CBP26 BREAKTHROUGH THERAPY STATUS as “EXPEDITED FDA REGULATORY APPROVAL? BUT WHAT ABOUT THE PAYERS?

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OBJECTIVES: The breakthrough therapy pathway provides an expedited Food and Drug Administration (FDA) review where preliminary clinical evidence suggests potentially substantial clinical improvement for a serious, life-threatening condition. This has enabled regulatory approval on data packages as early as phase 1 data (ceftinib and pembrolizumab). We wanted to research the question of whether such clinical data would be sufficient for US payer coverage. METHODS: On 5th December 2014, publically available benefits documents were extracted from 3 national (AETNA, Anthem, and United Healthcare [UHC]) and 1 regional (Rocky Mountain) insurance companies for the 14 therapies approved by the FDA under this pathway. The coverage status, prior authorisation criteria, and price were documented. RESULTS: Among the 14 FDA approved therapies, Therapy designation was covered by these insurers (AETNA: 10/14, UHC: 10/14; Anthem: 9/14, Rocky Mountain: 7/14). Most instances of drugs not covered reflected those approved very recently. However, the majority were subject to prior authori-
sation (AETNA: 10/10, Anthem: 9/9, UHC: 5/10, Rocky Mountain: 7/7). These prior authorizations sometimes included clinical criteria more stringent than those in the FDA label (15/31 similar to FDA label, 9/31 slightly more restrictive, 7/31 much more restrictive). The drugs most frequently subject to much greater restrictions than the FDA label were Sovaldi and Harvoni. The level of restrictions were not seemingly related to the patient cost per treatment which ranged up to $307,000 (Kalydeco) but rather correlated with budget impact (very large with Sovaldi and Harvoni, intermediate with HepaSphere, small with Hemlibra). CONCLUSIONS: We found that the shift to a European-style price competition, US payers. With variable usage of distinct cost-containment tools by different payer administra-
tors were interested in real-world outcomes data in their specific patient 
tus), type of treatment employed, years of nursing experience, healthcare institu-
tional diseases were found associated with the status of the CMP. The stepwise 
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OBJECTIVES: To identify the predictors of the nurses undergoing a Compliance Monitoring Program (CMP) for substance/drug abuse successfully and assessing the effect of these variables on the successful completion of program. METHODS: This was a retrospective cross-sectional cohort study using the de-identified data from the Florida Intervention Project for Nurses (FIN). Status of CMP program categorized as ‘completed’ and ‘incomplete’ formed the dependent variable. The independent variables were characteristics of the nurses - demographic (education, mental sta-
tus), type of treatment employed, years of nursing experience, healthcare institu-
tional setting that employed the nurses, healthcare specialty of nurses, diagnostic and 
therapeutical nature of mental disorders (DSM-axes), lab results for presence of 
drugs, presence of substance related disorders (dependency, abuse), family history 
of biological, non-biological and mental diseases, lab test results during relapse, if 
aftercare is required at end of program, status of treatment at end of program, type of 
care setup for detoxification, type of aftercare to take hold. As the variables grow, 
such cost-management tools will become further embedded in a wider variety of 
US payers. With variable usage of distinct cost-containment tools by different payer 
aries, the US payer landscape will likely increasingly resemble that of Europe.

PHP28 UNITED STATES DECISION MAKER PERCEPTIONS OF DATA FROM OBSERVATIONAL STUDIES AND OTHER HEALTH ECONOMICS AND OUTCOMES RESEARCH

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OBJECTIVES: To identify United States (US) decision maker perceptions of data from observational studies and other health economics and outcomes research and to evaluate emerging health technologies. METHODS: We conducted qualitative one-on-one interviews with payers (5), clinicians (6), and hospital administrators (4) in different states to determine perceptions of data collected outside of randomized con-
trolled trials in the evaluation of emerging health technologies. RESULTS: Clinical efficacy and safety postmarketing assessments have more of an impact on decision making than other types of study data collected outside clinical trials. Compared with European stakeholders, clinicians placed a particularly high value on patient reg-
isters, whereas, hospital administrators placed a high value on budget-impact analysis. Annual/semiannual review of drug classes by health plans and hospital formularies is key. Data that are available will form the basis of the majority of decisions, confidence in prescribing, and subpopulation data. Payers and hospital 
administrators were interested in real-world outcomes data in their specific patient 
opinions, and data that could have an impact on costs, cost offsets, resource utili-
zation, and readmissions. CONCLUSIONS: Stakeholders in the US are seeking more

cost-effective and economics information to better inform decision making 
in the evaluation of new health technologies. The impact of comparative 
effectiveness research and economics on formulary decision making will likely have more impact in the future. If study data are to be considered valuable in supporting 

PHSP29 A NECESSARY CONVERGENCE US PAYERS ADOPTING EU BEHAVIORS

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OBJECTIVES: The US is the largest prescription drug market in the world, charac-
teristics of high drug costs are internationally more tradable and fungible. This 
sustainability of the largely free-pricing of pharmaceuticals has long been 
questioned against the background of increasing pharmaceutical spend. The recent 
market entry of innovative Hepatitis C virus (HCV) therapies with potentially 
substantial budgetary implications have driven US public and private payers to 
implement a range of cost-containment mechanisms. This research aims to com-
pare these new changes with European processes and predict how the future 
impact of these variables on the successful completion of program.

PHP30 CHARACTERISTICS OF NURSING ASSOCIATED WITH COMPLETION OF COMPLIANCE MONITORING PROGRAM FOR SUBSTANCE ABUSE

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OBJECTIVES: To identify the predictors of the nurses undergoing a Compliance Monitoring Program (CMP) for substance/drug abuse successfully and assessing the effect of these variables on the successful completion of program. METHODS: This was a retrospective cross-sectional cohort study using the de-identified data from the Florida Intervention Project for Nurses (FIN). Status of CMP program categorized as ‘completed’ and ‘incomplete’ formed the dependent variable. The independent variables were characteristics of the nurses - demographic (education, mental sta-
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PHP31 FDA BREAKTHROUGH THERAPY STATUS - A SYSTEMATIC ANALYSIS OF ALL THERAPIES APPROVED UNDER THIS NEW EXPEDITED APPROVAL PATHWAY

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OBJECTIVES: Since July 2012, a new therapy may be allocated Breakthrough Therapy Status if it a) treats a serious and life-threatening condition, and b) preliminary evidence suggests substantial clinical improvement over existing therapies based on on by such aged endpoints. For such studies, the FDA will expedite their 
development and review. This research aimed to systematically analyse all therapies that have been approved under this new FDA expedited review pathway. METHODS: All therapies that have been approved since the introduction of the breakthrough status were extracted up to 28th November 2014 and their date, drug type, and supportive trial package were extracted. RESULTS: The FDA has approved 14 therapeutic agents designated as breakthrough therapies (to 1st December 2014), 7 oncological and 7 non-oncological, with 7 applications filed in 2014 alone. 6/14 also received FDA accelerated approval. 9 submissions were first approvals whereas 5 were line extend-
itions. 7 of these submissions were based on Phase 3 trial data, 5 on phase 2, and 2 on phase 1 data. The average review time from submission to approval was 181 days (range: 126 – 242 days). There appeared no correlation between review times and