Implementing The Medicare Drug Benefit

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Overview

- A market in play
- The thin edge of the wedge
- Managed markets on steroids
- Changing physician practice economics (Part B dynamics)
- A look into the future
Historically, drug coverage under Medicare has been limited to one of three categories.

There are 3 major categories of covered Medicare Part B drugs:

**Type 1:** Drugs billed by physician that cannot be self-administered  →  e.g. Chemotherapies

**Type 2:** Drugs billed by pharmacy supplier and delivered through Durable Medical Equipment  →  e.g. Drugs administered through a nebulizer

**Type 3:** Drugs billed by pharmacy supplier but are patient administered and explicitly covered by statute  →  e.g. Immunosuppressant agents, some oral cancer drugs

Patients pay a 20% co-insurance for all of these drugs

As a result, many beneficiaries are left without coverage of outpatient prescription drugs.

**Sources of Rx coverage among elderly (2003):**

- No drug coverage: 38%
- Employer-Sponsored: 28%
- Medicare HMO: 15%
- Medicaid: 10%
- Medigap: 7%
- Other Public: 2%

- 38 percent of beneficiaries are left without any drug coverage
- Over the course of the year, the percentage without coverage will be much higher

Source: Kaiser Family Foundation, 2003
The CBO estimated approximately 29 million beneficiaries will enroll in the short term, although this is in question.

![Graph showing enrollment percentages]

- Third Party: 25%
- Medicaid: 100%
- Uncovered: 80%
- Other: 75%

Total: 28.8M


...But beneficiaries suggest greater uncertainty

- Will Enroll: 37%
- Don’t Know: 7%
- Need More Info: 42%


While total volumes are expected to increase due to MMA, the impact on any particular brand is less certain...

**Market Level Impact**

- Based on CBO estimates, we expect the TRx impact will be 1-2% per year through 2008
- However, total dollar impact could vary depending on pricing pressures (contracting) and brand vs. generic mix

**Brand Level Impact**

- The overall impact on any given product will depend on the specific dynamics
  - Market drivers, TA dynamics, product attributes
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Part D turns the government into the largest purchaser of prescription drugs

Source of Rx Spend, 2005
Today, the government accounts for less than 25% of Rx spending

Source of Rx Spend, 2006
In six months, the government proportion of Rx spend grows to over 40%

Source: Center for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, 2006
The costs of covering Medicare services are high and already exceed revenues

Medicare Income and Cost as a Percentage of Taxable Payroll (Part A)

2004: Costs exceed revenues
2019: Part A becomes insolvent
2077: would have to raise taxes by 300% to afford hospital benefit alone

With the addition of the drug benefit, even more strain will be placed on the government to reduce costs

Physician and Rx Expenditures and Premiums as a % of GDP

- The cost of the physician and drug benefits would grow to 30+% of Federal Budget by 2080
Over the medium term, there is significant risk for some form of government intervention

- Implement Tax
- Increase General Revenues
- >25% cost-sharing
- Mandatory Generics
- Medically-needy only

Financing

- Low-Income
- Catastrophic
- Disease-based
- $400 Billion?
- Importation
- FSS

Eligibility

- Benefit
- Best Price
- Reference Pricing

Price

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USP’s broad therapeutic class definitions makes excluding branded products an option

Formulary inclusion is only half of the access battle, as CMS explicitly allows the full arsenal of management tools

- Multi-tiered formularies
  - Zero dollar co-pay are acceptable
  - 100% co-pay levels are acceptable
  - Low income co-pay limitations
- Prior authorizations
- Step therapies
- Therapeutic interchange (with physician consent)
- Mail-order
- Financial incentives to encourage use of generics
Initially, formularies may look similar to today’s commercial plans, but things may evolve

In 2006:
• Plans compete for lives with access
• Plans approach management similar to commercial market
• CMS endorses utilization tools and a subset of plans manage aggressively

By 2008 and beyond:
• Profitability and sustainability correlate to level of control
• Lower control plans exit market
• Less beneficiary choice and option as high-control gains market traction

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Under the FFS benefit, the MMA has altered the way IV drugs can be purchased and reimbursed

<table>
<thead>
<tr>
<th>AWP-5%</th>
<th>AWP-15%</th>
<th>ASP + 6%</th>
<th>ASP + 6% or CAP</th>
</tr>
</thead>
</table>

- Beginning in 2006, physicians can continue to acquire, bill, and be paid for products under
  - average sales price (ASP) methodology or
  - competitive acquisition program (CAP)
- Each year, physicians must elect a payment method per category of products and (if CAP is elected) a contractor per category of products

Under the ASP model, physicians remain the purchasers and hold the risk for drugs

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Physician</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer supplies CMS with ASP data</td>
<td>CMS reimburses physicians for drugs at ASP + 6% plus a procedure fee</td>
<td>Many oncologists claim that in order to break even on their “bad debt”, they require ASP + 9%</td>
</tr>
<tr>
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</tbody>
</table>

Product Flow: Manufacturer → Physician → Patient → CMS
Payment Flow: CMS reimburses physicians for drugs at ASP + 6% plus a procedure fee → Many oncologists claim that in order to break even on their “bad debt”, they require ASP + 9%
However, ASP dramatically changes a physician’s economic perspective

**Illustration**

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>AWP Price</td>
<td>$1000</td>
<td>$1000</td>
</tr>
<tr>
<td>Acquisition Price</td>
<td>$800</td>
<td>$800</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>$950</td>
<td>$848</td>
</tr>
<tr>
<td>AWP-5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASP+6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure Fee</td>
<td>$100</td>
<td>$150</td>
</tr>
<tr>
<td>Physician Economic Perspective</td>
<td>$250</td>
<td>$198</td>
</tr>
</tbody>
</table>

At the end of the day, this bottom-line will influence physician behavior.

Moving forward, Medicare reimbursement/acquisition differentials will be decreased.

Procedure based fees for some products will be increased to compensate for lost product margins.

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With the implementation, the market could evolve in a variety of ways

To manage growing costs under tightening budgets, plans become increasingly aggressive in using the various management tools available to them

Beneficiaries are given economic ownership and are empowered to make treatment decisions

Despite the best efforts of the private sector, costs continue to escalate leading the government to implement some form of price/reimbursement controls

Managed Care on Steroids

The Age of the Consumer

Government Intervention

Under a more extreme managed care environment, there will be intense competition for access

Implementation
- Introduction of more limited preferred formularies
- HE increasingly used to rationalize access
- Intense competitive between competing brands for access
- Aggressive use of step therapy
- More common use of generic only formularies in TAs with strong generic options

Pharma Strategies
- Evaluate creative contracts (risk sharing, pay for outcomes, etc.)
- Target subpopulations for which product has compelling value proposition
- Conduct head-to-head trials to demonstrate superiority
- Use access as a variable for physician targeting/messaging
- Build target market access profile early in development
The “age of the consumer” potentially will turn the market dynamics upside down

### Implementation
- A multitude of plan offerings available to beneficiaries
- The donut hole and coinsurance makes price a primary decision criteria for consumers
- More open formularies, with payer management replaced with choice and economic incentives

### Pharma Strategies
- Build direct relationship with consumers through more personal communication
- Target subpopulations for which product has compelling value
- Empower physicians to be product champions (not just prescribers)
- Develop workable patient assistance programs

Ultimately, if the budget impact becomes too extreme, government intervention could come

Government intervention could be precipitated by a variety of factors...
- Politics
- Public outcry
- Budget impact
- Failure of the private sector

... and suggest specific strategies for manufacturers
- Intense HE/HO evaluations
- Head-to-head trials
- Target indications for sub-populations
- Partnership with patient groups for policy initiatives

... take various forms
- Fixed reimbursement
- Price controls
- Health technology assessment
- Group purchasing
As MMA evolves these trends likely will force the transition of the pharmaceutical industry

**The increasing aggressiveness of managed care**
- The use of generics and step therapy, as well as heightened competition for preferred access…
- …Requires clinical differentiation for specific patient populations

**Growing power of the consumer**
- Allowing broad choice, but requiring patients to experience the price more directly…
- …Necessitates building strong relationships directly with patients

**Intervention by government in pricing and reimbursement**
- The government either controlling price or dictating reimbursement
- ….Suggests greater focus on HE/OR and policy to optimize price

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