PRICING AND REIMBURSEMENT STRATEGIES FOR DIAGNOSTICS:

Overcoming reimbursement issues and navigating the regulatory environment

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- The U.S. healthcare system is comprised of both private and public sectors but is dominated by the former. The US reimbursement system is comprised of both private and public sectors. The public sector consists of various federal government agencies such as Medicare, Medicaid, State Children's Health Insurance Plan (S-CHIP), Veteran Affairs, etc.

- The Center for Devices and Radiological Health (CDRH) is the governing medical device regulatory body in the US and is directly responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the US.

- The public and private sector have five basic operations, benefit eligibility, billing process, coding systems, pricing process and guidelines for coverage decision making.

- The regulatory structure for medical devices in Europe differs from country to country. Within Germany, it is administered by Der Gemeinsame Bundesausschuss (G-BA), in France by the Haute Autorite de Sante (HAS), In UK it is National Health Service (NHS), in Italy by the Servizio Sanitario Nazioanale (SSN) and in Spain by the Instituto Nacional de la Salud. Consequently the reimbursement structure for European nations for healthcare procedures also differ from country to country due to differences in healthcare budgets, differences in healthcare policies, etc.

- However, all the countries in the EU follow the EU's directive for medical device regulations. Within this directive, the medical device needs to have the Conformité Européenne (CE) mark to be sold within the respective member countries.

Key findings

- The reimbursement structure in the US and European countries are affected by high healthcare costs, increasing patient queues for treatment, deficit financing within the US for its burgeoning healthcare expenditure, etc. this has led to US and European governments to come up with legislations restricting the reimbursement amounts with respect to expensive healthcare diagnostic procedures.

- From the payor's perspective, only the most essential healthcare service at the lowest cost should be reimbursed. This perspective often leads to an arrest in innovation in medical technology from an OEM perspective.

- From a healthcare service provider perspective, only the most reimbursed diagnostic procedure is attractive as a service to provide. This perspective often leads to an arrest in distribution (service offerings) of innovative diagnostic technologies.

- The pricing for medical devices by OEMs is a long and complicated exercise. It is affected by various factors such as the type of device, financial requirements, procedure reimbursements, market dynamics and customer prices.

- However, in case of the unavailability of reimbursement for some diagnostics, it becomes difficult for the OEMs to price their equipments and also have to face challenges such as low adoption rate for their equipments. The OEMs still continue to launch the products with updated technology to sustain their market share, thereby making trade-off on the price in case of absence of reimbursement.

- The recent reduction made by the CMS in the reimbursement amount for non-facility units is expected to impact the diagnostic devices market especially in the form of a lack of innovation.

- Most often, in the initial stage of Product Life Cycle, the companies generally prefer competitive pricing or follow the market trends. However, enhancement of brand

image leads to increased product sales allowing the company to charge premium for its products (most often with value addition).

Analyzing best-fit strategies for novel pricing and reimbursement

- There are various strategies adopted by OEMs in the US and Europe while pricing their diagnostic products after considering the reimbursement regulations within these countries. Examples of these strategies include value based pricing, return on investment (ROI) based pricing among others.
- There are different strategies employed by the OEMs when gaining reimbursement for their diagnostic products depending on various factors such as the type of product (new or existing technology).
- For a product using existing technology but with extra add on features, the most commonly used pricing strategy is value based pricing, while for a product using entirely new technology the most commonly used strategy is a premium pricing strategy.
- Considering how important the role of reimbursements is for the new product to be successful in the US and European markets, the OEMs apart from focusing on product pricing also focus on engaging with payors from as early as product development.
- For this payor focus, the OEMs also float separate Strategic Business Units (SBUs) such as pricing and reimbursement SBU within their company.
- Apart from the standard product pricing methods, and OEMs have come up with newer models of product pricing such as Fair value pricing, Risk based pricing, etc.

Strategic recommendations

- OEMs employ various methods of pricing after taking country wise reimbursement structures into considerations. The demand price premium strategy (Value Pricing), one of the most commonly employed strategies used by OEMs world wide while launching a new product have recently seen variations such as Fee for Service.

- Within this variation, the offered services by healthcare service providers are not in a form of a package i.e. unbundled and hence are paid for individually by the patient.

- As competition is extremely high and new products get replicated very quickly, the OEM needs to reduce the time to market for any new product to generate substantial return on investment.

- To achieve this OEMs need to make sure that the FDA reimbursement approval procedure and payor engagement from the product development stage as well as the product pricing strategy are working in harmony.

CHAPTER 1

Introduction

Chapter 1 Introduction

Summary

Key take aways

- Identify critical issues related to the pricing and reimbursement of diagnostics.
- Identify the impact of the evolution of diagnostic technologies on the current pricing and reimbursement scenario and implications for stakeholders in the current and future scenarios.
- Strategically analyze the current pricing methods and loopholes and suggest novel pricing strategies for new technologies and existing technologies.
- Gain an understanding of the key regulatory and reimbursement pathways for diagnostics.
- Global outlook for the in vitro and in vivo diagnostics market.
- Strategic recommendations and conclusions for the reimbursement and pricing issues in diagnostics.

Report description

Reimbursement of diagnostics is a key issue for both diagnostic providers and payors because while only 5-7% of the hospital cost is incurred by diagnostics, they are used for around 70% of healthcare decisions. Developing an optimum price especially with respect

to emerging diagnostic technologies such as molecular diagnostics has been very challenging as evidence-based pricing does not suffice for such technologies. This complicates the scenario for early movers in diagnostics. However, there has been an on-going issue even with respect to existing technologies, as diagnostic companies have an immense need to re-consider their pricing strategies to deal with cost and demand versus reimbursement issues. Hence, it is crucial to identify novel pricing strategies to maintain a optimum pricing and market access.

Stakeholders

- Diagnostic service providers
- Diagnostic companies
- Social and private payors
- Outsourcing service providers

CHAPTER 2

Market overview

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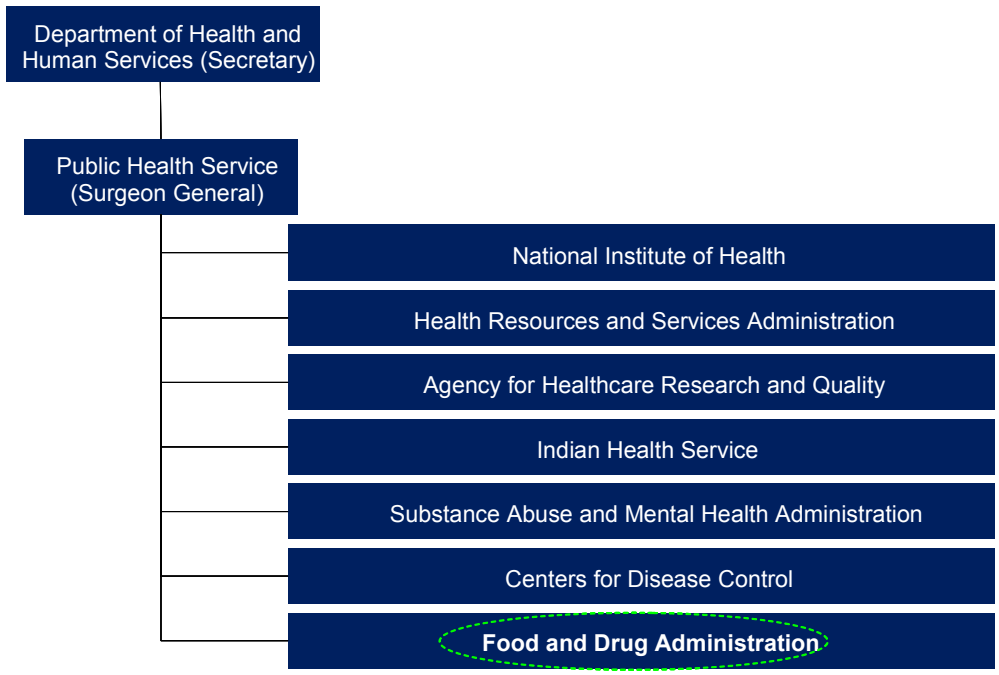
Summary

- The US healthcare system is comprised of both private and public sectors but is dominated by the former. The Center for Devices and Radiological Health (CDRH) is the governing medical device regulatory body in US and is directly responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the US.
- The US reimbursement system is comprised of both private and public sectors. The public sector consists of various federal government agencies such as Medicare, Medicaid, State Children's Health Insurance Plan (S-CHIP), Veteran Affairs, etc.
- The public reimbursement sector is financed by the federal government through public taxes, while the private reimbursement sector is financed by risk premiums paid by patients.
- The public and private sector have five basic operations, benefit eligibility, billing process, coding systems, pricing process and guidelines for coverage decision making.
- The regulatory structure for medical devices in Europe differs from country to country. Within Germany, it is Der Gemeinsame Bundesausschuss (G-BA), in France it is Haute Autorite de Sante (HAS), In the UK it is National Health Service (NHS), in Italy it is Servizio Sanitario Nazioanale (SSN) and in Spain it is Instituto Nacional de la Salud.
- The reimbursement structure for European nations for healthcare procedures also differ from country to country due to difference in healthcare budgets, difference in healthcare policies, etc.

US regulations for medical devices & diagnostics

Figure 2.1: US healthcare regulatory organizational chart



Source: Author's analysis

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United States Department of Health and Human Services (HHS)

The United States Department of Health and Human Services (HHS) is a department of the US government with the goal of protecting the health of the American population and actively providing necessary human services.

United States Public Health Services (PHS)

United States Public Health Services (PHS) is a primary division of the HHS. It comprises all agency divisions of Commissioned Corps. and Health & Human Services. This agency is responsible for public health in the US and administers a number of other health agencies such as the Food and Drug Administration (FDA), National Institutes of Health (NIH) and Centers for Disease Control (CDC).

National Institutes of Health (NIH)

The National Institutes of Health (NIH) is an agency of the HHS responsible for health and biomedical related research. This agency operates through its 27 different centers such as the National Cancer Institute (NCI) and the National Institute of Dental and Craniofacial Research including the office of the Director. The NIH aims to acquire new knowledge in order to prevent, diagnose, and treat disability and diseases.

Agency for Healthcare Research and Quality

This agency is an important part of the HHS and has a support function for research design aimed at the improvement of healthcare quality, cost reduction, reduction in medical errors and issues of patient safety.

Indian Health Services

IHS acts as an Operating division under the HHS and is the principle provider of federal healthcare to and advocate for the health of American Indians and Alaska Natives.

Substance Abuse and Mental Health Administration

SAMHSA is an agency under HHS established to target effectively the services related to substance abuse and mental health services and research translation in the same field in the general healthcare system. The agency carries various programs through the different centers such as Center for Mental Health Services (CMHS), Center of Substance Abuse prevention (CSAP), Center of Substance Abuse Treatment (CSAT) and the office of Applied Studies (OAS).

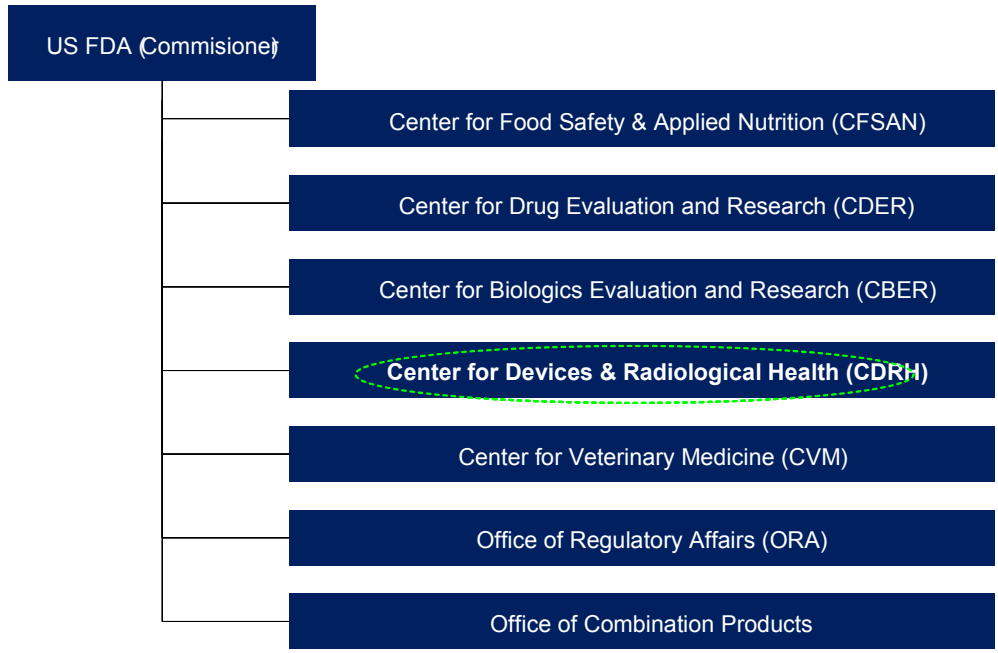
Centre for Disease Control and Prevention

The Center for Disease Control and Prevention (CDC) is a federal agency operating under the HHS for the protection of public health and safety through information thereby assisting in making health decisions. It is also involved in health promotion through the partnerships with various organizations and departments such as state health departments.

Food and Drug Administration

The Food and Drug Administration (FDA) is an agency of the HHS. The FDA is responsible for the protection and promotion of public health through the means of regulation and supervision of tobacco products, dietary supplements, food safety, over the counter pharmaceutical drugs, bio-pharmaceuticals, medical devices, blood transfusions, electromagnetic radiation emitting devices (ERED), vaccines, prescriptions, cosmetics and veterinary products. For these various tasks mentioned above the FDA has different centers responsible for them respectively as shown in Figure 2.2.

Figure 2.2: US FDA organizational chart



Source: Author's analysis

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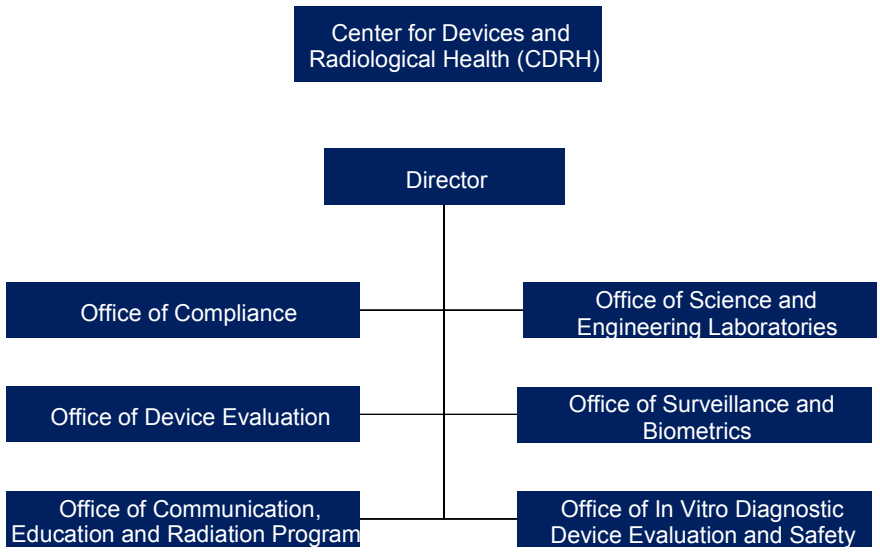
The Center for Devices and Radiological Health (CDRH) is directly responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices sold in the US and ensuring their efficacy and safety.

Figure 2.3: CDRH Organization Chart



Source: Author's analysis

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The CDRH is responsible for ensuring that medical device manufacturers follow various regulatory procedures laid down by the federal regulatory authorities within the Food, Drug and Cosmetic Act (FD&C Act). It has classified medical devices into 16 medical specialties. They are Chemistry/Toxicology, Hematology/Pathology, Immunology/Microbiology, Anesthesiology, Cardiovascular, Dental, Ear Nose and Throat, Gastroentelogy/Urology, General Plastic Surgery, General Hospital, Neurological, Obstetrical/Gynecology, Ophthalmic, Orthopedic, Physical Medicine, Radiology.

After classifying the devices as per specialties, to determine the extent of regulatory control, medical devices are further classified; Class I (Low Risk), Class II (Medium Risk), Class III (High Risk). The basic regulatory requirements that manufacturers of medical devices distributed in the US must comply with are:

- **Establishment Registration**: Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA. All establishment registrations must be submitted electronically unless a waiver has been granted by the FDA. All registration information must be verified annually between October 1st and December 31st of each year. In addition to registration, foreign manufacturers must also designate a US Agent. Beginning October 1, 2007, most establishments are required to pay an establishment registration fee.

- **Medical Device Listing**: Manufacturers must list their devices with the FDA. Establishments required to list their devices include manufacturers, contract manufacturers and contract sterilizers that commercially distribute devices, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, manufacturers of accessories and components sold directly to the end users and US manufacturers of "export only" devices.

- **Premarket Notification – 510 (k):** The objective of the 510(k) document is to demonstrate that the new device/equipment entering the US market is either equivalent to one in commercial distribution within the US: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be equivalent.

- **Premarket Approval (PMA):** Products requiring PMAs are Class III devices, which are high risk and pose a significant risk of illness or injury. These devices are also those, which are found not equivalent to Class I and II devices, for which the 510(k) process is not required. The PMA process is more involved than the 510(k) process and includes submission of clinical data to support claims made for the device.

- **Investigational Device Exemption (IDE):** An investigational device exemption (IDE) allows investigational devices to be used in a clinical study in order to collect the safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to the FDA. Clinical studies with devices of significant risk must be approved by the FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of non-significant risk must be approved by IRB only before the study can begin.

- **Quality System Regulation (QS)/Good Manufacturing Practices (GMP):** Quality system regulation includes requirements related to the methods used in facilities and controls used for: designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. Manufacturing facilities undergo FDA inspections to assure compliance with QS requirements.

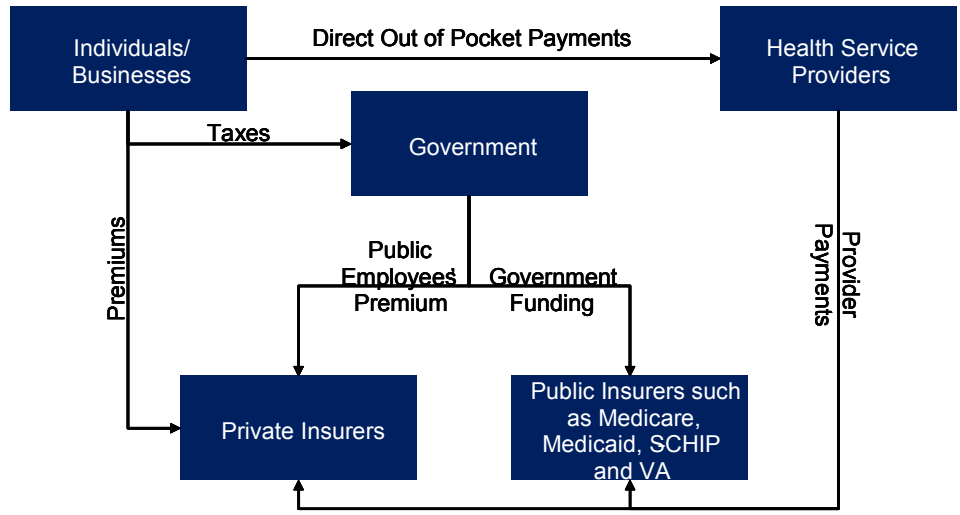
- **Labeling:** Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device.

- **Medical Device Reporting (MDR):** Incidents in which a device may have caused or contributed to a death or serious injury must be reported to the FDA under the MDR program. The MDR regulation is a mechanism for the FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner.

US reimbursement structure

The reimbursement structure in the US and most European countries is governed by healthcare authorities such as the Centre for Medicare and Medicaid Services (CMS) and the National Healthcare Service (NHS) respectively. These health insurance authorities lay down guidelines for reimbursement approval and payment procedures. Reimbursement providers in these countries are commonly a mix of both public and private payors. In the following sections detailed reimbursement structures in the US and European countries are discussed with respect to the present reimbursement scenario.

Figure 2.4: US healthcare reimbursement and financing structure



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Financing revolves around two streams of money: collection of money for healthcare (money going in), and reimbursement of healthcare service providers for healthcare (money going out). Private insurance companies as well as the government, share these

functions. They are known as “payors.” As such, the US can be thought of as a having a “multi-payor” system.

US reimbursement payors

Public health insurance

Medicare

- **Overview:** A federal program which covers senior citizens (aged ≥ 65, & disabled individuals).
- **Administration:** A single-payor program directly controlled by the federal government.
- **Financing:** It is financed by income taxes. Contributors include employers and employees, and individual enrollee premiums.
- **Benefits:** It is divided into four groups. Medicare Part A covers hospital services, Medicare Part B covers physician services, and Medicare Part D offers a prescribed procedure benefit. Medicare Part C refers to Medicare Advantage (Not under the purview of the study)
- **Need gaps:** There are many gaps in Medicare coverage, including incomplete coverage for skilled nursing facilities and preventive care, while no coverage is offered for dental, hearing, or vision care.

Medicaid

- **Overview:** A program designed for the low-income and disabled. It covers very poor pregnant women, children, elderly, disabled, and parents. It does not include childless adults. Apart from the federal screening criteria, individual states have the option of

expanding eligibility if they so choose. For example, states have an option to increase eligibility levels of income.

- **Administration:** Individual states and the District of Columbia are responsible for administering the Medicaid program; thus, there are effectively 51 different Medicaid programs in the country.

- **Financing:** Medicaid is financed jointly by the states and the federal government through taxes. It is comparable to the provident fund schemes employed within an organization. In this case, the employer is the government, and the employee is Medicaid. Overall, federal government pays for 57% of the Medicaid costs.

Other public systems

- **S-CHIP:** The State Children's Health Insurance Program (S-CHIP) was designed to cover children from those families which do not qualify for Medicaid but yet are unable to purchase private health insurance. S-CHIP and Medicaid share similar administrative and financing structures.

- **VA:** The Veteran's Administration is a government administered program for military veterans. Healthcare is delivered in public VA hospitals and clinics. The VA is funded by taxes.

Private health insurance

Employer-sponsored insurance

Overview: Private health insurance provided by employers to their employees is the main way that US citizens cover their healthcare costs.

Administration

Private companies administer insurance plans, both for-profit (e.g. Aetna, Cigna) and not-for-profit (e.g. Blue Cross/Blue Shield). Some big companies such as GE are also self insured, i.e. they pay for all healthcare costs incurred by the employees directly. In this case, the company forms an agreement with a third party to administer the insurance plan.

Financing

Financed both by employers and employees. In 2005, annual insurance premiums that were covered by private employers averaged approximately $4,024 for a single person and approximately $10,880 for a family of four.

Private non-group (individual market)

Overview

This covers people who are self-employed, retired or unable to obtain insurance through their employers. In contrast to the group market, the individual market allows health insurance companies to deny people coverage based on pre-existing conditions. It is similar to the private health insurance structure existing in developing countries such as India.

Administration

The plans are administered by private insurance companies.

Financing

The insurance premium for coverage is paid by individuals through out-of-pocket contributions. Risk in the individual market depends only on the health status of the individual, in contrast to the group market, where risk is spread out among multiple

individuals. As such, low-risk, healthy patients have a low premium, whereas the opposite is true for high-risk, chronically ill patients.

US reimbursement procedures

There are five processes that both public and private insurers follow before granting reimbursement:

Benefit eligibility

Whenever an individual is enrolled in a health plan (either a private plan or Medicare), he is entitled to reimbursements for a set of healthcare services as per the plan. Such patient reimbursements are possible because the set of healthcare services agreed as per the health plan fall within the "benefit category" of the plan. The health plans under discussion also have "exclusions," which mean services that are not covered by the health plan. For example Medicare may exclude certain screening tests; a private plan might exclude chiropractic benefits, etc.

Medicare perspective: Medicare covers a broad range of healthcare services, but they should mandatorily fall into a specific "statutory" category. These categories include physician services, hospital inpatient services, hospital outpatient services, ambulance services, diagnostic tests, and other categories.

Diagnostic tests covered by Medicare need to contribute to the diagnosis or disease management for the patient except for a short list of "screening tests." Some screening tests from this short list are reimbursed for the entire Medicare population (i.e. everyone covered under Medicare are eligible for reimbursements if they undergo these screening tests). While some screening tests cover only that part of Medicare population which is

classified as “at risk”. For example a periodic stool-guaiac test to screen for colon cancer is covered for all beneficiaries. But periodic glucose tests are covered only for patients pre-defined as “at risk” for appearance of diabetes.

Private payor perspective: Usually, the private players within reimbursement can be classified into two categories: Health Insurers and Administrative Service Only (ASO) organizations. While the former category of private payors is subject to benefit mandates as per states they are active in, the latter is not.

Health insurers: The private payors offer health insurance in exchange for premiums. Here the risk is borne by private payors. These payors are regulated by insurance mandates as per state legislations they are active in. The state may legislate certain screening tests to be covered mandatorily for these payors and they have to abide by them. Apart from these mandatory requirements, private payors can offer various health plans with options for patient benefits at their own discretion.

ASO Organizations: Some private payors manage benefits such as claims processing and other administrative services for a large employer (can be public or private). These plans fall under a separate regulation The Employee Retirement Income Security Act of 1974 (ERISA) and are free from state insurance mandates.

As discussed earlier, private payors differentiate reimbursements based on benefit categories such as screening, preventive, and diagnostic services. Due to variable state-to-state requirements, the insurance have variable diagnostic test benefits requirements. For e.g. All states require private insurance plans to cover mammography while very few require coverage of PSA and colorectal cancer screening due to comparatively lower incidence rates.

Billing process

The billing process is the path from the medical care event to payment for that service. Within this pathway, there are various processes involved such as coding, provider enrollment, determining who will bill for the service, etc. Since coding is a very complicated process in itself, it is discussed separately.

Medicare perspective: Medicare regulations for various billing laboratory tests are very complex, and have evolved into newer categories and exceptions over time. The regulations are categorized as per multiple locations of specimen collection, test-performing entity (hospital lab, independent lab), type of test performed ("pathology" versus "chemistry" tests), whether the specimen entered an archive, the date the test was ordered, and the time between specimen collection and test order. These billing rules for a specimen defy condensed description.

Private payor perspective: Generally, the healthcare service providers (private payor, hospital, or independent laboratory) bill the insurers for various healthcare services to the patients. It may also be the case that as per the healthcare plan of the insurers, the patients may receive reimbursements only if they take services from a select network of healthcare service providers.

Coding systems

As per the Health Insurance Portability and Accountability Act (HIPAA), it is mandatory to establish standard code sets for the transmission of healthcare services data between providers and payors. In 2000 the regulations were finalized and the American Medical Association's (AMA) CPT-4 was accepted as the standard code set for physician services and laboratory tests, while the AMA's ICD-9-CM as the standard code set for diseases.

CPT-4 describes numerous physician services and approximately 9000 laboratory tests by using a five-digit code for each service (e.g. 12345). Factors such as widespread use of the test, acceptance of the test as medically necessary by a multispecialty review panel, and a timeline of roughly 18 months between proposal of the test (e.g. by the manufacturer) and activation of a new code are required for issuance of a new CPT code.

ICD-9-CM: The ICD-9-CM codes are assigned for patient conditions such as appendicitis or acute leukemia, and symptoms such as abdominal pain or cough. The basic format for ICD-9 codes is five digits, of which two are decimals (e.g. 555.12). Usually, the healthcare providers submit a procedure code and one or more related diagnosis codes on their insurance claims.

Medicare perspective: It is mandatory for Medicare contractors to follow all rules in the AMA CPT manual as well as the additional rules released by Medicare. As per the CPT manual the codes used must "precisely, not approximately, match the service rendered". When it is not possible to find the precise code, a not-otherwise-classified code should be used.

Private payor perspective: As the HIPAA and federal regulations apply to all provider:payor transactions for "healthcare services", the CPT-4 and ICD-9-CM code sets are used by private insurers as well.

Pricing processes

Pricing sets the payment transferred between payor and healthcare providers. Usually it is a flat per-item reimbursement. Recently, there are newer reimbursement models such as risk-sharing arrangements between the provider and the payor

Medicare perspective: Medicare prices most laboratory tests based on a clinical laboratory fee schedule set in 1983. It occasionally revises upward or downward as based on legislations. Every time a new AMA CPT code is issued, the Medicare-specific pricing process is triggered.

There are two methods which Medicare employs for setting prices for newly issued AMA CPT codes for healthcare services: cross walk or gap fill. A cross walk is set primarily using the price of a similar/existing laboratory service, while a Gap fill is set primarily interpolating the price (e.g. 10% above Code X, 20% less than Code Y).

Private payor perspective: Although private payors are not required to follow the Medical Clinical Laboratory Schedule, most of the private payors still do so. Some payors have come up with innovative risk-sharing coverage and payment for complex molecular tests. For example United Healthcare and Genomic Health for reimbursement of the Oncotype DX test. Here the price of reimbursement to healthcare providers is tied to the drug's observed effects in individual patients.

Guidelines for coverage decision-making

Both public and private payors wish to pay for only medically necessary services. But defining whether a given procedure or service is "medically necessary" is entirely qualitative and the distinction between "investigational" and "medically necessary" care is extremely difficult to define. Hence there is a requirement for a standard set of guidelines for coverage decision making.

Medicare perspective: Medicare coverage decisions are published in National Coverage Decisions (NCDs), and Local Coverage Decisions (LCDs), For NCDs, the guidelines are conclusions of a national coverage analysis (NCA). This analysis contains an extensive

discussion of the published literature on the technology or service under discussion. For LCDs, Medicare has published a general guidance for coming to decisions.

Private payors perspective: Private payors publish their coverage decisions on their websites as per their discretion. Payors such as Aetna and Cigna maintain large websites with regularly updated coverage policies. Aetna lists approximately 500 medical policies.

US diagnostic imaging reimbursement structure

Medicare perspective

Medicare reimbursement for diagnostic imaging procedures is comprised of a professional component (amount paid for physician's interpretation and report), and a technical component (amount paid for all other services including staffing and equipment costs). When combined and paid to the same individual or entity, this amount is referred to as the global or total amount. The method of reimbursement for diagnostic imaging procedures in Medicare is based on the site of care. In a hospital outpatient department, the technical component of a procedure is reimbursed under an Ambulatory Payment Classification (APC) under Medicare's hospital Outpatient Prospective Payment System (OPPS), while the professional component of the procedure is reimbursed under the physician fee regardless of the site.

European healthcare reimbursement structure

The EU's reimbursement environment is not uniform as each member state has its own policies with reimbursement being approved by either private or public insurance companies or a mixture of the two. Approval for reimbursement from the public health providers often requires lengthy negotiations. The pricing of the product also differentiates due to various factors such as supply-demand gyrations, differences in various government tax rates (for e.g. VAT, customs), etc. For example France has reduced VAT on medical devices whereas countries including Germany maintain the maximum rate of VAT.

European healthcare regulatory structure

All diagnostic products in the EU must carry the CE mark before reimbursement can be granted for tests performed by them. However, this is not the only pre-requisite for a device to be sold in the EU with many member states also adopting complex reimbursement policies wherein along with the CE mark the device should be listed in the approved reimbursement list. These lists are making the reimbursement issue more complicated as they vary country by country, between public and private insurers, between hospitals and outpatient clinics.

The reimbursement agencies have compiled a list of medical procedures along with the value of reimbursement of the same. The reimbursement procedures in several member states are based on DRGs. In this system similar medical procedures are grouped. Coding of each group is done and a value is assigned, which sets the amount of money that will be reimbursed for that diagnosis. DRGs are determined over a long period of time while collecting data from the hospitals and the treatments. Then, an average cost is identified. Due to this method procedures costing less are more likely to be reimbursed for their full cost than expensive procedures.

The reimbursement allocation issue is a cause of concern for OEMs, which is, should a hospital manage to undertake more than half the procedures at a cost less than the reimbursement value, they will only then make a profit.

In addition to DRGs, government bodies conduct Health technology assessments (HTAs). HTAs assess the cost effectiveness of a medical procedure and are often used in reimbursement making decisions. As a result of HTAs and DRGs, the amount of clinical and supporting data needed to market a medical device in Europe has increased substantially thus making entry into this market more challenging.

All the countries in the EU have independent control over the pricing of medical devices. Generally all member countries have evidence-based pricing where the evidence of safety and efficacy is required for devices. The strategies required to gain market entrance, reimbursement and optimum pricing to give sufficient market penetration differ between countries within the EU. Europe's regulatory requirements necessitate several levels of compliance, and a manufacturer must retain an on-the-ground representative who will act as a liaison between the company and the EU regulatory authorities.

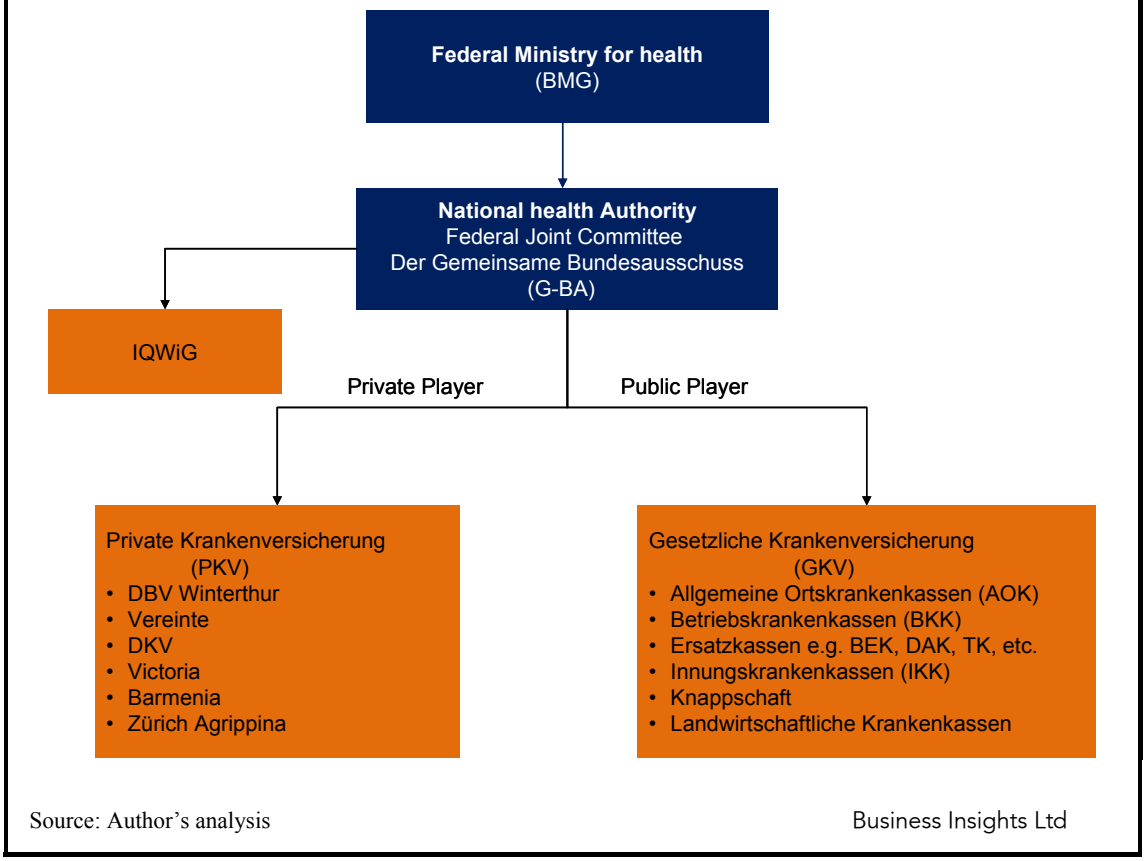
The medical device/equipment reimbursement process in Europe takes two forms:

- Product reimbursement: - Reimbursement levels will be set for the device/equipment itself which is providing health benefit in its own right.
- Total reimbursement packages: Similar to the diagnosis-related group system in the United States- payment for the device/equipment, physician, surgical intervention must come from within the budget set for the procedure as a whole.

Each of the above affects the sales, market growth and profits of the medical device/equipment market within a country. The pricing of the product also differentiates as different countries have different rates of VAT imposed.

German healthcare system

Figure 2.5: Healthcare structure in Germany



Source: Author's analysis

Business Insights Ltd

The supreme decision making body relating to healthcare in Germany is the Federal Joint Committee also known as Der Gemeinsame Bundesausschuss (G-BA), which is managed by the Federal Ministry of Health.

Diagnosis-related groups (DRGs): Germany is one of the largest markets in the EU and has developed a diagnosis-related group (DRG) hospital care reimbursement system for medical device/equipment procedures. There are approximately 600 to 800 DRGs in the German DRG system. Each DRG consists of a specific class of patients who suffer from identical clinical conditions and require identical hospital services. Whenever a person comes into the hospital, the symptoms are matched with any one of these groups and the diagnosis and treatment is done in accordance to these. Reimbursement in a DRG is done through a catalogue of diagnoses maintained by the German Health Technology Assessment (HTA). This system operates in collaboration with the Institute for Quality and Efficiency in Healthcare (IQWiG) an independent advisory body that reviews the efficacy and quality of the healthcare to understand which therapeutic and diagnostic services are feasible and valuable.

HTAs: The Federal Institute of Medicinal Products and Medical device/equipment is a national agency which not only reviews clinical trials, but also sets prices that affect the percentage of the cost of devices/equipment and procedures covered by the government or other payors.

There are three options for health coverage in Germany:

- The government regulated state health insurer -Gesetzliche Krankenversicherung (GKV).
- Private health insurance from a German or international insurance company- Private Krankenversicherung (PKV)
- A combination of the two.

The health insurance system driven by private and foreign insurers is known as the Private patient and the statutory healthcare system (the Krankenkassen) and insures the Kassenpatienten, and covers about 90 percent of the population.

Gesetzliche Krankenversicherung or GKV- Approximately 70 million people are members of the government healthcare system. The majority of Germans receive health coverage through the Statutory Health Insurance (SHI) system of sickness funds. Sickness funds are non-profit insurance companies that are publicly funded as they collect a premium from their members and pay healthcare providers on a negotiated term. GKV is mandatory for any citizen whose gross salary is below $67,750 per year or $5,648 per month (Exchange Rate 1 Euro = 1.39463 USD, 2009). Some of the leading SHI providers include:

- Allgemeine Ortskrankenkassen (AOK)
- Betriebskrankenkassen (BKK)
- Ersatzkassen e.g. BEK, DAK, TK, etc.
- Innungskrankenkassen (IKK)
- Knappschaft or
- Landwirtschaftliche Krankenkassen

Private Krankenversicherung (PKV) – Only citizens which fall in the below mentioned categories can avail private insurance:

- Workers whose gross monthly income for the third consecutive year exceeds $67,750 per year or $5,648 per month.
- Self employed, freelancers and artists
- Beneficiaries of reimbursement and officials such as judges, and the Bundestag

Popular PKV companies include:

- DBV Winterthur
- Vereinte
- DKV
- Victoria
- Barmenia
- Zürich Agrippina

Impact of regulations on pricing and reimbursement

DRGs with fixed prices compel providers to limit their technological advancement as they will receive the same reimbursement for the test and procedure irrespective of the device/equipment used.

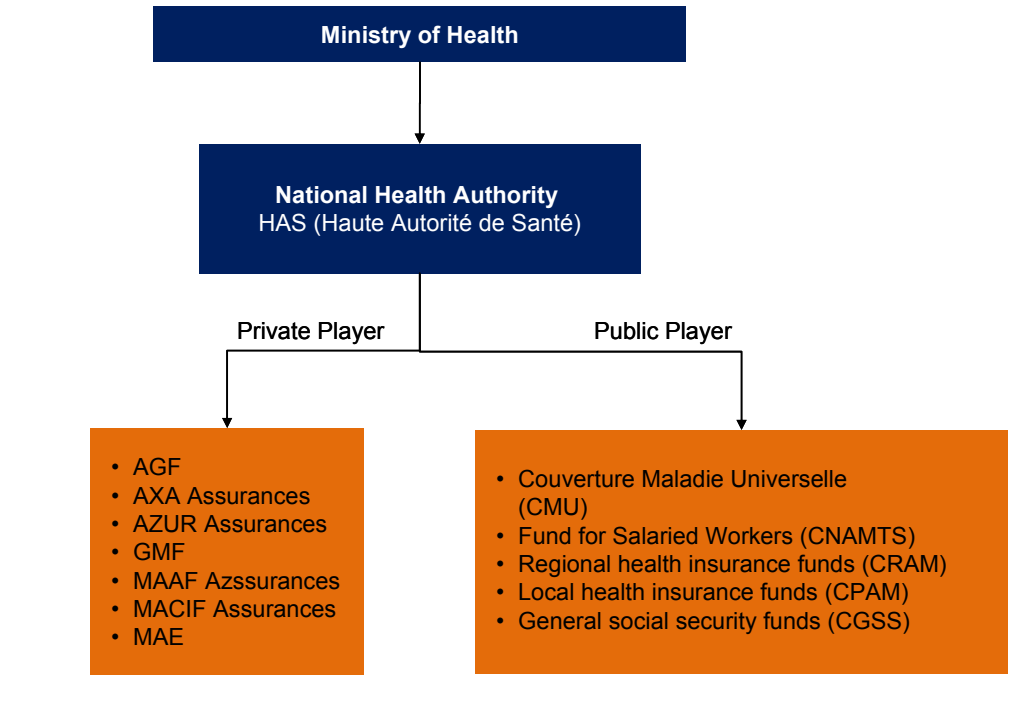
The laboratory market has started to consolidate with private laboratories starting to penetrate the hospital market by purchasing or operating labs on behalf of hospitals, this has encouraged the formation of purchasing groups that are impacting the market.

Case I: If a manufacturer in Germany develops a medical device/equipment which is included in the existing coded medical procedure in Germany then gaining reimbursement at an existing value only requires the CE mark. However, if the reimbursement value is much lower in comparison to the cost of technology then the manufacturer has to apply for the new device/equipment assessment against existing treatment options to IQWiG. This takes a minimum of three years during which the marketing of the medical device/equipment will not be possible at the existing reimbursement value without rejection of the application for greater reimbursement.

Case II: If a medical device/equipment is innovative and new and is not covered in the existing reimbursement procedure then it will have to apply to IQWiG for a full assessment which could take years even after CE marking. Although the German government has identified barriers that slow the process and it is trying to resolve them.

French healthcare system

Figure 2.6: Healthcare structure in France



Source: Author's analysis

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The Ministry of Health is the supreme authority for healthcare in France and is responsible for healthcare and health insurance.

HAS (Haute Autorité de Santé): HAS is an independent public body with financial autonomy mandated by law, which deals with the government health agencies, insurance

companies, healthcare professionals, patients, and research organization. Its activities include assessment of drugs, medical device/equipment, and publication of guidelines and certification of doctors. To assess the benefits and effectiveness of a new technology as compared to the existing ones the HAS does single technology assessments (STAs) and multiple technology assessments (MTAs). It is seen that a new medical procedure can be added to the benefit list for sickness funds only if it proves beneficial in terms of technology and effectiveness.

The French market is the most heavily regulated market in Europe and there is a centralized control over spending on the purchase of medical device/equipment. France has a national agency for medical device/equipment regulation called the Health Care Product Safety Agency which is responsible for reviewing trials and setting up the price affecting the percentage of device/equipment and procedure that are covered by the government or other private payors.

Groupes Homogenes de malades (GHS): The French government has introduced Groupes Homogenes de malades (GHS) translated as Standard Stay Groups. According to this scheme, the healthcare providers are paid an amount based on the average cost of treating a given condition, multiplied by the number of patients treated. From 2004, the funding in public hospitals has shifted to a new reimbursement system called fee-for—reimbursement (T2A). According to this new system public hospitals are reimbursed on the basis of the complexity involved in the cases and the number of cases treated by them. "Liste de Produits et Prestations Remboursables" (LPP) includes related services and medical goods which the statutory health insurance fund reimburses. The National Union of Health Insurance Funds (UNCAM) not only maintains the list of procedures, devices and drugs reimbursable but it also sets the tariff for them and determines the levels of co-payment and co-insurance. Medical treatment in France, either private or public, is not free at the point of delivery.

All tariffs and the cost of the medical treatment comes under tarif de convention. The providers that follow the tarif de convention are classed as conventioné. Those that do not are classed as non-conventioné and can charge whatever they like, however they are not liable to disclose their prices. Visiting a non-conventioné will add extra cost, which the patient has to bear. This is called depassement. Around 97% of healthcare providers are conventioné in France.

Statutory Health Insurance system: France has a universal public health insurance system. This public insurance program started in 1945. The working population funds the French Healthcare System. French employees pay about 20% of their gross salary, which is deducted at source to fund the social security fund known as Sécurité sociale. Once a person subscribes to the Sécurité sociale, part of the cost of their medical treatment is covered by the state under CMU (Universal Health Coverage Act). Further at the regional level, the authorities are called departments which directly take care of the health insurance needs at the local level. The French social security system gives freedom to both the patients and the providers. Patients are free to choose any physician they want to and the providers are free to prescribe and enjoy sufficient autonomy and are paid on a fee-for-service basis. The patient has to pay the full fees for which they are reimbursed later and Sécurité sociale on an average reimburses 70% of the cost to the provider.

The scheme operates through three different tiers:

- National Health Insurance Fund for Salaried Workers (CNAMTS),
- 16 regional health insurance funds (CRAM),
- 128 local health insurance funds (CPAM) in mainland France and four general social security funds (CGSS) in the overseas departments.

Private Payor: Although France has a universal system the coverage it provides is incomplete and a large part of the French population has private complementary health insurance. Private health insurance helps patients by sharing costs with the public system for medical goods and services for which reimbursement levels are inadequate to cover the full cost.

Popular private insurers include:

- AGF
- AXA Assurances
- AZUR Assurances
- GMF
- MAAF Assurances
- MACIF Assurances

Classification des Actes Médicaux (CCAM): CCAM is a procedure catalogue used in France since 2002 for reimbursement and other healthcare decisions. It is hierarchically structured and each procedure mentioned in it is illustrated by a code through a multiaxial classification framework. CCAM offers multiaxial four-digit codes, representing body system, anatomical site and action (procedural type). Reimbursement of providers is based on the patients' diagnoses as coded at discharge. The physician only performs data abstraction and coding of medical records. It is extra work which is equally important as on this basis only the physicians get their reimbursement.

Impact of regulations on pricing and reimbursement

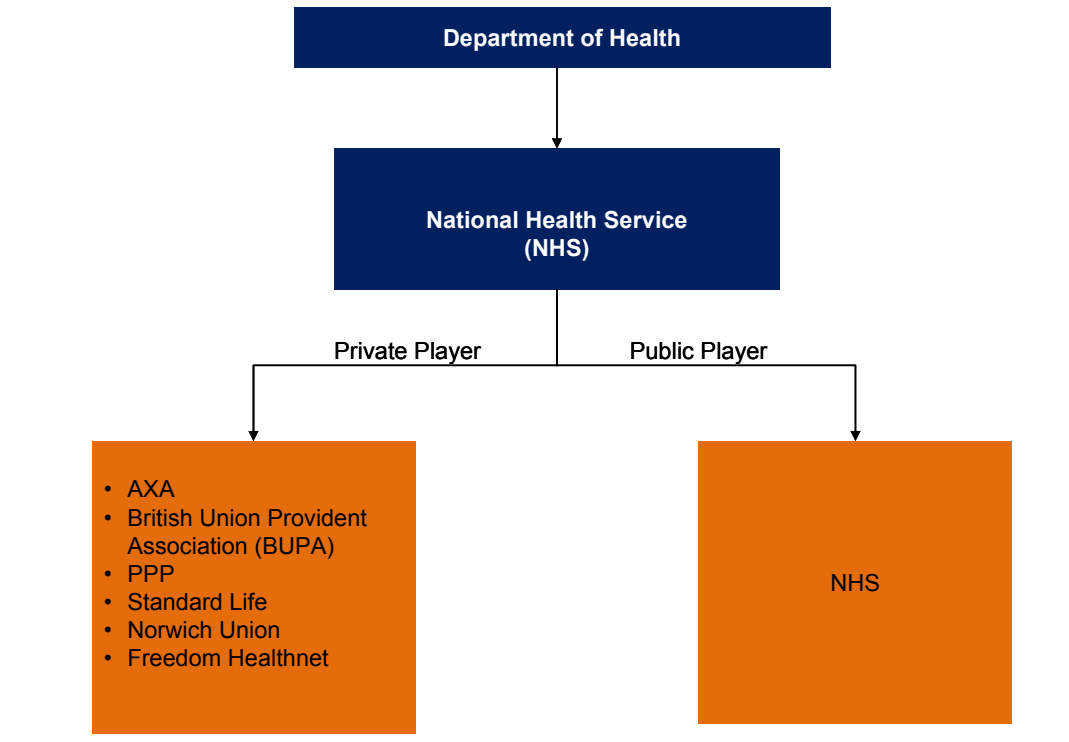
If the wrong coding is used for the treatment it will result in inappropriate reimbursement, similarly if the wrong diagnosis is made then it will result in lower reimbursement

Case I: If the manufacturer wants to introduce a new device/equipment in to the market then the CE mark can only be approved if it is included in the existing GHS procedure code.

Case II: If the device/equipment is not included in the GHS procedure code or needs to be added in the LPPR (Liste des Produits et Prestations Remboursables), the device/equipment cannot be introduced until and unless it is included in GHS or listed in LPPR. On average the process takes three to four years and there is no other way to enable a payment in the in-between period. Introduction of some temporary registration schemes are under consideration to encourage the introduction of innovative device/equipment in to the market. If a company in France claiming a government approved reimbursement exceeds the agreed upon sales volume, the negotiation process is reopened and further price reductions may be negotiated.

UK healthcare system

Figure 2.7: Healthcare structure in the UK



Source: Author's analysis

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The National Health Services (NHS) in the UK follows a universal concept of coverage and all the citizens are entitled to use healthcare services that are free at the point-of-use. All the services like inpatient, outpatient, ambulatory, dentist care, rehabilitation, physician, drugs, and learning disabilities are free. It is governed by the Department of Health. The NHS is funded entirely through taxation. The NHS is divided into two kinds of trust

Commissioning Trusts: These analyze domestic needs and negotiate with the providers to provide healthcare.

Provider Trusts: These look after healthcare services delivery, the UK has Healthcare Resource Groups (HRG) which are similar to the German DRGs except for the fact that they also cover the day patients also. In the UK the majority of diagnoses are made by NHS laboratories, recently however private laboratories have also entered the diagnostic market. Laboratories get a part of the allocation from the hospital's total allocation for their services. Due to the way the NHS works it makes it impossible to introduce new tests. To run the pathology services the expenditure on product and supplies is 20% and the rest 80% is laboratory overhead cost, mostly wages.

Directives and CE mark: All the products within the European Union (EU) and the European Economic Area (EEA) have to comply with EU directives and also local member state laws. The directives serve the purpose of providing minimal technical hurdles, balancing rules on safety, quality and the performance of device/equipment. The CE mark has to be applied on every product launched in the European market. The mark illustrates that the manufacturer has signed the declaration of conformity and it complies with the IVD directives. Different category of IVD have different CE marks depending upon the directives and the risk of use associated with it. IVD are primarily categorized into four products according to the level of risk involved in the treatment.

- Device/equipment listed in Annex II List A - This includes test kits for HIV, HTLV and hepatitis and some blood grouping products including those used to test donated blood.

- Device/equipment listed in Annex II List B – This includes, among others, test kits for rubella, PSA, toxoplasmosis and phenylketonuria, as well as self-test device/equipment for blood glucose,

- Device/equipment for self-testing intended for home use by laypersons- This includes other IVDs for self-testing other than for blood glucose,
- All other IVDs are in a fourth, general category as they are considered to be of low risk and for which the manufacturers can self-certify the product.

Authorized Representative: There should be a designated authorized representative who is legally responsible for the product and its post marketing activities for the products, if they are manufactured outside of the EU. The standardization is done by CEN (European Committee for Standardization) with inputs from national standards bodies such as British Standards Institute (BSI) in the UK.

The Medicines and Healthcare products Regulatory Agency (MHRA) ensures that manufacturers maintain a systematic procedure to review product performance and implement any necessary corrective actions that will reduce the risks associated with it.

Private payors: Private healthcare also runs in parallel to the NHS and gives patients the freedom to choose the physician that they see whilst also avoiding long waiting lists. Approximately 8% of the population has private healthcare coverage in addition to the coverage the NHS provides. It is a mix of for-profit and not-for-profit insurers. Private healthcare provides far fewer treatments compared to the NHS. Private healthcare is either funded by employers as an employee benefit or by patients taking insurance out privately. The private sector also subcontracts for the NHS. If a particular private hospital has subcontracted with the NHS then the treatment may be carried out by the private sector. Some popular private insurance companies are:

- AXA
- BUPA

- PPP
- Standard life
- Norwich Union
- Freedom Healthnet

Impact of regulations on pricing and reimbursement

The manufacturers of medical devices have to undergo conformity assessment routes in order to classify the medical device category as per the medical device directive and regulation. The categorization classifies the medical devices into three broad categories i.e. Class I, Class II, Class III. The respective class of a medical device depends on the risk associated with each of them to the patients and also on the level of regulatory controls.

Class I: The medical devices in this category have a minimum amount of regulatory control. These devices are simple in their manufacturing process and design and pose the least threat to the user and have historical evidence of safe use.

Class II: For the medical devices in this category, in addition to the general controls special controls are also essential which includes mandatory performance standards, medical device specific guidance as per Medical device directive and regulation. These devices have more specifications associated in regards to their usage as compared to Class I devices.

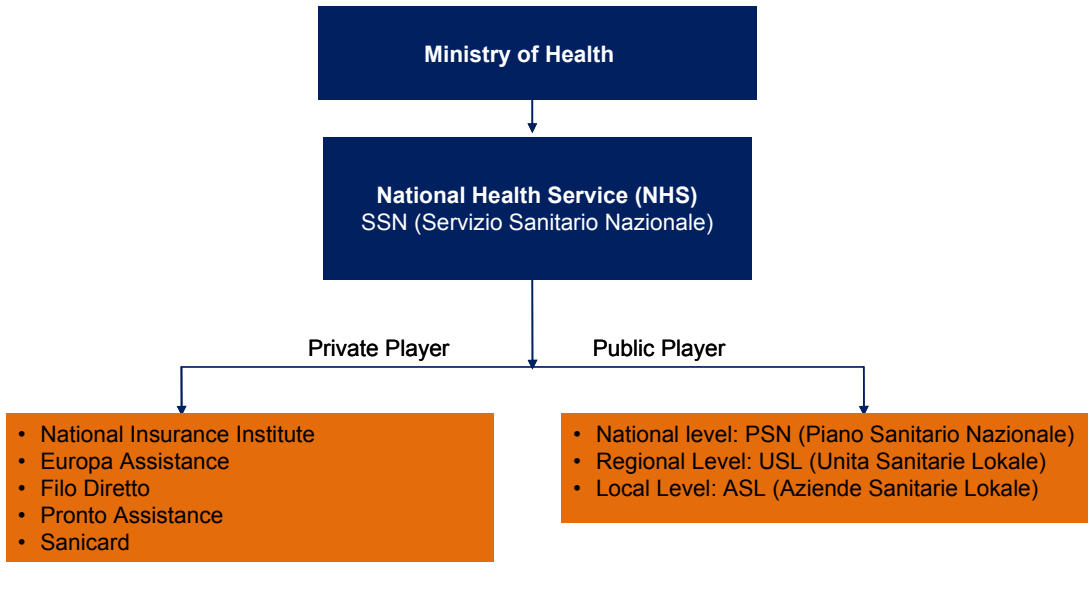
Class III: These medical devices have the most stringent regulatory controls. They are generally used to support human life and are of high importance for preventing human health impairment.

The conformity assessment of these devices is done through different conformity assessment routes which differs between the respective classes of the medical devices. Afterwards these conformity assessment procedures are evaluated by the notified body which is a certification organization designated by the national authority for carrying out conformity assessment procedures.

A similar process has to be followed for the device/equipment listed in List A and B. Firstly, the notified body has to verify the manufacturer's working practices and then it will either undertake a full audit of the quality assurance system or carry out type testing and some form of production audit or sample examination. For List A products, the manufacturer will also have to demonstrate conformity with "common technical specifications", which detail the required performance evaluation and batch release criteria.

Italian healthcare system

Figure 2.8: Healthcare structure in Italy



Source: Author's analysis

Business Insights Ltd

Italy's national health plan, the SSN instituted in 1978 is tax funded and universal and provides healthcare at minimal or no cost to Italian citizens. The SSN operates on a national level through the PSN (Piano Sanitario Nazioanale) and further penetrates into the regional and local healthcare system using the USL (Unita Sanitarie Lokale) and ASL (Aziende Sanitarie Lokale), respectively. In-patients are reimbursed through DRG and out-patients are reimbursed through a positive list of services.

The cost covered includes in-patient and out-patient costs, medicines and the cost of the hospital stay. All necessary treatments, which are borne by the government is set in the form of LEA (fundamental levels of care, Livelli essenziali di assistenza). The public sector has a distinct feature of paying the practitioner's salary in the form of a fee per-capita per-year and it does not reward repeat visits, testing and referrals. Some portion of funding comes from public resources, but a larger part comes from health insurance contributions paid by employers (2.88% of the gross earnings) and the rest from additional private payments.

Private payors: The private sector has an advantage over the state as it gives freedom to the patients to choose a doctor and a specialist and hence avoid the long queue for a particular doctor. The private sector plays a dominant role in dental services. The private payors are:

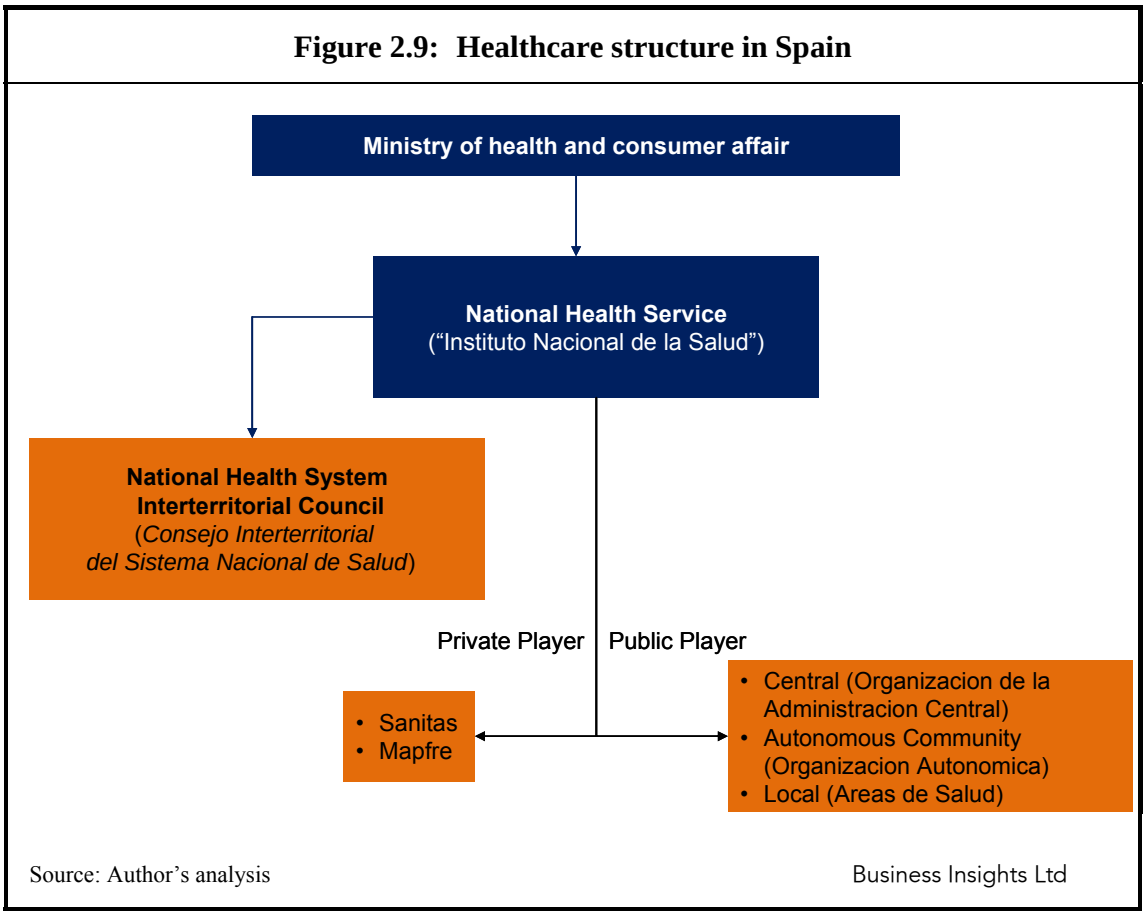
- National Insurance Institute
- Europa Assistance
- Filo Diretto
- Pronto Assistance
- Sanicard

Impact of regulations on pricing and reimbursement

Late payment is a major problem in Italy. It takes on an average between 500 and 800 days for a product to be paid for after delivery. The products, which are not in the reimbursement list, might still be purchased because they might be financed by regional budgets. Manufacturers face a series of problems if they are to sell their products across Italy if their device/equipment is not included in the national tariff. Since different regions have the liberty to develop their own coding systems, the differences not only in terms of tariff but procedures have also increased, which cause an issue with the reimbursement pattern.

Spanish healthcare system

Figure 2.9: Healthcare structure in Spain



Source: Author's analysis

Business Insights Ltd

The healthcare system in Spain is continuously striving to employ better technology and equipment to provide the best possible facilities to its population. Thereby Spain is a becoming a lucrative market for diagnostic equipment. In 2009, Spain had approximately 6000 high-tech imaging devices installed, the majority of which are CAT, MRI and mammography units. There are more than 45 PET units, out of which PET-CAT constitutes 50%.

Spain's universal public healthcare system is ranked seventh in the world by WHO. The INS was instituted in 1986 and is called ("Instituto Nacional de la Salud"). It is made up of both state (Organizacion de la Administracion Central) and autonomous community health departments (Organizacion Autonomica). The funding of the INS is made through taxation included in the general budget for each autonomous community.

The INS is coordinated by the National Health System Interterritorial Council (Consejo Interterritorial Del Sistema Nacional de Salud), which decides the inclusion or exclusion of technologies in the national catalogue. The Interterritorial Council's decision is implemented by the central and state governments. Spain's healthcare system is at three levels:

- Central level as Organizacion de la Administracion Central
- Territorial level as Organizacion Autonomica
- Local level as Areas de Salud

Public healthcare is free at the time of use and covers all citizens. The services included are:

- Preventive care
- Diagnostic and therapeutic techniques

- Rehabilitation
- Health promotion and maintenance

Primary healthcare in Spain includes family and GP services, social workers, nursing, pediatrics, physiotherapists and is readily accessible due to its well established infrastructure in terms of resources and technologies. However, specialist care includes caring of diseases such as cardiovascular, cancer, in vitro and in vivo diagnostics. This involves comparatively higher costs for diagnostics and therapeutics, due to the need for specialized resources and niche technologies.. Financing for SSN is done through public resources, employer's contribution (2.88% of gross earning) and rest from the additional private payments. The government determines prices and reimbursement of products, which can take two to four years. The foundation of the price is based on innovativeness, expected sales volume international price comparison, expected profits, domestic research and development, manufacturing and marketing costs.

The autonomous communities (Andalucia, Basque Country) have introduced payment systems based on DRGs with funding in the hospitals made following negotiations between the hospital and the regional authority third-party payor. The salary of the primary healthcare physician includes a component calculated on the basis of the nature, density and percentage of population over 65 years.

Private health system: Healthcare at private hospitals is paid either by a private insurance company or directly. Mainly private insurance is opted to avoid the long waiting time to see a doctor associated with public healthcare system. The private insurance companies offer quick and additional services such as private rooms, quick test results and information updates through email and SMS. The major private insurers are Sanitas and Mapfre.

Impact of regulations on pricing and reimbursement

In Spain, the public healthcare system provides IVD analysis directly and free of cost. Hence, there is no reimbursement process. In case of private insurers the diagnostics services are covered through monthly payments to the insurance company. Self test at pharmacies are also not reimbursable.

European diagnostic imaging reimbursement structure

Reimbursement for diagnostic imaging technologies in Europe is decided at the national level. Hence each country varies drastically on the fees paid covered by state and private payors. For example the government financed systems of Italy, Spain, France and Switzerland cover all PET indications, but in Germany, PET is nationally reimbursed only for pulmonary tumors for other indications patients must either have some form of private insurance to cover these costs or cover the costs themselves.

In Europe there is also a spectrum of reimbursement coverage for molecular imaging technologies. Government health insurance based countries such as Italy or France look to policies in countries, like the US to determine their reimbursements. An example of disparity in reimbursements in diagnostic imaging in Europe is that SPECT in oncology has received widespread support for reimbursements, while the same MRI procedures currently face a threat of reimbursement withdrawal due to the dangers of radiation.

Pricing and reimbursement: pharmaceutical vs. diagnostics

As compared to the reimbursement of diagnostics, the reimbursement process for pharmaceuticals is much less complex. The reimbursement of pharmaceuticals covers various types of drugs that can be categorized into the following groups:

- Generic prescription drugs
- Brand-name and preferred prescription drugs

- Brand-name and non preferred prescription drugs
- Unique and high priced prescription drugs

In diagnostics, the system of reimbursement is quite complex. Diagnostic procedures are categorized according to the indications in the patient such as Cancer detection and neurological diagnosis.

As compared to diagnostics the reimbursement of pharmaceuticals has a wider scope of coverage. This is because there are a limited number of procedures with specifications, which are reimbursed in diagnostics. Within pharmaceuticals the reimbursement payments for generic drugs is easier as compared to diagnostic because there are few substitutes for high tech procedures. Also, the procedural cost involved in diagnostics is high as compared to that in pharmaceuticals. Hence, the health authorities are highly stringent while including any procedure for reimbursement. However, in pharmaceutical reimbursement, segmentation is quite simple.

Table 2.1: Payment & coverage in pharma

Tier	Payment	Coverage
1	Lowest Copayment	Most generic prescription drugs
2	Medium Copayment	Brand-name and preferred prescription drugs
3	Higher Copayment	Brand-name and non preferred prescription drugs
Special	Highest Copayment/Coinsurance	Unique and highly costing prescription drugs

Source: Author's analysis

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Level of pricing transparency for diagnostic devices

In the present scenario, the diagnostic devices market is characterized by a large number of players and high consumer base globally. Hence, the level of price transparency is still low in this market. Manufacturers traditionally follow different pricing strategies for healthcare providers. Most diagnostic devices are sold in the competitive market; however specialized and expensive devices function in an oligopolistic market with less competition as the number of market participants in these segments is low.

The lack of transparency in this sector can be attributed to the market power of the manufacturers which is influenced by various factors including:

- The similar kind of diagnostic devices manufactured by different OEMs have differentiating features.
- The patent protected features of devices enable OEMs to charge premiums.
- Lack of comparative knowledge on product and price information
- Relative industry concentration in the hands of limited number of companies
- Devices lacking substitutes

The transparency in pricing is also hindered by various methods adopted by the OEMs such as contracts with the buyers. These contracts have several clauses, which include those preventing buyers from disclosing the final negotiated prices to any third party.

The US government is continuously trying to implement a pricing disclosure policy to increase the level of transparency to buyers. According to the 2009 Patient Protection and Affordable Care Act, device manufacturers must disclose their prices to the CMS. Manufacturers failing to report or involved in misrepresenting would be subjected to

monetary penalties of between $10,000 and $100,000. Such measures also act as a method for active price disclosures in future. CMS has proposed the price list that should be made available to the public

CHAPTER 3

Key findings

Chapter 3 Key findings

Summary

- The reimbursement structure in the US and European countries is affected by high healthcare costs, increasing patient queues for treatments, deficit financing within US for its burgeoning healthcare expenditure, etc.
- This has led to US and European governments to come up with legislations restricting the reimbursement amounts with respect to costly healthcare diagnostic procedures.
- The reimbursement mechanism within US and European countries is characterized by various inter-relationships between payor (e.g. Medicare, etc.), patient, healthcare provider (e.g. laboratories, hospitals, physicians, etc.) and OEM.
- From the payor's perspective, only the most essential healthcare service at the cheapest cost should be reimbursed. This perspective often leads to an arrest in innovation in medical technology from an OEM perspective.
- From a healthcare service provider perspective, only diagnostic procedures that are fully reimbursed will be attractive as a service to provide. This perspective often leads to an arrest in distribution (service offerings) of innovative diagnostic technologies.
- The pricing for medical devices by OEMs is a tedious and a very complicated exercise. It is affected by various factors such as the type of device, financial requirements, procedure reimbursements, market dynamics and customer prices.

Introduction

The reimbursement structure in the US and European countries is affected by high healthcare costs, increasing patient queues for treatments, deficit financing within the US for its burgeoning healthcare expenditure amongst other factors. This has led to US and European governments to introduce legislation restricting available reimbursement with respect to costly healthcare diagnsotic procedures. Understanding and addressing critical issues such as the decline in the reimbursement amount as well as the conventional approach of the health authorities for reimbursement approval is necessary for the OEMs to successfully market their equipment.

Impact analysis: role of pricing in risk minimization

Patient-payor: The payor aims to provide maximum coverage of diagnostics to the population, however it has to balance this desire against the need to contain burgeoning healthcare costs. Hence, payors are highly selective while deciding which diagnostic technologies to grant reimbursement too.

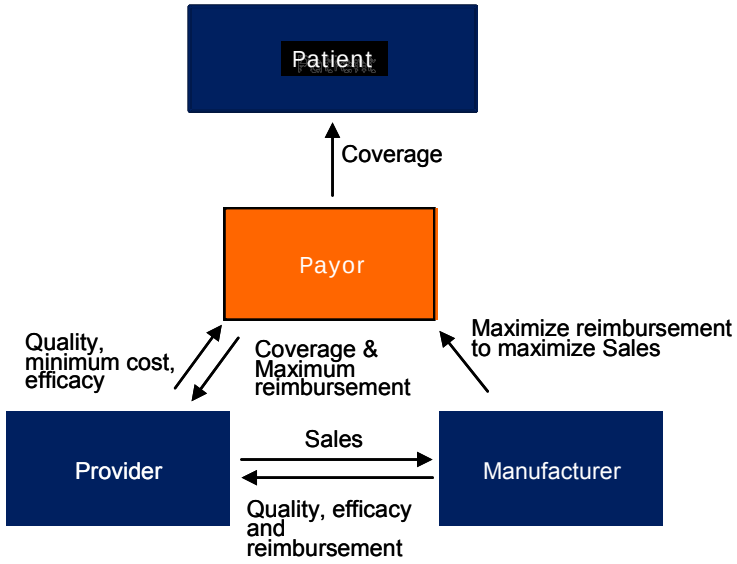
Payor-provider: The Payor and Provider share a mutual relationship in diagnostic reimbursement. Providers seek payors for reimbursement payments for different diagnostic procedures undertaken. Hospitals expect the payors to provide maximum coverage in order to maximize payments. Payors in turn expect high quality and cost-effective procedures to be used by providers.

Provider-manufacturer: Diagnostic device manufacturers continuously strive to provide the best possible product-price mix to their end customers i.e healthcare providers.

However, the reimbursement approval from the payor plays a significant role in the acceptance of these products by the healthcare providers. OEMs in the diagnostic industry are highly interested in getting the prior approval for the tests/procedures performed by their devices/equipment. Approved reimbursement is one of the important deciding factors for the providers to purchase equipment. OEMs with devices/equipment based on existing technology and evidence generally find it easy to get reimbursement approval, however, in the case of any novel technology is can be a much more difficult. Hence, providers consider the availability of reimbursement, product quality and high level of accuracy in diagnosis are considered to be key influencing factors when purchasing any diagnostic device/equipment.

Manufacturer-Payor: OEMs try maximize reimbursement payments in order to assure the providers that they will get a return on the sizeable investment that they have to make initially. Devices/equipments with higher reimbursement are widely accepted by the providers compared to devices that have low levels of reimbursement where quality and efficacy are of a similar standard. Considering the case of SPECT where the US government proposed to reduce the reimbursement amount by 46%, any high cost device/equipment from the OEMs is expected to face challenges in terms of acceptance by providers. In contrast to this, with an increase in the reimbursement payment for PET procedures by 22%, it is expected to offer much better scope for the OEMs for promoting their PET devices/equipment.

Figure 3.10: Reimbursement mechanism



Source: Author's analysis

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Payor's (health insurance companies) perspective

Payors mainly focus on the issues such as cost, safety and effectiveness of the procedure of a particular device. A procedure might have a higher chance of getting insurance coverage, if it reduces the overall healthcare cost. For example an ED-administered coronary CT angiography(CCTA) procedure used in the diagnosis of cardiovascular disease has reduced the total expenses from approximately $4500 (conventional tests) to around $1500 along with reducing the in-hospital stays to 7-8 hours only.

The medical device/equipment OEMs involve the payor from the product development stage. This is beneficial to the OEMs as they understand the feasibility of obtaining reimbursement for their developmental products through ongoing negotiations with payors.

Usually payors evaluating diagnostic imaging procedures and clinical diagnostics look at scientific evidence in order to access diagnostic device quality when deciding on coverage. The diagnostic industry is expected to shift from first generation amplification to next generation biochips, microfluids and gene expression profiling using microarrays. Hence, it is expected that there could be massive reimbursement grants for molecular diagnostic procedures once payors are convinced of their scientific validity. These novel, high value diagnostic tools must not only prove efficacy but also cost-effectiveness; this can be demonstrated by not only being safe and highly accurate but also by improving other aspects of care which can lead to a reduction in the amount of money being paid out in reimbursement.

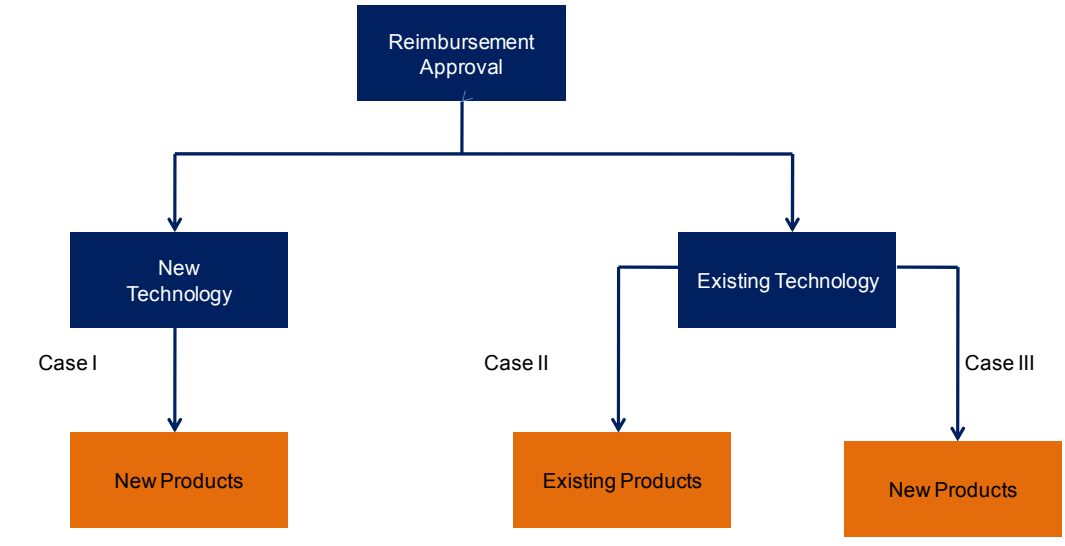
Diagnostic provider's perspective

The diagnostic provider screens the equipment in two stages:

- Technical specifications;
- Other factors such as service, price and reimbursements.

Once the technical specifications of their requirements are met, only then do they look at other factors to decide which technology provider to go with. Other factors considered are initial return on investment as well as government regulations with regards to imports of spare parts, etc.

Figure 3.11: Different cases for reimbursement approvals



Source: Author's analysis

Business Insights Ltd

A new device utilizing technology, which is just an advancement of the existing one that already has reimbursement approval is unlikely to gain greater reimbursement than the

existing product. If an additional reimbursement amount is not established then the provider would not be interested in buying the device as the existing device is fulfilling the desired task with adequate reimbursement and there is no incentive to deploy the new technology. For example the reimbursement of self monitoring blood glucose meters is getting established in private insurance segment in developed countries, but not for cholesterol measuring meters. As the cholesterol measuring meter does not divulge any critical information about the patient, the payors choose not reimburse the device.

Identifying critical issues in the pricing and reimbursement of diagnostics

The recent reduction made by the CMS in the reimbursement amount for non-facility units is expected to impact the diagnostic devices market especially in the form of a lack of innovation. The new developing technologies such as molecular diagnostics may face further challenges in getting approval for reimbursements. This might result in the slow adoption by the healthcare providers.

Decline in the reimbursement for non-facility units in US

The cost of Medicare has been increasing gradually and the US government has made an effort of reduce expenditure. The CMS has published a regulation reducing reimbursement for medical imaging with non- facility units from the beginning of 2010.

Table 3.2: Reduction in US. medical procedure reimbursement

Test	% decrease in payments to non-facility units (Approximately)
MRI	46
CT scan	48
Cardio vascular related services	27
Cancer care	6 (including 1% for oncology)

Source: Author's analysis Business Insights Ltd

Evolving molecular diagnostics causing further complications

As a marketing manager from Becton Dickinson in one of the European market put it;

> *"In European nations only innovative technologies that are of high quality or alternatively of low relative cost can make a pilot entry in the market and gain successful reimbursement."*

The reimbursement structure is restraining the growth of innovative technologies such as molecular diagnostics. The technically complicated procedures are hindering the coding structure while the initial high costs of the procedures are an obstacle to the reimbursement payments.

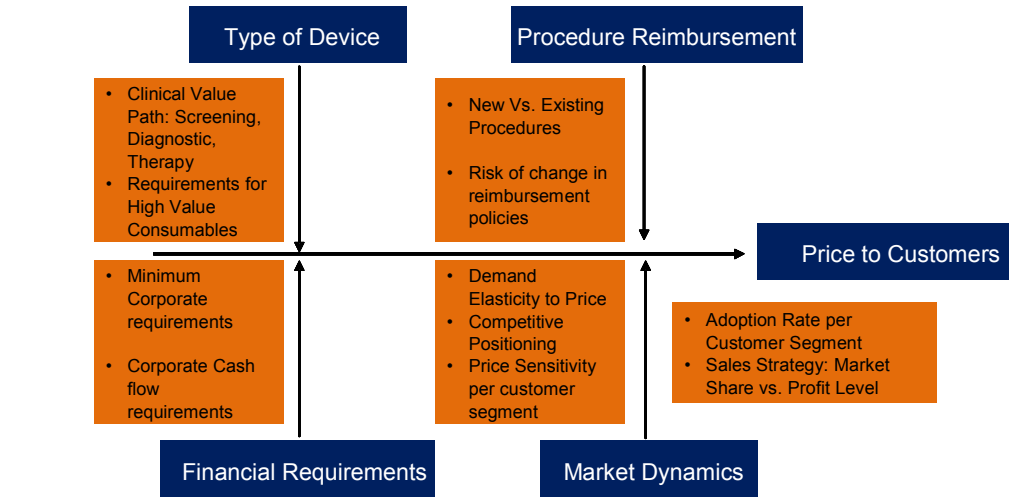
For example the difficulties faced by the CPT Editorial Panel (AMA) when issuing a code for novel molecular diagnostics include:

- The generic description for CPT code of new technologies
- The possibility of development of codes for the technology, which is not universally used or which can become obsolete shortly
- Molecular diagnostic tests are gene-based tests for a particular disease and the CPT coding system is based on the technology and procedure. This mismatch creates a problem in the issuance of a code as it is difficult to follow the number of tests for each disease condition.
- The current CPT generation system taking into consideration the technology and procedure would not be able to include the important variable expenses due to which the cost differs. For example, reagent expenses which depends on the type of condition tested. The difference in the amount of reagent expenses limits the adequate reimbursement payment of the test and offer profitability which indirectly affects the manufacturer's R&D expenditure on the development of new tests.

Similar problems occur with immunoassay tests where the code is issued based on it being an immunoassay and the reimbursement amount even for better tests employing hi-tech devices is the same as for the conventional tests. Hence these codes do not take into the consideration the novelty of the marker or the expenses incurred in R&D. Payors have created a process to reimburse such novel tests called the Medicare Gap filling process where processes with the same analytical technique are bundled together. However, this process also has shortcomings as there is nothing common between tests other than the analytical technique. If the coding and payment system fail to take the cost of a new technology into consideration then the level of R&D will fall.

Factors affecting price of healthcare diagnostic products

Figure 3.12: Factors affecting pricing in a healthcare diagnostic OEM



Source: Author's analysis

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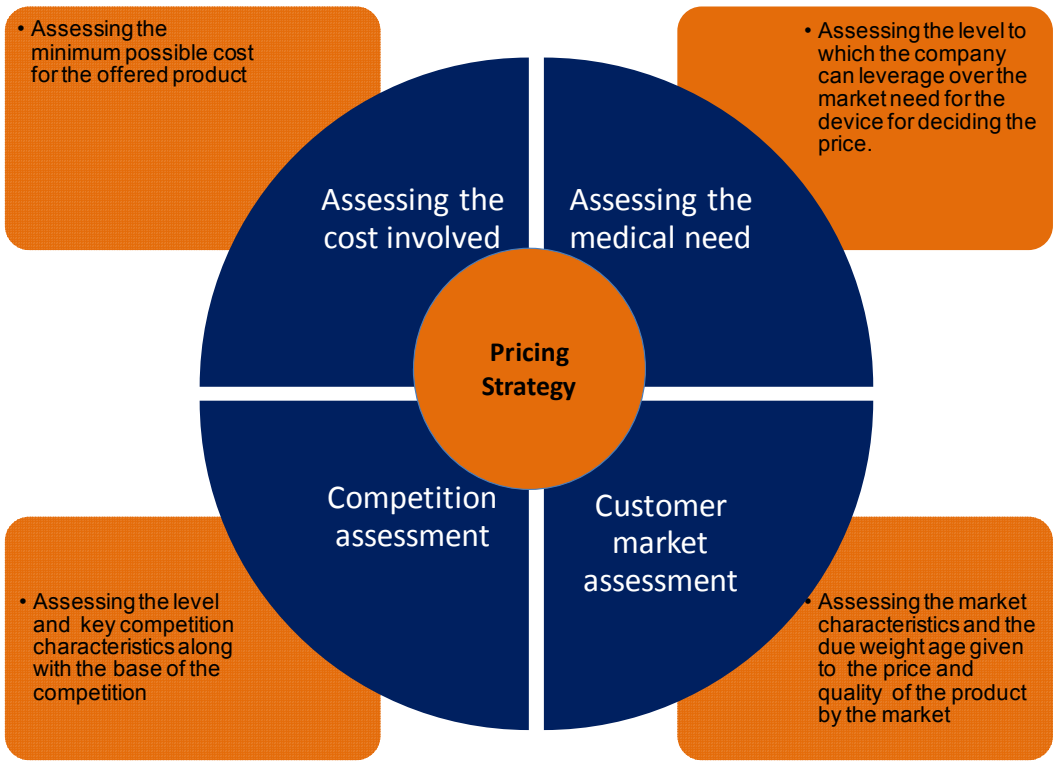
The pricing of medical devices is an important process for medical diagnostic OEMs prior to the launch of their product into the market. The pricing strategies adopted in the industry

are dynamic. Almost all the OEMs consider pricing as a tool to differentiate themselves amongst their peers within the industry. For example The Indian Self Monitoring Blood Glucose market already has major players in Roche (35% market share), Abbot (15%), Bayer (8%) and Johnson & Johnson (30%). When Ark Ray Piramal entered the market, it differentiated itself with discounted pricing. It offered its products at a 10-15% discount compared to those offered by Roche and J&J, and 5-7% discount to the rest of the players. Within the 1st year of operation, Ark Ray Piramal was able to garner a 5% market share.

Figure 3.13: Pricing work flow in a healthcare diagnostic OEM



Source: Author's analysis

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However, pricing a product offering can be extremely difficult. It depends on a multitude of factors such as the market structure, competition, regulations, reimbursements, etc. Also

these factors vary from country to country. An OEM's pricing is fundamentally based on its desired return on investment and the overall cost of manufacturing its equipment.

Figure 3.14: Pricing equation

Price of the Product (P) ≥ Overall Cost of Manufacturing (M) + Return on Investment (ROI)
P ≥ M + ROI

Source: Author's analysis

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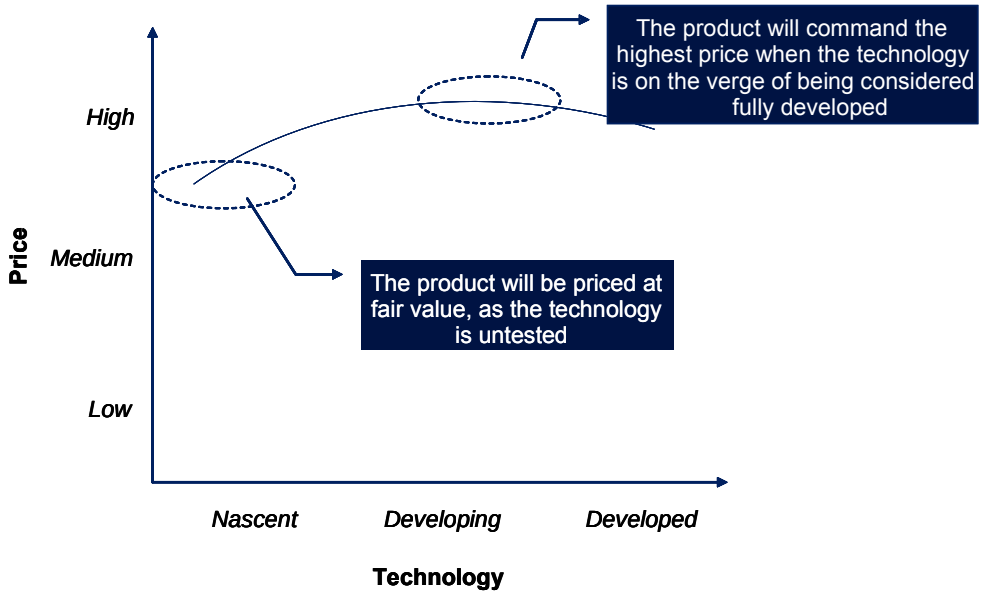
Some of the factors affecting pricing are listed below:

- Competition: Existing players, market shares, technology offered, prevalent prices
- Company profile in the local market: Existing brand positioning
- Government regulations
- Reimbursement/Insurance: Public healthcare insurance coverage

Competition: Existing Players, Market Shares, Technology Offered, Prevalent Prices

Every market goes through evolution in terms of the available technology and its price structure. A typical chart of evolution for technology and price for a healthcare diagnostic product is produced below:

Figure 3.15: Product lifecycle for a diagnostic product



Source: Author's analysis

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Once the technology reaches its peak, the price starts to decrease and gradually a new technology takes over. Every type of market in the world can be mapped on to this chart. Europe can be mapped where the usage of 64 slice CT is evolving with applications such as CT Angiography (CTA), while India can still be mapped where the usage of single slice CTs are replaced with Dual Slice CTs.

An OEM after an in-depth study of the technology-price graph can make two conclusions about the market:

- Range of adopted technology,
- Range of existing prices.

The OEM, knowing the difference in the product it is offering vs. the competitors, can immediately zero in on the acceptable price range its product can command in the market.

The pricing of any product for a company depends on which stage of the product technology chart it is entering that market. But a technology cannot be considered in isolation. When pricing and technology are discussed, the amount of competition, the OEMs' global brand image (in terms of price), regulations, etc. is also considered. When the competition within a product category is either low (fewer than three competitors), the price of the product is usually high or at a premium. While as the competition increases or reaches its peak (more than five major competitors) within that product category, the prices start flattening out or dropping. Hence, eventually, the prices directly or indirectly depend on the competition, OEMs brand image, regulations apart from technology of the product lifecycle. A case study would help understand the dependency much better.

Case Study: Philips was looking to enter the radiography market in one of the developing economies with its automated computed radiography (CR) system product. There are four major players in the CR market. Agfa and Fuji (Combined market share of >60%), Konica and Kodak (Combined market share of ~ 30%) and other players. The current installations for CR vs. digital radiography (DR) stand at 80:20 within the market. The growth rate of CR is between 15-20%, while that of DR is 20-25%. At what price range (low, medium, premium) should Philips price its product in as compared to its competitors?

Philips Response: (Since the pricing of diagnostic equipments is not public information, the discussion below is subjective and is deduced from discussions with various industry participants. The discussion in no manner claims to provide the exact details of pricing strategy employed by Philips within this particular market, but only reflects the opinions of these industry participants.) Philips follows a premium pricing strategy for majority of its product offerings in global markets. But to follow a premium pricing strategy in a price sensitive market while entering was not feasible particularly, where there are established

international competitors. Hence as per the opinion of industry participants Philips offered its CR products at either the same price of the competition or at 5-7% discount from the highest price in the market.

This case study reflects that the price of the product is not entirely dependent on the technology offered by the OEM. It is also a result of the existing competition structure along with its existing brand image with respect to price.

Company Profile in the local market: Existing brand positioning

A company leverages its existing brand image. For instance a company which is a new entrant in the medical device industry will try to build its brand image through various parameters such as technology, products and services etc. Most often, in the initial stage of Product Life Cycle, the companies generally prefer competitive pricing or follow the market trends. However, enhancement of brand image leads to increased product sales allowing the company to charge a premium for its products (most often with value addition).

Users of diagnostic products categorize the products as per price more than the any other factor. The reason is that the product quality is always the first screening criteria. Unless, the product does not deliver optimum results, with regards to patient diagnosis, the discussion for service and other factors do not even arise. Within such premises of the industry, price is usually the negotiation clincher. And that is why the healthcare providers usually remembers the OEM only by its pricing. Thus OEM pricing strategies contribute significantly to the brand image of the company.

Overtime the company goes about its pricing in a similar manner in various markets. In such a case, it is the pricing, which then follows the brand image. The reason is that it has

taken years to establish a brand image within the global markets. Any change in any of the factors contributing to the brand image is a risk. It is a risk too valuable to take. Thus, pricing follows the brand image now.

Within the above mentioned Philips case study, while deciding the price band, Philips took into consideration its brand image at a global level. In that case, Philips has been present in the healthcare diagnostic industry for more than a decade. It is present in almost all the countries in the world, both developed and developing. Its product quality is considered to be at par with its nearest competitors such as GE and Siemens. Its product prices are almost always either on par with the two above listed competitors or the highest within any market. Thus, while entering a new market, it has to keep in mind that it has to maintain that image. Eventually, Philips cannot price its products at the lower-end of the spectrum, even if that would achieve maximum market penetration.

Government: Regulations, import/export duties, local taxes

Government regulations vary from market to market. The developed markets such as the US and Europe have strict entry barriers in general and, in particular for healthcare diagnostic products. Though, the same is not true for developing markets such as India and China. Import duties over apply to the entire equipment, its spare parts, the consumables required for the procedure of the equipment and play a significant role in the penetration of the product in that particular market.

Every market also has a certain level of price absorption. Beyond that particular price, the market does not absorb products even though other factors are satisfactory. While the overall price of a product for any OEM can be within the price absorption level of the relevant market, but the government duties, shipping cost and other regulations may push

that price beyond it. The OEMs then have to decide whether to lower their return on investment and yet enter the market, or shun the market altogether.

A market such as the US has high price absorption and is the largest healthcare market. The OEMs might be tempted to enter the US market with a new technology despite high import duties. Even if they fail to make adequate returns in the early stages, they hope to make profits with high product volume. But, the same cannot be said to be true for a developing market such as India or Brazil.

The governments' technical regulations also push prices significantly higher than the original price of the OEM. For example, it is mandatory to get FDA/CE approval for every product imported or sold in the US/European markets. The administrative process, the fees of registration and quality control might push the price of the product beyond the price absorption level of any market.

Reimbursements: Public healthcare insurance coverage

As per various interviews conducted with the major OEMs in the European and US markets, reimbursement plays a significant role in the development and pricing of products. However, in the case of the unavailability of reimbursement for some diagnostics, it becomes difficult for the OEMs to price their equipment which also have to face challenges such as low adoption rates. However, the OEMs still continue to launch new products with updated technology to sustain their market share, thereby making trade-off on the price in case of absence of reimbursement.

One major reason for such high prices in developed markets is the amount of healthcare insurance penetration, which stands at ~ 70% as compared to that of India, which is at 4-8%. A CT procedure gets partially to fully reimbursed by either the government or the

private players in the US This lowers the entry barrier for the patient to use CT procedure during his/her treatment. This is not true for the developing countries. The patient in India who cannot afford chooses not to undergo such a procedure. It directly reduces the incentive for the concerned hospital to have such a product in place and directly affects the OEMs offering of the CT product in the relevant market. To offset such a condition, the OEMs resort to lower pricing. Hence in a developing market such as India, the reimbursement rate plays a huge role in the pricing of the product, but significantly less in developed markets.

CHAPTER 4

Analyzing best-fit strategies for novel P&R issues

Chapter 4 Analyzing best-fit strategies for novel P&R issues

Summary

- Various strategies are adopted by OEMs in the US and Europe when pricing diagnostic products after considering the reimbursement regulations within these countries.
- These pricing strategies include ROI based pricing, value based pricing, fair value pricing and risk based pricing.
- The strategies employed depend on various factors such as whether the product is based on new or existing technology.
- Value based pricing is most commonly used for products using existing technology, but which contain additional features, whilst for novel technology products the most commonly used pricing strategy is premium pricing.
- Considering the important role reimbursement has to play in determining the success of new product in the US and European markets in addition to focusing on product pricing, OEMs also need to focus on engaging payors at an early stage.
- For this payor focus, OEMs have separate Strategic Business Units (SBUs) such as pricing and reimbursement SBU within their company, or outsource this to consultants.
- The demand price premium strategy (value pricing) is one of the most commonly employed strategies by OEMs variations such as fee for service have recently been seen with the launch of new products.
- Due to intense competition, OEMs need to reduce the time to market for any new product in order to generate a substantial return on investment.

Introduction

Factors affecting the pricing of healthcare diagnostic products have been discussed earlier in Chapter 3. Next, existing pricing strategies often employed by the OEM are discussed, followed by novel pricing strategies which are being employed by the OEMs, and how these can be used to target reimbursement issues.

Pricing strategy

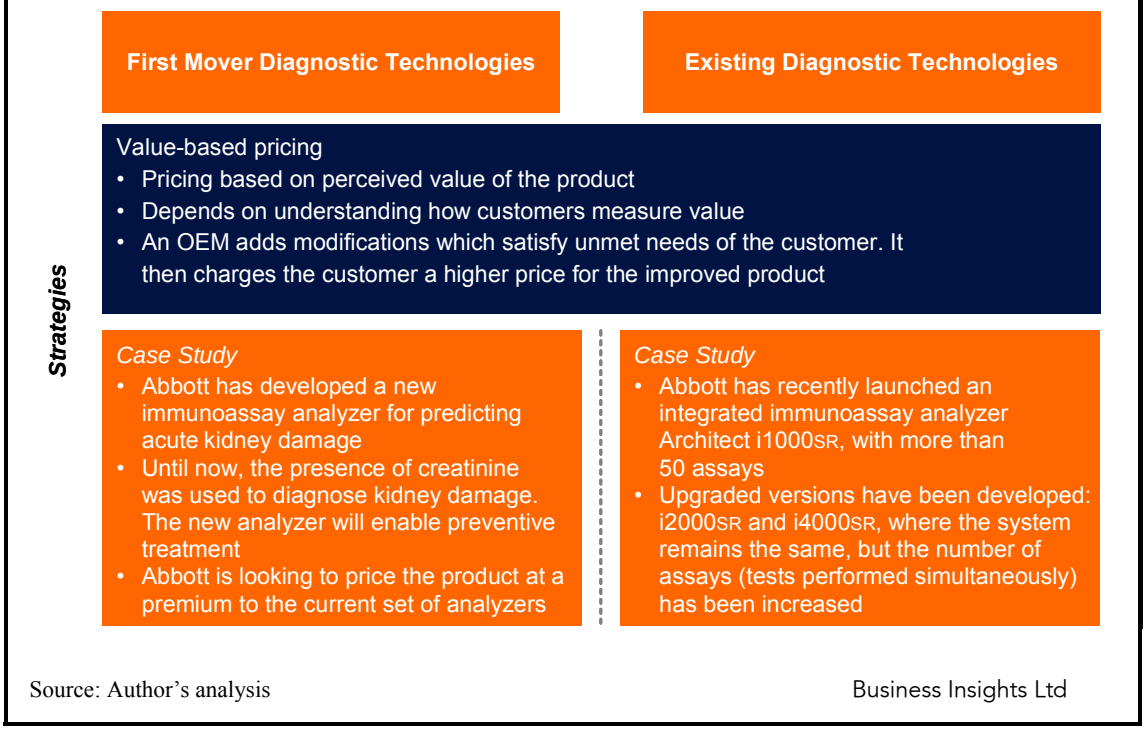
ROI-based pricing is on the verge of being obsolete, with most OEMs conceding that the cost of manufacturing is just one of the factors, and not the deciding factor, for the pricing of diagnostic products. With increasing globalization, factors that affect the pricing of the product primarily, are competition and brand image. Yet, ROI-based pricing still forms an integral part of the overall pricing strategy for any OEM. It acts as a base price, below which if the price absorption for any market is found then the OEM might not enter the market at all. In other words, it acts like a screening criterion for the OEM to decide whether to enter the market or not. Return on Investment is calculated in many ways and it differs from OEM to OEM in the way it is calculated based on the time frame it wishes to stay in the market. But what kind of pricing an OEM should keep depends on what product technology stage it is entering in a relevant market. Based on the above debate, any OEM falls into either of the two categories listed below:

- First mover diagnostic technologies;
- Existing diagnostic technologies.

Reimbursement as discussed earlier plays a role in deciding the pricing of the product for the OEM. The availability of reimbursement helps the OEM to price its product

considering only the need, competition, brand image, etc. But the non availability of reimbursement, forces the company to rethink its pricing strategy, altogether.

Figure 4.16: Value-based pricing & reimbursement



Source: Author's analysis

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Value-based pricing is currently the most commonly employed pricing strategy by all the market leaders. Any market which has scope for improvement in terms of anything apart from price is assessed by the OEMs and targeted. These OEMs then increase the price of their products as compared to the existing competition based on the added application/usefulness/need satisfied by the product.

Within developed markets such as Europe and the US, almost all the major players in healthcare diagnostics are on par with regards to the technology they offer. For example, Siemens, GE and Philips (in in vivo diagnostics), and Roche, Abbot, and Beckman Coulter (in in vitro diagnostics). Over a period of time, all major competitors in both these

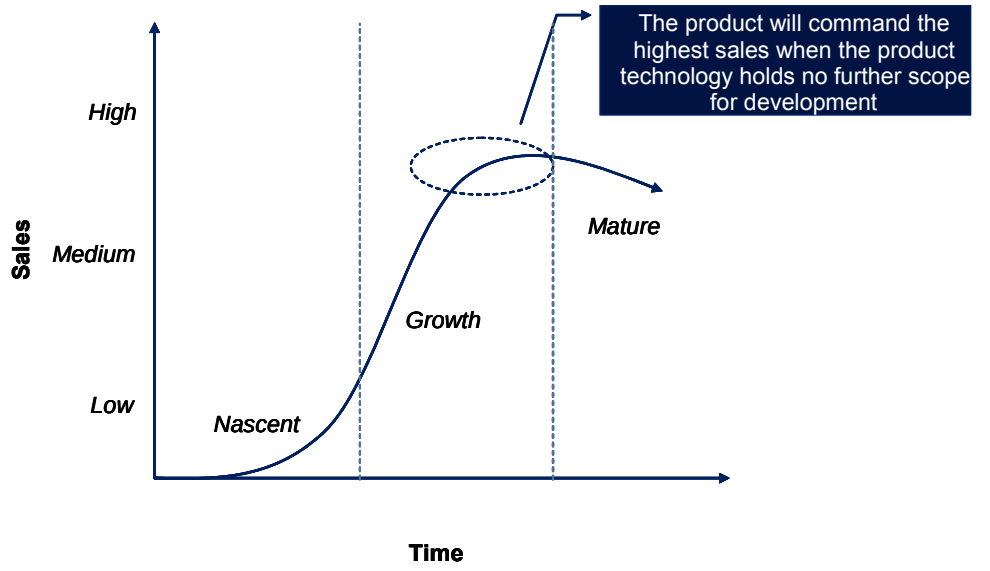
segments have aligned themselves in such a way that they are extremely similar to each other. In this case, reimbursement plays a critical role in differentiating the various players.

Example: Currently, the CMS, the chief reimbursement authority in the US reimburses patients for only one PET scan during initial treatment. This is primarily due to the high cost of the scan (> $2,500 per scan), as well as the amount of time it takes for one scan (~ 1-2 hours/ patient). But radiologists associations such as the leadership of the National Oncologic PET Registry (NOPR) Working Group, the Academy of Molecular Imaging, the American College of Nuclear Medicine, the American College of Radiology, the American Society for Radiation Oncology, the Institute for Molecular Technologies and Society of Nuclear Medicine (SNM) believe that at least two scans are required to assess efficacy of treatment. This is one of the reasons for a low number of PET scans in the US. If a major player in the market develops a PET scan which can deliver optimal patient care in only one PET scan, then the requirement of two scans becomes obsolete, and the product will be endorsed by almost all the radiologist associations in the US. As the product use guarantees patient care as well as reimbursement, whilst maintaining all other factors such as similar service, the product can be priced at a significant premium compared to existing products.

Price management and reassessment of pricing throughout the product lifecycle

Similar to Figure 3.15 which depicts the relationship between price and technology in a particular market, the product lifecycle for any healthcare diagnostics product also follows a similar pattern. A typical product lifecycle chart is shown in Figure 4.17.

Figure 4.17: Product lifecycle for a diagnostic product



Source: Author's analysis

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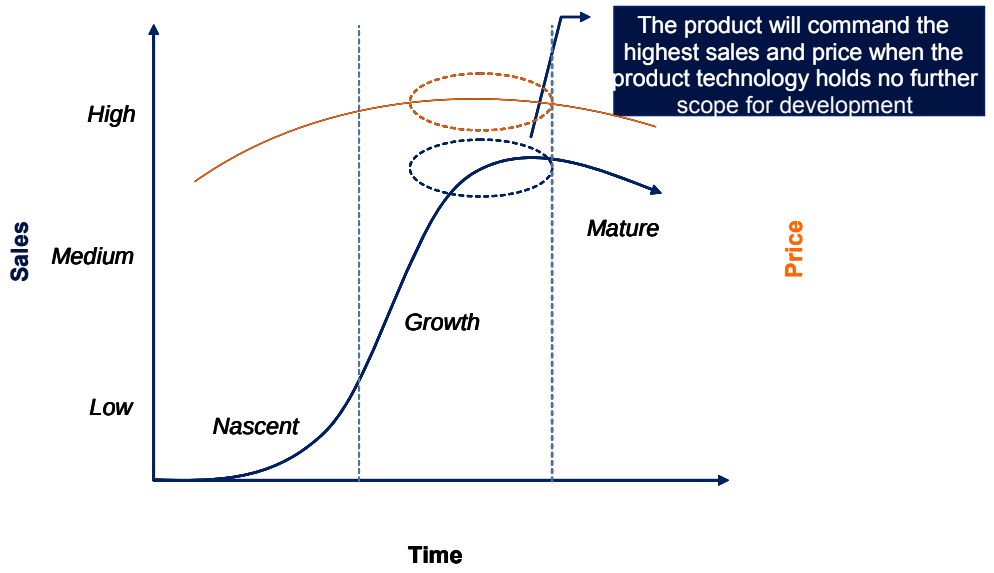
By merging the product lifecycle chart and sales vs. technology chart, we get combinations for sales – price and technology – time, as depicted in Figure 4.18. The pricing follows the product lifecycle. During the nascent stage the pricing strategies are largely influenced by market trends and competitive factors. However in the growth stage companies may increase revenues by charging a premium for a value addition in a product. During the mature stage the competitive and economical pricing are most often adopted due to entry of substitutes or novel technologies. However, pricing to a larger extent also depends on the investments in R&D. Novel technologies are therefore priced at a premium because of their sophistication with respect to ease of use and quality of output (E.g.: diagnosis). The adoption of novel diagnostics may not be boosted until higher reimbursement rates are provided for diagnostics employing innovative technologies as compared to conventional diagnostics, thereby restricting volume sales.

Figure 4.18: Price recommendations at product lifecycle stages



Source: Author's analysis

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Existing product technologies

If in a particular market, the OEM is only developing follow-on products (or a replica) of existing products on the market, then it has to follow the price which the market commands at that particular stage of the lifecycle.

For example when Arkray Piramal launched its self-monitoring blood glucose system (SMBG) in developing markets such as India, it followed the market in terms of existing price and thus priced its product between Bayer (bottom priced) and Roche (top priced). Thus, it had the option of pricing the product between the market leader and the market

laggard. This helped Arkray to achieve 5% market penetration in the developing markets. Arkray entered the market at the nascent to growth stage, where the number of sales are still expected to increase, along with the expected price appreciation. If it entered the market at the maturity stage, it would not have the option of pricing its product between Bayer and Roche. To achieve penetration, it would have had to price its product at the lowest price.

New product (first mover diagnostic) technologies

When the product technologies are new, the product lifecycle stage is nascent, and the price of the product is usually medium to high. This is justified by the product offering something superior to the existing products on offer. But the product cannot be highly priced as well. It needs the market to accept the product and use it. Hence the OEM cannot afford the price to become a barrier for purchase at the nascent stage. Once the market gets used to the product and the demand starts expanding, it can go for a price rise.

Payor engagement strategy

Almost universally, there are only two types of payors in the healthcare industry, public and private. In countries like the US and UK the public payor is the CMS and NHS. Any OEM when it comes to introducing a new product technology or a value-added product of existing technology understands the importance of reimbursement regulators. It understands the fact, that if the product is reimbursed by the regulators for the benefits it provides to patients, or can help solve any of the restraints affecting the healthcare industry in general, the regulators would provide incentives for such a product usage. For e.g. the UK faces a big problem of long patient waiting times for various procedures even for a CT scan, MRI scan or a mammography scan. A typical mammography scan using analogue systems takes about 1-2 hours to conduct. With an operating time of 8 hours per day a hospital may only be able to conduct five mammography scans. With OEMs focusing on

new technologies and developing digital mammographies, the amount of time required for the scan is greatly reduced to only 30 minutes. Additionally, its much easier, convenient and cost effective in the long term to archive and transport digital information as opposed to films. Various governments in Europe have started to either deploy digital mammography machines in their hospitals or are promoting and creating awareness among the patients to get their mammography scans done. In this way, they are looking to increase the number of patients diagnosed with potential breast cancer and provide preventive healthcare therapy.

To enable a scenario similar to the mammography instance listed above, it is imperative for the OEM to communicate with regulators and convince them of the added benefits to the patient, or to the healthcare industry as a whole. Taking the US as an example, the OEM takes the following steps in its pursuit of payor approvals.

The CMS follows the mantra of "reasonable and necessary". Hence OEMs invest considerably in gaining expertise to manage details of the approval process with the CMS. They also try to develop a long term business plan and accelerate the process of approval. There are two major strategies the companies employ to engage the payor:

- Convince the CMS of the added benefits to justify reimbursement or increase in reimbursement as compared to the existing status of reimbursement;
- Convince the local or the state government of the added benefits to justify reimbursement or increase in reimbursement as compared to the existing status of reimbursement. This is a particularly useful strategy for any OEM who is already working alongside state governments for any other venture.

Although, there are other ways to accelerate the process of approval for reimbursement, it is accepted that a minimum of 1-2 years would pass until the reimbursement is approved by the CMS or the state governments for the procedure under investigation.

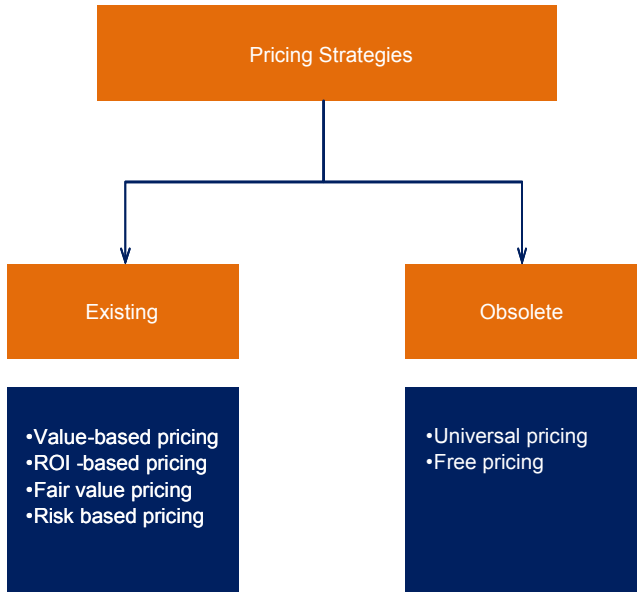
Introduction of separate business unit for pricing and reimbursement

The majority of OEMs present as major players in developed markets have a separate pricing and reimbursement department. This department usually works alongside the sales and marketing department. But it has specific responsibility to take on the regulatory authorities with regards to pricing and reimbursement. Usually the sales and marketing department concludes its negotiations on fair value pricing after which the product is introduced in the market with FDA/CE approval. The decision on reimbursement is only arrived at after a lengthy procedure and thus the reimbursement division negotiates with the CMS in the case of the US and tries to speed up the process. Its primary responsibilities include maintaining expertise for the company's related products, and help it achieve maximum reimbursement approval for its products. This prime motivation for OEMs to come up with a separate department is due to the amount of work involved in the reimbursement procedure. As mapped out earlier, the entire reimbursement pathway takes up almost 2 years. Within this time frame, the OEM needs to get the product into the market and start getting the requisite sales. Apart from that, there is a high level of expertise required while negotiating with the CMS authorities for the amount of reimbursements to pay for the procedure. This requires in depth knowledge of the reimbursement laws, coding structure, having extensive networks within the CMS, etc. The reimbursement department may or may not be integrated with the pricing department. The pricing department, usually headed by a pricing manager for the particular product or modality, has two major responsibilities:

- Decide the optimum pricing range for the product based on the negotiations with the CMS and End User Consortiums;
- Prepare a long term business plan giving pricing outlooks for the next five years considering the changing dynamics of the industry.

Novel pricing for existing and first mover diagnostic technologies to overcome reimbursement issues

Figure 4.19: Different pricing strategies



Source: Author's analysis

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We have already discussed two methods in which the OEMs price their products for existing diagnostic technologies: ROI-based pricing and value based pricing. Apart from these two methods of pricing, there are other pricing strategies which the OEMs follow at present, followed by those which are obsolete.

Fair value pricing

Apart from microeconomic factors affecting the price of products, currently the OEMs in developed countries face a unique dilemma. This has changed the structure of pricing in healthcare diagnostics permanently. This factor is the "Consortium of End Users". Almost all the high volume end users in the developed countries have formed a union or an association. This may or may not include the related public hospital authorities depending on the degree of public health penetration. These consortiums negotiate with the OEMs about the price before new products reach the market. Therefore the price range is decided between the OEMs and the end users before the OEMs price the product independently. For e.g. if Siemens is about to market 3T MRI in any Eastern European country, then the large hospitals, prominent radiologists and diagnosticians, will sit down with Siemens executives and negotiate the price for which they would buy the product. This concept of pricing is called 'Fair Pricing'. A fair price for any product is an agreed upon price between the OEM and the consortium of end users; in this case Siemens and the association of radiologists and hospitals. This is now being adopted in developed markets. This has also rendered the concept of premium pricing obsolete. Although, the product pricing range is decided only for a set time i.e. 2 -3 years, after that the OEM is free to price the product in a manner it feels suitable.

Risk based pricing

Adopted by many lenders in the mortgage and financial services industry risk based pricing primarily measures loan risk in terms of interest rates and other fees. The interest rate on a loan is arrived at by estimating the time value of money, and the probability that the borrower will default. Risk-based pricing can be considered a complex form of free pricing, but necessarily functions on the same fundamentals with regards to a balance between supply and demand.

This concept of pricing has entered the healthcare diagnostics industry recently. Currently, the OEM prepares a product for the industry and charges the end users a price in return for it. The OEM decides the price of the product based on the factors discussed above. There can be many end users who might not be able to afford that price. Hence, these end users stand a chance of losing out on business opportunities that services attributed to that new product could offer. To circumvent this and to increase their product penetration, the OEMs decide to take the risk of entering into partnerships with the healthcare service providers.

For e.g. Roche currently offers immunoassay solutions in most of the countries it has a direct presence in. Within the immunoassay market, there are three revenue segments for Roche.

- Immunoassay analyzer;
- Immunoassay reagents;
- Immunoassay analyzer service contracts.

Consider a top 20 pathology laboratory in the US, which performs almost 1,000,000 tests per month. The pathology lab wishes to invest in Roche's new immunoassay analyzer based on electrochemiluminescence technology, but is unable to finance it completely. Roche is willing to provide the analyzer, as the business of the laboratory in terms of the number of tests is excellent. Hence the following solution:

Roche would offer the analyzer at a discounted price, if the pathology lab agrees to provide Roche with at least 100,000 tests per month. For doing these tests, the pathology lab requires assays which they agree to buy from Roche, in return, at a market price. Therefore Roche has shared the end user's risk by discounting the new analyzer whilst including a clause in the contract which guarantees a large amount of business in other segments. In

addition by taking a risk sharing approach Roche is also earning revenue from the supply of consumables i.e. assays.

There can be many types of risk based pricing such as those based on:

- Revenue;
- Patients;
- Number of surgeries
- Accreditation, etc.

OEMs are seeking full market penetration, but they face the hurdle of high initial investment required by the end user for their equipment. To reduce this risk and make the product more viable when compared to competitors, OEMs employ these types of risk sharing pricing arrangements.

Outsourcing pricing & reimbursement strategies

Increasing numbers of OEMs stuck in an existing market with average to low growth rates and facing intense competition are looking to outsource their pricing and reimbursement strategies to third party specialists. These specialists are primarily consultants and are experts in understanding the reimbursement mechanism for the market under study. They are also experts in terms of determining the optimal level of pricing for any product in these mature markets. Due to the above factors and enhanced interaction with reimbursement and regulatory bodies and negotiation abilities outsourcing stands differentiated from the creation of separate business unit. However, confidentiality issues in this model still remains a challenge.

The primary objective of outsourcing pricing and reimbursement services to consultants is to allow the OEM to concentrate on product development and sales and distribution. Pricing and reimbursement issues cannot be overlooked, and at the same time require experts, which increase manpower costs, which would result in deviation from the company's original expertise of product development, and sales and marketing of its products. Rather than developing an in-house expertise, this is outsourced to experts. For e.g. one of the top consultants in Europe, confirmed with us that most of his clients within the medical device segments have approached him for two reasons, expertise in the field of reimbursements and saving administrative costs.

Universal pricing

Universal pricing refers to when a particular product is launched simultaneously in all markets at the same price. Within healthcare diagnostics, the market conditions vary from country to country, and OEMs source various parts of products from different countries which results in it being almost impossible for OEMs to decide on only one price for its products. As such this strategy is rarely employed. Yet there are many possibilities where such a scenario can be employed, such as:

- If the OEM manages to manufacture the product at only one location and sources the parts from that location only;
- If the OEM decides to bring in transparency with respect to pricing. Such a move has a positive impact on brand equity of the OEM with respect to end users;
- If the OEM has a monopoly with respect to the products and its technology.

Free pricing

A free price mechanism followed by OEMs in an ideal macroeconomic environment, is where prices are set by the interchange of supply and demand. One of the major

advantages of free pricing is that the pricing reflects the result of the balance between demand and supply. While the disadvantage is that pricing will continuously fluctuate and is thus not advisable for healthcare diagnostic products, especially keeping in mind competition and brand image. A perfect example of free pricing can be equity and bond rates within the financial ecosystem. The price fluctuates continuously reflecting the status of demand and supply for the underlying security. Although under a free pricing economy and a dynamic market with a very short life span this type of pricing is usually undertaken. However, owing to the long gestation period for innovation and commercialization (10 to 15 years), free pricing has not been very relevant to medical devices. Another major risk with a free pricing mechanism is the threat of extremely low prices if product demand goes down. Fluctuations in prices may therefore impact the business to a significant level. Therefore this pricing method is no longer employed with respect to the medical device industry.

Strategic recommendations

Innovations to demand a price premium

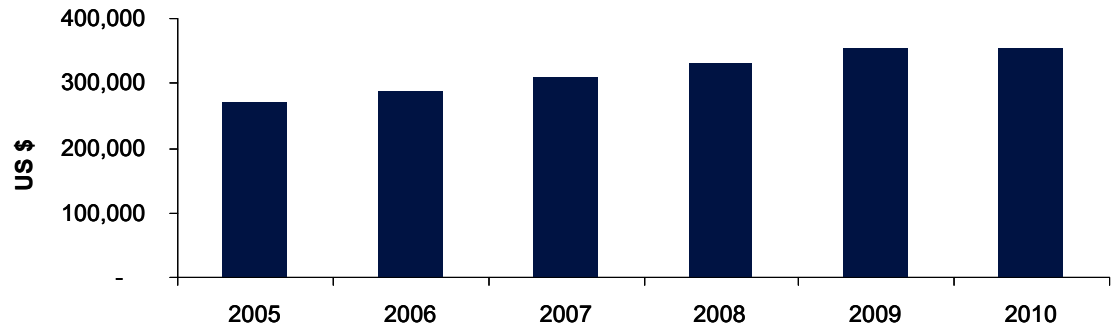
The demand price premium strategy (value pricing) as discussed earlier is one of the most commonly employed strategies by OEMs worldwide when launching a new product. Yet in recent times certain modifications have been made to this strategy, such as fair value pricing, universal pricing, etc.

Case study – Average selling price of mammography units

As shown in Figure 5.19, the average selling price of mammography units over the years has grown marginally by ~ 7%. Prices are gradually flattening out. This is primarily due to various factors such as the advent of new technologies, digital mammography and an increase in competition. But one of the significant factors contributing to the plateauing of

prices is the absence/partial reimbursement for procedures with these machines. This is starting to affect the demand for these systems negatively. Consequently, OEMs fear a possible rejection of their new technologies by the market due to reimbursement policies. To avoid this a different type of pricing "fee for service" for new technologies has been introduced. Some of these new technologies are exact 3D mammography in the digital segment and breast CT mammograms.

Figure 5.19: Mammography: Average selling price ($)for U.S., 2005-10



Source: Primary Research Demand side

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Fee for service

This is a model where the offered services are not in a form of a package i.e. unbundled and as such are paid for individually.

For example doctors and other healthcare providers provide services such as consultation, diagnostics tests, in-patient services, etc. Fee-for-service plan allows a patient to choose the care from doctors or hospitals but in return for this flexibility they are required to pay higher co-payments or deductibles. Mammography with Breast CT service providers are looking to follow this model while providing the services.

Reduced time to market to generate faster ROI

Healthcare diagnostic products currently face a highly competitive environment. OEMs return on investment (ROI) is becoming severely compromised particularly in developed markets, with the lack of support from the government in terms of reimbursement for new procedures and high cost of market introduction. This has resulted in greater emphasis on reducing the time to market for new products. OEMs all over the world are thus concentrating their efforts on and investment in areas other than their sales channels such as intellectual capital, and building relationships with key opinion leaders (KOL), etc.

For instance, the use of sensitizers in PET scan still has a long way to go in terms of inspiring confidence for its usage commercially. Yet there are various OEMs who are looking to invest additionally to receive patents and FDA approval for these compounds. Apart from increasing intellectual capital, various OEMs are also looking to consolidate their sales channels. For example Bayer and Medtronics have collaborated within the diabetes segment with Bayer's Contour blood glucose test systems wirelessly transmitting results to Medtronics' Minimed Paradigm insulin pumps and Guardian glucose monitoring systems. Such alliances utilize synergies of OEMs for the benefit of both companies and reduce the need for additional investment in sales and distribution channels. This freed up capital is used to invest in bringing new products to the market as early as possible.

Technologies addressing unmet clinical needs to benefit diagnostics providers

Increased focus on innovations and new technologies result in providing the OEMs with a head start against their competitors. Hence the product development teams within all the major OEMs are constantly looking at unmet needs of the end users i.e. practicing medical professionals as their source of ideas for new products. This practice by OEMs is backed by Professor Clayton M. Christensen, a thought leader on innovation and business growth at Harvard Business School and the author of the best selling, 'The Innovator's Solution'. While studying the innovations in healthcare, he too found that the majority of medical

device innovations are actually a result of ideas within the minds of practicing medical professionals. Hence OEMs place great emphasis on collaborating with end users directly when the product is in the development stage.

One such example is that of collaboration within the field of molecular imaging. Philips Healthcare and VU University Medical Center, Amsterdam have signed an agreement to jointly conduct a research on new multimodality solutions. These solutions are aimed at improving the early detection and treatment of cancer and neurological and cardiovascular diseases. While Philips is able to design a product with the help of end users, it addresses the unmet needs with current technology. It's a win-win situation for both OEMs and end users.

CHAPTER 5

Appendix

Chapter 5 Appendix

Table 6.3: Indicative prices for in vitro diagnostic equipment – US

Types	Cost ($)	Specification
Hematology Analyzer	8,575 to 9,645 10,720 to 13,934	3 Test 5 Test
Urine Analyzer	2,143	
Immunoassay Analyzer	32,154 to 42,873	
Biochemistry Analyzer Fully automated Semi-automated	 32,154 to 42,873 2,786 to 4,288	
Microbiology Culture Analyzer	34,000	

Source: Author's research/primary research Business Insights Ltd

Table 6.4: Indicative reimbursement for in vitro diagnostic tests – US

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Acetaminophen	82003	Acetaminophen		$28.99
Acid Phosphatase (Not on the 1200)	84060	Phosphatase, acid; total		$10.57
Albumin	82040	Albumin; Serum, Plasma or whole blood		$7.09
Alk Phosphatase AMP	84075	Phosphatase, Alkaline;		$7.41
Alk Phosphatase DEA	84075	Phosphatase, Alkaline;		$7.41
Alpha- 1-Antitrypsin	82103	Alpha-1-antitrypsin; Total		$19.24
ALT	84460	Transferase; Alanine Amino (ALT) (SGPT)		$7.58
ALTP5P	84460	Transferase; Alanine Amino (ALT) (SGPT)		$7.58
Ammonia	82140	Ammonia		$20.87
Amylase	82150	Amylase		$9.29
Anti-Streptolysin (Not on the 1200)	86060	Antistreptolysin 0; Titer	CCI	$10.46
Apolipoprotein A1	82172	Apolipoprotein, Each		$22.19
Apolipoprotein B	82172	Apolipoprotein, Each		$22.19
AST	84450	Transferase; Aspartate Amino (AST) (SGOT)		$7.41
ASTP5P	84450	Transferase; Aspartate Amino (AST) (SGOT)		$7.41

Source: www.codemap.com

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Table 6.5: Indicative reimbursement for in vitro diagnostic tests – US (contd. 1)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Basic metabolic panel (Calcium, total)	80048	Basic metabolic Panel. This panel must include the following: Calcium (82310) Carbon dioxide (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) UREA Nitrogen (BUN) (84520)	CCI	$12.12
Bilirubin_2, Direct	82248	Bilirubin; Direct		$7.19
Bilirubin_2, Total	82247	Bilirubin; Total		$7.19
CardioPhase hsCRP	86141	C-Reactive protein; high sensitivity (HSCRP)	CCI	$18.54
C3	86160	Complement; Antigen, each component		$17.20
C4	86160	Complement; Antigen, each component		$17.20
Calcium	82310	Calcium; Total	CCI	$7.39
	82331	Calcium; After Calcium Infusion Test	CCI	$7.41
	82340	Calcium; Urine Quantitative, Timed specimen		$8.64

Source: www.codemap.com

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Table 6.6: Indicative reimbursement for in vitro diagnostic tests – US (contd. 2)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Calcium_2	82310	Calcium; Total	CCI	$7.39
	82331	Calcium; After Calcium infusion test	CCI	$7.41
	82340	Calcium; Urine Quantitative, Timed specimen		$8.64
Carbamazepine	80156	Carbamazepine; Total		$20.85
Carbon Dioxide-L	82374	Carbon dioxide (Bicarbonate)		$7.00
Chloride ISE	82435	Chloride; Blood		$6.58
	82436	Chloride; Urine		$7.20
Cholesterol	82465	Cholesterol, Serum or whole Blood, Total	CCI NCD	$6.24
Cholinesterase	82480	Cholinesterase; Serum		$11.29
Creatine Kinase	82550	Creatine Kinase (CK), (CPK); TOTAL	CCI	$9.33
Creatinine, Enzym_2	82565	Creatinine; blood		$7.34
	82570	Creatinine; other source		$7.41
	82575	Creatinine; clearance	CCI	$13.53
Creatinine_2	82565	Creatinine; blood		$7.34
	82570	Creatinine; other source		$7.41
	82575	Creatinine; Clearance	CCI	$13.53
CRP_2	86140	C-reactive protein;		$7.41

Source: www.codemap.com

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Table 6.7: Indicative reimbursement for in vitro diagnostic tests – US (contd. 3)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Cystatin C	82610	Cystatin C		$19.47
Digoxin	80162	Digoxin	NCD	$19.02
Direct LDL Cholesterol	83721	Lipoprotein, Direct measurement; LDL Cholesterol	CCI NCD	$13.66
Ecstasy	80101	Drug screen, qualitative; Single drug class method (EG, immunoassay, enzyme assay), Each drug Class	CCI	$19.72
	G0431	Drug screen, Qualitative; Single Drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Ethanol	82055	alcohol (ethanol); any specimen except breath		$15.47
GGT	82977	Glutamyltransferase, GAMMA (GGT)	NCD	$10.31
Gentamicin	80170	Gentamicin		$23.48

Source: www.codemap.com

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Table 6.8: Indicative reimbursement for in vitro diagnostic tests – US (contd. 4)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Glucose-Hexokinase	82947	Glucose; Quantitative, Blood (except reagent strip)	CCI NCD	$5.62
	82950	Glucose; Post Glucose dose (includes glucose)	CCI	$6.80
	82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)	CCI	$18.44
	82952	Glucose; tolerance test, each additional beyond 3 specimens	CCI	$5.61
	82955	Glucose-6-Phosphate Dehydrogenase (G6PD); Quantitative		$13.89
Glucose-Oxidase	82947	Glucose; Quantitative, Blood (except reagent strip)	CCI NCD	$5.62
	82950	Glucose; Post glucose dose (includes glucose)	CCI	$6.80
	82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)	CCI	$18.44
	82952	Glucose; Tolerance test, each additional beyond 3 specimens	CCI	$5.61
Haptoglobin	82030	Adenosine, 5-Monophosphate, Cyclic (cyclic amp)		$36.95
HbA1c	83036	Hemoglobin; Glycosylated (A1C)	NCD	$13.90

Source: www.codemap.com

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Table 6.9: Indicative reimbursement for in vitro diagnostic tests – US (contd. 5)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Direct HDL Cholesterol	83718	Lipoprotein, Direct measurement; High density Cholesterol (HDL Cholesterol)	CCI NCD	$11.73
IgA_2	82784	Gammaglobulin (Immunoglobulin); IGA, IGD, IGG, IGM, each	CCI	$13.32
IgG_2	82784	Gammaglobulin (Immunoglobulin); IGA, IGD, IGG, IGM, each	CCI	$13.32
IgM_2	82784	Gammaglobulin (Immunoglobulin); IGA, IGD, IGG, IGM, each	CCI	$13.32
Inorganic Phosphorus	84105	Phosphorus Inorganic (phosphate); Urine		$7.41
Iron_2	83540	Iron	NCD	$9.28
Lactate	83605	Lactate (Lactic acid)		$15.30
Lactate Dehydrogenase L-P	83615	Lactate Dehydrogenase (LD), (LDH);		$8.64
Lactate Dehydrogenase P-L	83615	Lactate Dehydrogenase (LD), (LDH);		$8.64
Lipase	83690	Lipase		$9.86
Lithium	80178	Lithium		$9.46
Magnesium	83735	Magnesium		$9.60
Microalbumin	82043	Albumin; Urine, Microalbumin, Quantitative	CCI	$8.29
Pancreatic Amylase	82150	Amylase		$9.29

Source: www.codemap.com

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Table 6.10: Indicative reimbursement for in vitro diagnostic tests – US (contd. 6)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Phenobarbital	80184	Phenobarbital		$16.41
Phenytoin	80185	Phenytoin; Total		$18.99
Potassium ISE	84132	Potassium; Serum, Plasma or whole blood		$6.58
	84133	Potassium; Urine		$6.16
Prealbumin	84134	Prealbumin		$20.89
Rheumatoid Factor	86431	Rheumatoid factor; Quantitative		$8.13
Salicylate	80196	Salicylate		$10.16
Serum Barbituates	80101	Drug screen, Qualitative; Single drug class method (EG, immunoassay, enzyme assay), Each drug class	CCI	$19.72
	G0431	Drug screen, Qualitative; single drug class method (E.G., Immunoassay, enzyme assay), each drug class		$19.72
Serum Benzodiazepine	80101	Drug screen, Qualitative; Single drug class Method (EG, Immunoassay, enzyme assay), Each drug class	CCI	$19.72
	G0431	Drug screen, Qualitative; Single drug class method (E.G., Immunoassay, enzyme assay), Each drug class		$19.72

Source: www.codemap.com

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Table 6.11: Indicative reimbursement for in vitro diagnostic tests – US (contd. 7)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Serum Tricyclic Anti-depressant	80101	Drug screen, Qualitative; Single drug class method (EG, Immunoassay, enzyme assay), Each drug class	CCI	$19.72
	G0431	Drug screen, Qualitative; Single drug Class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Sodium ISE	84295	Sodium; Serum, plasma or whole blood		$6.89
	84300	Sodium; Urine		$6.96
Theophylline	80198	Theophylline		$20.27
TIBC	83550	Iron binding capacity	NCD	$12.52
Tobramycin	80200	Tobramycin		$23.09
Total Protein (UA) (UPRO_2)	84156	Protein, total, except by refractometry; urine		$5.25
	84157	Protein, total, except by refractometry; other source (eg, synovial fluid, cerebrospinal fluid)		$5.25
Total Protein_2	84155	Protein, total, except by refractometry; serum, plasma or whole blood	CCI	$5.25
Transferrin	84466	Transferrin	CCI NCD	$18.29

Source: www.codemap.com

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Table 6.12: Indicative reimbursement for in vitro diagnostic tests – US (contd. 8)

Test Name	CPT Code	Code Description	Medicare Coverage	National Reimbursement
Triglyceride	84478	Triglycerides	CCI NCD	$8.24
Urea Nitrogen (BUN)	84520	Urea nitrogen; quantitative		$5.65
	84540	Urea nitrogen, urine		$6.80
	84545	Urea nitrogen, clearance		$9.46
Uric Acid	84550	Uric acid; blood		$6.47
Valproic Acid	80164	Dipropylacetic acid (valproic acid)		$19.40
Vancomycin	80202	Vancomycin		$19.40
wrCRP	86141	C-reactive protein; high sensitivity (HSCRP)	CCI	$18.54

Source: www.codemap.com

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Table 6.13: Indicative reimbursement for toxicology/DAU (Drugs of Abuse) tests

Test Name	CPT Code(s)	CPT Description	Medicare Coverage	National Reimbursement Limit
Amphetamines (AMPHET)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Barbiturate (BARB)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72

Source: www.codemap.com

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Table 6.14: Indicative reimbursement for toxicology/DAU (Drugs of Abuse) tests

Test Name	CPT Code(s)	CPT Description	Medicare Coverage	National Reimbursement Limit
Benzodiazepine (BENZO)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Cannabinoid (THC)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Cocaine Metabolite	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay)		$19.72

Source: www.codemap.com

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Table 6.15: Indicative reimbursement for toxicology/DAU (Drugs of Abuse) tests

Test Name	CPT Code(s)	CPT Description	Medicare Coverage	National Reimbursement Limit
Methadone (METHA)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Methadone Metabolite (METMTB)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Opiate (OP2000)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay),	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay)		$19.72

Source: www.codemap.com

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Table 6.16: Indicative reimbursement for toxicology/DAU (Drugs of Abuse) tests

Test Name	CPT Code(s)	CPT Description	Medicare Coverage	National Reimbursement Limit
Opiate (OP300)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Phencyclidine (PCP)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72
Propoxyphene (PROPOX)	80101	Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class	CCI	$19.72
	G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class		$19.72

Source: www.codemap.com

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Table 6.17: Indicative reimbursement for point of care tests

Product/Test	Instrument System Reimbursement	CPT Code(s)	CPT Description	Medicare Coverage	National
Multistix® 10 SG N-Multistix® SG N-Multistix® Multistix® 9 Multistix® 8 Multistix® 7		81000	Urinanalysis, non-automated, with microscopy	CCI	$4.54
Multistix® PRO Hema-Combistix Combistix Multistix® 2 Ictotest Labstix Microstix-3t	Manual methods	81000	Non-automated, without microscope	CCI	$3.66

Source: www.codemap.com

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Table 6.18: Indicative reimbursement for Microalbumin and Creatinine tests

Product/Test	Instrument System	CPT Code(s)	CPT Code Description	National Reimbursement
CLIA Certificate of Waiver Methods				
Microalbumin	CLINITEK® 50 Analyzer	82044-QW	Albumin, urine, microalbumin, semiquantitative (e.g. reagent strip assay)	$ 6.56
Creatinine	CLINITEK® Status Analyze	82570-QW	Creatinine, other source	$ 7.41
CLIA Moderate/High Complexity Methods				
Microalbumin	CLINITEK® 100 Analyzer CLINITEK® 50 Analyze	82044	Albumin, urine, microalbumin, semiquantitative (e.g. reagent strip assay)	$ 6.56
Creatinine	CLINITEK® Status Analyze	82570	Creatinine, other source	$ 7.41

Source: www.codemap.com

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Table 6.19: Indicative Reimbursement for various kind of Hemoglobin tests

Product/Test	Instrument System	CPT Code(s)	CPT Code Description	Medicare Coverage	National Reimbursement
A1C	DCA Vantage™ Analyzer	83036-QW	Hemoglobin A1C	NCD	$13.90
	DCA 2000+ Analyzer				
Microalbumin	DCA Vantage™ Analyzer	82043	Microalbumin	CCI	$8.29
	DCA 2000+ Analyzer				
Creatinine	DCA Vantage™ Analyzer	82570	Creatinine, other source		$7.41
	DCA 2000+ Analyzer				

Source: www.codemap.com

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Table 6.20: Indicative prices for in vivo diagnostic equipment ($) – US

	2005	2006	2007	2008	2009	CAGR
CT (64 Slice)	1,732,050	2,000,000	2,309,400	2,666,664	3,079,197	15%
Mammography	270,000	288,900	309,123	330,761	353,914	7%
MRI	2,947,200	3,619,162	4,444,330	5,457,638	6,701,979	23%

Source: Author's research and analysis

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Table 6.21: Indicative reimbursement for in-vivo diagnostic tests – US

2009 Medicare Reimbursement for CT Colonography

CPT Code	Reimbursement Component	Hospital Inpatient Department	Hospital Outpatient Department	IDTF and Physician Office
CPT 0067T Computed tomographic (CT) colonography (ie, virtual colonoscopy); diagnostic [Do not report 0066T or 0067T in conjunction with 72192-72194, 74150-74170]	Technical	Included in MS-DRG	$194.39	Carrier-priced
	Professional	Carrier-priced	Carrier-priced	Carrier-priced
	Total	MS-DRG + Carrier-priced	$194.39 + Carrier-priced	Carrier-priced/ CAP

Source: www.gehealthcare.com

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Table 6.22: Medicare reimbursement for mammography services

Technology Outpatient/	CPT/HCPCS Code	Reimbursement Component	Hospital IDTF/ Physician Office8
Computer Aided Detection (CAD)	CPT 77051 Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography (List separately in addition to code for primary procedure)	Technical Professional Total	$14.02 $3.03 $17.05
	CPT 77052 Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; screening mammography (List separately in addition to code for primary procedure)	Technical Professional Total	$14.02 $3.03 $17.05
Plain Film	CPT 77055 Mammography; unilateral	Technical Professional Total	$44.72 $33.35 $78.07
	CPT 77056 Mammography; bilateral	Technical Professional Total	$56.09 $41.31 $97.40
	CPT 77057 Screening mammography, bilateral (2-view film study of each breast)	Technical Professional Total	$48.51 $33.35 $81.86

Source: www.gehealthcare.com

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Table 6.23: Medicare reimbursement for mammography services

Technology Outpatient/	CPT/HCPCS Code	Reimbursement Component	Hospital IDTF/ Physician Office8
Digital	HCPCS G0202 Screening mammography, producing direct digital image, bilateral, all views	Technical Professional Total	$98.15 $33.35 $131.50
	HCPCS G0204 Diagnostic mammography, producing direct digital image, bilateral, all views	Technical Professional Total	$101.19 $41.31 $142.50
	HCPCS G0206 Diagnostic mammography, producing direct digital image, unilateral, all views	Technical Professional Total	$81.48 $33.35 $114.83

Note: Values for 2007; reflect national rates, unadjusted for locality

Source: www.gehealthcare.com

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Table 6.24: 2005 Medicare payment for magnetic resonance imaging of the joints of the extremities

CPT Code	Reimbursement Component	Independent Diagnostic testing Facility(IDTF) or physician office
CPT 73221 Magnetic resonance (eg, proton) imaging, any joint of upper extremity; without contrast material(s)	Technical Professional Total	$439.23 $70.11 $509.34
CPT 73721 Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material	Technical Professional Total	$439.23 $70.11 $509.34

Source: www.gehealthcare.com

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Table 6.25: 2007 Medicare reimbursement for SPECT/CT for selected tumor imaging and localization

CPT Code	Reimbursement Component	Hospital Inpatient Department	Hospital Outpatient Department	IDTF and Physician Office
CPT 78803 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic	Technical	Included in DRG	$245.47	$245.47
	Professional	$52.68	$52.68	$52.68
	Total	DRG + $52.68	$298.15 (SPECT)	$298.15
CPT 78999 Unlisted miscellaneous procedure, diagnostic nuclear medicine	Technical	Included in DRG	$84.54	Carrier Priced
	Professional	Carrier Priced	Carrier Priced	Carrier Priced
	Total	DRG + Carrier Priced	$84.54 + Carrier Priced	Carrier Priced

Source: www.gehealthcare.com

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