

Pricing and Reimbursement Trends in the US: Impact of Comparative Effectiveness Research and Cost-Effectiveness Analysis

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Abstracts

Public healthcare costs are rising. Governments need to get them under control. In Europe, that means the systematic use of health technology assessments (HTA) and reference pricing. The US, on the other hand, focuses on comparative effectiveness research (CER) to identify drugs that maximise clinical efficacy, minimise clinical harm and are more in tune with individual needs. Vastly different solutions - but are they working?

Report Overview

In Pricing and Reimbursement Trends in the US: Impact of Comparative Effectiveness Research and Cost-Effectiveness Analysis, FirstWord Dossier lays bare the US model by defining comparative effectiveness research and exploring its limitations with regards to drug trials. The report expertly examines direct versus indirect cost effectiveness analysis, the role of key government institutions and managed care organisations and the impact such research is having on blockbuster drugs. Based on au courant research, expert interviews and several compelling case studies, the report takes a critical look at US policy decisions and trends and offers a clear, uncluttered view of the US drug reimbursement system.

Highlights

Key Report Features

Wide-ranging analysis of US drug and reimbursement policies and how they differ from European models

Pricing and Reimbursement Trends in the US: Impact of Comparative Effectiveness Research and Cost-Effectivenes.



Review of the use of CER in the US, with particular attention to Medicaid and Medicare

Up-to-date insight into the role of branded biologics and biosimilars in the US market

Insight into cost-containing managed care tools

Examination of the benefits and drawbacks of head-to-head trials and combination therapy

Analysis of future CER proposals and their implications

Key Benefits

Expert insight from ten industry voices on the effect of CER and CEA on the US system of drug reimbursement

In-depth examination of pertinent policy decisions and trends in the US pharmaceutical industry, explaining the utilisation of CER and direct versus indirect CEA

Multiple case studies and comprehensive references to key literature

Key Questions Asked

How does the US now control prescription drugs costs and what roles do reimbursement and pricing play?

How are US and European models similar and how do they differ?

How do branded pharmaceutical cost considerations influence reimbursement decisions and policy at the federal level in the US, as government costs outpace government revenue?

What are the implications of these trends for pharma and how will it respond?



Who Would Benefit From This Report?

Global health economists

Global HTA directors

Managed care/market directors

Pricing and reimbursement managers

Marketing, brand and sales managers

Business development executives

Regulatory and government affairs professionals

Key quotes

"Where is the risk/benefit quantitative standardised analysis that goes hand-in-hand with the CER analysis? It should never just be about avoiding a safety event in the absence of having a discussion of what is the married benefit. What's the right ratio we're looking for, not just the lack of a serious adverse event or the production of a clinically beneficial event? I think it's both."

-John Doyle, Senior Vice-President and Practice Lead, Managed Markets at Quintiles

"There's a paradox of lots of CER data collected, but the companies don't know what to do with it. But they are getting better at finding the right data sources and understanding how to analyse it. There is going to be a tipping point, I believe, when the very purpose of comparative effectiveness will become clear." -Samuel Wagner, head of Health Economics, Oncology, for Bristol-Myers Squibb

"There are more similarities than differences, in terms of the US and Europe, regarding most of the key issues. Accordingly, it is time for cooperation between the industry, HTAs and payers. The adversarial tones that we can read about currently, do not lead to a good place - for anyone."

-Alicia Granados, Senior Director Global HTA Strategy at Genzyme



Expert Views

Leela Barham, MSc, Independent Health Economist

Marc Botteman, Managing Partner, PharMerit

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Samuel Wager, PhD, Executive Director, Bristol-Myers Squibb

Jeff Waite, Pharmapricing.org

Leslie Williams, MBA, President and CEO, ImmusanT



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Medicare Medicaid The Food and Drug Administration (FDA) The FDA's response to GSK's Avandia in type 2 diabetes New criteria for the approval of biosimilars Managed care tools to restrain utilization and costs The Managed Care Formulary **Prior Authorization** Open-label naturalistic studies: Focus on Medco's study of Plavix and Effient Impact of the managed care tools Disease indications that mitigate the impact of managed care Oncology drugs Amgen's Xgeva Roche's Avastin Orphan drugs and the lack of alternative treatments Atypical antipsychotic agents via the Medicaid connection Governmental agencies practicing CEA indirectly: Case studies Age-related macular degeneration: Avastin versus Lucentis Erbitux in advanced/metastatic colorectal cancer FDA delays me-too with a Novel Mechanism of Action Pros and cons of conducting head-to-head clinical trials The combination therapy compromise Implications of combination therapy on branded drug costs Fixed-combination drugs Future considerations Contentious CER proposals



Cooperative CER Proposals Potential renaissance in drug development Implications of the renaissance in drug development

REFERENCES

ACKNOWLEDGEMENTS

APPENDIX 1

Use of CER by international governmental agencies Health Technology Assessment: The UK's NICE Reference pricing Risk-sharing strategies Risk sharing in the US



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