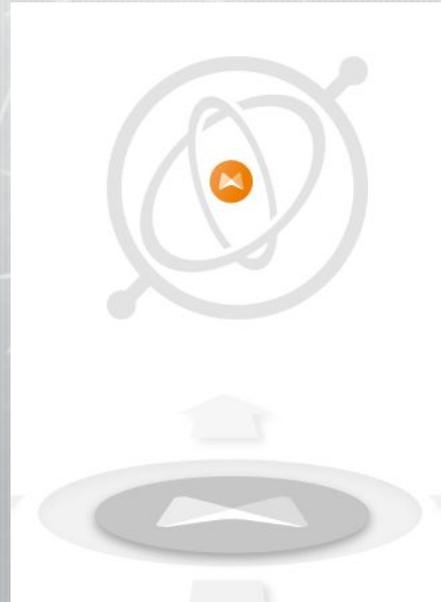


IACBE Fall Case Competition 2019

Project: Munevo Go-To-Market Strategy



Case Objectives

- Analyze the market size for the number of people that require a special control wheelchair such as Munevo DRIVE.
- Report key foundations and institutions that work on key diseases or conditions that lead to the need of specially controlled power wheelchairs.
- Assess key U.S. hospitals and departments that work with patients needing a wheelchair.
- Assess the distribution system and relevant players that work with medical devices, including specialty wheelchairs.
- Bonus: Find the required steps that are needed to have the product reimbursed by U.S. public healthcare.



Disease Prevalence

- Multiple sclerosis affects about 400,000 people in the United States, and about 2 1/2 million worldwide. In the United States, the prevalence of the condition — that is, the number of people who have it compared with the general population — is nearly 90 cases per 100,000 people. (Multiple Sclerosis Statistics - Multiple Sclerosis News Today, 2017)
- Approximately 5,000 people in the U.S. are diagnosed with ALS each year. The incidence of ALS is two per 100,000 people, and it is estimated that at least 16,000 Americans may be living with ALS at any given time. About 90 percent of ALS cases occur without family history (Facts You Should Know, 2019)



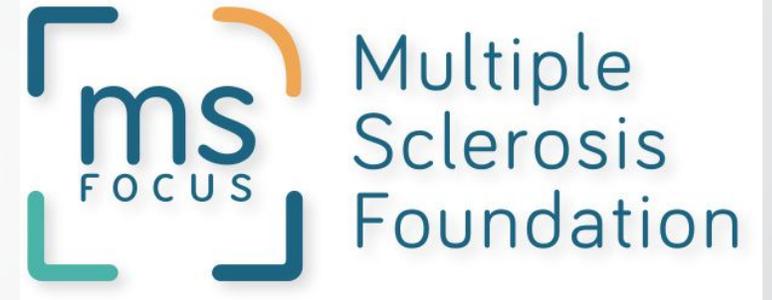
Key Foundations and Institutions

- American Spinal Injury Association (ASIA)
 - North American organization that is dedicated to spinal cord injury care, research and education
 - Promotes research that aims at preventing SCI, improve care, and help find cures to acute/chronic SCI
- American Spinal Research Organization (ASRO)
 - Canadian/American research organization
 - Keeps up-to-date with the latest clinical trials, research, and advocacy updates



Key Foundations and Institutions Cont..

- Multiple Sclerosis Foundation (MS Focus)
 - Aims to provide the support, education, and assistance that is needed to adapt to these difficult circumstances
 - This foundation has affiliations with seven big agencies that help MS Focus access more resources for their clients
- The ALS Association
 - Only national non-profit organization that leads in global research
 - Fostering government partnerships, enhance quality of life, and search for novel treatment and cures



U.S. Healthcare Market

- Approximately 6 million power wheelchair users in the U.S.
- Each year more than 10,000 people require a special control for their wheelchair
- In 2018, 1.825 million wheelchair users were age 65+
- 17.4% of working age wheelchair users were employed
- An expected \$3.9 billion in 2018, in the power wheelchair market due to the large need among the baby boomer generation (Wheelchair Facts, Numbers and Figures [Infographic], 2015).



U.S. Healthcare Market

The U.S healthcare market may seem complex to foreign companies hoping to enter the medical device market. The market itself primarily consists of two main health insurance sanctions..

Government



Private Insurers



FDA Approval

★ The most important step for entering your product into the U.S medical device market

FDA approval consists of:

- Determining what class your product aligns with (most likely Class II)
- Filling out appropriate paperwork per the class (510k Premarket Notification)
- Find a product already approved by the FDA with substantial equivalence

Category	Level of risk to patient	Examples	Type of review before device can be marketed
Class I	Low	<ul style="list-style-type: none">• Elastic bandages• Examination gloves• Handheld surgical instruments	Most devices required only to register; a small share must submit a 510(k) notification.
Class II	Moderate	<ul style="list-style-type: none">• Powered wheelchairs• Infusion pumps• Surgical drapes	Most devices must submit a 510(k) notification; a small share of devices are required only to register.
Class III	High	<ul style="list-style-type: none">• Heart valves• Silicone breast implants• Implanted cerebella stimulators	Devices must submit a PMA application; in the past, a significant number of devices were able to submit a 510(k) notification.

What is a 510(k) Premarket Notification?

Under section 510(k) of the FD&C Act, a **510(k)** to FDA at least **90 days** before commercialization.

To demonstrate that the device to be marketed is **at least as safe and effective**, that is, substantially equivalent, to a legally marketed device.

Substantial Equivalence (SE)!



Key Hospitals and Departments

- Shriner's Hospitals for Children- 22 main locations across the country/ St. Jude Children's Research Hospitals- 8 locations across the country
- Department of Defense/Veteran's Administration (Military-specific/located at every base in the world)
- Hospital Corporations of America (HCA)- 166 locations
- Universal Health Services, Inc.- 350+ locations



Distribution and Suppliers

Top Wheelchair Manufacturers in the U.S. (2018)

21st Century Scientific Inc.

Invacare Corp.

Ottobock Healthcare GmbH

Permobil AB

Pride Mobility Products Corp.

Sunrise Medical Inc.

GF health Products, Inc.

Hoveround Corp.

Levo.AG

Medical Depot Inc.

Merits Health Products Co. LTD.

Meyra Wilhelm Meyer GmgH & Co. KG



Healthcare Reimbursement

Easiest route would be to target Medicare. Generally, once Medicare approves a product, private insurance companies follow (Medpac Report 2017)

Route for Medicare Approval

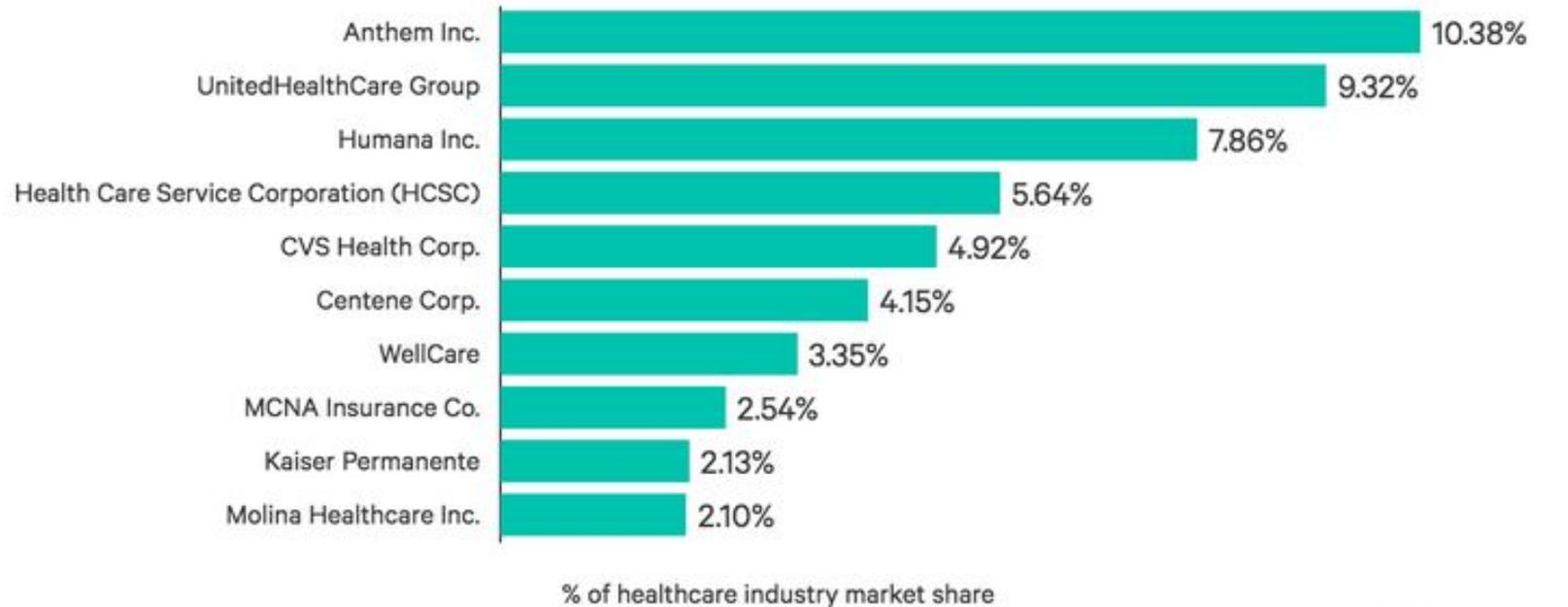
- **Completing an application for national coverage determination (NCD)**
- **Highly recommended to give heads up to bureau before submitted (Federal Register Notice 2017)**
- **This is done by an informal conference call with the Coverage and Analysis Group (CAG) within the Center for Clinical Standards and Quality Control (CSSQ)**
 - **Contact Information: Tamara Jensen, Director of CAG**
E-mail: tamara.syrekjensen@cms.hhs.gov



NCD Outline [Here](#)

Largest U.S. Health Insurance Companies

Market Share of the Largest Health Insurance Companies



Market share data was generated by using the S&P Global market share tool. The companies share of the market is based on its total health enrollment during the year.

Market Share



Product Reimbursement

- **Part 1: Getting a Certificate of Necessity.**
 - **Need Medicare, Part B coverage.**
 - **Talk with your doctor for availability.**
- **Part 2: Getting your wheelchair.**
 - **Make sure you have Part B deductible.**
 - **Know how much you need to pay, sometimes it is 20%.**
 - **Find a supplier approved by Medicare.**
 - **Are you eligible for Competitive Bidding Program?**

Contact a supplier; you will have 45 days after obtaining the Certificate of Necessity in order to make your purchase.



RECOMENDATIONS

- Applying for FDA approval prior to contacting distributors and suppliers
- Look into e-commerce marketing
- Consider supplying to rehabilitation services and those specializing in physical therapy /homecare
- Look into attending U.S. conferences/conventions¹ – demo/networking
- Website- consider moving your awards to the main page; changing the colors of your social media icons so they 'pop'

REFERENCES

Clarke, D. Boston MedTech Advisors (2017, May 31). From "Approved" To "Covered" - What Medical Device Companies Need to Know. Retrieved from <https://www.meddeviceonline.com/doc/from-approved-to-covered-what-medical-device-companies-need-to-know-0001>.

Commissioner, O. of the. (n.d.). What We Do. Retrieved from <https://www.fda.gov/about-fda/what-we-do>.

Facts You Should Know. (2019). Retrieved November 10, 2019, from ALSA.org website: www.alsa.org/about-als/facts-you-should-know.html#:~:targetText=Approximately%205%2C000%20people%20in%20the,cases%20occur%20without%20family%20history.

REFERENCES

Medicare Program; Revised Process for Making National Coverage Determinations, Vol 78 No

15 pg. 48164–48166 (2013). Department of Health and Human Services. Centers for

Medicare and Medicaid Services. Retrieved from

[https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR0807201](https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf)

3.pdf

Medpac. (2017). *Report to the Congress: Medicare and the Health Care Delivery System.*

Retrieved from

[http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0.](http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0)

REFERENCES

Multiple Sclerosis Statistics - Multiple Sclerosis News Today. (2017). Retrieved from

Multiple Sclerosis News Today

website: <https://multiplesclerosisnewstoday.com/multiple-sclerosis-overview/statistics/>

Qualifying Diagnoses For Wheelchairs & Mobility Equipment. (2019). Retrieved from Freedomhme.com

website : <https://www.freedomhme.com/Qualifying-Diagnoses>

REFERENCES

Wheelchair Facts, Numbers and Figures [Infographic]. (2015a). Retrieved from Smart Chair website:

<https://kdsmartchair.com/blogs/news/18706123-wheelchair>

-facts-numbers-and-figures-infographic

World Health Organization. (2010). *Features of a wheelchair [pdf file]*. Retrieved from

http://www.searo.who.int/entity/disabilities_injury_rehabilitation/wheelchair

[Factsheet.pdf](#)