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Expect Varied Terrain: The Diverse Pricing And Reimbursement Landscape Of Durable Medical Equipment Across The United States And Europe

- The durable medical equipment (DME) market is an attractive and growing market which covers wheelchairs and other orthoses
- Pricing and reimbursement systems for DME across the United States (U.S.) are unique due to the presence of various healthcare payors, while in the European Union (EU) they are specific to each member state
- In this piece, Marwood examines how these differences impact on the uptake of DME products and explores Spain's national health system (SNS) to demonstrate how crucial it is for investors to understand pricing and reimbursement for DME products when considering investments in DME manufacturers

Durable medical equipment (DME) is any medical equipment used in the home to improve a patient's quality of life. The term includes equipment and supplies ordered by a healthcare provider for everyday or extended use. DME is a benefit covered by U.S. payors and most national healthcare systems in Western Europe. Coverage for DME may include oxygen equipment, wheelchairs, or crutches. In this piece, Marwood delves into the key issues by taking a closer look at important differences in pricing and reimbursement setting mechanisms which impact on the uptake of DME products in the U.S. and Europe. The Spanish public-pay pathway for DME reimbursement and pricing is also distilled to reveal the nuances of these dynamics.

To succeed within the U.S. DME market, an understanding of the various payor segment coverage and reimbursement dynamics is necessary

The U.S. DME pricing and reimbursement system can be broadly divided into four major payor categories: "Traditional" Fee-for-service Medicare, "Traditional" Fee-for-service Medicaid, Managed Care (e.g., employer-sponsored commercial health insurance, individual commercial health insurance, Medicare Advantage, managed Medicaid), and self/private pay. Each payor category adheres to specific regulations and has unique pricing and coverage dynamics.

Overall, the U.S. DME industry has continued to be an attractive target for private equity due to its large size (~$70B in 2021) and continued growth driven by an aging population, increased prevalence of chronic conditions, shift to value-based care contracts between payors and providers, and increased consumer preference for at-home care. However, the fractured payor landscape and various regulations per product category adds nuance to market dynamics that requires an acute understanding of federal, state and commercial payor dynamics for each product to make informed investment decisions.

From a federal perspective (i.e., "Traditional" fee-for-service Medicare), select DME products have been/can be subject to competitive bidding. The Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program was mandated by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and required that Medicare replace the established federal fee schedule payment methodology for selected DME with a competitive bid process. For example, the competitive bidding program substantially reduced reimbursement for many wheelchairs, though most complex wheelchairs and accessories have not been affected. With respect to other governmental DME payors, Medicaid programs are managed on a state-wide basis, and even though every state will have its

own unique coverage, delivery system, reimbursement, and budget environment, there are some commonalities. Specifically, all states choose to cover DME products, and these products can be delivered by Fee-for-service (FFS) or managed care. In addition, some states will contract with exclusive or preferred suppliers to deliver DME (or specific categories of DME) to the FFS population. Reimbursement tends to be set on a fee schedule with little annual updates, and if there is budget pressure, states have been known to limit utilization or lower reimbursement until such time that the budget improves.

Health insurance plans will typically refer to government-set fee schedule rates, depending on the beneficiary population (e.g., Medicare Advantage, commercial and Medicaid), but have flexibility in establishing networks and setting in-network contracts, as well as benefit coverage levels. Although plans find value in the utilization of DME, historically, plans have expressed fraud, waste, and abuse concerns with DME, which has led to a narrowing of networks and selective relationships. In terms of reimbursement, commercial plans were historically reimbursing at rates lower than Medicare (and sometimes Medicaid), but after the Centers for Medicare & Medicaid Services' (CMS) competitive bidding program was implemented, reimbursement has aligned for most products; these commercial plays continue to consider government-set fee schedule rate changes, though they are typically not automatically adopted.

EU regulation has limited competence in the management of national healthcare

Medical devices are primarily regulated the EU Member State level, and there are no rules governing the pricing and reimbursement of medical devices at the European level. The Medical Device Regulation (MDR, 2017), which DME are subject to, establishes EU-wide requirements for market access.

Domestic health and social care funding remains a Member State competency. The MDR does not harmonize national pricing and reimbursement of medical devices in the EU, and it does not stipulate any criteria on which EU public payors must base their pricing and reimbursement decisions for these products. In the realm of pricing and reimbursement, EU Directive 89/105/EEC outlines a general framework to increase the transparency of national pharmaceutical products pricing and reimbursement. Although Directive 89/105/EEC does not strictly apply to medical devices such as DME, in practice the general framework and key requirements contained within this may apply at the national level.

This includes three key requirements with respect to national pricing and reimbursement decisions:

(1) Decisions must be made within a specific time frame (90 to 180 days)
(2) Decisions must be communicated to the applicant and contain a statement of reasons based on objective and verifiable criteria
(3) Decisions must be open to judicial appeal at national level

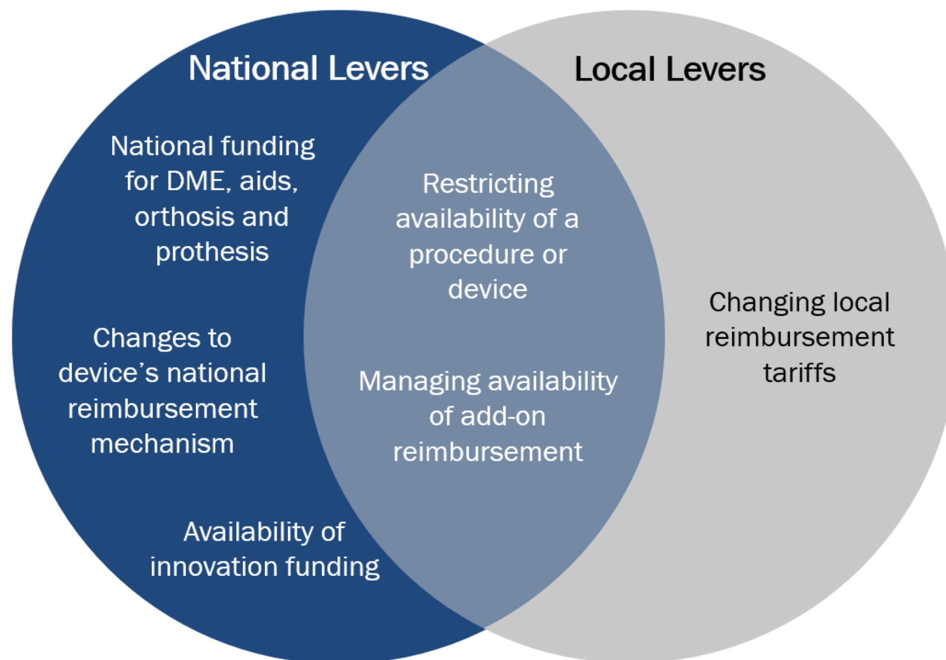
National level pricing and reimbursement are important determinants of DME uptake in a market

EU Member States are responsible for establishing and organizing their national healthcare systems or systems of statutory health insurance. This includes the introduction and management of healthcare policies to promote the financial stability of public-pay health systems.

EU countries, and in some cases, regions within them, can define the criteria on which they base their pricing and reimbursement decisions. DME including aids such as orthoses and protheses

are no exception to this. In fact, these products are usually subject to some form of cost-sharing mechanism whereby patients are required to contribute via a co-pay. These dynamics can strongly impact the uptake of DME products, so investors considering investments in this area should carefully assess the likelihood of their target companies' products ability to obtain and maintain reimbursement in key markets.

To promote access to DME, aids, orthoses and protheses, while containing costs, there are several levers available to public health system payors



Source: Marwood Analysis

Even once a medical device, procedure or reimbursement code is available within a country, the willingness to pay for DME may vary across EU geographies.

This can be based on:

- Policy direction from national commissioners (e.g., NHS England)
- Changes within health benefit catalogs (e.g., as in Spain and Italy)
- Changes to national clinical guidance (e.g., NICE in the UK, Haute Autorité de Santé in France)
- National health technology assessments in connection with reimbursement decisions (e.g., NICE for Technology Appraisal in the UK, Haute Autorité de Santé in France)
- Specific funding frameworks (e.g., "New method" in Norway)

There has been significant expansion of DME public-pay coverage in Spain since 2015

The SNS provides three distinct benefit packages across Spain. National legislation from 2015 regulates the authorization and inclusion of medical devices and aids as part of the basic package of benefits, as well as the methodology for their evaluation. The introduction of Order SSI/1356/2015 represented a significant expansion of the coverage of DME products across the

country. This standardized the availability of specific DME at the time, and harmonized patient co-pays across all Autonomous Communities.

The decision to include a medical device or aid into the three main benefit packages is made by the Interterritorial Council (composed of Autonomous Community representatives and the Ministry of Health). Autonomous Communities, which hold the budget for health care delivery, can complement the SNS packages within their jurisdiction with additional products.

Three Types of Benefits Packages Within the Spanish SNS	
Basic package	Includes “essential” activities, such as medical visits and hospitalizations for all those insured and their dependents
Supplementary package	Includes pharmaceutical products and medical devices which are subject to co-pays by patients (in practice, co-pays predominantly affect outpatient pharmaceutical prescriptions as well as specific orthosis and orthopedic prosthesis)
Accessory package	Includes vaguely defined “non-essential” activities, services, and products

Notable inclusions of DME as part of the Spanish SNS’s basic package were made in 2022, particularly in external protheses, wheelchairs, orthosis and special orthoprostheses

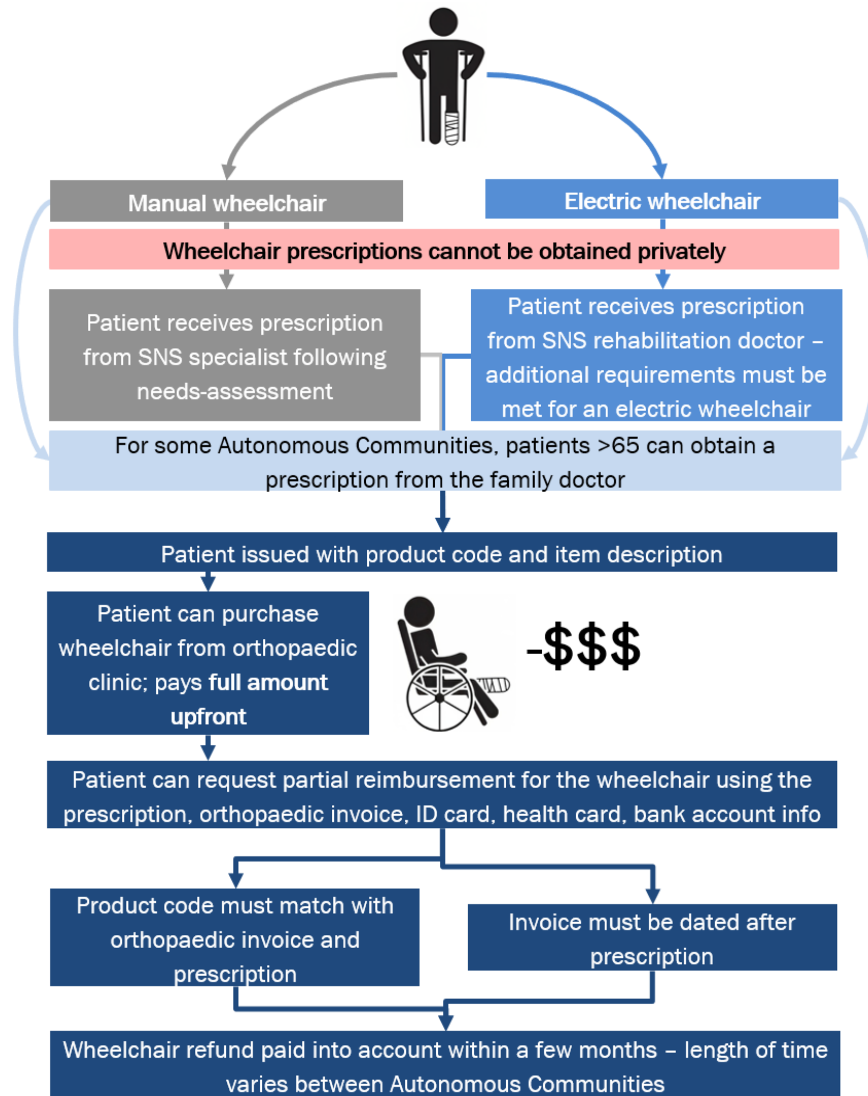
The list of DMEs which are reimbursed by the SNS are set by national legislation and outlined in a national catalog of orthopedic and prosthetic benefits. The relevant national legislation has been amended three times in the last 17 years. The last of these in 2022 was the most significant, with new inclusions for external upper and lower limb prostheses, agenesis prostheses, wheelchairs, orthoses, and products for the lymphoedema therapy. As “external orthoprostheses", select wheelchair models are reimbursed alongside some accessories, components, and spare parts.

The SNS Reimbursement of wheelchairs is between 90 and 100% of the cost

Orthopedic and prosthetic products covered by the SNS require a patient co-pay. The co-pay is dependent on the level of income of the individual; and can range from 10% to 60%. For wheelchairs there is a reduced co-pay of 10% of the cost and vulnerable groups for whom the co-pay is zero.

Spain’s government is progressing a draft bill which includes a proposal to remove co-pays for more categories of DME

The draft bill on Equity being progressed in the Spanish parliament includes a proposal to remove co-pays for a greater range of prostheses and wheelchairs for vulnerable groups. If passed, the bill may significantly increase the volume of DME accessed via the SNS, as co-pays may act as a barrier for patients. It is expected that Autonomous Communities will need to allocate funding to cover this additional volume, and that some cash-strapped regions will look to modify the eligibility criteria in order to contain costs. However, this will need to be in keeping with the national legislation.



Source: SNS; Marwood Analysis

Conclusion

Marwood can assist investors to understand the nuances and outlooks for reimbursement and coverage dynamics across the unique payor categories in the U.S. system (e.g., “Traditional” Fee-for-service Medicare, Employer-sponsored Commercial Health Insurance, Medicaid, and self/private pay). Complementing our knowledge in reimbursement and coverage trends with consumer demand/utilization and provider referral patterns, as well as competitive landscape, Marwood also offers the capability to calculate and size DME markets holistically, as well as its submarkets (i.e., wheelchairs).

While DME manufactures may look to the CE Mark as a key milestone in accessing the EU market, DME products may not necessarily gain positive reimbursement and pricing decisions from EU Member States. Marwood can help investors to understand which DME products get reimbursed in different Member States and how these decisions are made. Marwood has extensive experience in navigating the varied terrain that is the funding and reimbursement landscape within EU health systems to inform robust profit forecasts. Marwood can also assist investors in understanding which products from a target's portfolio are getting reimbursed (e.g., which model of manual vs electric wheelchairs) and at what level, to ensure sales projections are robust.

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