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Biomarkers and Companion Diagnostics - Payer views

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Abstracts

Winning Payer Support for Companion Diagnostics & Biomakers

How can you positively influence payer attitudes to biomarkers and companion diagnostics (CDx)?

Biomarkers and CDx are critical to realising the personalised medicines agenda. They support clinician decision making and are cost efficient for payers. But payers identify challenges around evidence of clinical utility, inconsistent practice between - and within – countries, and question who, ultimately, should pay the biomarker/CDx bill. What can pharma, biomarker and CDx developers learn from these critical insights?

Report Overview

In Biomarkers and Companion Diagnostics: Payer Insights, 10 US and EU5 payers with expertise in product assessment, formulary management and healthcare strategy reveal the touchpoints that impact payer decision making and the ways industry can both meet their needs and achieve successful commercial outcomes.

Report Features

Unique insights from US and EU payer experts

Key actionable insights for how pharma and CDx developers can improve payer engagement

Specific focus on the differing payer attitudes and practices in the EU5 and US

Table: FDA approved drugs with CDx

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Key Benefits

Get up to speed on the latest US and EU CDx regulation and guidance

Investigate on a country by country basis how CDx/biomarkers are assessed and funded

Know the critical evaluation and evidence criteria payers set for CDx/biomarkers

Appreciate the difference between CDx and complementary diagnostics and why it matters

Identify the challenges payers face in making adoption and reimbursement

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decisions for CDx/biomarkers

Develop strategies to support payers via risk sharing and patient access agreements

Stay ahead of the game by fully engaging payers early on upcoming product/CDx launches

Understand how better pharma/payer communications will be essential as more biological drugs with CDx hit the market.

Key Questions Answered by this report

Guidance: What is the latest FDA and EMA CDx and biomarker guidance and how is it impacting practice and approach?

How accurate? Positive and negative CDx results can be valuable, but too many false negatives undermines confidence. What must companies do to keep payers supportive?

Who pays? While payers accept the obligation to use mandated CDx, what support and initiatives can pharma deliver to mitigate the cost burden

Early Engagement: What are the benefits to pharma of engaging with payers early and what development stage is seen as most appropriate?

Complementary Diagnostics: What are payer attitudes to complementary diagnostics and how might that influence product development strategies?

Country variables: How does the assessment and reimbursement of CDx vary between the US, UK, Germany, Italy, France and Spain and what practical impact does that have for your marketing and communications strategy?

Biosimilars: What are the issues biosimilar developers need to take into account when developing a product with a mandated CDx on the original product label?

Expert Views

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Each industry expert has been carefully selected for their practical experience and detailed current knowledge of payer pressures and the payer/pharma relationship.To ensure candid responses, the identities of all respondents have been kept anonymous./Paragraph>

French Payer

This individual is a key influencer on a pricing and reimbursement committee and he has particular awareness of current and evolving trends in biomarkers and companion diagnostics. His department comprises research units in clinical pharmacology and pharmaco-epidemiology and he is directly responsible for purchasing relevant high-impact medicines that have associated biomarkers/CDx.

German Payer

The Head of Pharmaceutical Management at a company that represents 40 sick funds in the German healthcare system covering eight million lives. This individual is involved in price negotiations at the GKV in the AMNOG process, and is part of the negotiation team for every new drug in Germany, including those with companion diagnostics.

Italian Payer

This individual is a chief hospital pharmacist who is involved in the purchasing of drugs and devices for the hospital and takes part in local and regional formulary discussions. At regional level, the payer has roles in the laboratory component of Pharmacoeconomics, the National and Regional-Hospital Committee for the Formulary, the Ethics Committee, the Committee for Good Use of Blood, and the Hospital Infection Committee.

Spanish Payer

This individual is a payer and pharmaceutical economic expert in Spain; a member of the Spanish Agency for Medicines and Health Products (AEMPS) and committee member of a Clinic Hospital Pharmacy; an Economics University Professor and Consultant for the Ministry of Health, Inter-Ministerial Commission for Pharmaceutical Prices (CIPM) Activity.

UK Payer

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This individual works as a Commissioning Lead Pharmacist. She is responsible for medicines optimisation and commissioning high cost drugs. Her work includes pathway development, gain share and service improvement involving both primary and secondary care clinical engagement. She is also responsible for working with the pharmaceutical industry on new products and joint working initiatives. She is a member of the Medicines Evaluation Committee and District Prescribing Committee. Previously, she worked in the pharmaceutical industry.

US Payer 1

As a Medical Director on the Clinical Policy Team who sits on the Technology Assessment Committee that uses companion diagnostics for coverage and reimbursement, this individual is a licensed pharmacist in New Jersey. With more than 30 years of experience providing pharmacy services in a retail and clinical setting, he has a track record of establishing positive relationships with customers, pharmaceutical manufacturers, medical professionals, healthcare organisations and insurance providers.

US Payer 2

This individual’s career spans 35 years with experience in staff, group and IPA model health plans as well as Managed Medicaid and Medicare Part D programmes. Currently the Manager of Specialty and Pharmacy Contracts at a full-service health benefits company covering over 1.3 million lives in the New England market. In this role, he negotiates pharmaceutical rebate contracts, specialty pharmacy contracts and participates in formulary management, benefit design, trend analysis, utilisation review programmes, pipeline monitoring, medical drug management and financial modelling for the pharmacy programme.

US Payer 3

This individual oversees all clinical and purchasing services for CPS, including clinical programme development, corporate purchasing process, clinical education, quality disease state management and clinical contract evaluation. His extensive background includes serving as Clinical Coordinator at several large and small hospitals, Director of Disease State Management for a large physician group as well as Pharmacy Director and Pharmacy Buyer.

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US Payer 4

This individual is Chief Pharmacy Officer and Business Director for an innovative prescription drug benefit initiative. The Rx benefit serves over 600,000 self-insured enrolees, primarily in the public sector, and provides consultative guidance and support to its clients in the areas of benefit design and analysis, clinical programme design and selection, formulary development and trend management.

US Payer 5

This pharmacy expert is responsible for pharmacy contracting and related supply chain activities as part of a pharmacy and therapeutics committee. He has more than 38 years of experience in a variety of roles, including Director of Pharmacy Operations, Manager of Pharmacy Purchasing and Distribution, and Area Chief Pharmacist. He has extensive expertise in pharmacy utilisation strategies and drug benefit design. With regard to diagnostic testing and biomarkers, he is involved in the approval process and in determining the value of reimbursement.

3 Key Quotes

“We have around 20 companion diagnostics in Germany. For [specific] drugs, the testing is reimbursed and for all other tests there is no reimbursement… There is no negotiation about the cost of the test; if it costs €1,000 [or] €2,000, there is no negotiation and it is reimbursed over the EBM system.” German Payer

“If you just have a NICE guideline where it [the biomarker] is just briefly mentioned, then you get a huge amount of variation from different hospital trusts as to how they implement that, whereas if it is something that is targeting treatment, then more national support with local buy-in is where we would want to be. So, for example, we have got an oncology biomarker in which my hospital, as a research centre, is very interested so it’s self-funding for patients; whereas there is another hospital that is also within my area, where even though the NICE guideline says it is cost-effective and you should use it, it is not used at all. [This is] because there is no additional payment for it, so it would have to come from the existing hospital tariff, and there is no incentive for them to use it."UK Payer

“There's a general rule: does the diagnostic have a direct impact on the care? There are some diagnostics that are curious. Let's say we have a diagnostic that tests for ALK+ cancer patients; it's 60% predictive [and] 40% of the time it's inconclusive. We

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wouldn't want to pay for that test because if the patient's going to get the drug whether the test is positive, negative or inconclusive, then why bother paying for the test? So, with a positive test you get the drug, and a negative test you don't, then obviously the positive tests are the ones you want to cover." US Payer 2

"I think risk sharing is a great concept. Nothing's absolute, so I would never expect it to be 100 percent, but I would say 50:50 or 70:30. Something where everybody has a stake in it."US payer 3

Who Would Benefit from This Report?

Commercial teams incorporating CDx into risk sharing and patient access agreements

HEOR teams building evidence of CDx value for use by payers

CDx/Biomarker development companies planning/refining research and development programmes

Business development teams in pharm forging collaborative ventures with biomarker and CDx developers

Biosimilar developers needing CDx tests for regulatory approval

Market Access teams preparing CDx/biomarker support data for payer assessment

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