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Comparative Effectiveness Research-CER

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Comparative Effectiveness Research CER

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A new current in Pharmaceutical Brand Management

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-------Description

- Pharmaceutical Comparative Effectiveness Research (CER) provides insight to:
  - Clinical/cost effectiveness of individual medications
  - Comparative performance between therapies
  - Comparative performance of therapies vs. procedures

-------Description

- CER is an extension of Evidenced-based Medicine and Health Economics Outcomes Research
- Consumer-driven health plans (CDHP) are growing, high consumer demand for value
- Medical/pharmacy benefit cost issues and national economic concerns increase the interest in healthcare cost-justification
- Employers, managed care organizations and other entities are actively assessing CER's potential
- The Federal Government's interest and investment in CER is substantially growing

-------Description

The cycle of care and cost evaluation…

-------Description

- Outcomes of a brand's CER performance may directly impact:
  - Commercial, Medicaid and Medicare policies and prescription drug coverage
  - Patient/consumer opinion
  - Physician prescribing
  - Marketplace success

-------Government

- Federal government is largest payer and is seeking ways to better control/reduce healthcare costs
  - Over last 30 years, Medicaid/Medicare spending has risen from 1.3% in 1975 to roughly 4% in 2007
  - Total healthcare spending was about 8% of the GDP in 1975 and about 16% of GDP in 2007
  - Current trend rate is about 20% of GDP by 2016

-------Government

- The Medicare Modernization Act of 2003 allocated over $50 million dollars to evaluate outcomes, comparative effectiveness and healthcare items & services for Medicare and Medicaid enrollees

- In 2007, the Congressional Budget Office (CBO) issued a formal report on CER, “Research on the Comparative Effectiveness of Medical Treatments”

- The National Institute of Health (NIH), CMS/HHS, and Veteran’s Administration (VA) are assertive CER advocates

-------Government

- $1.1 billion dollars assigned to CER in American Recovery and Reinvestment Act of 2009 (AARA)
  - Encompasses drugs, devices and other treatments
- Funds will be distributed to:
  - Agency for Healthcare Research and Quality (AHRQ)
  - Health & Human Services (CMS/HHS)
  - National Institute of Health (NIH)

-------Government

- Further discussions will determine which areas of evaluation the CER stimulus money is allocated towards
- Legislators, policy experts and various healthcare advocates are lobbying Federal government to create an “Institute for Comparative Effectiveness Research”
- Concepts include utilization registries, data analysis and specific clinical trials to develop optimum protocols for “average” patients with certain conditions/diseases

-------Government

- Drug Effectiveness Review Project (DERP) is a public/private effort to conduct CER and other drug therapy research
- AHRQ contracts with 13 evidenced-based practice centers in academic/private sectors to accumulate data and expertise
  - Alberta, BCBS, Duke, ECRI Institute, John Hopkins, OHSU, McMaster, Minnesota, Ottawa, RTI-UNC, Stanford, Tufts-NEMC and USC

-------International

- CER is a global healthcare management concept
- Leading international CER entities include:
  - Australia-Pharmaceutical Benefits Advisory Committee
  - Canada-Health Policy Research Program
  - Germany-Institute for Quality and Efficiency
  - Great Britain-National Institute for Health and Clinical Excellence

-------Marketplace

- BCBS, Kaiser and other health plan entities have CER evaluation initiatives underway
  - Health plans may choose not to divulge their CER findings and decisions to industry counterparts who have not contributed any resources to the research
  - Public sector health (Medicaid/Medicare) which accounts for over 40% of national health spend actively monitors costs but does not have necessary resources to initiate/maintain ongoing CER programs

-------Marketplace

- National Business Group on Health (NBGH), a coalition of employers, is strongly supportive of federal effort to bolster CER

- The American College of Physicians (ACP) has assertively endorsed CER measures

-------Marketplace

Primary CER Stakeholders:

- Patients
- Pharmaceutical Manufacturers
- Pharmacy Directors (PBM/MCO)
- Medical Directors (Employer/MCO/PBM)
- Employers/Employee Benefit Consultants
- Federal/State Government Health Agencies

-------CER Challenges

- There are no CER Federal guidelines or healthcare industry clinical/analytical standards except those recognized as “best practices” by professional researchers and industry
- Complexity of patient variables/co-morbidities/side-effects may not be accounted for
- Potential focus on cost savings versus patient benefit
- CER expense may drive drug/healthcare costs up further and add complexity to care/cost management

-------CER Challenges

- Results need to be undeniable, minimize risk to patients
- New therapies would have to be continually benchmarked, lack of data may disadvantage new therapies
- Very difficult to account for therapies effectively prescribed by physicians for off-label uses
- Patients changing medical/pharmacy benefit plans create data/outcome inconsistencies

-------CER Challenges

- Concerns CER may lead to restrictive selection for patients/physicians
- Flexibility necessary to account for subgroups of patients with special therapeutic needs
- Additional input required from healthcare and government entities to create guidelines/coverage rules for commercial, Medicaid and Medicare plans based on findings

-------CER Challenges

How are evaluative standards applied to:

- Comparative cost of products/course of therapy?
- Long or short term benefits performance?
- Definition of treatment failure/success?
- Duration of therapy/prescribed dosing?
- Patient co-morbidities/demographics?
- Brand vs. Brand, Brand vs. Generic?
- Sample side/sources of data?
- Products sharing indications?
- Sample size/sources of data?
- Products only within class?
- Side effects?

-------Outlook

- Due to complexities, expense and care concerns, government CER initiatives likely to be highly specialized:
  - Applied to those areas offering greatest return based on maximum care with cost-saving results
  - Widely prescribed brand product versus generic
  - High safety, low side-effect risks
  - Result in creation of reinforced guidelines, not mandates

-------Outlook

- Largest national/regional MCOs and BCBS plans
  - Follow government CER guidelines/results closely and apply them to their own plans when appropriate
  - Duplicate government CER models, apply them in their own research according to specific categories
  - Contract for medications with high performance ratings at preferred status, allocate lesser performers to 3rd tier and require higher rebates

-------Opportunity

- A strong CER performance by the brand:
  - Empowers its market position
  - Fortifies it against existing products/upcoming agents
  - Helps gain/retain preferred formulary status
  - Strengthens its marketing message
  - Links clinical/cost justification to physician/patient choice

-------Opportunity

- Throughout the brand's product development and marketplace lifecycle, it will be beneficial to align its value and fortify its position according to managed care parameters:
  - Level of incidence/increase or decrease
  - Co-morbidities and associated costs
  - Per member per year (PMPY) costs
  - Overall treatment cost trends
  - Average per treatment cost

-------Opportunity

- A brand may demonstrate overwhelming clinical superiority over competitors in clinical trials and in select clinical studies
  - Is it feasible for the brand to embark on a CER initiative?
  - Can the brand deliver solid results by cross-examination of care, clinical and cost attributes and performance?
  - Will its performance be duplicated in a large-scale?

-------Risks

- Brand may have subpar care/cost performance compared to competitor's
- Brand may demonstrate less favorable outcomes versus medical procedure conducted to treat the same condition/disease
- Results may be inconclusive, no significant care/cost differences between the brand and competitor's)

-------Assessment

- Assess latest treatment standards which positively/negatively impact the brand and its competitors
- Review results of competitor’s clinical studies
- Review current/ongoing clinical resources, including:
  - HEOR projects completed or underway
  - Post-launch surveillance data
  - Syndicated reports

-------Assessment

- What is the position of the brand and its competitors in managed care circles and formularies?
- Initially consider widest used indications for greatest impact
  - Lesser indications may provide utility in niche applications channeled through managed care PA edits

-------Assessment

- Survey medical, pharmacy and managed care professionals to learn their:
  - Greatest challenge treating particular conditions/diseases
  - Perceptions/issues of brand's care/cost performance
  - Preferred approach to drug care/cost evaluation
  - Opinions concerning competitor care/cost performance
  - Requirements to fill knowledge gaps

-------Assessment

- Based on compiling latest clinical data and industry input:
  - Is the brand's performance robust enough and competitor's performance vulnerable to the extent a pilot CER initiative would yield positive results?
  - What are financial, staff and time resources available?
  - How would a pilot CER program be implemented and can it be designed to be scalable if initial results are solid?

-------Pilot Profile

- Define specific indications(s), competitor(s), patient sample, and care/cost considerations being evaluated
- Is the design/methodology a truly “head to head” evaluation?
- Would a competitor execute the evaluation in the same way?
- Does the pilot meet professional research standards which may be migrated to a full-scale CER initiative?
- Are the expected results promising enough to move to the next level and will there be sufficient funding to do so?

-------Pilot Profile

- Base evaluation parameters:
  - Acute or chronic treatment application
  - Approved indication(s)
  - Competitive agent(s)
  - Co-therapies (therapeutic and/or reduce side effects)
  - Duration of therapy
  - Medical/pharmacy claims data
  - Patient characteristics (age, sex, ethnicity, co-morbidities)
  - Pertinent medical/pharmacy benefit plan design features
  - Re-treatment/discontinuation of treatment
  - Therapy cost and medical treatment cost data
  - Timeframe

-------Pilot Profile

- Sources of data:
  - Actuarial firms
  - Managed care organizations
  - Contract research organizations
  - Healthcare data management/reporting companies
  - Prescription benefit management companies/PBMs

-------Pilot Profile

- Leading data source considerations:
  - Comprehensive medical/pharmacy files
  - Access/ownership/security
  - Data Integrity
  - Timeframe
  - HIPPA
  - Cost

-------Pilot Profile

- Upon completion of the pilot:
  - Do results favor the brand enough to proceed to a full-scale CER initiative?
  - Did results lead to other areas of research?
  - If large scale results were realized, how would they be used to benefit the brand?

-------Summary

- CER is a growing healthcare management concept in the United States
- Government, managed care and other entities have an active interest in the development of CER
- Driven by clinical and cost data, it requires substantial financial, staff and time resources to accomplish

-------Summary

- CER will play a pivotal but controversial role in select drug and medical management applications
- There is a high risk/reward ratio for a brand to successfully undertake its own CER initiative
- Pharmaceutical manufacturers need to consider care/cost performance earlier in drug development stages to better manage R&D resources and assess pipeline forecasts

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