158	\$37
Pertzze	\$188	\$38	\$25	\$0
Viokace	\$297	\$0	\$154	\$0
Zenpep	\$751	\$35	\$161	\$20

¹² Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon’s commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.

¹³ Based on Oregon’s 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

¹⁴ Ibid.

Rubric considerations

Domain	Consideration
Utilization	18,427
Price evaluation	Avg percent change in WAC >5%, outpaced inflation for five years
Price concessions	<25% of claims discounted
System & payer costs	Total gross spend \$15M-\$50M, total net spend \$3M-\$10M
Enrollee burden	Total APAC OOP \$200-\$700
Equity impact	Yes
Access restrictions	No
Therapeutic alternative fail to reduce system spending	Yes
Stakeholder input identify access or financial hardship?	Yes
Patent expirations more than 18 months from time of review?	Yes
Excluded from CMS Maximum Fair Price List (MFP)	Yes

Review background

This review incorporates supporting information from Medi-Span, FDA databases (e.g., Orange Book, Purple Book), and other publicly available data where applicable.

Two primary data sources inform this review: the Oregon All Payers All Claims (APAC) database and the commercial carrier data call. APAC aggregates utilization data across all payer types in Oregon, including Medicaid, Medicare, and commercial plans, and presents gross cost estimates. In contrast, the data call reflects submissions from 11 commercial health insurers, and reports primarily net costs after manufacturer rebates, PBM discounts, and other price concessions. As a result, APAC generally reflects larger total utilization and cost figures due to broader reporting, while the data call offers insight into actual expenditures from private payers in the commercial market.

This review addresses the affordability review criteria to the extent practicable. Due to limitations in scope and resources, some criteria receive minimal or no consideration.

In accordance with OAR 925-200-0020, PDAB conducts affordability reviews on prioritized prescription drugs selected under OAR 925-200-0010. The 2023 drug affordability review selection included the following criteria: orphan-designated drugs were removed; drugs were reviewed based on payer-paid cost data from the data call submissions; and drugs reported to

the APAC program across Medicare, Medicaid, and commercial lines of business were included. To ensure broader public impact, drugs with fewer than 1,000 enrollees reported in APAC reports were excluded from consideration.

Senate Bill 844 (2021) created the Prescription Drug Affordability Board (PDAB) to evaluate the cost of prescription drugs and protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon and other stakeholders within the health care system from the high costs of prescription drugs.

Drug information¹⁵

Drug proprietary name(s)	Creon®
Non-proprietary name	<i>pancrelipase</i>
Manufacturer	ABBVIE
Treatment: Creon is a combination of porcine-derived lipases, proteases, and amylases indicated for:	<ul style="list-style-type: none"> the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.
Dosage and Strengths	<ul style="list-style-type: none"> Delayed-Release Capsules: 3,000 USP units of lipase; 9,500 USP units of protease; and 15,000 USP units of amylase. Delayed-Release Capsules: 6,000 USP units of lipase; 19,000 USP units of protease; and 30,000 USP units of amylase. Delayed-Release Capsules: 12,000 USP units of lipase; 38,000 USP units of protease; and 60,000 USP units of amylase. Delayed-Release Capsules: 24,000 USP units of lipase; 76,000 USP units of protease; and 120,000 USP units of amylase. Delayed-Release Capsules: 36,000 USP units of lipase; 114,000 USP units of protease; and 180,000 USP units of amylase.
Route	Oral capsule

¹⁵ U.S. Food & Drug Administration. *Creon (pancrelipase) Prescribing Information*. Abbvie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020725s028lbl.pdf.

FDA approval

Creon was first approved by the FDA on April 30, 2009.¹⁶

The drug qualified for the following expedited forms of approval: Standard

At time of review, the drug had no approved designations under the Orphan Drug Act.

Health inequities

ORS 646A.694(1)(a) and OAR 925-200-0020 (1)(a) & (2)(a)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source through APAC.

Equity in pancreatic enzyme replacement therapy for exocrine pancreatic insufficiency (EPI) remains a challenge. Creon (*pancrelipase*) is underutilized in underserved populations, where EPI is frequently underdiagnosed and dosing titration is delayed, leading to avoidable malabsorption and nutrient deficits.¹⁷ Delays often stem from limited access to gastroenterology specialists and insufficient clinical follow-up in lower-resourced communities.

Additionally, racial and socioeconomic disparities influence treatment initiation and continuity. Evidence demonstrates that minority patients face structural barriers to care in pancreatic related conditions, including delays in treatment and limited specialty referrals.¹⁸ Shortages of Creon have further exacerbated access gaps, disproportionately affecting those who cannot easily switch products or afford alternatives.¹⁹

Creon represents a high-cost therapy within an already inequitable health system. While no single pricing metric is universally available, the economic burden of treating chronic conditions like EPI disproportionately falls on public insured or uninsured patients, many of whom are from marginalized communities. This contributes to the larger systemic cost of racial and ethnic health inequities, estimated in the hundreds of billions annually.²⁰

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data source from APAC.

¹⁶ FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used.

¹⁷ Barkin, Jodie A. MD*; Harb, Diala PharmD, PhD†; Kort, Jens MD, PhD†; Barkin, Jamie S. MD, MACG. Real-World Patient Experience With Pancreatic Enzyme Replacement Therapy in the Treatment of Exocrine Pancreatic Insufficiency. *Pancreas* 53(1):p e16-e21, January 2024. | DOI: 10.1097/MPA.0000000000002273 .

¹⁸ Reddy, K., Patrick, C., Liaquat, H., Rodriguez, E., Stocker, A., Cave, B., Cave, M. C., Smart, L., Cutts, T., & Abell, T. (2018). Differences in Referral Access to Care Between Gastrointestinal Subspecialty Patients: Barriers and Opportunities. *Health equity*, 2(1), 103–108. <https://doi.org/10.1089/heq.2018.0001>.

¹⁹ “National Patient Safety Alert: Shortage of Pancreatic enzyme replacement therapy (PERT) – Additional actions.” Community Pharmacy England, Dec. 18, 2024. <https://cpe.org.uk/our-news/national-patient-safety-alert-shortage-of-pancreatic-enzyme-replacement-therapy-pert-additional-actions/>.

²⁰ Cacari Stone, L., Wallerstein, N., Gonzales, M., Martin, R., Boursaw, B., Kim, E., Simmons, J., & Verney, S. (2025). Evaluating the Translation of Research Evidence Into Practice and Policy for Behavioral Health Equity. *Health Education & Behavior*, 52(1_suppl), 66S-73S. <https://doi.org/10.1177/10901981251346742>.

Based on APAC claims, **18,427** Oregonians filled a prescription for Creon in 2023.²¹

²¹ Number of 2023 enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data visit: [: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx](https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx).

Price for the drug

ORS 646A.694(1)(c) and OAR 925-200-0020(1)(c) & (2)(e), (f), & (g). Data source from Medi-Span, APAC, and carrier data call.

This section examines the pricing dynamics of Creon, drawing on multiple data sources to characterize its historical price trends and implications for affordability. It includes an analysis of the drug’s wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), compared to its therapeutic alternatives. Together, the data provides a comprehensive view of Creon’s list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

Price history

WAC per 30-day summary was calculated with unit WAC from Medi-Span and was reviewed as an indication of historic price trends for the drug. However, WAC does not account for discounts, rebates, or other changes to the drug’s cost throughout the supply chain.

Table 3 30-day supply for review drug and its therapeutic alternatives

	Creon	Pancreaze	Pertzye	Viokace	Zenpep
30-day supply	240 units (240 pills)				

Table 4 Drug vs therapeutic alternatives and 2018-2024 WAC per 30-day supply²²

Year	Creon	Pancreaze	Pertzye	Viokace	Zenpep
2018	\$1,044		\$650		
2019	\$1,109	\$747	\$684		
2020	\$1,191	\$747	\$714		
2021	\$1,265	\$1,179	\$739	\$1,257	\$1,535
2022	\$1,344	\$1,179	\$775	\$1,376	\$1,596
2023	\$1,411	\$1,238	\$797	\$1,507	\$1,644
2024	\$1,479	\$1,299	\$797	\$1,507	\$1,694
Avg. Annual % Change	6.0%	13.1%	3.5%	6.3%	3.3%
% change 2018 between 2024	41.6%		22.8%		

The WAC of Creon, averaged across nine NDCs reported, was approximately **\$6.16 per unit** at the end of 2024.²³ Between 2018-2024, the unit WAC increased at an average annual rate

²² Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

²³ Ibid.

of **6.0 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019, 2019-2020, 2020-2021, 2022-2023, and 2023-2024.²⁴

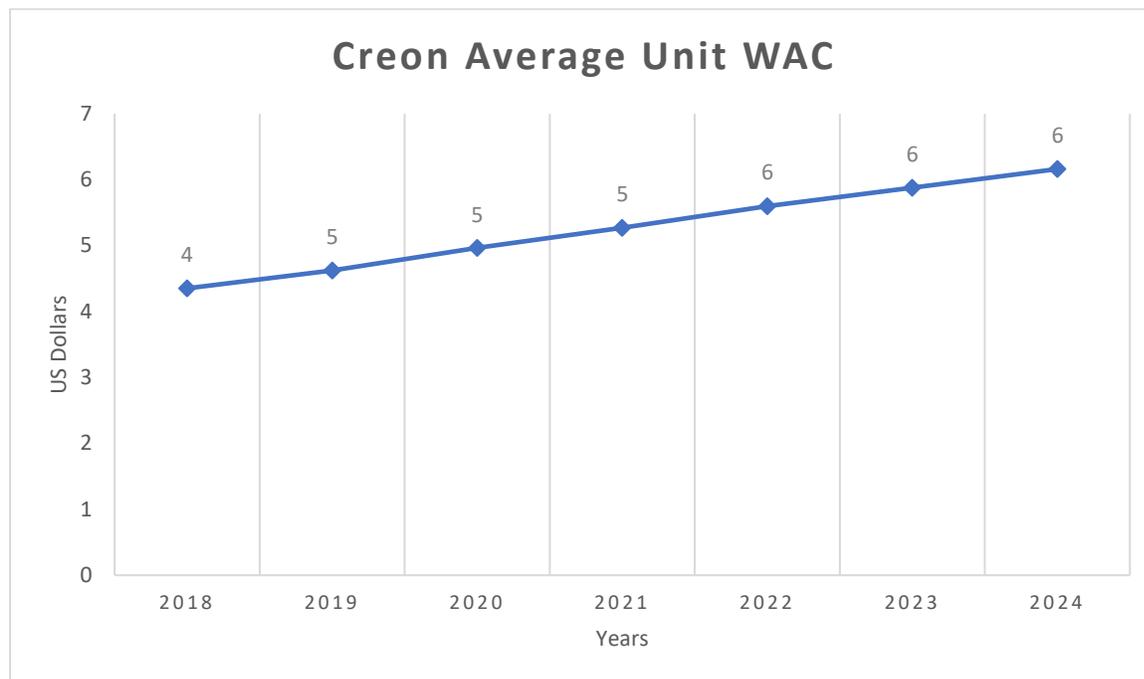


Figure 1 Creon average unit WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison²⁵

Year	Creon	Pancreaze	Pertzye	Viokace	Zenpep	CPI-U
2018-2019	6.2%		5.3%			1.7%
2019-2020	7.4%		4.3%			0.7%
2020-2021	6.2%	5.6%	3.5%			5.3%
2021-2022	6.2%	0.0%	4.9%	9.5%	4.0%	9.0%
2022-2023	5.0%	5.0%	2.9%	9.5%	3.0%	3.1%
2023-2024	4.8%	5.0%	0.0%	0.0%	3.0%	3.0%

²⁴ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

²⁵ Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.

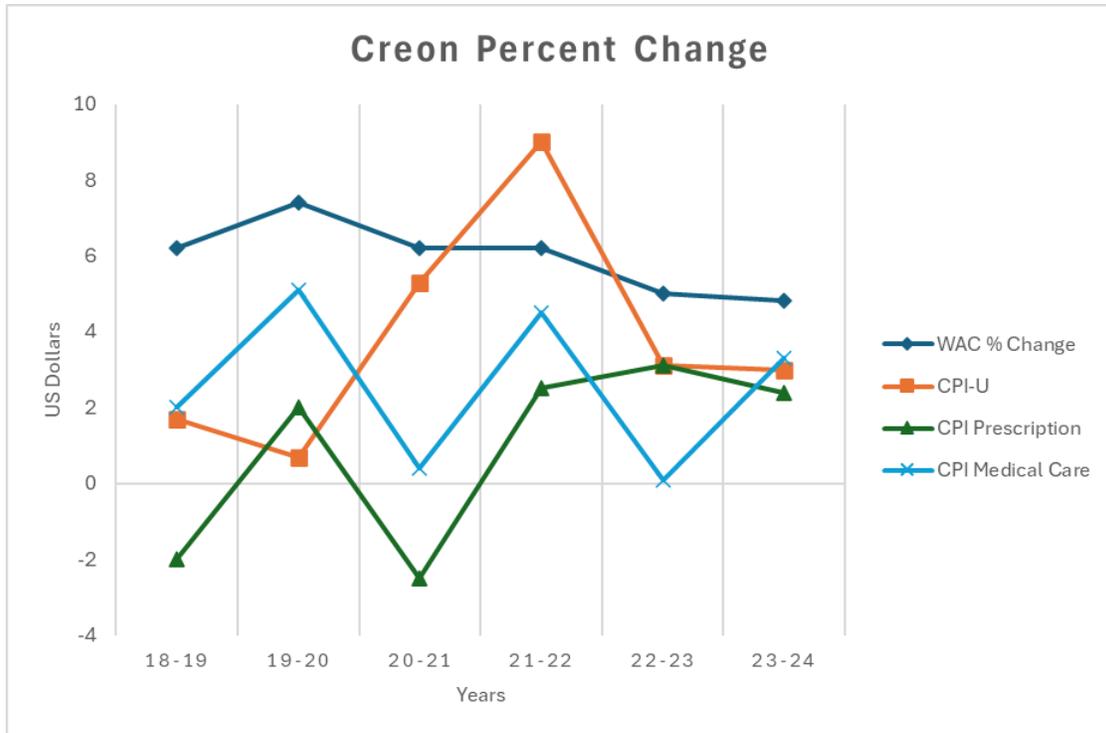


Figure 2 Year over year change in unit WAC compared to inflation rates²⁶

Pharmacy acquisition costs

The AAAC, which reflects pharmacies’ actual purchase prices for Medicaid fee-for-service claims, rose from **\$4.84 per unit in Quarter 1 of 2020 to \$5.50 per unit in Quarter 4 of 2024**, an approximate **13.6 percent increase** over the period (Table 6).²⁷ Relative to the **\$6.16 WAC** in end-of-year 2024 an **AAAC discount of 10.7 percent** is indicated.

While WAC provides a standardized benchmark of list price, it does not account for negotiated price concessions. In contrast, the AAAC offers a more representative estimate of the net price incurred by Medicaid payers in Oregon, derived from regular pharmacy surveys conducted by the Oregon Health Authority. Monitoring these trends over time contextualizes Creon’s price trajectory relative to inflation and affordability for public and private payers.

²⁶ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

²⁷ Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2024. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. <https://myersandstauffer.com/client-portal/oregon/>.

Table 6 2020-2024 AAAC Medicaid FFS quarterly purchase prices

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Average AAAC	Average WAC
2020	\$5	\$4	\$4	\$4	\$5	\$5
2021	\$5	\$5	\$5	\$5	\$5	\$5
2022	\$5	\$5	\$5	\$5	\$5	\$6
2023	\$5	\$5	\$5	\$5	\$5	\$6
2024	\$6	\$6	\$6	\$6	\$6	\$6

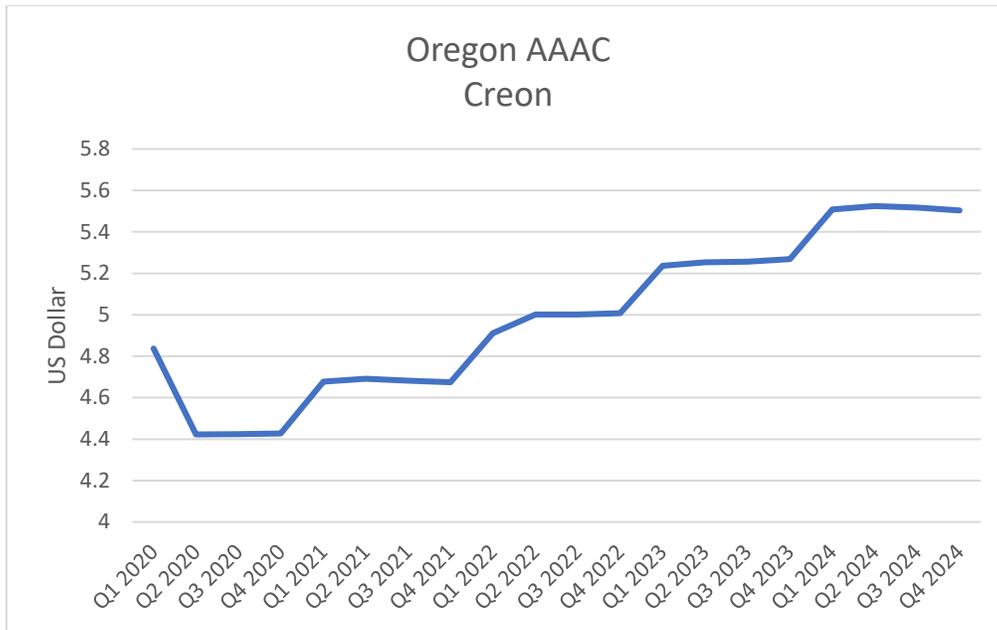


Figure 3 AAAC for Creon from Q1 2020 to Q4 2024

Estimated average monetary price concession

ORS 646A.694(1)(d) and OAR 925-200-0020(1)(d) & (2)(d) & (2)(L)(A-B). Data source information provided from data call.

This section provides an analysis of the average monetary discounts, rebates, and other price concessions applied to Creon claims in the commercial market. Drawing on data submitted through the 2023 carrier data call, it evaluates the extent to which these concessions reduced gross drug costs and estimates the average net costs to payers after adjustments. The analysis includes claim-level data on the proportion of claims with applied discounts and the breakdown of the total concession amounts by type, offering insight into the reduced costs provided through manufacturer, PBM, and other negotiated price reductions.

Based on carrier-submitted data for 2023, the **average gross cost of Creon per enrollee in the commercial market was approximately \$8,242**. After accounting for manufacturer rebates,

pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately \$6,563**, reflecting an **estimated mean discount of 20.4 percent** relative to gross costs.

Across all reporting carriers and market segments, the total cost of Creon before concessions was **\$6,131,905**, with total reported price concessions amounting to approximately **\$1,248,787**, as detailed in Table 7. Notably, **92.4 percent of claims benefited from some form of price concession**, leaving **7.6 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	744
Total number of claims	2,293
Total number of claims with price concessions applied	2,119
Percentage of claims with price concessions applied	92.4%
Percentage of cost remaining after concessions	79.6%
Percentage of discount	20.4%
Manufacturer price concessions for all market types	\$1,098,093
PBM price concessions for all market types	\$148,856
Other price reductions for all market types	\$1,838
Cost before price concessions across all market types	\$6,131,905
Total price concessions across all market types	\$1,248,787
Cost of after price concessions across all market types	\$4,883,118
Avg. payer spend per enrollee without price concessions	\$8,242
Avg. payer spend per enrollee with price concessions	\$6,563

Including all market segments, the **gross spend of Creon per claim for commercial carriers was \$2,674** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$2,130**, meaning that insurers reported a price concession of **\$545** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types from data call²⁸

	Average	Individual market	Large market	Small market
Spend per claim, gross	\$2,674	\$2,376	\$2,698	\$2,911
Spend per claim, net	\$2,130	\$1,803	\$2,202	\$2,231
Price concession per claim	\$545	\$573	\$495	\$680

Figure 4 shows manufacturer concessions comprised the largest share, supplemented by PBM discounted price arrangements and other adjustments across the payer types.

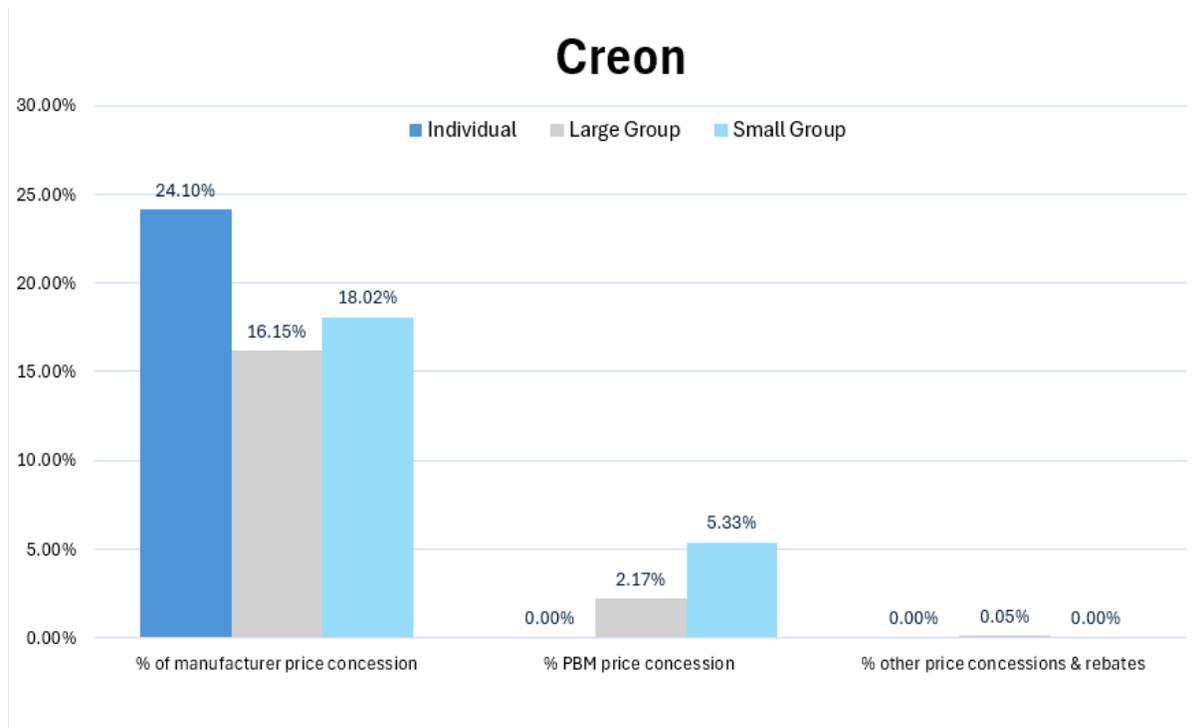


Figure 4 Percent of price concession in each market type^{29, 30}

²⁸ Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon’s commercial insurance carriers.

²⁹ Price concession refers to any form of discount, directed or indirect subsidy, or rebate received by the carriers or its intermediary contracting organization from any source that serves to decrease the costs incurred under the health plan by the carriers. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on purchase agreement, coupons, free or reduced-price services, and goods in kind. Definition adapted from Code of Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 423, Subpart C. See more at: [CFR-2024-title42-vol3-sec423-100.pdf](https://www.ecfr.gov/current/title-42-chapter-iv-subchapter-b-part-423-subpart-c).

³⁰ Rebate refers to a discount that occurs after drugs are purchased from a pharmaceutical manufacturer and involves the manufacturer returning some of the purchase price of the purchaser. When drugs are purchased by a managed care organization, a rebate is based on volume, market share, and other factors. Academy of Managed Care Pharmacy. <https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary>.

Estimated total amount of the price concession

ORS 646A.694(1)(e) and OAR 925-200-0020(1)(e) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source carrier data call.

This section is intended to quantify the total discounts, rebates, or other price concessions provided by the manufacturer of Creon to each pharmacy benefit managers, expressed as a percentage of the drug's price. At the time of this review, there was no specific data available to PDAB to determine the total amount of such price concessions in the Oregon market.

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through improved reporting or additional disclosures from manufacturers, PBMs, and payers.

Estimated price for therapeutic alternatives³¹

ORS 646A.694(1)(f) and OAR 925-200-0020(1)(f), (2)(c) & (2)(m). Data source information provided from APAC.

This section presents information on the estimated spending associated with Creon and its therapeutic alternatives using data from APAC and data call collection for 2023 information. APAC data reflects gross spending across Medicare, Medicaid, and commercial health plans in Oregon, while the data call includes net spending submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concessions or rebates.

Creon's **gross total payer paid**, based on APAC data, was **\$32.9 million**, while total net payer paid received from the **carriers indicated a cost of \$5.7 million**. **Creon has the highest gross total pay in consideration** with its therapeutic alternatives. The second highest is Zenpep, with \$10.5 million. Notably, **Creon has the most utilization** among the drugs, **at 18,427 claims**, as compared to the second highest utilization of Zenpep, at 3,669 claims. Zenpep also has a higher payer paid per claim as compared to Creon, \$2,863 and \$1,784 respectively.

Creon also has the **highest total enrollee paid at \$1.2 million** and Zenpep follows behind with \$459 thousand. Zenpep has the highest patient paid per claim of \$161. **Creon's patient paid per claim, at \$90**, is the lowest, just above Pertzye at \$75.

Neither the drug nor the therapeutic alternatives were reported by the FDA for drug shortage, thus availability is assumed to be unaffected.

³¹ Therapeutic alternative to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. [ORS 925-200-0020\(2\)\(c\)](#).

Table 9 Average healthcare and average patient OOP costs vs therapeutic alternatives³²

Proprietary name	No. of enrollees ³³	No. of claims	Total payer paid	Total enrollees paid ³⁴	Payer paid/claim	Patient paid/claim ³⁵
<i>Subject Drug</i> Creon (Data call) ³⁶	744	2,293	\$5,707,517	\$211,955	\$2,489	\$92
<i>Subject Drug</i> Creon (APAC)	3,198	18,427	\$32,874,312	\$1,218,960	\$1,784	\$90
Pancreaze	82	339	\$456,954	\$20,387	\$1,348	\$158
Pertzye	3	21	\$25,567	\$375	\$1,217	\$75
Viokace	19	49	\$70,729	\$4,455	\$1,443	\$154
Zenpep	718	3,669	\$10,504,953	\$459,505	\$2,863	\$161

Estimated average price concession for therapeutic alternatives

ORS 646A.694(1)(g) and OAR 925-200-0020(1)(g) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement.

This section addresses the estimated average of discounts, rebates, or other price concessions associated with therapeutic alternatives to Creon, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

³² The therapeutic alternative information is based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

³³ The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 9, as compared to other totals indicated in this report.

³⁴ The cost includes all lines of business.

³⁵ Ibid.

³⁶ Information from the data call with the cost information after price concessions.

Estimated costs to health insurance plans

ORS 646A.694(1)(h) and OAR 925-200-0020(1)(h) & (2)(h) & (m). Data source information provided from APAC and data call.

This section quantifies the financial impact of Creon on health insurance plans in Oregon, based on claims and expenditure data from APAC and the carrier data call. Costs are delineated by payer type—including commercial, Medicaid, and Medicare—as well as by market segment within the commercial population. These estimates highlight the distribution of expenditures across different health coverage lines and inform assessments of the drug’s budgetary implications for public and private payers.

In 2023, the Oregon APAC database recorded **18,427 total claims for Creon among 3,198 total enrollees**, corresponding to a **total payer expenditure of \$32.9 million**.

Table 10 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Medicare** accounted for the largest share of utilization, with 8,321 claims from 1,735 enrollees and a total spend of **\$13.8 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **\$10.5 million** and **\$8.6 million**, respectively.

Table 10 Estimated 2023 APAC total annual gross payers’ expenditure for total enrollees and total claims ³⁷

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,026	5,264	\$10,475,268	\$10,210	\$1,990
Medicaid	873	4,842	\$8,550,295	\$9,794	\$1,766
Medicare	1,735	8,321	\$13,848,749	\$7,982	\$1,664
Totals³⁸	3,198	18,427	\$32,874,312		

Table 11 provides utilization for the healthcare system for Creon and its therapeutic alternatives, distinguished by lines of business. **Creon has the most utilization** among the drugs, with **18,427 claims**. In all lines of business, Creon is the most utilized. **Zenpep is the second most utilized at 3,669 claims**.

³⁷ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

³⁸ The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives³⁹

Proprietary Name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total Claims ⁴⁰
Creon	5,264	4,842	8,321	18,427
Pancreaze	68	210	61	339
Pertzye	15	6	0	21
Viokace	9	20	20	49
Zenpep	1,175	815	1,679	3,669

Table 12 shows the overall payer expenditure of Creon and its therapeutic alternatives, distinguished by lines of business. Creon has a **total expenditure of \$32.9 million** with **edicare being the biggest portion at \$13.8 million**. The therapeutic alternative with the **least expenditure is Pertyze, at \$25,567**.

Table 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business⁴¹

Proprietary Name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total ⁴²
Creon	\$10,475,268	\$8,550,295	\$13,848,749	\$32,874,312
Pancreaze	\$133,486	\$260,090	\$63,378	\$456,954
Pertzye	\$22,191	\$3,376	\$0	\$25,567
Viokace	\$15,441	\$14,565	\$40,723	\$70,729
Zenpep	\$3,571,823	\$2,470,824	\$4,462,306	\$10,504,953

Table 13 compares the overall payer cost per enrollee of Creon and its therapeutic alternatives, distinguished by lines of business. **Creon has the second highest total cost per enrollee at \$10,280**. Creon has the **second highest cost per enrollee in Medicare at \$7,982**, though the cost per enrollee of the commercial line of business is lower than therapeutic alternatives,

³⁹ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁴⁰ Total is the sum of all utilization for the drug across all lines of business.

⁴¹ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁴² Total is the sum of all expenditure for the drug across all lines of business.

Pertzye and Zenpep. **The median cost per enrollee for Creon is \$1,292**, which is less than the median cost per enrollee for Pertzye and Zenpep.

Table 13

*Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives*⁴⁴

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total ⁴³ cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee, 75 th percentile	Cost per enrollee, 95 th percentile
Creon	\$10,210	\$9,794	\$7,982	\$10,280	\$1,292	\$2,263	\$2,667	\$7,123
Pancreaze	\$7,416	\$5,308	\$3,961	\$5,573	\$955	\$1,285	\$1,420	\$5,553
Pertzye	\$11,096	\$1,688	\$0	\$8,522	\$2,368	\$1,853	\$2,812	\$2,957
Viokace	\$2,573	\$2,428	\$4,525	\$3,723	\$577	\$1,708	\$1,884	\$6,963
Zenpep	\$13,685	\$15,158	\$12,192	\$14,631	\$1,934	\$3,387	\$4,056	\$9,394

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. The collected **total net cost to the healthcare system was around \$18.7 million**, with payer paying \$16.2 million, and enrollees out-of-pocket estimating to be \$2.5 million. Table 14 includes the average plan costs per enrollee in the commercial market, ranging from **\$8,558 (small group)** to **\$6,600 (individual)** annually.

*Table 14.a Estimated 2023 total net costs to the healthcare system, payers and OOP/enrollee*⁴⁵

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
Individual	449	148	\$1,057,076	\$976,811	\$80,265
Large Group	1,419	464	\$3,688,738	\$3,601,081	\$98,657
Small Group	425	132	\$1,162,658	\$1,129,625	\$33,033
Total	2,293	744	\$5,919,472	\$5,7807,517	\$211,955

⁴³ The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

⁴⁴ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁴⁵ Cost information from the data call is the cost of the drug after price concessions.

Table 14.b Estimated 2023 total net costs to the healthcare system, payers and OOP/enrollee

Market	Avg. plans spend/claim	Avg. payer paid/claim	Avg. enrollee paid/claim	Avg. plans spend/enrollee	Avg. payer paid/enrollee	Avg. OOP/enrollee
Individual	\$2,354	\$2,176	\$179	\$7,142	\$6,600	\$542
Large Group	\$2,607	\$2,538	\$70	\$7,974	\$7,761	\$213
Small Group	\$2,736	\$2,658	\$78	\$8,808	\$8,558	\$250

As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (63% of total), followed by small group and individual markets.

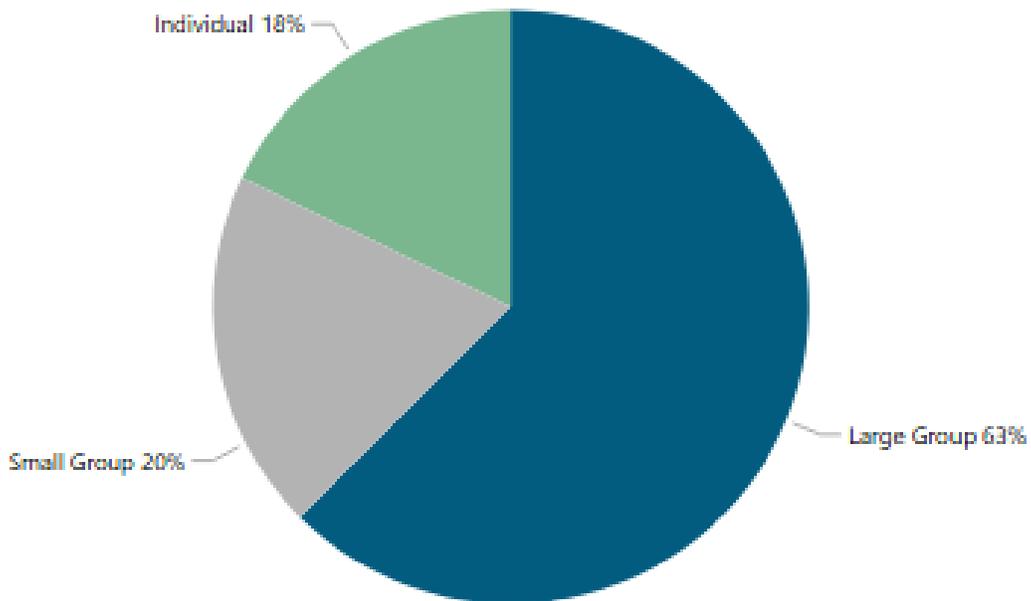


Figure 5 Data call total annual spend (payer paid) for each market type

Impact on enrollee access to the drug

ORS 646A.694(1)(i) and OAR 925-200-0020(1)(i). Data source information provided from carrier data call.

Review of rejected claims and drug benefit designs

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Creon, including prior authorization requirements, step therapy protocols, and formulary placement. The data describes how the drug is positioned within insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the following plan design features were observed for Creon. In 2023, approximately **1.2 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **0.0 percent of plans required step therapy** before approving its use.

For formulary placement, **0.4 percent of plans categorized Creon as a non-preferred drug** and **no plans excluded it entirely from the formulary.**

Table 15 Plan design analysis from 2023

Percentage of plans	
Required prior authorization	1.2%
Required step therapy	0.0%
On a non-preferred formulary	0.4%
Not covered	0.0%

Note: percentages can equal over 100 percent as some carrier and market combos may have multiple plans that fall under different designs. For example: Carrier A may have three plans in the small group market that require prior authorization but two other plans in the small group market that do not require prior authorization.

Relative financial impacts to health, medical or social services costs

ORS 646A.694(1)(j) and OAR 925-200-0020(1)(j) & (2)(i)(A-B). Limitations in scope and resources available for this statute requirement.

This section addresses the extent to which the use of Creon may affect broader health, medical, or social service costs, as compared to alternative treatments or no treatment. At the time of this review, there was no quantifiable data available to PDAB to assess these relative financial impacts in the Oregon population.

The statutory and regulatory criteria contemplate consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through carrier reporting, manufacturer disclosures, or other sources.

Future reviews may incorporate findings from real-world evidence, health technology assessments, or economic modeling as such data become available.

Estimated average enrollee copayment or other cost-sharing

ORS 646A.694(1)(k) and OAR 925-200-0020(1)(k) & (2)(j)(A-D). Data source information provided from APAC and carrier data call. Data limitations with patient assistance programs

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Creon in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC).⁴⁶ These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Tables 16 and 17 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. For example, **Medicare enrollees recorded higher average annual OOP costs**. Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

Table 16 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee⁴⁷

Proprietary name	Medicare OOP cost/enrollee	Commercial OOP cost/enrollee	Total ⁴⁸	Median	IQR	75 th percentile	95 th percentile
Creon	\$507	\$331	\$451	\$25	\$100	\$100	\$948
Pancreaze	\$870	\$359	\$600	\$80	\$250	\$250	\$1,109
Pertzye	\$0	\$188	\$188	\$38	\$38	\$56	\$71
Viokace	\$485	\$15	\$297	\$0	\$72	\$72	\$780
Zenpep	\$716	\$757	\$751	\$35	\$173	\$173	\$1,576

⁴⁶ Gross costs from the APAC database are prior to any price concessions such as discounts or coupons. Net cost information from the data call is the cost of the drug after price concessions.

⁴⁷ Based on 2023 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁴⁸ The total is the overall cost per claim across commercial insurers and Medicare.

Table 17 Review drug vs. therapeutic alternatives and out-of-pocket cost per claim⁴⁹

Proprietary Name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total ⁵⁰	Median	IQR	75 th percentile	95 th percentile
Creon	\$106	\$64	\$90	\$8	\$47	\$47	\$450
Pancreaze	\$228	\$95	\$158	\$37	\$196	\$196	\$552
Pertzye	\$0	\$25	\$25	\$0	\$75	\$75	\$75
Viokace	\$218	\$10	\$154	\$0	\$80	\$80	\$741
Zenpep	\$156	\$168	\$161	\$20	\$90	\$90	\$755

Clinical information based on manufacturer material⁵¹

ORS 646A.694(1)(L) and OAR 925-200-0020(1)(L). Information provided from manufacturers and information with sources from contractor(s).

Drug indications

- FDA Approved:
 - The treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.
- Off Label Uses: None

Clinical efficacy

Pancrelipase (Creon) is a pancreatic enzyme replacement therapy (PERT) consisting of lipase, protease, and amylase. It is indicated for the treatment of exocrine pancreatic insufficiency (EPI) due to conditions such as cystic fibrosis, chronic pancreatitis, pancreatectomy, pancreatic cancer, or other conditions. This is typically lifelong therapy for patients who require pancreatic enzyme replacement.

⁴⁹ Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

⁵⁰ The total is the overall cost per claim across commercial insurers and Medicare.

⁵¹ U.S. Food & Drug Administration. *Creon (pancrelipase) Prescribing Information*. Abbvie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020725s028lbl.pdf.

The clinical efficacy of *pancrelipase* was demonstrated in two pivotal randomized, double-blind, placebo-controlled trials, both of which measured the Coefficient of Fat Absorption (CFA) as the primary efficacy endpoint.

Table 18 Clinical efficacy pancrelipase vs placebo⁵²

Study population	Endpoint	Pancrelipase result	Placebo result	Treatment difference	p-value
Study 1: Adults & children (>7 yrs)	Primary: Coefficient of Fat Absorption (CFA)	88.6%	49.3%	+39.3%	<0.001
	Secondary: Coefficient of Nitrogen Absorption (CNA)	85.1%	58.0%	+27.1%	<0.001
Study 2: Children (7–11 yrs)	Primary: Coefficient of Fat Absorption (CFA)	83.0%	51.7%	+31.3%	<0.001
	Secondary: Coefficient of Nitrogen Absorption (CNA)	81.0%	54.1%	+26.9%	<0.001

Clinical safety

- FDA safety warnings and precautions:
 - Fibrosing Colonopathy
 - Mucosal irritation
 - Potential for Risk of Hyperuricemia
 - Potential Porcine Viral Exposure from the Product Source
 - Hypersensitivity
- Contraindications:
 - None
- Common side effects:
 - Headache (> 10%)
 - Peripheral edema
 - Hyperglycemia, hypoglycemia
 - Gastrointestinal symptoms (abdominal pain, abnormal stools, constipation, diarrhea, flatulence, gastritis, nausea)
 - Cough, nasopharyngitis

⁵² U.S. Food & Drug Administration. *Creon (pancrelipase) Prescribing Information*. Abbvie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020725s028lbl.pdf.

Therapeutic alternatives:^{53,54,55,56,57}

Table 19 FDA approved indications

Proprietary name	Non-proprietary name	Indications	Available Strengths
Creon	<i>pancrelipase</i>	exocrine pancreatic insufficiency.	<ul style="list-style-type: none"> • 3,000 units lipase, 9,500 units protease, 15,000 units amylase • 6,000 units lipase, 19,000 units protease, 30,000 units amylase • 12,000 units lipase, 38,000 units protease, 60,000 units amylase • 24,000 units lipase, 76,000 units protease, 120,000 units amylase • 36,000 units lipase, 114,000 protease, 180,000 amylase
Pancreaze	<i>pancrelipase</i>	exocrine pancreatic insufficiency.	<ul style="list-style-type: none"> • 2,600 units lipase, 6,200 units protease, 10,850 units amylase • 4,200 units lipase, 14,200 units protease, 24,600 units amylase • 10,500 units lipase, 35,500 units protease, 61,500 units amylase • 16,800 units lipase, 56,800 units protease, 98,400 units amylase • 21,000 units lipase, 54,700 units protease, 83,900 units amylase
Pertzze	<i>pancrelipase</i>	exocrine pancreatic insufficiency.	<ul style="list-style-type: none"> • 4,000 units lipase, 14,375 units protease, 15,125 units amylase • 8,000 units lipase, 28,750 units protease, 30,250 units amylase • 16,000 units lipase, 57,500 units protease, 60,500 units amylase • 24,000 units lipase, 86,250 units protease, 90,750 units amylase

⁵³ U.S. Food & Drug Administration. *Creon (pancrelipase) Prescribing Information*. Abbvie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020725s028lbl.pdf.

⁵⁴ U.S. Food & Drug Administration. *Pancreaze (pancrelipase) Prescribing Information*. Vivus, Inc., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022523s016lbl.pdf.

⁵⁵ U.S. Food & Drug Administration. *Pertzze (pancrelipase) Prescribing Information*. Digestive Care, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022175s008lbl.pdf.

⁵⁶ U.S. Food & Drug Administration. *Viokace (pancrelipase) Prescribing Information*. Viokace, LLC, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022542Orig1s007CorrectedLbl.pdf.

⁵⁷ U.S. Food & Drug Administration. *Zenpep (pancrelipase) Prescribing Information*. Zenpep, LLC, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022210Orig1s024_CorrectedLbl.pdf.

Proprietary name	Non-proprietary name	Indications	Available Strengths
Viokace	<i>pancrelipase</i>	exocrine pancreatic insufficiency.	<ul style="list-style-type: none"> • 10,440 units lipase, 39,150 units protease, 39,150 units amylase • 20,880 units lipase, 78,300 units protease, 78,300 units amylase
Zenpep	<i>pancrelipase</i>	exocrine pancreatic insufficiency.	<ul style="list-style-type: none"> • 3,000 units lipase, 10,000 units protease, 14,000 units amylase • 5,000 units lipase, 17,000 units protease, 24,000 units amylase • 10,000 units lipase, 32,000 units protease, 42,000 units amylase • 15,000 units lipase, 47,000 units protease, 63,000 units amylase • 20,000 units lipase, 63,000 units protease, 84,000 units amylase • 25,000 units lipase, 79,000 units protease, 105,000 units amylase • 40,000 units lipase, 126,000 protease, 168,000 units amylase

Comparative efficacy and safety:

There is no high-quality evidence from randomized controlled trials providing data that one *pancrelipase* product is more effective than another. There is insufficient evidence to determine any differences in efficacy or safety between products. Pancreatic enzyme agents are not automatically interchangeable since enzyme amounts can vary. The most important factor to consider when treating exocrine pancreatic insufficiency is administering the appropriate amount of lipase units to each individual patient based on diet. The recommended dose is individualized based on clinical symptoms and dietary fat content.

They are all derived from porcine pancreatic glands and have similar safety profiles. Agents that are not enteric coated (e.g. Viokace) need to be given in combination with a proton pump inhibitor. All agents include a warning for the rare but serious complication of fibrosing colonopathy from lipase administration. Selection of a *pancrelipase* product is based on cost, insurance coverage, and formulation characteristics.

Table 20 Efficacy: Treatment vs placebo and percent change for Coefficient of fat absorption (CFA)

Proprietary name	Non-proprietary name	Treatment CFA %	Placebo CFA %	Mean % Change
Creon	<i>pancrelipase</i>	89.0	49.0	41.0
Pancreaze	<i>pancrelipase</i>	87.0	56.0	37.1
Pertzye	<i>pancrelipase</i>	83.8	46.0	32.6
Viokace	<i>pancrelipase</i>	86.0	58.0	28.0
Zenpep	<i>pancrelipase</i>	88.3	63.0	26.0

Table 21 Efficacy: Treatment vs placebo and percent change for Coefficient of nitrogen absorption (can)

Proprietary name	Non-proprietary name	Treatment CNA %	Placebo CNA %	Mean % Change
Creon	<i>pancrelipase</i>	86.0	49.0	37.0
Pertzye	<i>pancrelipase</i>	79.0	47.0	32.0

Table 22 Adverse effects comparison

Proprietary name	Non-proprietary name	Type	Clinical Considerations
Creon	<i>pancrelipase</i>	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow
Pancreaze	<i>pancrelipase</i>	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow
Pertzye	<i>pancrelipase</i>	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow
Viokace	<i>pancrelipase</i>	Non-enteric coated	Must be used with proton pump inhibitor Tablets must be swallowed whole
Zenpep	<i>pancrelipase</i>	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow

Input from specified stakeholders

ORS 646A.694(3) and OAR 925-200-0020(2)(k)(A-D)

See appendix page for all stakeholder feedback.

Patients and caregivers:

Note: The information presented is based on self-reported survey responses from individuals prescribed certain medications. Participation in the survey was voluntary, and the responses reflect each individual's personal understanding and interpretation of the question asked. As such, the data may contain inconsistencies or inaccuracies due to varying levels of comprehension, recall bias, or misinterpretation of question intent. These limitations should be considered when interpreting the responses.

Survey information was collected from **nine individuals** taking or having an association with Creon. According to the survey results, 89 percent of respondents had insurance coverage for Creon.

Three patients were on Medicaid, zero patients were on Medicare, and six patients had private health insurance. One patient reported their prescription was not covered, although they were under private health insurance. Three patients reported being on patient assistance programs.

Below are written answers from Oregon patients and caregivers who responded to the PDAB survey in April 2025. Survey responses have been edited for readability, length and to protect patient privacy.

““ Creon ””

- ✚ The patient takes Creon, two capsules before every meal or snack, for cystic fibrosis. She has taken it since birth for the past seven years. Creon allows her food to digest so that she can get the nourishment she needs to live and grow. This is the only option that works for her. She is covered by private health insurance. (Submitted by a caregiver.)
- ✚ The patient takes Creon 6000, 3 capsules with every meal, 15 capsules per day for cystic fibrosis and has since birth. It allows digestion of food, otherwise it would be impossible to get nutrition. It is life supporting. The patient has private insurance and Oregon Health Plan/Medicaid as secondary. Medicaid covers the co-pays. (Submitted by a caregiver.)
- ✚ The patient took Creon, one capsule right before every meal or snack. He took it for six months and it helped his body absorb fat and nutrition, which helped him start gaining weight. The patient is on Medicaid. (Submitted by a caregiver.)
- ✚ The patient took Creon 24,000, five capsules with all meals and snacks, 25/day, for cystic fibrosis, for the past 21 years. The patient's monthly out-of-pocket cost is \$120. In cystic fibrosis, the pancreas is no longer able to provide necessary digestive enzymes to the

body. Any time anything is consumed, replacement digestive enzymes are necessary to both digest the food and facilitate nutrient absorption. Without these replacement enzymes, the body would simply waste away, with body systems unable to function leading to extreme weight loss, malnutrition, and death. In the past, the patient tried Pancreaze, Pertzye, and Ultrace, all resulting in inadequate system support and health decline. The patient has private health insurance. It is not on the standard formulary but my employer brokered a separate agreement to have it covered. When I first began with this employer and discovered it was not covered, the patient was required to try the other versions listed above and "fail" on those medications before it would be covered. For the record, "failing" on a digestive enzyme is miserable (think horrible indigestion, gas, bloating, awful loose stool, etc). Creon is the medication that has allowed my child to grow and thrive when the alternatives were causing, not only extreme discomfort and pain, but an actual inability to function in everyday life. It is absolutely an essential part of their every day care. While there are other enzymes on the market, not every one works for every person and it is imperative that there be multiple options for patients of all ages. (Submitted by a caregiver.)

- ✚ I just got a letter in the mail this month from Oregon Health Plan/Medicaid telling me that I need to switch to Creon because Pancreaze DR will no longer be covered by my insurance. So I don't yet know what my dosage will be for Creon. I have been diagnosed with pancreatic insufficiency. The medications help make me able to pass stool. Without it, I end up severely constipated and in the emergency room. I was originally prescribed Creon, but the pharmacy said that OHP wouldn't cover it. So, I started taking Pancreaze, which worked fine, but now it is no longer covered and I need to switch to Creon next month because I am told that it is now covered. I wish this was easier! Thank you for your help.
- ✚ I take Creon six capsules of 12,000 USP units each with meals (three times per day), with additional capsules with snacks (usually three to four). I take it for cystic fibrosis-related pancreatic insufficiency. I have been taking it for 14 years. Creon assists the digestive system in breaking down nutrients in food when the pancreas is unable to make the chemicals itself. I have private health insurance and have no out-of-pocket costs for Creon. Without the effect of this medication, eating and nutrition are arduous processes, with unnecessary chronic abdominal pain to the point it often interferes with everyday life. Additionally, it is difficult to gain and maintain a healthy body weight, putting a patient at greater risk for long term health issues and susceptibility to complications from minor illnesses.
- ✚ I take Creon 2400UNT two to three capsules per day for enzyme deficiency and have been taking it for three years. My recent monthly out-of-pocket cost is \$175 with private health insurance. I had to get approval and it took forever. But I can digest food now.
- ✚ I take Creon 24,000-unit EC Caps five times per day for pancreatic insufficiency and have been taking it for two years. My recent monthly, out-of-pocket cost was \$24 with insurance through the Veteran's Administration. Creon allows food to be properly digested and nutrients absorbed.

Individuals with scientific or medical training

A survey of healthcare professionals with scientific or medical training identified key barriers for patients accessing medications. There were six healthcare professionals that reported the prior authorization, step therapy, and formulary issues with Creon was an administrative burden and laborious for patients to access the medication, even though it is considered a first line of therapy.

Below are selected written responses about Creon from the survey for individuals with scientific or medical training, edited for length and to protect their privacy.

- ✚ Usually requires a lengthy and involved prior authorization process despite being the gold standard for CF-related malabsorption for the last 50 years. Many times we have to fight insurance companies for approval of Creon. RN, cystic fibrosis, from OHSU
- ✚ Prior authorization is nearly always necessary. While there are different brands which are formulated slightly differently, individuals will tolerate some brands better than others, so it is often necessary to "try and fail" a patient hasn't done well with in order to keep the medication that is known to work. Sometimes recurrent pancreatitis can be treated with this therapy as supplementation of pancreatic enzymes can cause feedback inhibition to reduce pancreatic stimulation and reduce chronic pain associated with pancreatitis, even if there is pancreatic insufficiency. This reduces the need for opiate therapy, missed days of work/school, and greatly improves quality of life. Sometimes the medication has not been approved by insurance leading to missed doses. - Associate Professor of Medicine, Pulmonary Medicine, Cystic Fibrosis, OHSU
- ✚ Some patients will have better fat absorption and less G.I. discomfort and bloating on Creon versus the other available alternatives. The other alternatives are typically priced in a similar range and there is no generic available. There are non-FDA approved, herbal formulations that are unregulated, medically not appropriate and contraindicated. One advantage of Creon is that there are many different dosing strengths measured in numbers of international units of lipase per capsule to accommodate all ages, sizes to include newborns all the way up to adults. – Representative of the Cystic Fibrosis Foundation and Inova Fairfax Hospital, Maryland
- ✚ Without this drug, CF pancreatic insufficient patients will develop malnutrition. Malnutrition leads to poor lung health, decline in health and earlier death. – MD Pediatrics, Kaiser Permanente
- ✚ This drug is first-line therapy for those with Exocrine Pancreatic Insufficiency. It is essential for nutrient absorption to support life. This drug is essential and irreplaceable. - MD, MS; Pediatric Gastroenterologist with a focus in Nutrition, OHSU

Safety net providers

The information reported by safety net providers describes their experience dispensing Creon, particularly in relation to the federal 340B Drug Pricing Program. The survey collected information on utilization, if the drug was eligible for 340B discounts, dispensing arrangements, and payment and reimbursement levels.

A total of **11 safety net clinics** responded to the survey. Among respondents, **10 clinics indicated that Creon was covered as a 340B-eligible prescription** within their programs.

Most clinics (91%) reported operating an internal pharmacy for dispensing 340B-eligible medications, and 64 percent reported using one or more contract pharmacies for this purpose.

Additionally, **82 percent of clinics reported having a prescription savings program**, and all respondents (100%) reported employing a staff member dedicated to 340B compliance.

Regarding expenditures under the 340B program, respondents reported a range of total amounts paid: 27 percent reported paying between **\$0–\$100,000**, 18 percent reported between **\$100,001–\$300,000**, while **55 percent declined to report, citing trade secret protections**.

Reported reimbursement for dispensing under 340B also varied: 18 percent of respondents reported reimbursement between **\$0–\$100,000**, 9 percent between **\$100,001–\$500,000**, and 18 percent between **\$500,000–\$10,000,000**.

Without additional detail on the volume of patients treated or the per-claim costs, it is difficult to interpret the figures in terms of clinic financial risk or access outcomes. The wide range may reflect differing clinic sizes, patient populations, or inventory management practices. Notably, the absence of full reporting by 55 percent of clinics makes it challenging to assess how 340B drug costs affect long-term affordability or sustainability for safety-net providers.

These results suggest that while Creon is incorporated into many safety-net programs, further data would be necessary to understand how reimbursement aligns with acquisition cost and whether 340B discounts adequately mitigate financial exposure for patients and the healthcare system.

Table 23 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	10
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between \$0-\$100,000	27%
Reported total amount paid for drug under 340B was between \$100,001-\$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%

Survey information	Response
Reported total reimbursement for drugs dispensed under 340B was between \$0-\$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between \$100,001-\$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between \$500,000-\$10,000,000	18%

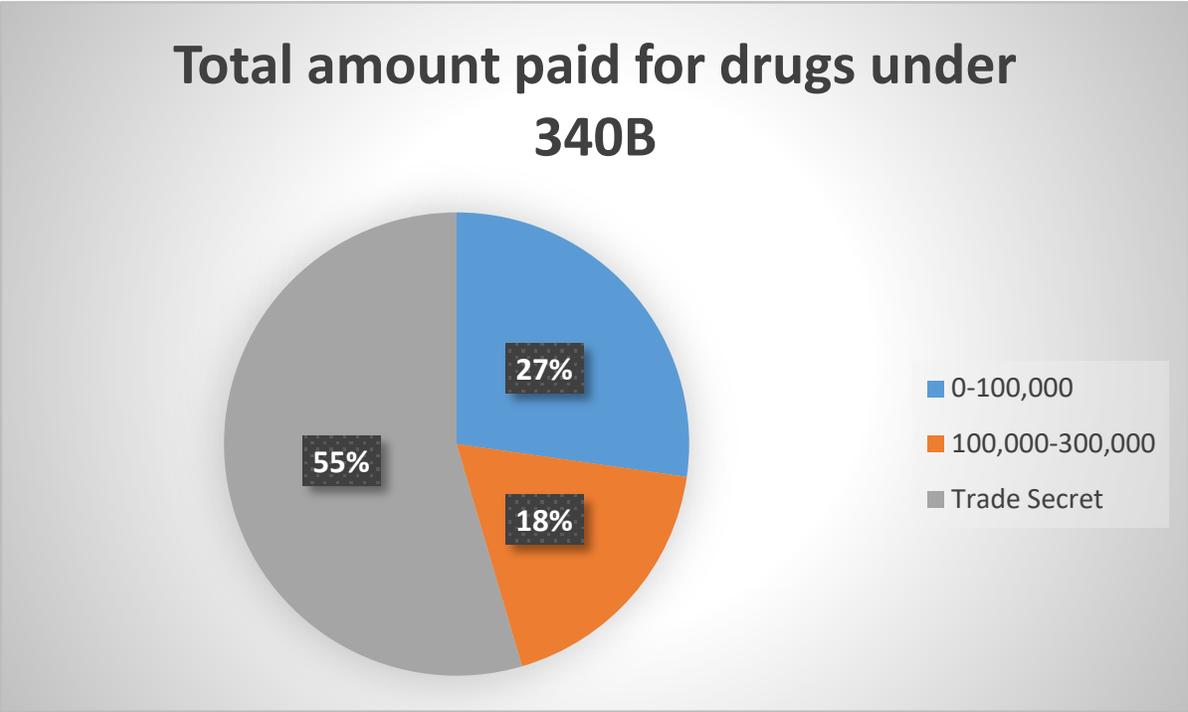


Figure 6 Amounts paid for drug under 340B discount program

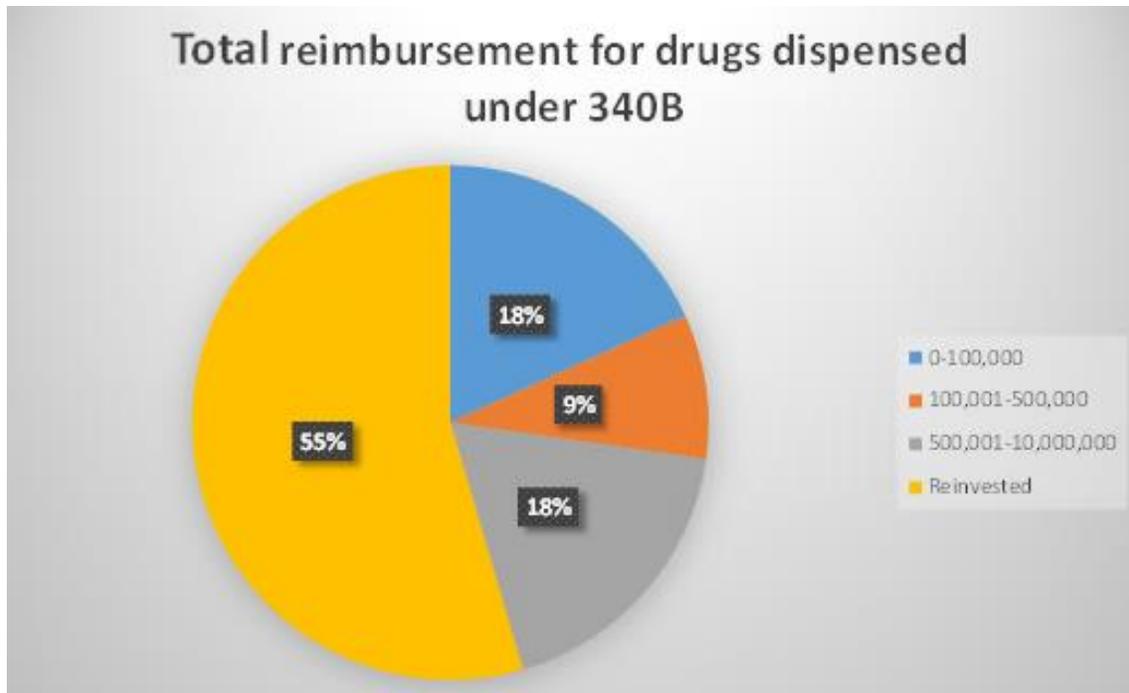


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

Payers

Relevant information from payers is incorporated throughout the material packed based on the data submitted through the formal data call process. This includes details on the total cost of care for the disease, the cost and utilization of the prescription drug, the availability and formulary placement, therapeutic alternatives, as well as reported impacts to member costs.

The data provided through the carrier data call serves as a comprehensive source of payer input and reflects aggregate insights across participating organizations. No separate qualitative feedback or narrative statements were requested or received from individual payers for inclusion in the section.

Appendix

Stakeholder feedback:

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Albert Faro et al	Cystic Fibrosis Foundation	Creon	Letter	5/21/2025	Exhibit A
Lindsay Silva	Mother/primary care giver to someone living with Cystic Fibrosis	Creon	Speaker	5/21/2025	Exhibit B