AMCP NEXUS 2019 –

THE INTERSECTION OF VALUE AND CARE

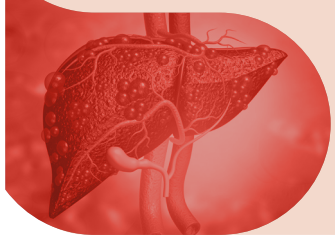
The **2019 Academy of Managed Care Pharmacy (AMCP) Nexus conference** took place Tuesday, October 29 through Friday, November 1 in National Harbor, MD.

- This year the conference came at a particularly critical time for health care: the 2020 election season has arrived and politicians and voters are again scrutinizing the rising cost of pharmaceuticals
- Over **30** continuing education sessions, as well as pre-conference programs and a buzzing exhibit hall, provided attendees with exceptional opportunities to stay up-to-date in a changing healthcare world
- TKG was thrilled to attend this exciting event, which included **80** speakers and panelists, **50** peer-to-peer breakout sessions, and which drew more than **2,000** healthcare leaders

PLEASE CLICK ON THE BUTTONS BELOW TO READ OUR KEY TAKEAWAYS FROM EACH OF THE CONFERENCE'S 5 ESTABLISHED EDUCATION TRACKS:

THE INTERSECTION OF VALUE AND CARE

DRUGS, DISEASES AND THE MANAGED CARE IMPACT



LEGISLATIVE AND REGULATORY TRENDS: FROM RHETORIC TO PRACTICE

MANAGED CARE RESEARCH IN ACTION

SPECIALTY MANAGEMENT: KEEPING UP WITH RUNAWAY INNOVATION

DEVELOPED BY

THE KINETIX GROUP

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THE INTERSECTION OF VALUE AND CARE

- A move from volume-based to value-based reimbursement can help achieve affordability and sustainability goals
  - ◇ Contracting linking drug-pricing discounts to patient population outcomes may present a feasible approach
  - ◇ Pricing strategies linked to product efficacy can help meet growing challenges posed by the increasing availability of high-cost therapies targeted to small patient populations
- Meeting regulatory and data requirements is crucial to the successful implementation of outcomes-based contracts, especially as the design of these contracts becomes more innovative and complex
  - ◇ Many current value-based arrangements are designed by taking into consideration regulatory issues around rebates, outcomes data, and payor limitations with respect to changing existing contracts
  - ◇ Value-based contracts that require outcomes data not traditionally captured by payors may be more challenging to establish since the required data may be difficult or costly to track and measure
- Widespread adoption of value-based pricing is challenged by the operational complexity of implementing these types of arrangements, as well as by the potential legal and financial risks they present to manufacturers
- The key is *value*: policymakers need to see that the healthcare-spend amount, rate, and distribution established produce better results than would be produced by alternative spending methods

> **At the end of the day it is really about trust – you need to build the relationship because that is how we will move forward with reimbursement models.**
>
> Chief Physician Executive
> Large Regional Health Plan

DRUGS, DISEASES AND THE MANAGED CARE IMPACT

- Non-alcoholic steatohepatitis (NASH) is the more aggressive subtype of nonalcoholic fatty liver disease (NAFLD) and may replace hepatitis C as the leading cause of liver transplantation by 2020
  - ◇ Hypertension, heart disease, high blood lipids, insulin resistance, type 2 diabetes, and obesity are health conditions that increase a person's risk to develop NASH; as worldwide obesity and diabetes rates grow dramatically, so too will the prevalence of NASH
  - ◇ There are an estimated 16.5 million people with NASH, and 5.5 million of those have NASH with stage 2 or 3 fibrosis. Among NASH patients, the leading driver of mortality is cardiovascular disease
- Liver biopsy, abdominal ultrasound (e.g., FibroScan®), MRI/MRE, and elastography are the methods currently available for diagnosing NASH
  - ◇ More biomarkers are needed to identify which patients will progress to more serious stages of NASH; the presence of fibrosis is the strongest predictor of mortality in patients with this disease
- The first line of management in NASH involves lifestyle modifications, mainly sustained weight loss and increased physical activity. While a modest weight loss of about 3% may reduce hepatic steatosis, up to 10% or more is needed to reduce inflammation and for the regression of fibrosis in NASH patients
  - ◇ As it can be difficult for even highly motivated individuals to lose the weight needed to resolve NASH and for the regression of fibrosis, pharmacotherapies are urgently needed
- Besides lifestyle changes, there are currently no FDA-approved medications for patients with NASH
  - ◇ Vitamin E and pioglitazone are common medications that have shown good results in reducing disease activity, but these have no consistently reliable effect on fibrosis
  - ◇ 61 drugs targeting fibrosis and other elements involved in the pathogenesis of NASH are currently in various stages of clinical study; when these become available, patients with stage 3 fibrosis are most likely to initiate therapy immediately

> **[NASH] will not be going away – we will see a lot of evolution [with respect to detection and treatment] over the next 5-10 years.**
>
> Manager
> Large National Pharmacy Benefit Manager

LEGISLATIVE AND REGULATORY TRENDS: FROM RHETORIC TO PRACTICE

- More than 20 million Americans have gained coverage through the Affordable Care Act (ACA); however, employer-sponsored coverage continues to be the main source of coverage, followed by Medicare and Medicaid
  - ◇ 37 states have expanded Medicaid and 13 million Americans have gained coverage across those states as a result
  - ◇ The rate of uninsured Americans has increased since 2017, but does remain below pre-ACA levels. Of note, since 2016 the greatest increases in insurances rates have occurred for individuals aged 18-34 years, among women, and for those in households with annual earnings of less than $48,000
- 2019 is the first year that Americans will no longer face a tax penalty for failing to carry ACA-compliant health insurance
- Issuers in most states responded to the 2017 cessation of cost-sharing reduction (CSR) payments by including costs of CSRs in premium calculations for Silver plans. Federal funding of premium subsidies has continued, and the premium subsidies themselves are considerably larger than they would have been if CSR funding hadn't been eliminated
- Public concern over health care has shifted from coverage to cost, especially regarding drug pricing; there is a big push towards price transparency
- Americans may like the idea of 'Medicare for All', but also seem to think they will be able to keep their employer-sponsored insurance; the path that consistently garners public support is a Medicare/Medicaid buy-in option

MANAGED CARE RESEARCH IN ACTION

- The distinguishing feature of real-world evidence (RWE) is the setting in which the evidence is collected (i.e., it is collected in healthcare settings rather than in a research environment), and not the presence or absence of a planned intervention or the use of randomization
  - ◇ It is crucial that all stakeholders understand the potential for RWE to inform coverage decisions and price negotiations. The opportunities must be balanced with the limitations
- RWE is currently being used in the USA in 6 key areas: drug development decisions; regulatory approval decisions; post-approval safety monitoring; initial heath technology assessments and payor coverage decisions; reassessments of heath technology and payor coverage decisions; and outcomes-based contracting
- Key concerns around RWE use include: the potential for bias; incomplete data; data mining; limited access to data; a lack of universally accepted methodological standards; a lack of investigator expertise; and reliance on traditional evidence
  - ◇ To improve RWE quality and credibility, the creation of a mandatory national registry for observational studies is widely recommended. Also recommended is developing effective governance arrangements to regulate an appropriate balance between the protection of private information and the use of data to improve patient care
  - ◇ In tandem with innovative study designs, best practice methods are needed to extend the benefits and use of RWE
- RWE innovation opportunities include: real-time patient monitoring through wearables; analyzing RWE to update treatment methods; collecting RWE evidence on the comparative effectiveness and cost-effectiveness of drugs; and renegotiating price and/or access based on collected RWE

> **Expanding real-world evidence would expand opportunities for payors beyond formularies.**
>
> Editor-in-Chief
> Peer-Reviewed Medical Journal

SPECIALTY MANAGEMENT: KEEPING UP WITH RUNAWAY INNOVATION

- While specialty medications make up only about 1-2% of all prescriptions written, they account for nearly 50% of total drug spend
  - ◇ Oncology and autoimmune diseases are the top therapy areas in specialty drug spend
- In 2018, the FDA's Center for Drug Evaluation and Research approved 59 new novel drugs, many of them representing the first treatments for challenging diseases that previously had no therapeutic options available
  - ◇ Last year, 34 of the 59 drugs approved by the FDA were specialty drugs used to treat orphan diseases (rare diseases that affect relatively few people). These drugs are effective, but costly
  - ◇ Orphan diseases offer the opportunity to launch 'blockbuster' drugs
- Prescriptions for specialty drugs are climbing, with the biggest relative increase in those for autoimmune disease. Between 2013 and 2018 prescription growth in the following specialty therapy areas was:
  - ◇ Autoimmune: +55%
  - ◇ Oncology: +19%
  - ◇ Viral hepatitis: +18%
  - ◇ HIV: +5%
  - ◇ Multiple sclerosis: +3%
- Many of the specialty medicines are paid for through the medical benefit and not the pharmacy benefit; it is difficult for health plans to control the cost of these medications because payment is usually based on provider charges rather than on the price of the drug itself
  - ◇ Payors and PBMs are using site-of-service programs to direct patients receiving infused or injected drugs to the lowest cost settings, including their homes or physician offices
  - ◇ Specialty generics and a significant biosimilars market can help control the cost of specialty drugs