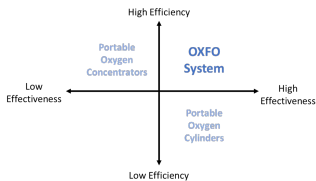


## Background/Clinical Unmet Need

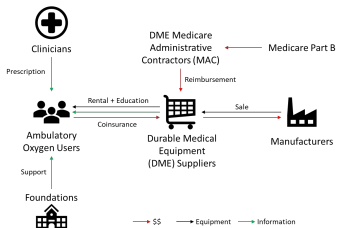
- >1.5 million Americans receive long-term oxygen therapy (LTOT) to treat chronic hypoxemia, improve their daily quality of life, and slow disease progression
- Medicare spends >\$2 billion annually for LTOT, constituting around 25% of the program's total expenditure on durable medical equipment
- Individuals relying on high-flow oxygen (>3 L/min) face even higher unmet burden, particularly as portable oxygen concentrators are not suited for those requiring more than 3 L/min of continuous flow

**Problem Definition:** To seize this opportunity to address the need for a portable, high-flow oxygen device in the U.S., OXFO is seeking a comprehensive market analysis and entry strategy to ensure a successful launch of the OXFO System upon FDA approval.

## Value Proposition



## The Patient Journey



Map of relevant stakeholders and flows in the U.S. oxygen therapy device market

## OXFO

The OXFO Corporation:

- Founded by Carlos Bazoberry, MD and Brent Young, MD
- Combat the global oxygen crisis in Boston, MA (2020)

The OXFO System:

- Portable, high-flow, on-demand oxygen delivered at ambient pressure and capable of dynamic response to patients' flow needs
- Compatible with available nasal cannulas and standard oxygen cylinders

Current Status:

- 2022 - Market and regulatory authorization in Colombia targeting ambulatory patients prescribed LTOT
- 2025 - Targeting FDA approval for U.S. market entry

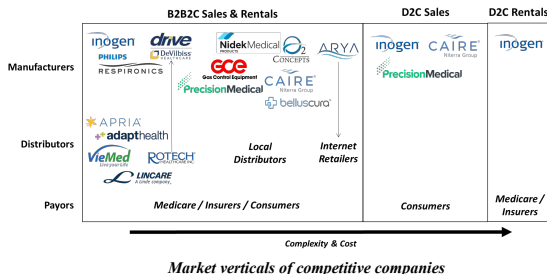


Rendering of the portable OXFO System

## Stakeholder Interviews

- "It's all about mobility" Mike Hess, Senior Director Oxygen360, COPD Foundation.
- "I would love to see more devices out there...that have a larger variety of options and settings to accommodate a larger variety of patients" Chrysalis Ashton, Director of Clinical Operations for CareLinc
- "Give me more portable tanks or supplies so I can leave the house more frequently and for longer periods of time" was the most frequent response when patients were asked the "...one thing you could change to improve your home oxygen experience".

## Business Models



## Reimbursement

- Oxygen delivery devices are not profitable for DME distributors
- Only rented oxygen equipment is eligible for coverage; purchased equipment is statutorily non-covered. Patients rarely purchase the device given costs and maintenance (as noted by interviewed stakeholders)
- The device needs to adhere to the reasonable useful lifetime (RUL) requirement commencing from the initial date of service and lasting for 5 years.
- Payment rules for oxygen equipment only cover a 36-month rental period. During this period, the reimbursement amount includes not just the equipment but also accessories, delivery, backup equipment, maintenance, and repairs.

HCPCS Code	Description	Est. Monthly Reimbursement	Max. Reimbursement
E1390	Stationary Oxygen Concentrator	\$145	\$5,220
E1392	Portable Oxygen Concentrator	\$49	\$1,764
E0431	Portable Gaseous Oxygen System	\$27	\$972
QB/QF	Modifier*	\$72	\$2,592
E0434	Portable Liquid Oxygen System	\$49	\$1,764

## Recommendations

Immediate (<1 year)

- Prioritize securing a distribution partner(s) for the OXFO System in a B2B2C model
- Focus on targeting users requiring >4 L/min and qualifying for the QB/QF modifiers per Medicare
- Initiate collaborations with distributors by participating in industry events such as MedTrade and forming partnerships with foundations like Oxygen360 to increase recognition, advocacy, and marketing

Short-Term (2-3 years)

- Explore direct-to-consumer (D2C) sales by beginning to market directly to consumers, clinicians, and hospitals

Long-Term (5+ years)

- Investigate the integration of the OXFO System with portable oxygen concentrators (POCs) and liquid oxygen
- It is not recommended to explore direct-to-consumer (D2C) rentals due to the outsized requirements

## Acknowledgements

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