



Specialty Drug Management

Is it possible?

John R. Adler
President/Consultant
ELMC Rx Solutions



Cost of Specialty Drugs

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, LDD's
 - Default Pricing—Future Releases
- Operational
 - Mining J Codes
 - Home Infusion



Latest Trends

- **CAR-T Drugs**
 - Zymriah is first to be released
 - Pipeline @ 420 additional meds
- **Value Based Chart**
 - Numerous Challenges
- **Precision Medicine**
 - Genetically Based Compounds

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



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





High Cost Drugs

The Paradigm is Inside Out

- **What Do We Currently Focus On?**
 - Easy Quantifiable Metrics
 - Discounts
 - Rebates
 - Clinical PA Costs
- **What Do We Need To Focus On?**
 - Clinical PA's
- **What Are The Challenges?**
 - Visibility
 - Expertise



Clinical PA Operational Criteria

- Clinical Prior Authorization Term can be as long as 3 years
- Not Requiring Updated Clinical When Extending Clinical PA Team - recent labs, monitor for side effects
- Not Following Clinical Criteria
 - Example: Verify intolerance or contraindication to methotrexate first over Humira
- Genetic Testing Required - Who is responsible & verifies it has been done?



Clinical PA Operational Criteria

- Skipping critical steps in the Clinical PA Criteria
- Not requiring Medical documentation - verbal or automated only
- Have Pharmacist or Clinical expert involved in approvals, not just denials
- Prior authorization transparency - screenshots & notes
- Adherence/analyze possession ratios

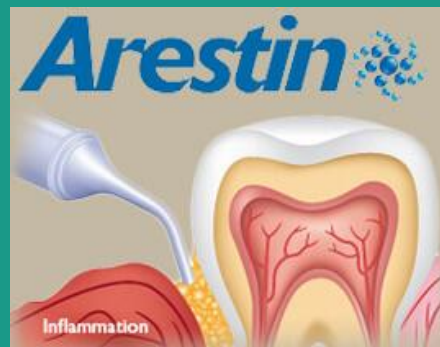
Clinical Prior Authorization Examples

- Right Drug?
- Cheaper Drug?
- Right Variables?

Clinical PA Example #1

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

- The patient was given a script for a \$5,200 injectable antibiotic - Arestin.
- There were several less expensive alternatives costing an average of \$150.
- The Clinical Pharmacist called the Dentist and talked about this medication.
- The Dentist was unaware of its high cost and immediately discontinued the therapy, issuing a script for a less expensive alternative.
- Subsequently excluded this medication from coverage.



Clinical PA Example #2

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

- Review of the patient's submitted medical records/labs found that the patient's condition warranted Harvoni x12 weeks, not Viekira plus Ribavirin.
- The Clinical Pharmacist submitted data from clinical trials to substantiate her findings to the physician.
- The plan savings in excess of \$100K
- The patient avoided an extra 12 weeks of therapy that would have worsened their condition.



Clinical PA Example #3

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.'
- They were unable to answer if the patient was homozygous for the 508del mutation.
- The only approved indication for Orkambi, in fact, the PBM only required a verbal authorization.
- The medical records were requested and received.
- Their review revealed that the patient did not have the mutation and did not meet the criteria.
- This saved the plan \$300K per year for the remainder of the patient's life.



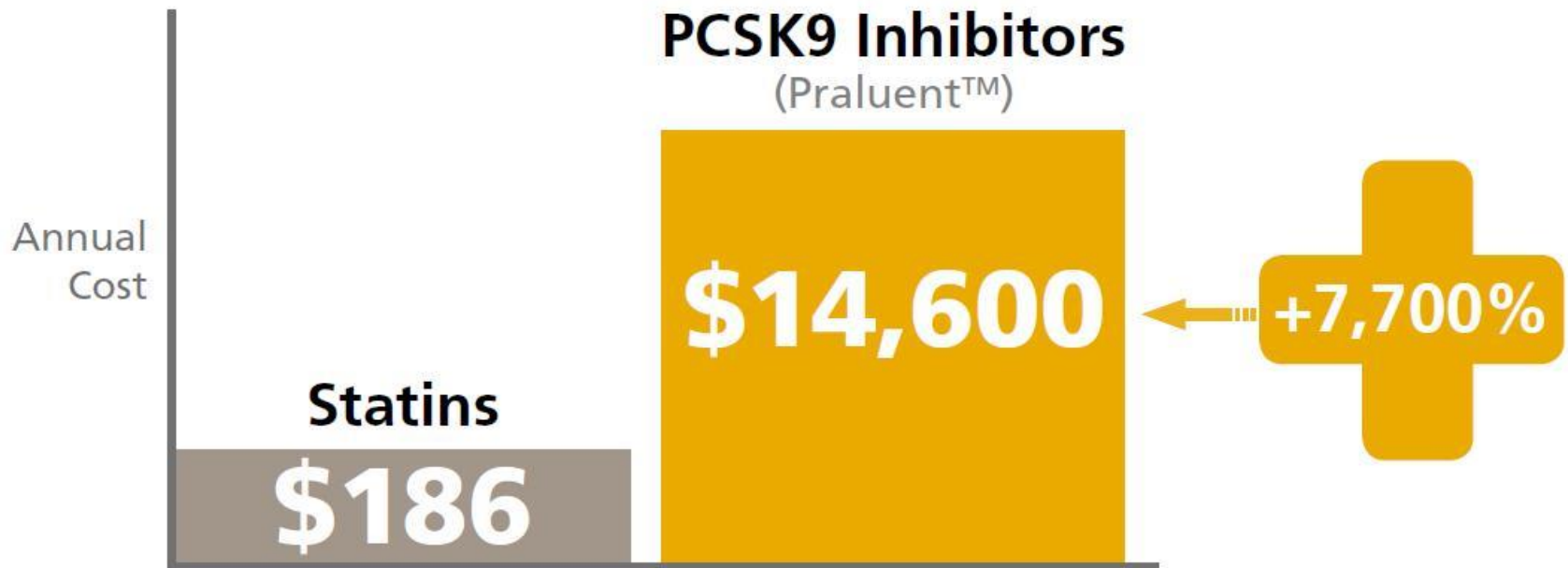
Cholesterol Drugs - PCSK9



Cholesterol Drugs - PCSK9

Average Annual Cost of Therapy

Costs could soar with widespread use of PCSK9 Inhibitors



Statin cost: WAC drug costs for atorvastatin. OptumRx Q2-2015 utilization data.
Reuters. New heart drugs come in more expensive than expected. Jul 27, 2015.

Case Study: PCSK-9 Super Status

Cost + Prevalence = Ouch!

- 2017 Long Term Study
- 2015 Off Label Lawsuit
- Expansion of indications - 1,000 drug reps
- Price increase from \$10,000 to \$14,600 - Why?
- ACA Minimum Value, Discrimination, and Custom Formulary Considerations
- ICER Value = \$2,342/year

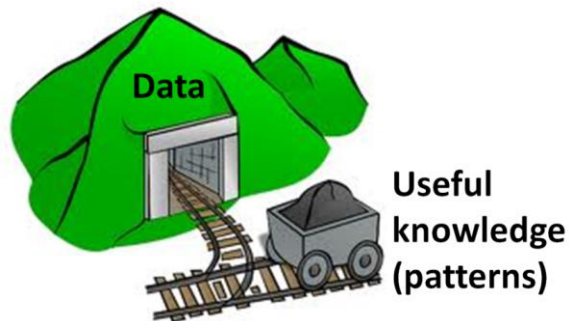
Methods for Protecting the Future



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

Methods for Projecting the Future

- **Challenges**
 - Who has what disease?
 - What drug will be approved for it?
 - What will it cost?
- **Mine Member Claims**
 - Compare to drug pipeline
 - Assume cost at \$100K/year minimum



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 PA's**
 - Eliminate disconnections between static protocols and real world administration
- **Eliminate coverage for ineffective medications**
 - 57% of cancer drugs

Key Takeaways

- **Contractual protection**
 - Define, Define, Define
 - AWP Control
- **Home Infusion Strategy**
- **J Code Analysis**
- **Humira/Methotrexate Analysis**
- **Patient Assistance Programs**
- **Rx Tourism**
- **International Mail Order**
- **Carve out Specialty**
- **Variable Co-pay Programs**
- **340b Program Offerings...???**
- **Hemophilia Factor Assay Guarantee**
- **Specialty Rx Clinical PA Oversight**
 - In real time