Medical Device Reimbursement in the EU, current environment and trends

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agenda

- national and regional nature of EU reimbursement
- trends in reimbursement in major EU countries
- an introduction to DRG systems, where they are used, procedure and diagnosis coding, groupers and tariffs
- the reimbursement of new technologies under DRGs and applications for additional payments
- the use of fee for service schedules in the ambulatory sector
- product specific and other reimbursement mechanisms in primary care
- the growing importance of Health Technology Assessment (HTA) and clinical guidelines
no EU-wide reimbursement system

- subsidiarity principle: Member States retain “competencies” in certain areas
- see, for example, the “4th whereas” (MD Directive 93/42/EEC)
  - Whereas the harmonized provisions (for placing a medical device on the market) must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the above mentioned measures provided Community law is complied with……
- in some countries reimbursement devolved to a regional level
current status of EU harmonisation

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<tr>
<th>harmonised</th>
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<td>• device approval</td>
<td>• healthcare financing</td>
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<td>• pharmaceutical marketing</td>
<td>• benefit package</td>
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<td>authorisation</td>
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subsidiarity and convergence

- despite the independence of, and differences between, national healthcare systems, they are converging because of:
  - cost drivers
  - use of evidence
  - information exchange
- see national or regional systems but with “similar" evidence requirements
drivers for budget management
payor focus on VFM (value for money)

- Payors need to reconcile rising demands for healthcare with public financing constraints.
- Conflict between societal and budget drivers - what do we want?
  - The best possible care?
  - "Acceptable" care at the best possible price?
- Payors emphasising VFM strongly e.g. increasing use of HTA.
budget holders’ priorities (in the UK)

most important 10
9
8
7
6
5
4
3
2
1
0

balancing budget
reducing “noise”
mortality
morbidity
patient convenience
system issues in reimbursement

different care settings have different funding systems

- inpatient care
- outpatient care
- homecare
System issues in reimbursement (2)

Inpatient care shows the least variation across the EU5

- Hospitals look the same in every country, and do the same things
- Public hospital physicians are generally salaried employees
- Limited range of funding options: total activity (e.g. global budgets) vs payment per case (e.g. DRGs)
Diagnosis Related Groups (DRGs)

- Hospitals are paid according to activity
- Activities are grouped
- Groups are considered to be iso-resource
- Payment usually includes all costs eg physician time, nursing time, diagnostic tests, drugs, devices, disposables, hotel costs, NB some exceptions
- Payments may vary by patient age, co-morbidity and complications, elective or emergency, location
- DRGs allocated from procedure codes and diagnosis codes.
assignment of G-DRGs

1. Diagnostic codes
   (according to ICD-10-GM)

2. Procedure codes
   (according to OPS)

3. G-DRG
   (Grouper)

Other features
   e.g. age, gender, discharge status
DRG systems key differences

Each country has its own codes and tariffs and its own system and timetable for updates

In France the trend is to include as much as possible in the GHS (DRG tariff). However in the private sector physician fees are excluded. Permanent implants can be listed on the LPPR and reimbursed in addition to the GHS

Germany recognises the inherent brake that DRG systems can apply to new technologies and has a formal system of innovation payments and supplemental payments that form part of a recognised procedure to support new technologies through the DRG system
DRG systems key differences

In the UK DRGs are called HRGs and come under the Payment by Results system. Some high tech devices are excluded from PbR and it is possible to negotiate local pass through payments to support the purchase of new technologies.

Italy has a highly regionalised system with both national tariffs and regional tariffs. With very few exceptions the DRG tariffs cover the full cost of the procedure including all fees and materials and there are no mechanisms to apply for additional funding.

Spain has a DRG system but it is used as a management tool to record activity rather than to fund hospital care. Instead hospital care is paid for on a budget based system. DRG tariffs do exist and are used to pay for cross regional care through the so called cohesion fund.
hospital behaviour under DRGs (1)

- hospitals become familiar with the concept of an essentially fixed income per case: old rules (often income = per diem x LOS) no longer apply

- hospitals also become familiar with potentially variable costs of “production”

- reducing length of stay becomes a focus

- purchasers eventually become more receptive to arguments concerning investing in high(er) cost technology if the net effect of such an investment on average is to reduce total production costs by more than the investment

- they often become correspondingly less receptive to arguments about cost-offsets in other parts of the healthcare sector
hospital behaviour under DRGs (2)

- products which represent a high proportion of the total variable costs of a DRG (e.g. implants, certain biotech drugs) come under intense price pressure, unless there are specific “carve-outs” or supplementary payments

- new technologies must work within old technology cost models

- behaviour change requires hospitals to have good data on their cost base, and understand the cost drivers for particular pathologies
applicability to Smith & Nephew

- in hospitals woundcare and endoscopy generally funded through DRGs and budget based system in Spain
- in some countries eg France and some regions of Italy orthopaedic implants funded separately on top of DRG
- in France GHMs are being revised to include hip, knee and shoulder implants
- some opportunities in Germany to obtain funding on top of DRG tariff through innovation and supplemental payments eg vertebral body implant qualifies for supplemental payment.
- hospital purchasing of wound care products generally through some form of tender or group purchasing system in place to improve efficiency and keep prices down
- DRG environment may be to manufacturer’s advantage with advanced woundcare products if they reduce length of stay or save time eg in number or length of dressing changes although may be difficult to prove.
System issues in reimbursement

Outpatient care much more variable, due to history, organisational issues & physician status

• In outpatient care, a medical device may be:
  • Part of an “episode of care” delivered by a hospital
  • Part of a “service” delivered by an office-based physician
  • Considered as a health benefit *in itself* (although a physician will usually be involved)
the 3 basic concepts outlined give rise to radically different types of reimbursement questions:

- if a device is part of an “episode of care” delivered by a hospital, the hospital funding system typically drives how new technology is viewed
- if a device is part of a “service” delivered by an office-based physician, how (& how much) the physician gets paid for performing the service is key: he/she should not be financially penalised for providing or using the device or it will not get used
- if the device is considered as a health benefit in itself there is usually some form of catalogue or list involved, with an approval or listing process – there are often similarities with drug pricing & reimbursement
Fee for service schedules in place for hospital ambulatory, doctor’s office socially insured and doctor’s office privately insured. In the doctor’s office implants may be paid on top of service fees if procedure is listed in appropriate catalogue. Supplies however generally restricted by quarterly budget. Med Tech Aids for use in the patient’s home are reimbursed if listed in the Hilfsmittelverzeichnis.
Separate GHM (DRG) codes and tariffs for day case procedures. Appropriate procedure coding essential for both public and private hospitals. Implants and wound dressings reimbursed through LPPR. LPPR listing for new products requires demonstration of clinical and economic benefits.
HRGs cover day case procedures and some outpatient procedures. Drug Tariff for reimbursement of medical devices for use by patients in their own homes. Direct funding by PCTs for community based clinics.
Fee for service schedule for out-patient procedures. Update expected later this year. National and regional tariffs. Technology adoption driven by clinicians with strong regional variation in payments. Devices for use in patient’s homes are prescribed by physicians and listed on the Nomenclatore.
Spain

Hospital out-patients managed on departmental budget basis. Products purchased through tenders. Devices for GP prescription listed on CEA. New applications limited by budget constraints.
applicability to Smith & Nephew

- wound care products generally require some sort of listing for primary and home care use. Exception is Germany where traditionally woundcare products have been treated as part of practice supplies.
- in Italy advanced woundcare was to be included in national basket of services, however implementation blocked by incoming government so reimbursement remains on a regional basis.
- in primary care standard wound care products are organised in generic categories.
- advanced woundcare products require individual listings with a high level of clinical data.
- many countries introducing reference prices and price cuts, particularly important in woundcare.
regulation ≠ reimbursement

- regulatory clearance allows you to place your product on the market

- it does not mean that there will automatically be a market
the fourth hurdle

market authorisation [CE mark]

costed business case

fourth hurdle for market access
who is really taking the decisions?

- payor
- budget holder
- prescriber
- patient carer family

Relative strength of decision makers depends on the product and the situation.
changes in decision-making

- shift from clinicians to managers/payors
  - recognise the limits to clinician discretion
  - focus on both the business and the clinical case
- shift towards patients
- increase in complexity
  - need to develop consensus among multiple stakeholders
trends in the use of evidence

- HTA
- using sound methodology
- measuring effectiveness
- measuring cost
- using outcome measures
- avoiding proxy measures, where possible
what is HTA?

HTA considers the effectiveness, appropriateness and cost of technologies:

- does the technology work?
- for whom?
- at what cost?
- how does it compare with alternatives?
the scope of HTA

- any method used by those working in health services to promote health, prevent and treat disease and improve rehabilitation and long-term care
- not confined to new drugs or pieces of sophisticated equipment – also includes costs and effects of e.g. screening programmes and education
- tends to focus on treatment packages rather than individual elements of these packages in isolation
comparators: not just other devices

but also…

- doing nothing
- pharmaceuticals
- other treatment approaches (surgery, counselling, acupuncture…)

33
HTA and regulatory submissions

- HTAs are much wider in scope than regulatory submissions

- HTA includes evidence of:
  - cost effectiveness
  - patient outcomes
  - impact on health care delivery
  - comparisons with current alternatives
# Levels of Evidence

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<thead>
<tr>
<th>Level of Evidence</th>
<th>Evidence Based On</th>
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<tbody>
<tr>
<td>Ia</td>
<td>Systematic reviews of studies according to level of evidence Ib</td>
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<tr>
<td>Ib</td>
<td>Randomized controlled trials</td>
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<tr>
<td>IIa</td>
<td>Systematic reviews of studies according to level of evidence IIb</td>
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<tr>
<td>IIb</td>
<td>Prospective comparative cohort studies</td>
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<tr>
<td>III</td>
<td>Retrospective comparative studies</td>
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<tr>
<td>IV</td>
<td>Case series and other non-comparative studies</td>
</tr>
<tr>
<td>V</td>
<td>Expert opinions not based on studies, reports of expert committees and consensus conferences; associated observations, pathophysiological considerations, descriptive presentations, isolated case reports, etc.</td>
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in the new world…

- clinical efficacy is no longer enough
- data accepted for registration purposes scrutinised differently and often considered useless by HTA agencies
- calculation/modelling of costs and benefits, and budget impact, is essential
- benefits are defined in terms of social goals as well as individual patient outcomes
evidence is increasingly important

- trial conditions
- clinical efficacy
- clinical effectiveness
- cost effectiveness
- achieving maximum clinical and cost effectiveness

- typical conditions
- costs vs. effectiveness overall vs. patient sub-groups

- introducing/managing the new service and choosing the right target group(s)
price and value

- the manufacturer has considerable discretion on launch price for most products
- how much price > cost is a matter of (commercial) judgement
- actual value depends to some extent on the target population proposed
- perceived value depends to some extent on the comparators payors are persuaded to accept
- modifying the price/value relationship may be important for securing reimbursement
List of common diseases and complaints

Treatment choice

Clinical guidelines

Training and Supervision

List of essential medicines

National formulary

Financing and Supply of medicines

Patient care and Information
Abbreviations

CEA: Catálogo de Efectos y Accesorios
DRGs: Diagnosis Related Groups
EU: European Union
GHM: Groupe Homogène de Malades (DRGs in France)
HRG: Healthcare Resource Group
HTA: Health Technology Assessment
LPPR: Liste des Produits et Prestations Remboursables
VFM: Value for Money
Questions and Comments

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