Practical Considerations With the Implementation of Innovative Medicines into Generally Accepted Practice That is Reimbursable

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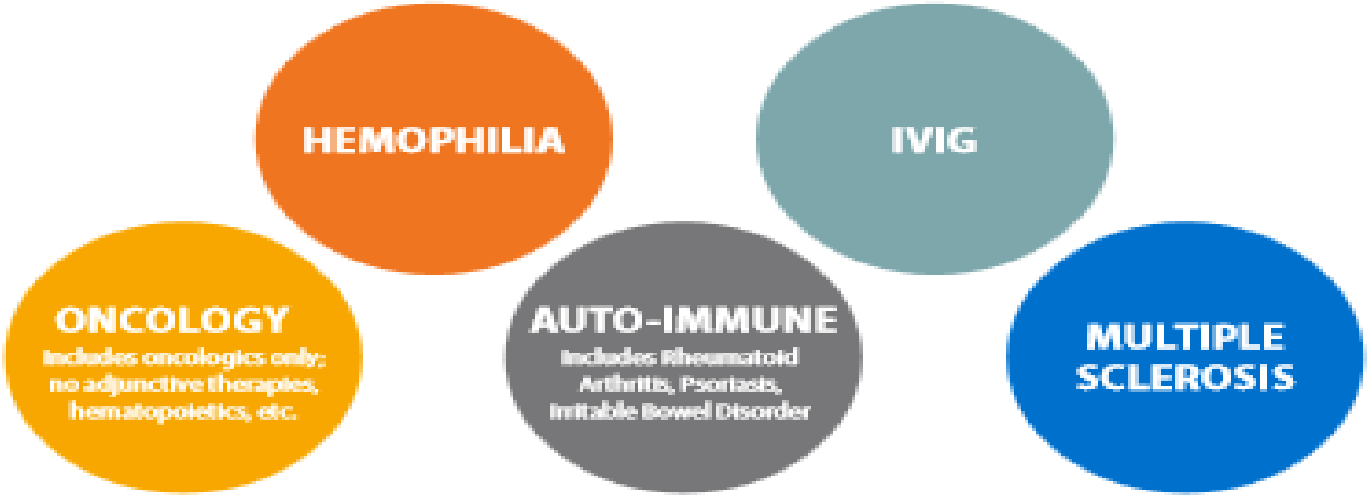
Dilemma of Unsustainable Health Care Cost

- 2012 specialty drugs cost $87 Billion, 25% of total drug spend and 3.1% of national health cost.

- This is an increase from 2010 where specialty drug cost was only 20% of drug spend.

Drug Categories That Are Driving Cost

Over 50% of specialty spend is in these **five therapeutic categories:**

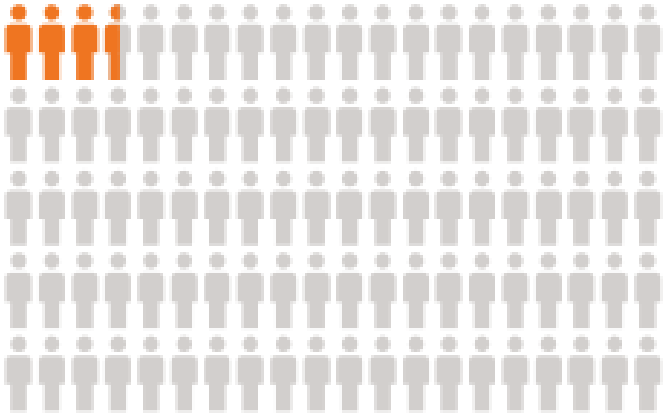


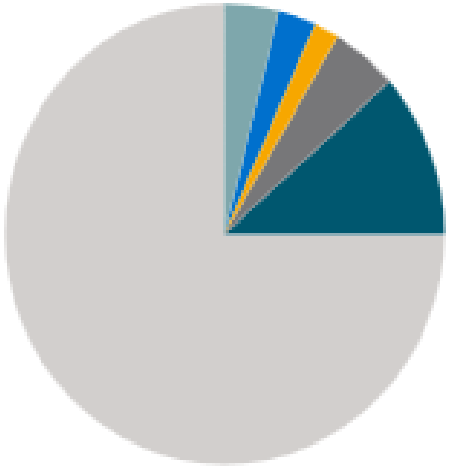
2013 Total Estimated Specialty Spend for these Categories: **$214M***

2014 Total Estimated Specialty Spend for these Categories: **$253M***

The Challenge: Double-digit specialty trend is driving pharmacy trend

The **3.6% of members** who use specialty medications account for **25% of health care costs.**[3]





TOTAL HEALTH CARE COSTS

17%
Specialty drug costs under pharmacy benefit

13%
Specialty drug costs under medical benefit

7%
Non-specialty medication under the pharmacy benefit

20%
Medical costs related to specialty condition

43%
All other medical costs

A small proportion of patients account for this drug spend, but their contribution to overall health care spend is substantial. Managing specialty pharmacy is critical not only to control drug costs, but to provide the best clinical management for these patients, reducing adverse events, and helping to manage overall spending. Because the drugs and the conditions they treat are complex, management can be more complicated, but we believe that, with guidance, every plan can identify and implement measures that will significantly improve their results.

This issue of INSIGHTS is intended to help plans decide **where to go next** to manage their specialty spend.

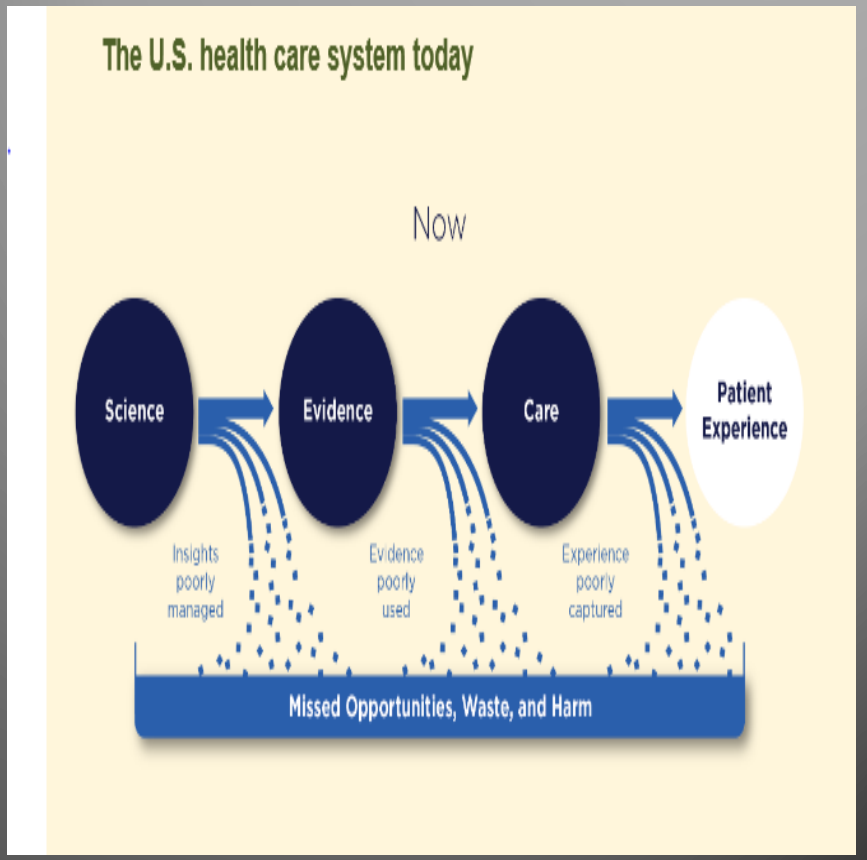
3 Source: Milliman Specialty Medication Benchmark Study developed using the 2010 and 2011 Truven Health MarketScan® Research Database for a commercial population. Specialty drugs are identified by leveraging Milliman's Health Cost Guidelines definition and other CVS proprietary definitions. Specialty medication utilizers were defined as having at least two specialty medication claims across any place of service in the study period. Health care costs include total allowed costs incurred (prior to cost sharing under the medical and pharmacy benefit). Medical costs associated with specialty conditions were identified using the primary ICD-9 diagnosis codes in the medical benefit data.

Ethical Issues Arise When Cost of is Too High

- Patients are more involved in their health choices and have a financial stake in health care cost.
- Typical co-insurance rates are 70 – 90% with out- of-pocket risk up to $6,000/13,000.
- Risk of mortality is small but risk of life time disability is tremendous

Current Treatment System is Set Up to Standardly Waste Resources

"Excess and waste estimates suggest that perhaps one-third of all health care spending is excessive and unnecessary, draining resources for expanded coverage, preventive care, and other important societal priorities"



IOM Best Care at a Lower Cost 2013

“Medical Necessity “ Defined

- “Medically Necessary” or “Medical Necessity” means health care services that a Physician, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
  - (a) in accordance with generally accepted standards of medical practice;
  - (b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient’s illness, injury or disease;
  - (c) not primarily for the convenience of the patient or Physician, or other Physician, and
  - (d) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

- For these purposes, “generally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations, the views of Physicians practicing in relevant clinical areas and any other relevant factors.

Medically Necessary as a Bases for Insurance Coverage

- a term that describes the scope of services that will be covered by an insurance product.
- Based on:
  - demonstration of comparative effectiveness,
  - generally accepted medical practice backed by evidence,
  - reproducibility with fidelity, and
  - important in achieving preservation of life and a reasonable level of functionality.
  - not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

Current Evidence Sources for Determining Medical Necessity

- Scope of evidence used for establishing Med Nec –
  - New technology reviews –
    - reviews, evaluates and ranks research to determine if the effectiveness of pharmaceuticals/technology is proven/established
  - Explicit practice guidelines from credible subspecialty organizations using IOM-like methodology
  - Credentialing/privileging criteria, from research protocols or device training manuals, for assuring competency and fidelity of treatment delivery by the clinician and/or device.

Typical Gaps in the Evidence

- Clarification of the sanctioned population(s) that are successfully effected by new pharmacology/technology.
  - Populations not researched
  - Application creep/off label use/practice experimentation.
- Routinely included clinical trials against standard treatments as a part of pre-FDA review.

  Comparative cost benefit analysis not done
- Long term and post clinical trial information sporadically available.

Recommendations

- Research evidence should clearly identify the specific effected population(s)
  - based on neurocircuitry not on just DSM diagnostic classification.
- Establish clearly populations not tested
- Clear delineation of drug effect, duration of effect, long term outcomes
- Routinely establish an after market patient registry process for high cost drugs or rush to market drugs.
- Evidence review from FDA should be practice guideline- ready. Practice guidelines should be practice -ready

“Opportunities for Health Care Organization Leadership Health care in America has experienced an explosion in knowledge, innovation, and its capacity to manage previously fatal conditions. Yet our heath care has also experienced poorly managed increases in complexity, unsustainable growth in costs, and shortfalls in quality and outcomes. The result is unacceptable occurrence of missed opportunities, waste, and harm to patients. Americans need a health care system that becomes more effective and efficient with each care experience.”

Thank You!

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