BACKGROUND

• Market access for innovative new technologies can be complex and time consuming. Decentralized health care decision making can be a significant hurdle.

OBJECTIVE

• To characterize the process and identify challenges for health technology assessment (HTA) and market access for new point of care (POC) tests in the European Union (EU-5).

METHODS

• Desktop research of published literature, HTA reports, and third-party websites was conducted to identify the critical path and data most valuable to reimbursement decision making.

• Twenty-four qualitative interviews were conducted with payer decision makers in the EU-5: 12 key opinion leaders (KOLs), 2 laboratory directors, and 10 academic health economists and HTA advisors.

RESULTS AND DISCUSSION

France

HTA

• National level
  – HTA is primarily conducted nationally by the HAS (National Authority for Health).
  – The CNEDEMTS (National Committees for Medical Devices and Technologies Assessment), within HAS, assesses usefulness, interest, and need of medical devices and other non-drug health care products.

• Regional level
  – The ARS regional health agencies) may conduct a separate assessment but largely rely on national level assessment.

Hospital level

• The COMEDIMS (Committees for Drugs and Sterile Medical Devices) may conduct separate assessments that fit in the diagnosis-related group (DRG) system.

Reimbursement

• National level
  – The Health Ministry uses appraisals conducted by CNEDEMTS to determine reimbursement for a medical device or diagnostic. Reimbursement rate is 80%.

• Regional level
  – The ARS plan hospital and ambulatory budgets according to population needs.

• Hospital level
  – COMEDIMS makes decisions for medical device listings on the hospital formulary.

Germany

Market Access for POC Diagnostics: Outpatient Sector

• Reimbursement for a POC diagnostic test must fit in an existing EBM (reimbursement tariff for outpatient services) code, or a new code must be established.

• Appendix 22 of the basic agreements between Statutory Health Insurance (SHI) and the SHI physicians may require national-level formal assessment to obtain a new EBM outpatient reimbursement code. Manufacturers would work with medical societies and professional physician organizations to get support for application of a new EBM code.

• Adoption will occur on a facility-by-facility basis.

• Manufacturers may work through the diagnostics industry association (VDG, Association of Diagnostic Industry).

Market Access for POC Diagnostics: Inpatient Sector

• Hospital-level purchasing decisions are driven by physicians’ needs and budgets. Stakeholders may include laboratory, unit, and medical directors, and administration staff.

• Manufacturers should provide samples, a convincing data package, and an evidence dossier.

Italy

Market Access for POC Diagnostics: No Formal Route

• Historically, there has been no national-level evaluation of medical devices and diagnostics before market entry; however, the national HTA agency (AGENAS, Agency for Regional Health Services) is evaluating more medical devices and diagnostics.

• After obtaining a CE mark, market entry of medical devices and diagnostics is highly localized and is approached at the regional and/or local levels through negotiations (based on evidence of clinical use and the budget impact).

Market Access for POC Diagnostics: Regional Level

• During clinical development, manufacturers should build stakeholder interest in the POC test. Conducting clinical trials in collaboration with KOLs may increase chances of adoption.

• After obtaining the CE mark, manufacturers should approach agencies sanitaria regionali (ASRs, regional health agencies) to gain market access.

  – Manufacturers should develop evidence dossiers that include key data supporting the value proposition (e.g., impact on patient adherence, resource use, and budget impact).

  – Some regions (i.e., Emilia-Romagna and Veneto) have CRM (regional medical devices committees) that are aligned with the ASRs that may evaluate the POC diagnostic.

Market Access for POC Diagnostics: Local Level

• Manufacturers should approach the ASRs (local health units), which administer the PSN (National Health Care Plan), to gain support and to initiate marketing and sales; manufacturers should provide an evidence dossier that incorporates clinical evidence, budget impact, and price, concentrating first on ASRs known to be early adopters of technology.

• Manufacturers should approach individual health care facilities and build support among physicians and facility directors/administrators.

• In some outpatient hospital facilities, manufacturers may approach decision makers on hospital HTA committees (CPTOs), which evaluate drugs and medical devices and diagnostics for purchase.

Market Access for POC Diagnostics: No Formal Route

• National and/or regional HTA review is not necessary for hospital adoption of medical devices and diagnostics, although favorable national HTA review may lead to approval listing with the Spanish Medicine Agency (AEMPS).

• Hospitals can purchase medical devices and diagnostics from their own budgets, regardless of national HTA review (under DRG-based hospital systems).

Market Access for POC Diagnostics: Local Level

• Depending on device profile, acceptance decisions may be made at the hospital/clinic level. For innovative devices, the decision can be made at higher levels.

• Manufacturers should approach decision makers at three to five hospital facilities. Per recommendation of hospital physician, hospital committees evaluate drugs and medical devices and diagnostics for purchase.

• Hospital clinicians and manufacturers should negotiate with facility budget decision makers to have the POC diagnostic paid for by the health care facility budget, established by the regional authority. Initial adoption will continue using the same procedure at subsequent health care facilities.

Market Access for POC Diagnostics: Regional Level

• Once a local-level use is established, manufacturers should approach the regional HTA agencies to conduct an evaluation of the POC diagnostic with support from leading academic facilities.

  – Key elements are test performance, convenience, impact on the internal working processes (e.g., reduce workload, time, complexity), and price.

  – If the regional HTA review is favorable, the regional can require use of the POC diagnostic (will paid for within the health care facility budget).

• Health care facilities can choose to use the test and pay for it with their budget on a facility-by-facility basis.

CONCLUSIONS

• Three mechanisms are used by primary care trusts (PCTs) to pay for health care products and services:
  – Payment by results: DRG system to fix prices for 1,000 hospital procedures (e.g., diagnostic testing and some outpatient procedures).
  – Block contracts: agreements between PCTs and health care providers to use and pay for a product or service.
  – Global budgeting: purchasing products or services with the health care system’s budget.

Market Access for POC Diagnostics: Start at the Local Level

• The UK is largely decentralized for medical devices and diagnostics, with no formal pathway to market access.

• Manufacturers should directly approach physicians and directors of health care teams and facilities and should use evidence communication materials (e.g., test performance, reliability, cost-effectiveness, price, budget impact, and anticipated cost savings).

Market Access for POC Diagnostics: Submission of Evidence to NICE

• Evidence dossier
  – The National Institute for Care Excellence (NICE) require more rigorous data than those targeted to providers, strategic health authorities, mental health trusts, secondary care trusts, or PCTs.

• Manufacturers producing frequent public information upon assessment by NICE, providing a reduced likelihood for negotiation at a provider-by-provider basic basis.

Market Access for POC Diagnostics: Future Changes

• The UK is moving to a more centralized (albeit still regionalized) market for medical devices with 151 local PCTs being replaced by regionalized GP commissioning consortia in 2014.

• Manufacturers should approach GP commissioning consortia directly rather than providers, mental health trusts, or secondary care trusts.

• GP consortia will require a NICE assessment to adopt POC diagnostics and select a NICE review if they are interested in adopting.

• Alternatively the manufacturer can initiate a NICE assessment at the national level.

REFERENCE


CONTACT INFORMATION

Susan L Hogue, PharmD, MPH, RTI Health Solutions
Phone: +1 313.541.6313 E-mail: shogue@rti.org

Point Of Care Tests: The Long and Winding Road to Reimbursement

Susan L Hogue, Andrew P Brogan, Anne Heyes

1 RTI Health Solutions, Research Triangle Park, NC, United States; 2RTI Health Solutions, Manchester, United Kingdom

Figure 2. Determination of Reimbursement Source in France

Source: ISPOR, 2011.

Figure 3. Critical Path for France

Figure 4. Critical Path for the UK

RTI Health Solutions, Research Triangle Park, NC, United States; RTI Health Solutions, Manchester, United Kingdom