REIMBURSEMENT: US, EU AND UK

Before reading this Fact Sheet you should first read the "Medical Device Reimbursement" Fact Sheet.

After reading this fact sheet you should:

- Have an introduction to the US reimbursement system for medical devices, and links to related resources.
- Know where to look for further information on reimbursement for select EU countries and the UK.

How is the US healthcare reimbursement system structured?

The has a decentralised system that features a large number of payer decision-makers:

- 1500+ commercial health insurance plans.
- 12 Medicare local contractors and one Medicare central office for elderly and disabled.
- 50+ Medicaid agencies for the poor/indigent.
- Managed Care: Integrated Delivery Networks (Kaiser), Accountable Care Orgs (ACOs).
- Military: Veterans Affairs, Tricare.

Reimbursement depends on the setting of care and benefit category, and each care setting has its own system for payment. Care settings are hospital inpatient, hospital outpatient, physicians services, and retail pharmacy.

What is Medicare and Medicaid?

Medicare: Medicare is the largest payer in the US. While it originally covered only those aged 65 or older, independent of income and medical history, it has now expanded to include citizens with permanent disabilities and end-stage renal disease in those aged under 65.

Medicaid: Medicaid is a health coverage program that provides care to people that cannot afford their own medical expenses. It is available to low-income individuals or families that fulfil certain criteria. Amongst the health services Medicaid covers are hospital stays/visits, doctor or emergency room visits, prescription drugs, and others.

To give context to the importance of Medicare and Medicaid in the US reimbursement landscape, the health insurance coverage breakdown of the US population is: Commercial insurers 55%, Medicaid 20%, Medicare 14%, 'Uninsured' 9% and Military <2%.

Where can I find resources for reimbursement in the EU?

Each EU country has its own pricing and reimbursement strategy, links for certain countries are below:

Germany: All medical treatment provided under the statutory health insurance system must be approved (either implicitly or explicitly) by the **federal joint committee** (Gemeinsamer Bundesausschuss – G-BA). Different systems operate for the inpatient and outpatient sectors.

Details of the 2020 G-DRG system are available on the InEK website at: **www.g-drg.de/G-DRG-System_2020**

France: Devices that are endorsed by the **Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDiMTS)** in terms of their clinical value must also be reviewed by the healthcare products pricing committee (**Comité économique des produits de santé - CEPS**). The CEPS is charged with setting official prices and reimbursement levels. The list of reference prices is known as the Tarif forfaitaire de responsabilité (TFR). The CEPS also sets prices of an additional list of hospital products outside the fee-for-service payment scheme.

There are two methods of reimbursement of medical devices in France:

- Medical devices integrated into homogenous groups (**Groupe Homogène de Séjour, GHS**) in health establishments (DRG); and
- Medical devices included on the Liste des Produits et Prestations Remboursables (**LPPR**).

Spain: The Agencia Española de Medicamentos y Productos Sanitarios (**AEMPS**, or Spanish agency for medicines and health products) operates as an autonomous body under the Ministerio de Sanidad, Servicios Sociales e Igualdad (**MSSSI, or Ministry of Health**). Hospitals use a DRG-system to record activity rather than fund hospital care. Therefore, hospital care is paid for on a budget-based system. In order to gain reimbursement, products must provide value for money, so the use of health technology assessment (HTA) is common.

Italy: There are three main national competent authorities. However, pricing & reimbursement must be negotiated at a regional rather than national level, with three major regional or hospital bodies. The reimbursement rates are defined in three tariffs at national level, in order to ensure a uniform approach is adopted among the regions:

- **Nomenclatore tariffario dell'assistenza specialistica ambulatoriale** – nomenclature tariff of specialist ambulatory care;
- **Nomenclatore tariffario protesi** – nomenclature tariff for prostheses; and
- **Tariffe delle prestazioni di assistenza ospedaliera per acuti** (sistema DRG) – tariff of care in acute hospitals under the diagnosis related group (DRG) system.

Netherlands: Reimbursement policy is developed by the **Ministry of Health, Welfare and Sport**, in conjunction with the National Healthcare Institute (**Zorginstituut Nederland – ZiN**) which is responsible for overseeing the benefits provided for under the basic health insurance package and advising the Health Minister on the reimbursement of new therapies and technologies and changes to the existing reimbursement schedule.

Denmark: There is no specific price setting mechanism in place for medical devices, but prices are influenced by degrees of reimbursement and/or public tenders. **The Danish Medicines Agency (DKMA)** is responsible for reimbursement decisions for both medicines and medical devices. Depending on the medical device, the reimbursement level is either fixed (e.g. at 100%) or variable according to the local authority decision. Denmark has developed a modified regional diagnosis related groups system (DkDRG) which has been used since 2012. This is based on the regional **NordDRG**, which was developed using definitions from ICD-10. The cost of many medical devices used in hospital procedures is included within the DRG tariff. Additionally, there has traditionally been an ambulatory group system (DAGS) for outpatient care. The DkDRG system is updated on an annual basis by the Danish Health Data Agency (**SDS - Sundhedsdatastyrelsen**).

Greece: Medical device pricing is regulated according to the Price Index Observatory, under the auspices of the **Ministry of Health**. For pricing and reimbursement purposes, guidelines have been drawn up for health technology assessment with regard to clinical and economic benefits. These are available online in Greek **HERE**.

What are the resources for reimbursement in the UK?

Pricing of medical devices and equipment in the UK is not directly regulated. To make the NHS more efficient, the UK government has put in place a **Payment by Results (PbR) system**. Under the PbR system, healthcare providers are paid for each patient seen or treated, taking into account the complexity of the patient's healthcare needs. The tariff received by the provider is adjusted to reflect the nationally determined market forces factor (MFF), which is unique to each provider.

NHS England will fast-track the introduction of selected innovative medical devices through the **Innovation and Technology Tariff (ITT)** program.