SPECIALTY DRUGS AND SPIRALING COSTS

Government Programs
WHO IS GORMAN HEALTH GROUP?

_Gorman Health Group_ is the leading solutions and consulting firm for government-sponsored health programs.

**Government Programs**
Leading enterprise of national consulting services and software solutions for payers and providers.

**Our Mission**
Our mission, as the industry’s most active professional services consultancy and provider of technology-based solutions, is to empower health plans and providers to deliver higher quality care to beneficiaries at lower costs, while serving as valued, trusted partners to government health agencies.

**Washington, DC**
Headquartered in Washington, DC, with more than 200 staff and contractors nationwide with over 2,000 combined years of Government Programs experience.

**Leadership**
Deep payer and provider knowledge coupled with Centers for Medicare & Medicaid Services (CMS) regulatory expertise.

**Privately Owned**
Founded in 1996
BROAD SERVICES

Our clients have one-stop access to expert advice, guidance, and support, in every strategic and operational area for government-sponsored programs, across seven verticals.

**CLINICAL**
Changing how you approach Medical Management, Quality and Stars.

**PHARMACY**
Leading experts in Part D, PBM, formulary and pharmacy programs.

**HEALTHCARE ANALYTICS & RISK ADJUSTMENT SOLUTIONS**
Implementing cross-functional risk adjustment programs for medical trend management and quality improvement.

**PROVIDER INNOVATIONS**
Supporting network design and medical cost control implementation.

**COMPLIANCE**
Offering guidance and support in every strategic and operational area to ensure alignment with CMS.

**OPERATIONS**
Bringing excellence to every aspect of your implementation from enrollment to claims payment.

**STRATEGY & GROWTH**
Driving profitable growth and member retention through strategic marketing, sales, and product development.
Factors Driving The Trend

- Specialty Drugs – Biologics
- Brand Name Drug Inflation
- Generic Drug Inflation
- Affordable Care Act and Medicaid Expansion
- Aging Population – Medicare
RECENT DRUG PRICING INCREASES

• Generics
  o Doxycycline-$20/500 capsules to $1849/500 capsules
  o Pravastatin 10 mg - $27 to $196 for 1 yr supply
  o Prandin - ↑ 38% in 2013
  o Captopril - ↑ 329% in 2014
  o Digoxin - ↑ 298% in 2014
  o Prednisolone Acetate - ↑ 166% in 2014

• Generic Utilization in New Jersey
  o 65.2-75.5%
  o Majority of rest of US >75.5%
SPECIALTY DRUGS
Pushing the Spending Curve

• Specialty drugs are the main driver at 30.9% of drug spend in the US in 2014

• Oncology drug spend $100B in 2014

• Hepatitis C Drugs Account for 45% of Specialty Drug increase in 2014

**Specialty drugs carry a high price tag**
From 2012 to 2020, spending on specialty drugs is expected to increase by 361%.

Specialty drug spending in US$ billions

- $87 in 2012
- $192 in 2016
- $402 in 2020

Source: PwC’s Health Research Institute: *Behind the Numbers 2015* and analysis of CVS Caremark data.
**SPECIALTY**

Top 10 Specialty Drugs 44.4% of PMPY spend for all specialty in 2014

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug</th>
<th>Therapy Class</th>
<th>PMPY Spend</th>
<th>% of Total Specialty Spend</th>
<th>Utilization</th>
<th>Unit Cost Increase</th>
<th>Total Increase in PMPY Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sovaldi</td>
<td>Hepatitis C</td>
<td>$66.22</td>
<td>9.1%</td>
<td>15,624%</td>
<td>476.7%</td>
<td>16,101.1%</td>
</tr>
<tr>
<td>2</td>
<td>Revlimid</td>
<td>Oncology</td>
<td>$47.78</td>
<td>6.6%</td>
<td>14.1%</td>
<td>6.3%</td>
<td>20.3%</td>
</tr>
<tr>
<td>3</td>
<td>Copaxone</td>
<td>MS</td>
<td>$36.91</td>
<td>5.1%</td>
<td>-2.2%</td>
<td>10.2%</td>
<td>8.0%</td>
</tr>
<tr>
<td>4</td>
<td>Enbrel</td>
<td>RA</td>
<td>$33.46</td>
<td>4.6%</td>
<td>3.4%</td>
<td>17.0%</td>
<td>20.4%</td>
</tr>
<tr>
<td>5</td>
<td>Humira</td>
<td>RA</td>
<td>$33.17</td>
<td>4.6%</td>
<td>6.4%</td>
<td>17.6%</td>
<td>24.0%</td>
</tr>
<tr>
<td>6</td>
<td>Gleevec</td>
<td>Oncology</td>
<td>$29.31</td>
<td>4.0%</td>
<td>6.0%</td>
<td>20.4%</td>
<td>26.4%</td>
</tr>
<tr>
<td>7</td>
<td>Zytiga</td>
<td>Oncology</td>
<td>$21.05</td>
<td>2.9%</td>
<td>39.9%</td>
<td>14.2%</td>
<td>54.1%</td>
</tr>
<tr>
<td>8</td>
<td>Olysio</td>
<td>Hepatitis C</td>
<td>$18.60</td>
<td>2.6%</td>
<td>25,964.2%</td>
<td>64.5%</td>
<td>26,028.7%</td>
</tr>
<tr>
<td>9</td>
<td>Harvoni</td>
<td>Hepatitis C</td>
<td>$18.01</td>
<td>2.5%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>10</td>
<td>Avonex</td>
<td>MS</td>
<td>$17.66</td>
<td>2.4%</td>
<td>-4.4%</td>
<td>11.6%</td>
<td>7.2%</td>
</tr>
</tbody>
</table>
US HEALTH CARE DEMAND

ADDED GROWTH THROUGH NEW ENROLLMENT

- Medicare Age-Ins
  - According to Pew Research center, 10,000 Baby Boomers turn 65 daily for the next 19 years
- Medicaid Expansion
  - Increase of 24% in 2015 to 71,754,506 Members
- Federal Exchanges
  - Added 16.4 million new members in 2015 according to HHS
CHANGE: MOVING THE MOUNTAIN

VALUE BASED PROPOSITION

• Drug Spending Growth is Unsustainable
  o Increased 13.1% in 2014 (ESI Trend Report)
  o The PMPY Medicare spend in 2014 is $2,987.36
    • Traditional $2,262.41
    • Specialty $724.94
• Tipping Point 2017

Specialty percent of total drug spend, 2009-2018 (p)
(combined medical and pharmacy expenditures)

Source: Forecast based on Prime commercial 8/8, 4Q2012
ACCESS TO AND COVERAGE OF – CRUCIAL CONSIDERATIONS FOR GOVERNMENT PAYERS

Specialty Medication

• What is included in the “specialty medication” category? What makes them “special:”
  o Complex to manufacture, require special handling and administration
  o Expensive – generally a small share of the population
  o Injectable or oral, self-administered or administered by healthcare provider
  o Difficult for patients to take without ongoing clinical support

ACCESS TO AND COVERAGE OF – CRUCIAL CONSIDERATIONS FOR GOVERNMENT PAYERS

Specialty Medication

- Often covered under both the prescription drug and medical benefits
  - Challenging to obtain a complete picture of the prescribing and utilization patterns across the two benefits

The IMS’ annual analysis on prescription drug use found medication spending reached its highest level (in 2014) since 2001
- $373 billion in prescription drug spending in 2014
- More than 4 billion prescriptions filled
- and almost 1/3 spent on specialty drugs

**ACCESS TO AND COVERAGE OF – CRUCIAL CONSIDERATIONS FOR GOVERNMENT PAYERS**

**Spending Estimates**

- Approximate monthly cost of commonly-used specialty medications, 2014

<table>
<thead>
<tr>
<th>Medication</th>
<th>Sample indication</th>
<th>Monthly cost for sample indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provenge (sipuleucel-T)</td>
<td>Metastatic Prostate cancer</td>
<td>$105,800</td>
</tr>
<tr>
<td>Sovaldi (sofosbuvir)</td>
<td>Hepatitis C</td>
<td>$29,900</td>
</tr>
<tr>
<td>Olysio (simeprevir)</td>
<td>Hepatitis C</td>
<td>$23,600</td>
</tr>
<tr>
<td>Rituxan (rituximab)</td>
<td>Non-Hodgkin’s Lymphoma</td>
<td>$21,900</td>
</tr>
<tr>
<td>Gleevec (imatinib)</td>
<td>Chronic myeloid Leukemia</td>
<td>$11,900</td>
</tr>
</tbody>
</table>

*Source: AHIP Issue Brief: Specialty Drugs July 2015*
ACCESS TO AND COVERAGE OF – CRUCIAL CONSIDERATIONS FOR GOVERNMENT PAYERS

Spending Estimates

• Expenditures for specialty medications helped drive up total U.S. prescription drug spending between 12-13% in 2014, depending on source
  o This was 5 times the prior year’s growth rate, according to the Centers for Medicare & Medicaid Services (CMS)
• The growth rate in 2014 for traditional medications was just 6.4%, while spending on specialty drugs increased by more than 30%

The number of patients treated for hepatitis C increased tenfold over 2013, to more than 161,000 in 2014
  - Sovaldi and Harvoni to treat Hepatitis C accounted for more than $11 billion of the 2014 spending

### Spending Estimates

<table>
<thead>
<tr>
<th>Year</th>
<th>Specialty Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>33% of total drug spend</td>
</tr>
<tr>
<td>2012</td>
<td>25% of total drug spend</td>
</tr>
<tr>
<td>2009</td>
<td>Made up 23% of total drug spending</td>
</tr>
</tbody>
</table>

*Sources: Modern Healthcare: Specialty drugs, Medicaid expansion drive jump in prescription spending April 14, 2015; AHIP Issue Brief: Specialty Drugs. July 2015*
## ACCESS TO AND COVERAGE OF – CRUCIAL CONSIDERATIONS FOR GOVERNMENT PAYERS

### New Drug Approvals

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>The Food and Drug Administration (FDA) approved 41 new drugs; this was the most in nearly two decades</td>
</tr>
<tr>
<td>2015</td>
<td>The FDA approved 45 drugs with never before sold ingredients in 2015</td>
</tr>
<tr>
<td>Prediction 2016-2020</td>
<td>IMS Health predicts 225 new drugs will be approved worldwide between 2016 and 2020</td>
</tr>
</tbody>
</table>

Sources: WSJ Out-of-pocket costs for pricey new drugs leave even some insured and relatively affluent patients with hard choices on how to afford them Dec 31, 2015; Washington Post. First-of-a-kind drug approvals continued rise in 2015. 1/4/16
“High prescription drug prices will be a top-tier political issue in 2016” as the introduction of many expensive specialty medications threaten to drive up healthcare spending.

Clinton and Sanders have outlined plans to negotiate prices with drug makers, and Clinton wants to cap consumers’ out-of-pocket costs for drugs.

Republican candidates generally favor easing the drug approval process to reduce drug development costs.

Source: Modern Healthcare. High drug prices will be a big political issue in 2016. 1/4/16
The U.S. Government Accountability Office (GAO) released a report November 20 (GAO-16-12) examining the impact of newly-approved drugs on Medicare Part B spending:

- 61% of the 83 drugs covered by Part B and approved from 2006 - 2013 were biologics.
- In 2013, Medicare spent $5.9 billion on new Part B drugs.
The HHS Office of Inspector General (OIG) released a report November 24 (OEI-12-14-00030) on what Part B paid for 340B drugs

- $3.5 billion in 2013.
- Covered entities retained approximately $1.3 billion of that amount.
Medicaid was the largest driver of retail prescription spending growth in 2014.

The number of prescriptions filled through the program rose by 17% in 2014, accounting for 70% of the overall growth in demand for medications (IMS’ annual analysis on prescription drug use).

- The first full year of the Affordable Care Act (ACA) enrollment saw Medicaid beneficiaries in states that expanded the program fill 25% more prescriptions in 2014, compared with a 3% increase in non-expansion states.

Source: Modern Healthcare April 14, 2015
Almost 50% of Medicaid beneficiaries with hepatitis C in 4 states were denied coverage of new antiviral therapies, according to a study by Burman’s Specialty Pharmacy and Penn Medicine.

- Presented at the recent American Association for the Study of Liver Diseases 2015 Liver Meeting.

Source: Specialty Pharmacy News Dec 2015
CMS sent this notice to all state technical contacts stating that “CMS remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share.”

The purpose of the letter was to specifically advise on the coverage of drugs for hepatitis C.
STATE MEDICAID PROGRAMS

Medicaid Drug Rebate Program Notice #172

Rules regarding Medicaid drug coverage – Reminder of compliance with the Social Security Act 1927(d)(1) and (2) of the Act. May subject drug to prior auth (PA) and must be for medically-accepted indication.

The notice reminds states that they are required to provide coverage for those covered outpatient drugs of manufacturers who have entered into a rebate agreement, including the HCV drugs.
STATE MEDICAID PROGRAMS

Medicaid Drug Rebate Program Notice #172

• CMS expresses concern that some states’ restrictions “should not result in the denial of access to effective, clinically-appropriate and medically-necessary treatment for chronic HCV infections.”
  o Limiting treatment – Liver damage that has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4.
  o Some states also require a period of abstinence from drug and alcohol abuse as a condition for payment for HCV drugs.
  o Requiring HCV meds to be prescribed by, or in consultation with, specific provider types, like gastroenterologists, hepatologists, liver transplant specialists, or infectious disease specialists.
COST CONCERNS

Pricing

• An investigation found that Gilead Sciences, Inc., priced its hepatitis C therapies Sovaldi and Harvoni in order to “maximize revenue.”

• According to a report from Senate Finance Committee members Ron Wyden (D-Ore) and Charles Grassley (R-Iowa), “fostering broad, affordable access was not a key consideration in the process of setting the wholesale prices,” which were $84K for Sovaldi and $94,500 for Harvoni.

• In the 18 months since Sovaldi has been on the U.S. market, Medicare spent almost $8.2 billion before rebates on both drugs.

Source: Specialty Pharmacy News Dec 2015 – News Brief
COST CONCERNS

Part D – Out-of-Pocket

• Part D enrollees pay only 5% of a drug’s cost when they have exceeded the catastrophic coverage threshold; those costs can total thousands of dollars for specialty drugs.
  o At the beginning of the year, 25-33% of drug costs, in addition to deductible in many plans, in the initial coverage period.
  o 2016 initial coverage limit $3,310 – enrollees will reach the coverage gap or “donut hole” quickly.
  o 2016 – In the coverage gap, enrollees pay 45% of drug costs until they hit the catastrophic threshold of $7,515 in out-of-pocket costs. After this, the 5% of drug costs kicks in.

COST CONCERNS

Part D – Out-of-Pocket

• Imbruvica (ibrutinib) – originally for a rare illness called mantle-cell lymphoma and later approved to treat some patients with chronic lymphocytic leukemia (CLL)
  o Medicare out-of-pocket $7,000 - $8,000/yr
  • More than half of Imbruvica users are on Medicare
  o Wholesale list price is $116,600 a year for leukemia patients
  o For the higher dose needed for lymphoma, it is about $155,400

Source: Out-of-pocket costs for pricey new drugs leave even some insured and relatively affluent patients with hard choices on how to afford them (WSJ Dec 31, 2015)
HEALTH PLAN EFFORTS

Pharmacy and Medical Integration

• Integration and Coordination of Pharmacy and Medical Benefits
  o Providing patients with tools and support to help successfully manage their specialty medications
    • Ex. Use of the most efficient site of care, including home or physician offices
  o Promoting collaborative arrangements with physicians and pharmacists with expertise in management of specific conditions

Source: AHIP Issue Brief: Specialty Drugs July 2015
HEALTH PLAN EFFORTS

Treatment Adherence

• Policies to Maximize Treatment Adherence
  o Health plans are engaging patients about their disease and how to take their medication correctly – coordinating with providers and helping them understand potential side effects
  o Condition-specific care management support teams to help patients adhere to their treatment regimens

Source: AHIP Issue Brief: Specialty Drugs July 2015
HEALTH PLAN EFFORTS

Utilizing Specialty Pharmacies

• Focusing on the supply side with the use of specialty pharmacies
  o Many health plans contract with specialty pharmacies who supply members with specialty drugs
    • They will coordinate the often complex delivery and treatment processes associated with these drugs.
    • They also employ dedicated teams of healthcare specialists who can help enrollees understand how to manage their medication and can help ensure these drugs are administered at the most appropriate site of care.

Source: AHIP Issue Brief: Specialty Drugs July 2015
HEALTH PLAN EFFORTS

Bundled Payments

• Bundled payment arrangements
  o Reimbursing physicians for the treatment episode as a bundled service – encouraging treatment consistent with evidence-based, accepted clinical guidelines.
    • Consumers and providers should be empowered to know which treatments and drug regimens work and which are less effective. In the absence of a national process for measuring the cost-effectiveness of procedures and drugs, many providers are attempting to control costs by basing coverage decisions on the relative costs of similar treatments.

Source: AHIP Issue Brief: Specialty Drugs July 2015
THINGS TO CONSIDER

Exclusivity Period

• Brand name biologic drugs given a 12-year exclusivity period upon approval from the FDA.
  o Although these exclusivity periods give pharmaceutical manufacturers the incentive to take on the risk of developing groundbreaking drugs, they also precipitate a number of negative policy consequences.
    • Possible solution: shorten the exclusivity period similar to patent protections for traditional drugs.
    • The U.S. Federal Trade Commission (FTC) has concluded the current 12-year exclusivity period as “unnecessary to promote innovation by pioneer biologic drug manufacturers” and may harm consumers.

Source: AHIP Issue Brief: Specialty Drugs July 2015
THINGS TO CONSIDER

Cost Effectiveness

• Expanding agencies’ authority to consider research on treatment effectiveness
  o Congress could provide new authorizing language for the Patient Centered Outcomes Research Institute (PCORI) that allows it to consider cost-effectiveness as a valid component of patient outcomes research.

Source: AHIP Issue Brief: Specialty Drugs July 2015
THINGS TO CONSIDER

Encouraging Competition and Innovation

• Congress and the FDA should seize opportunities to improve value to patients and reduce costs
  o Targeted incentives for true breakthrough therapies
  o Serious or life-threatening diseases where no treatments are available – a clear pathway for approval of biosimilars and encouraging market competition
THINGS TO CONSIDER

Biologics Price Competition and Innovation Act

• Passage of the Biologics Price Competition and Innovation Act
  o Generic biologics or “biosimilars” are highly similar to previously approved brand-name biologics but available at a lower cost.
  o The FDA approved the first biosimilar in March 2015.
  o The ACA authorized the FDA to develop an abbreviated licensure pathway for biosimilar drugs but has yet to issue final standards that will determine when a biosimilar drug is truly interchangeable with an already approved biologic.
THINGS TO CONSIDER

Reforming Medicaid Rebates

• Reforming Medicaid drug manufacturer rebates to promote competition
  o Drug manufacturers must provide a specific discount to states and the federal government for the drug they provide.
    • The discount must equal the greater of either:
      - 23.1% of the drug’s average wholesale price; or
      - The difference between the average wholesale price (AWP) and the lowest price the manufacturer receives for the drug from private purchasers (“best price”).

Source: AHIP Issue Brief: Specialty Drugs July 2015
Adopt a “least costly alternative” (LCA) standard for certain drugs covered under Medicare Part B
  
  • Allow CMS the flexibility to set a single payment rate for groups of clinically similar drugs based on the lowest-cost item
    • Consumers and patients selecting a higher cost drug would be responsible for any cost differential between the drug selected and the lowest cost, clinically-equivalent drug within a class

Source: AHIP Issue Brief: Specialty Drugs July 2015
QUESTIONS
Gorman Health Group, LLC (GHG) is a leading consulting and software solutions firm specializing in government health programs, including Medicare managed care, Medicaid and Health Insurance Marketplace opportunities. For nearly 20 years, our unparalleled teams of subject-matter experts, former health plan executives and seasoned healthcare regulators have been providing strategic, operational, financial, and clinical services to the industry, across a full spectrum of business needs. Further, our software solutions have continued to place efficient and compliant operations within our client’s reach.

GHG offers software to solve problems not addressed by enterprise systems. Our Valencia™ software reconciles membership of more than 10 million members in Medicare, Medicaid and the Health Insurance Marketplace. Over 3,000 compliance professionals use the Online Monitoring Tool™ (OMT), our complete Medicare Advantage and Part D compliance toolkit, while more than 33,000 brokers and sales agents are certified and credentialed using Sales Sentinel™. In addition, hundreds of health care professionals are trained each year using Gorman University™ training courses.

We are your partner in government-sponsored health programs