



# Winter is Coming:

## How to Effectively Manage Ultra-High Dollar Pharmacy & Medical Drug Claims

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Presented to:

**AIC Annual Meeting**

9/22/21 – 1:15 PM

# Speaker



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# Learning Objectives

1. List the categories of disease states and orphan drugs/gene therapies in the pipeline, along with proposed costs.
2. Analyze how to proactively manage orphan/gene/specialty drug costs inside self-funded plans across both medical and pharmacy benefits.
3. Given a hypothetical case, discuss how to implement orphan drug, gene therapy and high dollar specialty drug management moving forward in self-funded plans.



# What is a Specialty Drug?

- Treats a complex, and/or chronic medical condition, which may be progressive
- Often biologics
- Treats a rare or orphan disease indication
- Requires extensive monitoring by prescriber, additional patient education, and support. May require a procedure to be administered
- Could be an oral, inhalable, infusible or injectable drug or product
- Has unique storage or supply chain requirements, like refrigeration or freezing; may have limited distribution
- Is not often stocked at retail pharmacies – often billed through the medical benefit
- Treat diseases such as cancer, immunological disorders, multiple sclerosis, hepatitis C and many others
- Is high cost



# What is a Medical J/C/Q Code Drug?

- **Medical drugs** are used for acute inpatient hospital settings, but more and more maintenance therapies are showing up in medical drug benefits.
- Drugs can be billed under the medical or pharmacy benefits
- Medical drug maintenance therapies are nearly all infused or implanted
- They are billed most often under a special HCPCS code, a J, C or Q code, with billing units instead of by NDC
- Some newer J/C/Q code drugs are also **specialty drugs**

# Medical vs. Pharmacy Drugs

	Medical Drug (Outpatient)	Pharmacy Drug
• Route of administration?	Infused or inserted	Other routes (oral, topical, etc.)
• Where obtained?	Infused in hospital, doctor's office, home, or infusion center	At the pharmacy (chain, independent, etc.)
• Types of drugs? Example?	Chemotherapy, MS infusions, some biologicals	Tablets, capsules for maintenance
• Billed (generally) where?	Under the medical benefit	Under the pharmacy benefit
• Billed (generally) how?	J/C/Q Code drugs (billed by code and units)	Prescription drugs (billed by NDC and quantity)
• Price benchmark?	Average Sales Price (ASP)	Average Wholesale Price (AWP) or NADAC
• General cost?	Higher (more complex, + infusion or procedure cost)	Generally lower than medical drugs
• Covered under which part of Medicare?	Part B	Part D

# Largest J/C/Q Code Medical Drug Categories & Drugs on Commercial Plans

- |   |                                  |
|---|----------------------------------|
| 1. Oncology – <span>↑</span> 22% in 2020*         | 1. Remicade – <span>↓</span> 8%  |
| 2. Crohn's/UC – <span>↑</span> 9%                 | 2. Neulasta – Flat               |
| 3. Immune Globulins – <span>↑</span> 3%           | 3. Ocrevus – <span>↑</span> 85%  |
| 4. Multiple Sclerosis – <span>↑</span> 48%        | 4. Herceptin – <span>↑</span> 2% |
| 5. Colony Stimulating Factors – <span>↑</span> 7% | 5. Rituxan – <span>↑</span> 6%   |
| 6. Rheumatoid Arthritis – <span>↓</span> 15%      | 6. Keytruda – <span>↑</span> 74% |
| 7. Antihemophilic Factor – <span>↑</span> 11%     | 7. Avastin – <span>↑</span> 13%  |
| 8. Hematology – <span>↑</span> 32%                | 8. Entyvio – <span>↑</span> 42%  |
| 9. Asthma/COPD – <span>↑</span> 25%               | 9. Opdivo – <span>↑</span> 10%   |
| 10. Ophthalmic Injections – <span>↑</span> 21%    | 10. Perjeta – <span>↑</span> 18% |

\*(% change since 2018-2019 vs. 2019-2020)

Magellan. Medical Pharmacy Trend Report 2020, Eleventh Ed.

<https://www1.magellanrx.com/read-watch-listen/read/our-publications/medical-pharmacy-trend-report/> Last accessed 7/13/21.

# Unlocking the Universe of Specialty Drugs

## Specialty Drugs

Hundreds Approved  
2% of all Prescriptions  
40-85% of Total Rx Spend

## Limited Distribution Drugs

Not widely available drugs  
May have a REMS program  
Channels determined by the Drug Manufacturer  
45% of Total Rx Spend

## J & Q Code Drugs Medicare Part B Physician-Administered Drugs



Medical Infused Drugs or Drugs with Procedure; Administered in Doctor's Office, Home Infusion, Infusion Center, or Hospital

Requires coordination of care  
Medicare spent \$30B on J Code Drugs in 2019

## Orphan Drugs

730+ approved; 6,000 indications  
450+ in pipeline  
(60% of FDA approvals In 2020 were Orphan)  
The Orphan Drug Act of 1983

## Gene Therapies

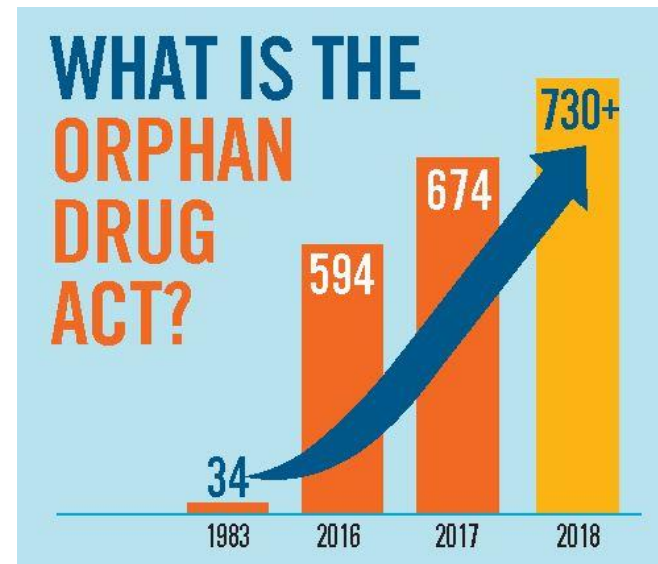
17 approved  
350+ in pipeline  
(6,000 clinical trials)

Sources: CMS, JMCP (<https://www.imcp.org/doc/pdf/10.18553/imcp.2020.26.3.234>), AMCP Midwest 2020, <https://decisionresourcesgroup.com/blog/limited-distribution-drugs-101/>



# Orphan Drugs








- In the United States, a **rare disease** is defined as a condition that affects **fewer than 200,000** people in the US
- **The Orphan Drug Act of 1983** incentivized manufacturers to research and bring therapies to market
  - Since then, **730+ orphan drugs** have been approved by FDA
  - **1,000 more in the drug pipeline**, according to PhRMA
- The average annual orphan drug cost rose from **\$7,136** in 1997 to **\$186,758** in 2017
- Orphan drugs are **25x more expensive** than non-orphan drugs.
- **~60% of new FDA drug approvals in 2020 were orphan drugs.**
- **~40% of new FDA drug approvals in 1H2021 were orphan drugs.**
- Orphan drugs can be both in the medical benefit or in the pharmacy benefit, depending upon the administration of the drug.










# 2021 FDA Approved Orphan Drugs

- 42% of the Novel FDA Drug, Cell and Gene Therapy Approvals in 2021 are orphan drugs as of 8/9/21.

## Cancer Drugs:

- **Lumakras** - \$17,900 per month<sup>4</sup> – non-small cell lung cancer 
- **Pepaxto** - \$9,928 per unit<sup>7</sup> – multiple myeloma 
- **Tepmetko** - \$10,919 for a 30 days' supply<sup>12</sup> – non-small cell lung cancer 
- **Ukoniq** - \$16,609 for a 30 days' supply<sup>11</sup> – marginal zone lymphoma and follicular lymphoma 
- **Truseltiq** - \$21,500 per month<sup>3</sup> – cholangiocarcinoma 
- **Rylaze** - \$5,268 per dose - acute lymphoblastic leukemia and lymphoblastic lymphoma 
- **Zynlonta** - \$23,500 per vial<sup>6</sup> – large B-cell lymphoma (CAR-T) 

## Drugs for Other Orphan Diseases:

- **Amondys 45** – \$350,000 w/ weight-based cost and dosing; 50 lb. child per year<sup>9</sup> – Duchenne muscular dystrophy 
- **Empaveli** - \$458,000 per year<sup>5</sup> – adult paroxysmal nocturnal hemoglobinuria 
- **Evkeeza** - \$450,000 wholesale acquisition cost per patient per year<sup>10</sup> – homozygous familial hypercholesterolemia 
- **Nulibry** – “just short of \$500,000 per patient per year”<sup>8</sup> – molybdenum cofactor deficiency Type A 
- **Nexviazyme** - \$905 per injection – Pompe Disease 
- **fexinidazole** – unknown cost – Sleeping Sickness 
- **Rezurock** - \$15,500 per month – Chronic graft vs. host disease (cGVHD) 

*FDA orphan drug approvals as of 8/9/21.*

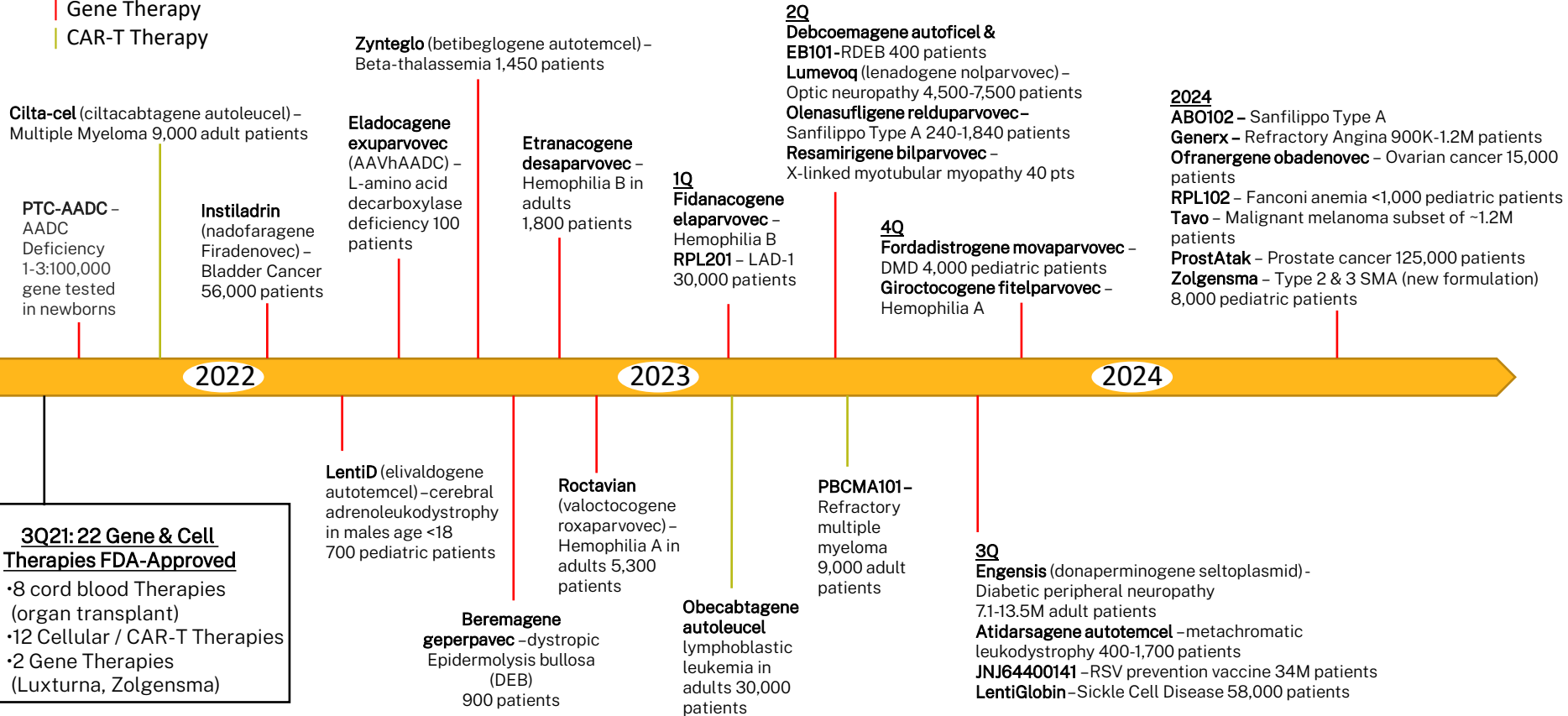
*Approximate costs were gathered from publicly available sources.  
Some costs may vary based upon use, weight of patient, and/or dose.*

# Gene & Cellular Therapies in Development

Many are for rare genetic disease with high morbidity and few or no treatment options

## Legend

- | Gene Therapy
- | CAR-T Therapy



# FDA-Approved Cellular and Gene Therapies

Currently, there are 22 FDA Approved Cellular and Gene Therapies; with procedures

- 8 are cord blood (used in organ transplants)
- Remainder: (Yellow are new in 2021 – 80% of approvals thus far are orphan designated)
- Cancer Therapies:
  - \* Abecma - \$419,500 per treatment – refractory multiple myeloma
  - \* Breyanzi - \$428,363 per treatment – refractory large B-cell lymphoma
  - \* Imlygic - \$65,000 per treatment average – melanoma after surgery
  - \* Kymriah - \$475,000 per treatment – B-cell leukemia/lymphomas
  - \* Provenge - \$93,000 for 3 infusions – prostate cancer
  - \* Tecartus - \$373,000 per treatment – mantle cell lymphoma
  - \* Yescarta - \$373,000 per treatment – some lymphomas

## Other Therapies:

- \* Gintuit – cost unknown – dental use for wound bed treatment
- \* Laviv - \$3,000-4,500 per patient - nasolabial fold wrinkles
- \* Luxturna - \$850,000 per treatment - rare form of genetic blindness
- \* MACI - \$45,000 per sheet - cartilage defects of the knee
- \* Ryplazim – cost unknown - plasminogen deficiency type 1
- \* StrataGraft – cost unknown – treatment of thermal burns
- \* Zolgensma - \$2,125,000 per treatment – spinal muscular atrophy

*FDA approvals as of 8/9/21.*

*Approximate costs were gathered from publicly available sources.*

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# Issues with J/C/Q Code Medical Drugs

## 1. Acquisition of the Drug

- Buy & Bill, White, Brown, or Clear Bagging (4 ways)?
- Payer mandates?
- State/Federal laws?

## 2. Site of Care for infusion or insertion

- At hospital, doctor's office, infusion center, or home?

## 3. Savings Programs for high dollar claims

- Rebates, discounts, coupons, patient advocacy programs?



# 1. How are these drugs acquired?

- Buy and Bill
- White Bagging
- Brown Bagging
- Clear Bagging

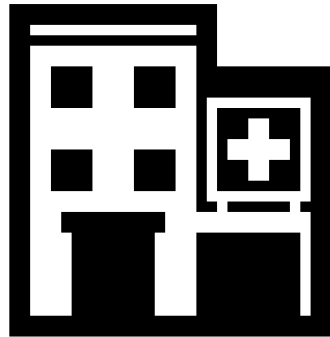
1. NABP. "White and Brown Bagging Emerging Practices, Emerging Regulation," published 4/18/18.  
[https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018\\_Final-1.pdf](https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf)



## 2. Site of Care - Infusion

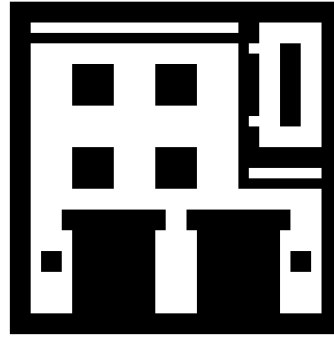


At Home



At Hospital

- ER
- Inpatient
- Outpatient



At Infusion Center



At Doctor's Office

# Payer Mandates on White Bag Medical Drug Acquisition

- UnitedHealthcare
- Anthem
- CIGNA

Benefits Apex B  
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Benefits Apex B  
Apex Benefits A  
Benefits Apex B  
Apex Benefits A  
Benefits Apex B  
Apex Benefits A



# Federal & State Laws on White Bagging

- **Federal:** Is accepting white bagged drug against the law of the Drug Quality and Security Act?
- **State of Indiana:**
  - Indiana General Assembly 2021 Session: Senate Bill 143 (Died)
  - Indiana



# Strategies to Contain High-Cost Claims: Payer Saving Strategies vs. Employer Savings Strategies

## Payer Strategies (N = 26)

1. Reinsurance/Stop Loss
2. Gene therapy carve-out
3. Orphan drug carve-out
4. Benefit exclusion
5. Shift coverage from the medical to the pharmacy (Rx) benefit
6. Risk pools
7. Amortization/installment model
8. Third-party subscription (PMPM) model

## Employer Strategies (N = 11)

1. Reinsurance/Stop Loss
2. Shift coverage from medical to Rx benefit
3. Benefit exclusion
4. Third-party subscription (PMPM model)
5. Risk pools
6. Amortization/installment model
7. Orphan drug carve-out
8. Gene therapy carve out

# 3. Specialty Savings Programs

What about:

- Drug Discounts
- Drug Rebates
- Manufacturer Copay Coupons or
- Patient Advocacy Programs

?

# Pharmacy Cost-Savings Tools



# Strategies to Contain High Dollar Claim Costs – Medical Claims

- Strong data analytics platform
  - “If you can’t measure it, you can’t manage it.” – Peter Drucker
- Have healthcare professionals monitor analytics on a frequent, regular basis
  - Make meaning out of the data
- Find a broker with peer-to-peer influence with the carriers:
  - Nurse to nurse or
  - Pharmacist to pharmacist

# Strategies to Contain High Dollar Drug Costs

- Ask for regular, high dollar drug analysis
  - Medical drugs
  - Pharmacy drugs
  - Are these drugs short-term, or long-term use for the patient(s)?
- Engage PBM in cost savings solutions for Specialty Drugs
  - Pharmacy drugs
  - Medical drugs

# Questions to Hold Your Carriers and Brokers Accountable

- What is being done to contain costs around high dollar specialty drugs?
  - PBM Contract Management
  - Utilization Management
  - Discounts
  - Rebates
  - Coupons
  - Bridge Programs
  - Patient Assistance/Advocacy, & Foundation Programs
- What is our Generic Dispensing Rate for drugs, and how can we increase it?
- What is being done to proactively prevent drug shock claims hitting the plan, such as orphan drugs and/or gene therapies?

# Trickle Down Savings to Stop Loss

- Once specialty drug costs are contained, be sure to share the savings with stop-loss carriers, if self-funded.
  - Most need the details of the claims
  - The savings programs
  - The length of the savings programs

Benefits Apex B  
Apex Benefits A  
Benefits Apex B  
Apex Benefits A  
Benefits Apex B  
Apex Benefits A  
Benefits Apex B  
Apex Benefits A



# Case

You manage a self-funded plan for your county.

Recently and for the first time ever, your advisor or broker reports there is a claim for clotting factor and a new member with Hemophilia B on the plan in the new plan year for 2021.

What questions do you need to ask your advisor/broker on managing this moving forward?



# High-Cost Claimant Report

## 2021 Running Monthly Clinical Report

Risk	Relation	Status	Diagnosis / Rx	Jan-21	Feb-21	Mar-21	Apr-21
High	EE	Active	Multiple cancer diagnoses	\$51,191	\$141,047	\$72,892	\$7,723
High	CH	Active	Eating disorder	\$8,335	\$21,053	\$15,208	\$76,109
Medium	SP	Active	Knee surgery	\$88,146	\$124	\$256	\$4,028
Medium	EE	Active	Atrial fibrillation	\$486	\$0	\$62,210	\$79
Medium	SP	Active	Spinal stenosis	\$7,239	\$1,411	\$6,903	\$44,290
Medium	EE	Active	Sepsis, diverticulitis, and peritoneal adhesions	\$58,940	\$100	\$0	\$0
High	CH	Active	Psoriasis on Stelara	\$22,010	\$0		\$22,122
High	SP	Active	Breast cancer	\$15,493	\$0	\$26,772	\$18
Medium	EE	Active	Atherosclerosis	\$23		\$0	\$41,250
Low	EE	Active	Endometriosis	\$14,754		\$24,023	
High	EE	Active	Ulcerative colitis on Stelara	\$2,188	\$71	\$35,805	\$553
High	EE	Active	Crohn's Disease	\$0	\$10,918	\$9,241	\$13,352
Low	EE	Active	Knee replacement surgery	\$31,980	\$25	\$0	\$0
Medium	SP	Active	Radiculopathy of the cervical spine	\$17,292	\$831	\$12,615	\$271
Medium	EE	Active	Myocardial infarction	\$409	\$23,486	\$1,711	\$5,375
High	EE	Active	Colon Cancer	\$15,466	\$21	\$10,280	\$2,710
High	SP	Active	Hereditary factor IX deficiency (Hemophilia B)	\$26,625	\$681		\$42
High	EE	Active	Ulcerative colitis	\$11,328	\$246	\$8,659	\$73
High	CH	Active	Crohn's Disease	\$37	\$6,927	\$189	\$12,762



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13. [FDA.gov](https://www.fda.gov) – for cellular and gene therapies, as well as orphan drug indications

# Thank You





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