



Specialty Drug Management

Is it possible?



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SPECIALTY DRUGS CARRY A HIGH PRICE TAG

From 2012 to 2020, spending on specialty drugs is expected to increase by 361%.



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

Defining Specialty Drugs

Categories/Types of Specialty Drugs

- **Brands**
 - Garden Variety
 - Orphan
 - Super Orphan
 - Brands
- **Biosimilars**
- **Limited Distribution Drugs**
- **Infused**
- **J Codes**
- **CAR-T Drugs**



Defining Speciality Drugs

Definition Challenges

- Non Specialty MediSpan- NOT!
 - CMS—\$600/30 Days
 - PBM's—Special Handling, Typically Injectables, etc.

Potential Solutions

- Contractual
 - Therapeutic Categories
 - Three Pricing Categories—Brand, Biosimilar, LDDs
 - Default Pricing—Future Releases
- Operational
 - Mining J Codes
 - Home Infusion



Latest Trends

- **CAR-T Drugs**
 - Zymriah is first to be released
 - \$625,000
 - Pipeline = 420 additional meds
- **Value Based Chart**
 - Numerous Challenges
- **Precision Medicine**
 - Genetically Based Compounds



Pharma- The Masters of All They Survey

- Direct to Consumer Advertising- \$4.3 Billion= 9:1 ROI
- High Cost Drug Couponing
- JBMA Cancer Medication Study- 57%
- Alignment with PBMs- Rebate Contracts
 - Formularies- Excluded Drugs
 - Control Clinical PA criteria
 - Up to 42% of PBM gross profit margins
 - 14 additional forms of revenue



Humira- The PBM/Pharma Poster Child – As of 2017

- \$20 Billion Annual Sales
- Lost Patent Protection
- Thicket of Lawsuits- 110
- Essentially extended patent for 6 years
- \$60k per year- raised price 17%
- Enbrel lower net cost after rebates

Managing High Costs

- Average Cost = \$5,000/Month, \$60K/Year
- Stop Loss = Bad News = Lasers and Potential Off Label Denials
- Complexity = Opportunities for Errors
- Defining What Is/Isn't
 - HIV & Transparent Meds
 - Specialty RX PBM Lists





High Cost Drugs

The Paradigm is Inside Out

- **What Do We Currently Focus On?**
 - Easy Quantifiable Metrics
 - Discounts
 - Rebates
- **What Do We Need To Focus On?**
 - Utilization Management
- **What Are The Challenges?**
 - Visibility
 - Expertise

AWP Control: Enoxaparin (Blood Thinner)

Manufacturer	Unit Price	AWP at 60 Units	Metric Strength
AMPHASTAR	\$27.00	\$1,620.00	150.00000
AMERINET	\$27.00	\$1,620.00	150.00000
NOVAPLUS	\$18.07	\$1,084.32	150.00000
TEVA	\$35.77	\$2,146.32	150.00000
FRESENIUS	\$35.77	\$2,146.32	150.00000
TEVA	\$79.20	\$4,752.00	150.00000
WINTHROP	\$134.01	\$8,040.66	150.00000
ACTAVIS	\$121.97	\$7,318.08	150.00000
WINTHROP	\$121.83	\$7,309.74	150.00000
SANDOZ	\$121.97	\$7,318.08	150.00000

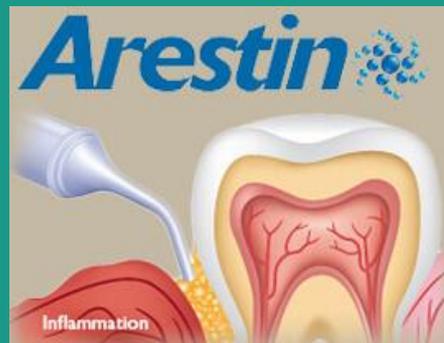
Enoxaparin Injection



“Real World” Results

Dental Prescription - Right Medical Condition, Alternative Drug Was Far Less Expensive

- The patient was given a script for Arestin - a \$5,200 injectable antibiotic
- There were less expensive alternatives costing an average of \$150.
- The Clinical Pharmacist contacted the Dentist to discuss the medication.
- The Dentist was unaware of the high cost and immediately issued a script for a less expensive alternative.
- The plan subsequently excluded this medication from coverage.



Meaningful Savings

Hepatitis C Prescription - Right Medical Condition, Wrong Variables, Wrong Drug

- Review of the patient's medical records/labs indicated that the patient's condition warranted Harvoni x12 weeks, not Viekira plus Ribavirin.
- The Clinical Pharmacist submitted data from clinical trials to the physician to substantiate her findings.
- Result - The plan achieved savings of \$89,000
- The patient avoided an extra 12 weeks of therapy.



Review Results in \$250,000+ savings

Orkambi Prescription - Right Medical Condition, Wrong Variables - a Drug was Unnecessary

- The PBM approved Orkambi, claiming that the MD had submitted all the necessary paperwork to the Orkambi 'hub.'
- PBM was unable to confirm that patient was homozygous for the F508deL mutation.
- The only approved indication for Orkambi, in fact, the PBM only required a verbal authorization.
- The medical records were requested and received.
- Clinical review revealed that the patient did not have the mutation and did not meet the criteria.
- **This saved the plan \$350K per year for the remainder of the patient's life.**



SCENARIO ONE

DRUG NAME: **KORLYM®**

Dx: NOT LISTED (ASSUMED CUSHINGS SYNDROME)

Hx: NONE

CLINICAL CRITERIA

DIAGNOSIS OF ENDOGENOUS CUSHING'S SYNDROME
WITH SECONDARY HYPERGLYCEMIA; **OR**

- DIAGNOSIS OF DIABETES;
- PATIENT MUST HAVE FAILED OR NOT BE
CANDIDATE FOR PITUITARY SURGERY

DENIAL REASON(S)

- NO FDA APPROVED DIAGNOSIS
- NO FAILED PITUITARY SURGERY
- NO PRIOR TREATMENT FOR CUSHINGS SYNDROME
- NO STANDARD TESTS TO PROVE CUSHINGS
SYNDOME

SAVINGS - \$163,000/YEAR

SCENARIO Two

THREE YR OLD MALE PATIENT

DRUG NAME: **SABRIL®**

Dx: COMPLEX PARTIAL EPILEPTIC SEIZURE

Hx: TRIED/FAILED 2 OTHER SEIZURE MEDICATIONS

CLINICAL CRITERIA

DIAGNOSIS OF INFANTILE SPASMS; **OR**

ALL OF THE FOLLOWING:

- DIAGNOSIS OF COMPLEX PARTIAL SEIZURES **AND**
- TAKING ADDITIONAL SEIZURE MEDICATION **AND**
- TRIED AND FAILED **TWO** SEIZURE MEDICATIONS **AND**
- INITIAL AND PERIODIC (EVERY 6 MONTHS) EYE EXAMS

DENIAL REASON(S)

- MONOTHERAPY
- USED FOR PT \geq 10 YRS OLD
- INSUFFICIENT EYE EXAMS
- DUE TO THE RISK OF POTENTIAL PERMANENT VISION LOSS

SAVINGS > \$258,000/YEAR

Methods for Protecting the Future



“She’s going to need a prescription for light-headedness. She fainted when I told her how much her meds cost.”

Role of PBM

- **Create programs that manage cost & utilization**
 - Variable co-pays
 - Outcomes-based drug treatments
- **Extract pricing concessions from Pharma**
 - Discounts & rebates
- **Properly administer Clinical PAs**
 - Eliminate disconnects between static protocols and real world administration
- **Eliminate coverage for ineffective medications**
 - 57% of cancer drugs

Key Takeaways

- Contractual protection
Home Infusion Strategy
J Code Analysis
- Home Infusion Strategy
Patient Assistance Programs
- Rx Tourism
- International Mail Order
- Carve out Specialty
- Variable Co-pay Programs
- 340b Program Offerings...???
- Hemophilia Factor Assay
Guarantee
- Veritas Specialty Rx Clinical
PA Oversight Program