Harvard Pilgrim Health Care

Challenges in Interpreting Evidence: Payor Perspective

Michael Sherman, MD, MBA, MS
Chief Medical Officer
Harvard Pilgrim Health Care
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Why are Drugs the Subject of Cost Savings Initiatives?

- Unit cost increases-particularly for drugs not new-to-market, where increases are inexplicable
- Lack of transparency around pricing
  - Seemingly what the market will bear
- Lack of planning/surprises
  - i.e. Hepatitis C treatment
- Realization that other developed countries paying far less than USA
- Pressure from employers and other stakeholders

Some Drug Metrics

- 35%- percent of recently requested premium increases attributable to pharmaceuticals
- 25%- percent of health care dollars spent on drugs in 2016 at Harvard Pilgrim
  - "Allowed" basis
  - Includes both Pharmacy and Medical Benefit drugs
  - Excludes drugs administered in the hospital
- 21.5%- percent of drug spend paid by member in 2016
  - 24%- percent of drug spend paid by member in 2015
  - 34%- percent of drug spend paid by member in 2011
- 20% - recent year-over-year increase in specialty pharma spend

* All data Harvard Pilgrim allowed

Why Clinical Trials ≠ Real World Evidence

- Clinical Trials are characterized by
  - Investigators who are experts in specific area under review
  - Large number of patients seen
  - Full compliance with all protocols
  - Patients carefully selected
  - Patients closely followed by Clinical Research Associates to rapidly address concerns and ensure adherence, etc.
- For diagnostics, concern whether the “right” path will be followed
- In addition, many community physicians are in environments where patient loads may limit ability to fully understand a recently introduced therapy

Challenges are Increasing

- Some payors looking to be more restrictive because of
  - Financial pressures
  - Pricing that appears arbitrary in many cases and divorced from any measure of value
  - Data that is highly limited
  - FDA approvals that may be viewed as overly broad
- Complicated by
  - FDA's understandable desire to provide access to patients who may lack any other option
  - Some conditions are so rare that it may not be reasonable to expect well done randomized clinical trails with sufficient numbers
  - Questions over ethics of delaying treatment that *may possibly* be effective, while awaiting better results

Opportunities to Promote Appropriate Use

- For new drugs, where there may be “imperfect” data, particularly for rare diseases with unmet need…
  - “Require” manufacturers to enter into value-based agreements that tie reimbursement to success of the drug (tied to outcome measures used to gain approval)
  - “Require” that manufacturers submit data to an objective third-party (e.g. ICER) and agree to pricing that aligns with findings
  - Encourage post-marketing payor-pharmaceutical company collaboration to utilize data generated by these value-base agreements
- Benefits to Pharma include
  - Reduced uncertainty regarding whether therapies will be covered
  - Above approach would itself generate true real world evidence