High-Cost Physician-Administered Drugs What the Future Holds: A Payer Perspective

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Strategic & Analytic Consulting Firm

- Founded in 1996
- Biomedical industry focus
- *Primarily manufacturers*
  - Biotechnology
  - Pharmaceutical
  - Device
- Current staff
  - Three Partners
    - ✓ Partners conduct research/analysis
  - Internal research staff
  - Outside expert panels
    - ✓ MCO Medical & Pharmacy Directors, physician thought leaders, other key providers

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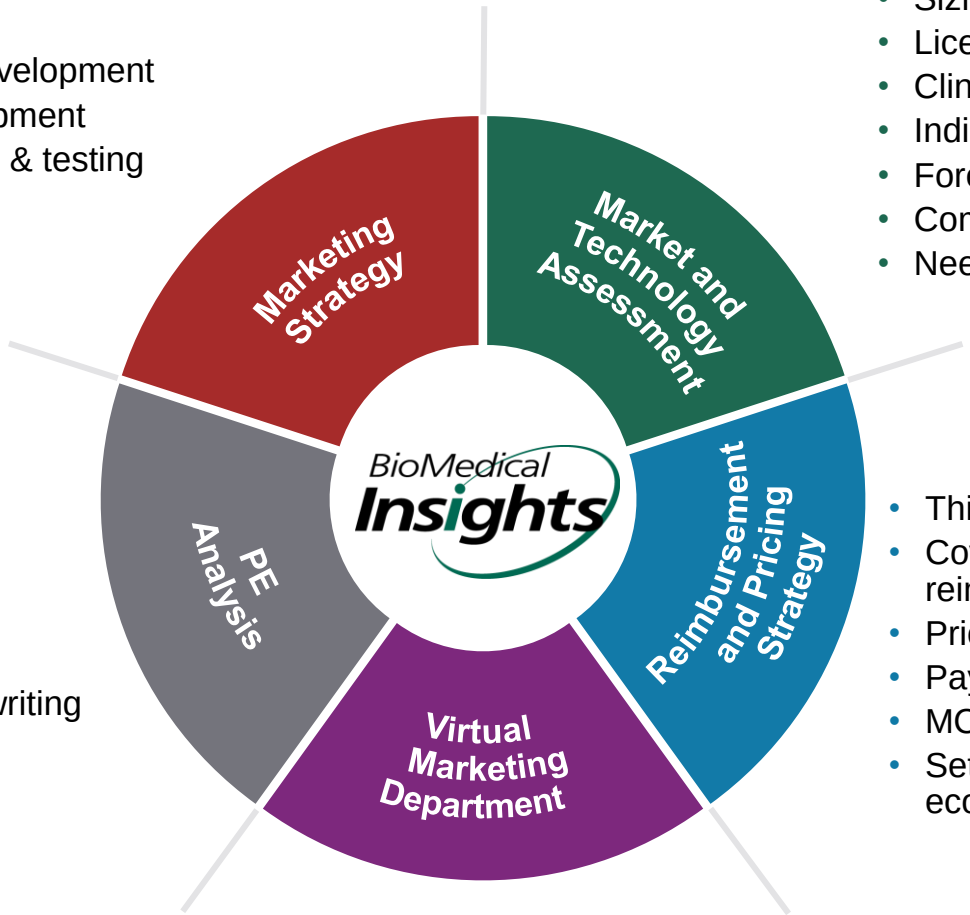
- Multiple functional areas
  - Marketing
  - Pricing/Health Economics/ Reimbursement
  - Business Development
  - Market Research
  - R&D

Services

- Strategy analysis & development
- Marketing plan development
- Message development & testing
- Distribution strategy

- Sizing, positioning, segmentation
- Licensing due diligence
- Clinical & commercial feasibility
- Indication planning
- Forecasts
- Competitive intelligence
- Needs & trend analyses



- PE planning
- Strategy
- PE selling models
- Cost-of-illness studies
- White paper & article writing

- Third-party payer strategy
- Coverage, coding, reimbursement
- Pricing
- Payer marketing strategy
- MCO contracting strategy
- Setting & customer economics

- Temporary management
- Business plan development
- Various marketing functions

Introduction & Method

- BioMedical Insights maintains a panel of Medical and Pharmacy Directors from a range of Managed Care Organizations (MCOs)
- Interviewed 14 Medical Directors about their most pressing concerns
  - One-on-one in-depth telephone interviews
  - Wide range of plan types and sizes
  - 1–1.5 hours per interview
  - Panelists paid an honorarium for their participation
- Key topics:
  - Top three general areas of concern for MCOs
  - Management of high-cost, physician-administered drugs, with focus on oncolytics
  - Expectations for the future

Top Areas of Concern

Rising Costs

- Specialty drug costs mentioned most frequently
- Hospital contracts, including outpatient surgery
- Molecular diagnostics
- Administrative costs

Changing Relations with Physicians

- How to reward positive outcomes
- Meaningfully affect physician behavior through increased risk assignment

Adapting to Affordable Care Act

- Monitor participation in/results of exchanges
- Deal with tremendous uncertainty

Rising Drug Costs

- The escalation of specialty drug costs was mentioned by everyone we interviewed as a top concern of managed care plans today
- Payers believe that most, if not all, specialty drugs introduced today are priced unacceptably high – will be unsustainable
- MCOs tend not to single out specific drugs' prices
- Instead, they focus on therapeutic categories:
  - Multiple Sclerosis
  - Cancer
  - RA, Crohn's disease, Psoriasis
  - Hepatitis C
- Importantly, these costs also represent an area over which plans believe they can have a *limited impact*

> ***Which drugs are <u>not</u> priced egregiously high?!***

> ***I expect us to get screwed on the costs of all new drugs.***

> ***It's predatory pricing. The system is imploding and no one has changed in pharma.***

Rising Drug Costs

- Most payers believe that oncology drug costs will continue to rise until one of two things occurs to stem the tide of the increases
  1. Government intervention
     - ✓ CMS/other requirements for price justification and/or controls
  2. Physician revolt, predicated on assumption of financial risk
     - ✓ Zaltrap demonstrates possibility but it is the exception – most new drugs are effective and differentiated enough that physicians cannot avoid use
     - ✓ However, if physicians are at financial risk for drugs, they may well consider price in their choice of drug, which could in turn reduce prices
- Third-party payers employ many tools
  - ➢ Expecting most to have limited impact
- Payer view is that the key to cost control = fundamental changes in provider behavior

> ***People think we have a lot more control than we do. [In oncology], you have to match FDA and NCCN guidelines. Even then, they will appeal and we often approve those… There's not a lot of arguments you can win when death is at stake.***

> ***The cost to the government will go up dramatically within 5 years and they will have to do something. MCOs have no leverage. Providers have better leverage and ACOs may help that, but even providers can't do anything if the new expensive drug is really good.***

Managing Oncology Costs

Current & Future

Payer Perspective

What ARE and What WILL Payers Do to Manage Increasing Cost of Oncolytics

Mature Stage

1. Increase UM Efforts (reduce inappropriate utilization)
2. Reduce profit incentive (level playing field low/high cost drugs)
3. Incentivize patients to choose cost-effective options

- **Wide use now**
- **Limited add'l savings**

4. Direct care to most cost-effective settings
5. Encourage appropriate end-of-life care

- **High interest, not common**
- **Moderate potential**

Early Stages

6. Change relationships with providers to align incentives
   - P4P
   - ACOs
   - Pathways
   - Bundled payment

- **Very high interest**
- **Potential unknown**
- **The future?**

Increase UM Efforts

Goal

- Limit inappropriate utilization via more rigorous/strict PA, step therapy, other UM

Status

- PA to label and/or compendia (typical)
- *Increasing:* monitor dose, limit duration of therapy (require re-authorization)
- *Increasing:* limit to approved line of therapy and concomitant medication; step therapy
- NDC Codes: Payers requiring in addition to J Codes
- *Increasing, but not common:* E-PA (typically IDN or staff model HMO)
- Preferred Agents: Limited/rare for medical benefit, but starting on pharmacy benefit

Impact

- ***Limited*** due to:
  - Most plans already limit high cost oncolytics to label and/or compendia
  - Legal/PR reasons
  - Wary about dictating medical practice (limited comparative effectiveness info)
  - Therapies differentiated

> ***If the data is there, we are stuck. If the data is not there, we can and will say no. But for most, the data is there. For the duds, plans may not cover them even if they are FDA-approved. In the future I can see that. But for every one we say no to there will be 10 that work and we have to cover. Will we save much by saying no to those few duds?***

Reduce Physician Profit Incentive

Goal

- Incentivize use of lower cost agents (where appropriate)

Status

- Payers have used multiple approaches to limit role of “profit” in decision making
  - *Reduced drug margins:* Shift from AWP - to ASP +
  - *Variable fee schedule (VFS):* Pay higher fee/margin on lower cost agents to make high cost/low cost drug profit more equal—a minority of payers (but not uncommon)
  - *MAC pricing for multi-source*
  - Payers do not expect significant changes in drug reimbursement, except ↑ in VFS and MAC

Impact

- ***Limited*** — payers not limiting BnB; do not expect to cut drug margins significantly

Incentivize Patients

Goal

- Incentivize use of lower cost agents by changing pt. behavior (using cost share)

Status

- Most PPOs: co-insurance on drug; most HMOs: drug co-pay or nothing (only office visit co-pay)
  - Typical co-insurance = 20% to 25%
  - Frequency and amount of cost share increased markedly over past 5+ years
  - *Cost Share will not increase significantly*
    - ✓ Already high (fear compliance issues)
    - ✓ For high-cost oncolytics, patients quickly reach MOOP ($6,350 under ACA)
  - *Limited payer interest in multiple cost share tiers for medical benefit drugs*
    - ✓ Expect limited savings (MOOP issue)
    - ✓ Difficult to implement (as claims adjudicated retrospectively)

Impact

- *Limited* — cost share already significant; mitigated by MOOP

Direct Care to Most C/E Settings

Goal

- Use most CE setting (e.g. office or contracted infusion center)
- Biggest concern: Increasing shift to HOPD

Status

- At present, most plans do not limit site of care (if in network)
- Mandatory SPP: Payers largely not mandating for oncology (view savings as small; concern about waste with white bagging; worry about pushing more patients to HOPD)
- *Of interest, but not common:* tiered network providers (e.g. level 1, 2, 3 with different patient cost share)
- *Increasing:* Contracting with infusion centers and incenting use of contracted facilities
- *Increasing:* Case management approaches

Impact

- ***Potentially moderate*** if can keep patients out of HOPD, use incentives to encourage providers to be more cost efficient (e.g. tiered networks)
- Note: for Medicare FFS cannot restrict patient choice or encourage use of certain providers

Encourage Appropriate EOL Care

Goal

- Increase use of palliative/supportive care in poor PFS, terminal cancer patients
- Important effort among our payer panel (a win/win: lower costs, better outcomes/QoL)

Status

- Payer perspective:
  - Limited involvement at present; fear "pushing" EOL options
  - Physicians – no incentives to provide EOL counsel or discuss alternatives
  - Patients/families – not educated on options
- Payers increasingly:
  - Offering more generous hospice benefit
  - Enhanced case management
  - Paying for home-based palliative care
  - Enhanced reimbursement for EOL counseling
  - Incorporation in pathways (when used)

> ***EOL is definitely an area for savings because there is a huge amount of money spent in the last few months of life for no reason. But that requires a societal move that we cannot push.***

Impact

- ***Potentially significant:***
  - Substantial costs for later lines of therapy, often aggressive, in patients with little hope of benefit (often at expense of toxicity and ↓ QoL)
  - Payers treading gingerly at present

Align Provider Incentives

- Attempt to align payer and provider incentives to promote most cost-effective care
- Early stage: Ultimately, payers want to transition from paying FFS to paying for value/outcomes – not close, but some P4P structures are an intermediate step
  - **Shared savings**
  - **Pathways**
  - **ACO**
  - **Bundled Payment**

> ***When we sit around the table at meetings, 100% of everyone is looking at something, be it episode of care, or pathways, or risk contracting.***

- Payers *hope* for savings and improved quality
  - Limiting multi-source to use of generics/similars
  - Reducing rates of medication error, toxicity-related hospitalizations & ER
  - Reducing unnecessary testing/radiology; inappropriate use of ESAs and CSFs
  - Encouraging palliative tx, single agent tx, for later lines of therapy & poor PFS
  - Limiting biologics/targeted therapies to agreed-upon pathways, specific lines of tx
  - Developing “real world” CE data to drive future pathway refinement

Align Provider Incentives

Shared Savings

- Growing in popularity, particularly in contracts between payers and IDNs or large multispecialty groups and between payers and ACOs (for example, Medicare Shared Savings Program ACOs)
- Provider cost compared to baseline/control for defined group of pts; shares savings with payer based on contracted formula
- Formula may be linked to quality measures (e.g. inpt days, ER visits, satisfaction), compliance with pathways
- *Of interest:* Contracts vary in their inclusion of retail pharmacy drugs (e.g. MSSP ACOs do not include)
- *Status:* Widespread, but payers believe too early to tell if will yield significant saving
- *Key:* Onc (not just organization) must realize savings to influence behavior

Align Provider Incentives

Treatment Pathways

- *Goals:* Reduce variability, improve outcomes, reduce costs, increase predictability
- At early stage, but gaining traction in certain geographic markets; largest pathway vendor (P4) estimates >10% of oncologists participating in their programs
- Pathways:
  - Address entire course of treatment (drugs, radiation, radiology, testing, supportive care, palliation)
  - Are very specific (e.g. for BC specific to HER2 status, node status, ER/PR status, and stage)
  - Rely on established guidelines as starting point; consider efficacy, safety, tolerability, then cost
  - Have to date focused on more prevalent cancers (BC, NSCLC, CRC)
  - Are collaborative effort (payers, providers and often pathways vendors)
- *Payment:* Can include: upfront $; extra $ for coordinating care; graded reimbursement or shared savings based on compliance & quality metrics; incentives for using generics
- *Status:* Pilot or early stage (most pathways); promising but substantial hurdles remain
- *Issues:* Variability in care; lack of comparative data; guidelines too broad; high degree of flexibility necessary; high upfront set-up costs
- *Keys:* Getting provider buy-in, ability to adapt to new agents/info, correct incentives, reporting infrastructure (to measure compliance, costs, provide feedback)

Align Provider Incentives

ACO/Medical Home

- Organization providing coordination of care through integrated services, financial incentives to cost effectively manage defined patient population
- Sponsor may be hospital, physician group, or insurer
- Most ACOs shared savings model; vary in inclusion of drug costs
- *Status:* ≈ 600 ACOs, 18 MM lives; Medicare models: MSSP: ≈ 345, Pioneer Model: 23 (decrease from 32 at start)
  - CMS results from Year 1: Savings, but mixed (≈ 25% achieved shared savings)
- ACO implications for oncology:
  - Still an evolving model (too early to tell if successful)
  - Not clear where oncology fits in; ACO concept most easily applied to primary care
  - Should specialty services should be provided through ACO or ancillary to ACO?
  - Concern that smaller oncology groups not equipped (infrastructure and risk)
  - Medicare ACO models do not have quality measures for oncology
- Regardless of oncologist relationship with ACO, incentives encourage “value”

Align Provider Incentives

Bundled Payment

- Bundled payment is a fixed dollar amount that covers a set of services (sometimes across multiple providers), defined as an episode of care, for a defined time period
  - Typically include pre- and post-treatment window during which provider responsible for all health care costs
  - Variables include length of bundle period, included services and settings of care, risk or case-mix adjustment
- An area of immense interest, but limited in oncology
  - CMS Innovation Center has the 4 models and 48 episodes under the BPCI initiative (but does not include oncology)
  - Numerous commercial bundled payment initiatives, but focus is orthopedic and cardiac surgeries – high volume, predictable costs; some oncology pilot programs
- Payers skeptical that bundling will be realistic for oncology, in the near term
  - For any provider, relatively low volumes for specific episodes of care
  - Per episode, too much unpredictability in costs and potential for huge losses

Case Study–UHC Oncology Bundled Payment Initiative

Program Parameters

- In 2010, UHC partnered with 5 oncology groups to pilot episode of payment program for BC, NSCLC, and CRC
  - Goal: reduce costs, improving outcomes, and determining best treatment practices
  - Groups share info with each other and UHC to identify best practices, compare results
- "Episodes" created for 19 clinical states in BC, NSCLC, CRC
  - Each group selected preferred regimens for each state, required to adhere 85% of time
- To determine payment amount for *treatment* regimen:
  - UHC calculated margin for each regimen (using ASP+)
  - Episode payment: Margin for treatment course and small case management fee (up to $200) paid prospectively – limited to 4 months (after which another episode)
  - Note: Separate payment for drugs (at ASP); office visits and other care paid using existing contracts (so episode = very limited in scope)

Results

- Results of 3-year pilot were very recently published[1]
- 1,024 enrolled; 810 used for analysis
- Actual costs were 34% less than that predicted (based on registry control ($64.7 MM vs. $98.1 MM)
- Actual costs of chemotherapy drugs far exceeded (179%) predicted costs ($21 MM vs. $7.5 MM)
- No difference between groups on multiple quality measures
- Overall, study notes "source of cost savings 'enigmatic'"; "not possible to make statistically valid quantification of savings"
- That said, subset analysis confirmed decreases in hospitalization and use of therapeutic radiology
- Other: Pilot found huge variations in cost & treatment, significant deviations from regimens, and cautioned that high upfront administrative cost/effort to set up & adhere

[1] Newcomer LN, Gould B, et al. Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode of Payment Model. *Journal of Oncology Practice*. July 8 2014 (Published Online Ahead of Print. @ jop.ascopubs.org)

Case Study–Aetna/Texas Oncology Pathways Program

Program Parameters

- Innovent Oncology Program
  - US Oncology Level 1 Pathways
  - Patient Support Services (employed nurses to provide clinical support in between treatment and visits)
  - Advance Care Planning (counsel patients on end-of-life planning and support)
- 350 oncs (Texas Oncology), focus BC, LC, CRC
- Oncs paid a PMPM management fee for each patient participating in program; get reduced margins for chemo (incentives for generic)
- Oncs get shared savings based on pathway compliance, total hospital days, total ER visits, and total drug costs vs. control group
  - Sliding scale of shared savings based on pathway compliance
- Program extended from Pilot; offered to Aetna Medicare Advantage and commercial patients

Results

- 221 patients, 2-year program (2010–2012)
- Pathway compliance: 76% vs. 63% baseline (control Texas Oncology cohort)
- ER Visits: 10% vs. 14% baseline
- Inpatient Admissions: 18% vs. 24% baseline
- Inpatient Days: 1.2 vs. 2.1 baseline
- Total savings of $506 K (≈ $2.3 K per patient) or ≈ 12% less than expected

Unlikely Approaches

- Despite much discussion, payers agreed that the following are very unlikely in the next 2–5 years:
- Significant shift to capitation models and/or payment per episode/bundled payment
  - Too much treatment variation/disagreement about appropriate approaches
  - Small Ns and significant variation in costs
  - Care from multiple providers/settings
  - Providers not equipped to handle risk (from a financial or information standpoint)
- Oncology ACOs as a primary means of delivery
- Shift to pathways for most providers, for most cancer states
- True outcome-based payment models

> ***"The whole field of oncology is moving towards personalized individual treatments. So we can't really, on the one hand ask physicians to treat each patient as an individual, and on the other hand pay them a standard bundled rate for each patient."***

Advice from Payers

> ***I will tell the manufacturer 'here's how we are paying providers under these new payment models and how we are aligning incentives. The old strategy of getting the doc excited about a new technology and they'll prescribe it and somebody else will pay for it are over. Because the docs in these kinds of models understand that to some degree it will impact how they are paid as well. You need to show docs the value, show them how you offset costs, decrease hospitalizations, or other benefits. The other thing (and this is a little more out there, but is something I am pushing) is that if they can figure out how to charge, instead of per dose, per course of treatment, for, say, a stage 2 breast cancer patient, so that the costs become more predictable for physicians, I think that would be a competitive advantage. Because that's how we pay physicians, population-based…***

> ***Don't follow the Solvaldi model. If you are going to charge a lot up front on the basis of saving downstream costs then you need harder data showing those downstream savings than they put out there!***

> ***If you really define a subgroup of patients that is most appropriate for your drug (which goes against you wanting all patients to be on it), then I can justify any high price for it!***

> ***They should know that we are more willing to make tough choices now than we were before…***

Q&A

For follow-up questions or copies of these slides, please contact

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