

This memo will outline the essential points that Munevo must consider for successfully entering and growing their business in the US market.

Key Institutions and Introduction Methods

To aid in Munevo's introduction into the US market, there are a few key organizations and foundations that will help its integration immensely. The Food and Drug Administration (FDA) will need to approve the sale of Munevo DRIVE as a medical device. The process will take around three to six months and requires a US agent. A US agent is anyone who resides in or owns a business in the US. They will be the connection between the FDA and Munevo since Munevo is a foreign company.

The foundations and associations that Munevo should create relationships with are: the National Multiple Sclerosis (MS) Society, Cerebral Palsy Group, Christopher & Dana Reeve Foundation, and the ALS Association. All of these organizations work to provide awareness for these disabilities, promote research to find cures, and aid those who are affected by these in finding medical devices to help them improve their daily lives. Some of these organizations, and others, offer grants to help cover medical devices that would assist in the everyday activities we perform. Aligning Munevo with these well-known organizations would help to popularize the product and possibly provide an alternative to insurance reimbursement through the aid of grants.

Target Market, Forecasting, and Product Introduction

When estimating the market for Munevo DRIVE we looked for the conditions in which someone may need the assistance of this technology before calculating what we expect the sales to be. We estimate that there is a need between 0.8% and 7.6% for those who suffer from some of the more populated disabilities that Munevo has identified as groups who benefit from the technology. We researched the number of new cases of ALS, MS, spinal injuries, and SMA because these conditions make up a significant portion of the market. Based on our earlier percentage calculations, we have determined that once Munevo is an established company in the US it should expect to sell between 347 and 3,281 units per year. We looked into the new cases specifically because those who already have a power wheelchair or are receiving treatment are less likely to purchase the system.

Using these calculations we forecast sales to be 0 units in the first six months as Munevo awaits FDA approval, and then it will increase to 80 in the first year. We estimate 80 because there have been 20 units sold in Germany in their first year and the US population is about three times the size. In years three through five we estimate 500 to 4,000 units per year when taking into account that the product will grow in popularity.

In order to successfully introduce Munevo DRIVE we recommend targeting primary care physicians (PCP) directly through medical conferences. The PCP's will be the ones to target specific patients who they find would benefit from the product. Attending conferences such as HIMSS and MD&D would allow the device to be showcased in tech-focused environments.

Insurance Reimbursement

There are two government funded groups that those who have disabilities can use to obtain medical insurance: Medicare and Medicaid. In order to receive insurance reimbursement for Munevo DRIVE the patient must qualify as per the requirements listed: face-to-face visit with a PCP, medical evaluating indicating need for the device, seven element prescription order,

and sending the aforementioned records to a power mobility device(PMD) within forty-five days of the evaluations. Suppliers of Munevo must also keep records of the paperwork proving all of the requirements were met as well as a detailed product description, home evaluation, and proof of delivery. Munevo DRIVE is considered a group 2 single power option power wheelchair(PWC) under Medicare and Medicaid regulations.

The two largest private insurance companies in the US are Aetna and Independence Blue Cross. Requirements from private insurance for a PWC are similar to those of Medicare and Medicaid under the group 2 single power option which requires a drive control interface, other than hand or chin, operated standard proportional joystick. Private insurance also varies by state so Munevo will need to start small and strategically branch out by starting with states who have the same requirements.

Potential Complications

The Affordable Care Act(ACA) builds on Medicaid's coverage by guaranteeing coverage for those with disabilities. If it is repealed many people with disabilities may go without insurance and would not be able to afford Munevo DRIVE. There is no definite answer as to when it could be repealed but before it can be repealed it must be heard in all twenty-one appeal cases and move up to the Supreme Court. At the earliest this could happen halfway through next year. It is also an election year in 2020 and this may delay any action taken to remove the ACA. A possible solution is that various institutions that work with the key disabilities mentioned earlier provide grants to cover necessary medical devices for those who cannot afford them.

Key Hospitals

The Mid-Atlantic region of the US is located on the East Coast. It has become the hub for medical innovation and is the perfect place for Munevo to begin building connections. Many hospitals provide services for those who need custom medical equipment. Penn and Jefferson Hospital each have their own outpatient clinics where they adhere to custom seating adjustments to ensure patient mobility. These services are performed by occupational and physical therapists and allow their patients to experience a trouble-free process as they become acclimated to their new assistive mobility device. Through a personalized rehabilitation process, patients can be informed and trained for their device and therapists can ensure each individual will have their own unique evaluation to match their specific needs.

Distribution and Dealer Channels

Two main distributors of PWC's are SunRise Medical and PerMobil. SunRise manufactures PWC's and has a nationwide network of dealers, and PerMobil designs and develops rehabilitation technology and provides educational support on the product. NuMotion is also a popular dealer that has Assistive Technology Professionals, Care Coordinators, Medical Documentation Coordinators, Funding Coordinators, Insurance Coordinators, and Service Technicians. There is also the route of direct-to-consumer sales. By setting up an online store with either outright purchase options or a subscription service, customers who are not medically in need of the product can purchase it on their own. Including tutorials on how to set up and use the technology would help to attract customers as it portrays the ease of integrating the technology into their daily lives.

In summation, Munevo DRIVE has the potential to be the next big thing in the US and will help to change the lives of so many people who struggle due to their disability.

Appendix

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