

MILLIMAN WEBINAR

PHARMACY BENEFIT MANAGEMENT

Rx for success: Navigating key PBM challenges

10am-11am ET
November 10, 2020



Today's speakers



Moderator

Suzanne Taranto, EA, MAAA

Principal

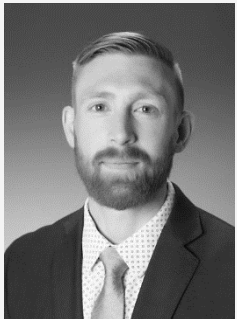
suzanne.taranto@milliman.com



Brandy Millen, ASA, MAAA

Consulting Actuary

brandy.millen@milliman.com



Dustin Pollastro, PharmD, MBA

Pharmacy Management Consultant

dustin.pollastro@milliman.com



Scott McEachern, FSA, MAAA

Consulting Actuary

scott.mceachern@milliman.com

Consolidation



Market Consolidation: Key Takeaways

Market share is increasingly concentrated among the biggest Medicare Plans

Market Consolidation: Key Takeaways

Market share is increasingly concentrated among the biggest Medicare Plans

Vertically-integrated mega-entities have new tools for margin optimization



Emergence of Pharmacy Benefit Manager (PBM) - owned offshore Group Purchasing Organizations (GPOs) is a natural result



Formulary access among key players increasingly important to manufacturers

Market Consolidation: Key Takeaways

Market share is increasingly concentrated among the biggest Medicare Plans

Vertically-integrated mega-entities have new tools for margin optimization



Emergence of PBM-owned offshore GPOs is a natural result



Formulary access among key players increasingly important to manufacturers

Vertical integration means the reach of the big players gets deeper

Market Consolidation: Key Takeaways

Market share is increasingly concentrated among the biggest Medicare Plans

Vertically-integrated mega-entities have new tools for margin optimization



Emergence of PBM-owned offshore GPOs is a natural result



Formulary access among key players increasingly important to manufacturers

Vertical integration means the reach of the big players gets deeper










































Understanding *margin drivers* of mega-entities = **increasingly important**

Recent merger timeline

2017 through December 2019

2017	2018	2019	2020
<p>Announced 10/18</p> 	<p>Closed 1/30</p> 	<p>Begins Operations in May</p> 	<p>Closed 1/23</p> 
<p>Closed 12/15</p> 	<p>Closed 3/13</p> 	<p>Closed 6/19</p> 	<p>Announced 4/30</p> 
<p>Closed 12/19</p> 	<p>Closed 6/28</p> 	<p>Announced 12/9</p> 	
	<p>Closed 11/28</p> 	<p>Announced 12/19</p> 	
	<p>Closed 12/20</p> 		

Several plans have merged with players across the value chain to maintain growth

Stakeholder	5 Mega-Health Care entities	Other vertical integrations
Health Plan Horizontal M&A declining	    	 
Pharmacy Benefit Manager Apparent pivot to vertical integration	    	 
Specialty Pharmacy Limited M&A options remain	    	 
Retail Pharmacy Getting involved in vertical integration now	 	  
Data and Analytics Increasing investments in capabilities	    	
Hospitals / Health Systems Consolidation continuing by geography	  	
Home Health Further horizontal and vertical integration likely		
Pathway Companies Increased provider and payer internalization	 	
Wholesaler and Group Purchasing Organizations Steady state with 3 players		 

Consolidation affects enrollment in the Part D market

Top 5 PDPs are 87% of the PDP market

PDP (Standalone Part D)	Enrollment (Millions)	% Market	% LIS	% EGWP
CVS Health	5.6	22%	36%	25%
UHC	4.8	19%	17%	18%
Centene	4.4	18%	33%	0%
Humana Inc.	3.8	15%	28%	1%
Cigna	3.3	13%	22%	53%
Subtotal Top 5	21.9	87%	28%	19%
Total all PDPs	25.1	100%	27%	19%

Top 5 MAPDs capture 65% MA market

MAPD (Integrated Parts A/B/D)	Enrollment (Millions)	% Market	% LIS	% EGWP
UHC	5.8	27%	32%	14%
Humana	4.0	18%	25%	8%
CVS	1.8	8%	18%	16%
Kaiser Permanente	1.6	7%	11%	31%
Anthem	1.2	5%	41%	3%
Subtotal Top 5	14.4	65%	27%	14%
Total all MAPDs	21.9	100%	28%	11%

Source: CMS enrollment in 2020; Includes Individual and Employer Group Waiver Plans (EGWP)

Note: Centene includes Wellcare and Aetna; ESI is now included under Cigna

GPO Overview

A Group Purchasing Organization (GPO)

is an “entity that helps [businesses]... realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors and other vendors.”

Source: 1 Healthcare Supply Chain Association, Accessed July 22, 2020 from <https://www.supplychainassociation.org/about-us/what-is-gpo/>

GPO Example

A Group Purchasing Organization (GPO)

is an “entity that helps [businesses]... realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors and other vendors.”

Source: 1 Healthcare Supply Chain Association, Accessed July 22, 2020 from <https://www.supplychainassociation.org/about-us/what-is-gpo/>

Generic Retail / Wholesale Drug Sourcing



Hospitals / Providers



PBM Services / Rebate Aggregation

Ascent

Zinc



PBM-owned GPOs are a bit of a black box



GPOs: In the shadows – Ascent and Zinc

Rebates are no longer a significant profit stream for PBMs – nearly all rebates are passed through to payers / employers

GPO model enables new revenue stream, captured via admin fees charged to suppliers (manufacturers) that are separate and distinct from rebates and do not necessarily directly pass through to the payers

- Admin fees either at the expense of some rebates or in addition to rebates

PBMs aggregate negotiating power, shield some fees from pass through to clients, and may provide protection from future US regulations requiring rebates to be passed through to POS

Ascent (ESI – late 2019) and Zinc (CVS – June 2020) - GPOs headquartered in tax-haven countries, likely operate as pay-to-play entities

- Suppliers (manufacturers) pay a fee, customers may also pay a fee
- Some payers purchase minority ownership to access supply chain contracts (e.g., IngenioRx, Prime)

Nephron Research Quote (June 2020):

The key questions here are to what extent the purchasing entities are truly creating incremental value for manufacturers and customers (fees beyond the admin fee should be bona fide reflecting the fair market value of the service performed) and to what extent contracting entities are shifting discounts from the rebate profit pool 99% of which flows to clients to fee pools that may be retained by the PBM.

Regulatory changes



Other key legislative / regulatory changes



Rebates in commercial medical loss ratio (MLR) reporting

Commercial MLR limits insurer admin costs

- Previously, claims must be net of:
 - Issuer-paid pharmacy rebates, and
 - Retail pharmacy spread, which must be reported as admin
- Starting in 2022, commercial plans must include PBM-retained rebates and other price concessions in the administrative component of the MLR
 - “Price concessions” still undefined

Milliman thought leadership:

<https://www.milliman.com/en/insight/Every-commercial-health-insurance-issuers-guide-pharmacy-benefit-managers-and-medical-loss-ratio>

<https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021>



Transparency in coverage

- October 29, 2020 rule finalized requiring health insurers to disclose drug pricing and cost sharing information starting in 2023
- Real-time price information will be available to patients prior to receiving treatment
- Historical net pricing information by pharmacy will be publicly available for research

<https://www.hhs.gov/about/news/2020/10/29/trump-administration-finalizes-rule-requiring-health-insurers-disclose-price-and-cost-sharing.html?language=es>

2021 Drug Pipeline



Drug Pipeline Overview

Pharmacy Drug Trend

Increased Competition

- Generic entrants
- Biosimilars

Specialty Conditions

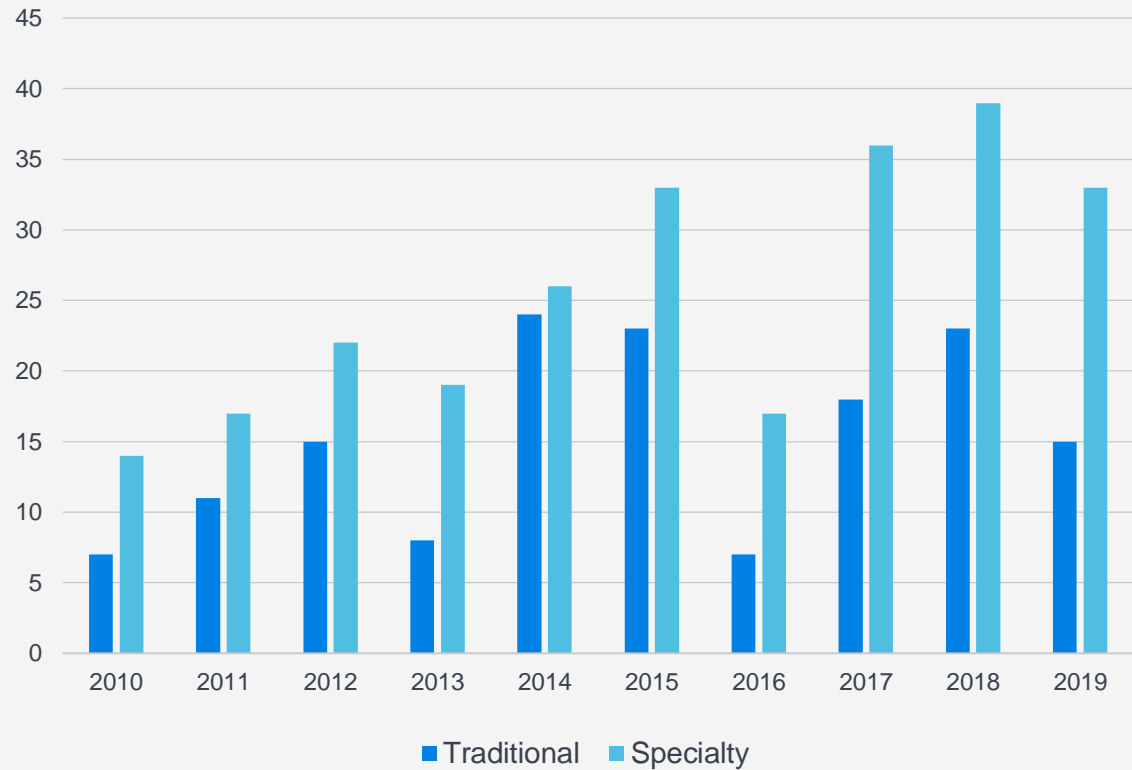
- Inflammatory conditions
- Cancer/Orphan diseases

Specialty Drug Pipeline

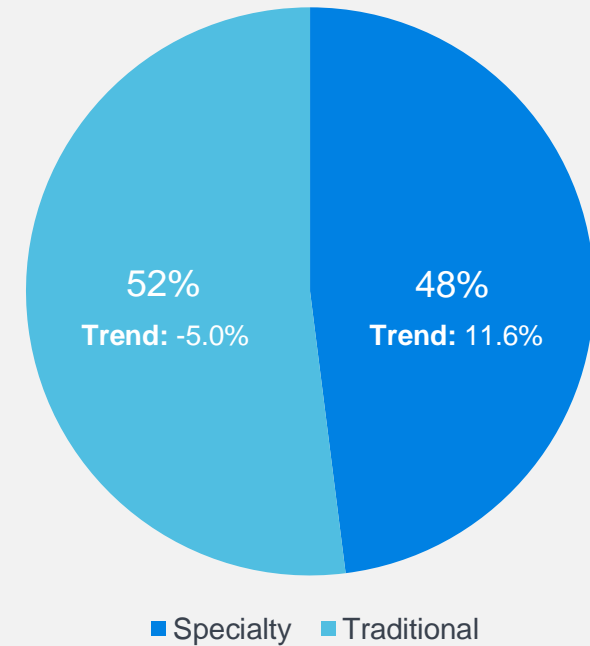


Pharmacy Drug Trend

FDA Drug Approvals



Pharmacy Drug Spend 2019*



*Express Scripts 2019 Drug Trend Report. <https://www.express-scripts.com/corporate/drug-trend-report#2019-in-review>. Accessed Oct. 25, 2020.

Biosimilar Approvals

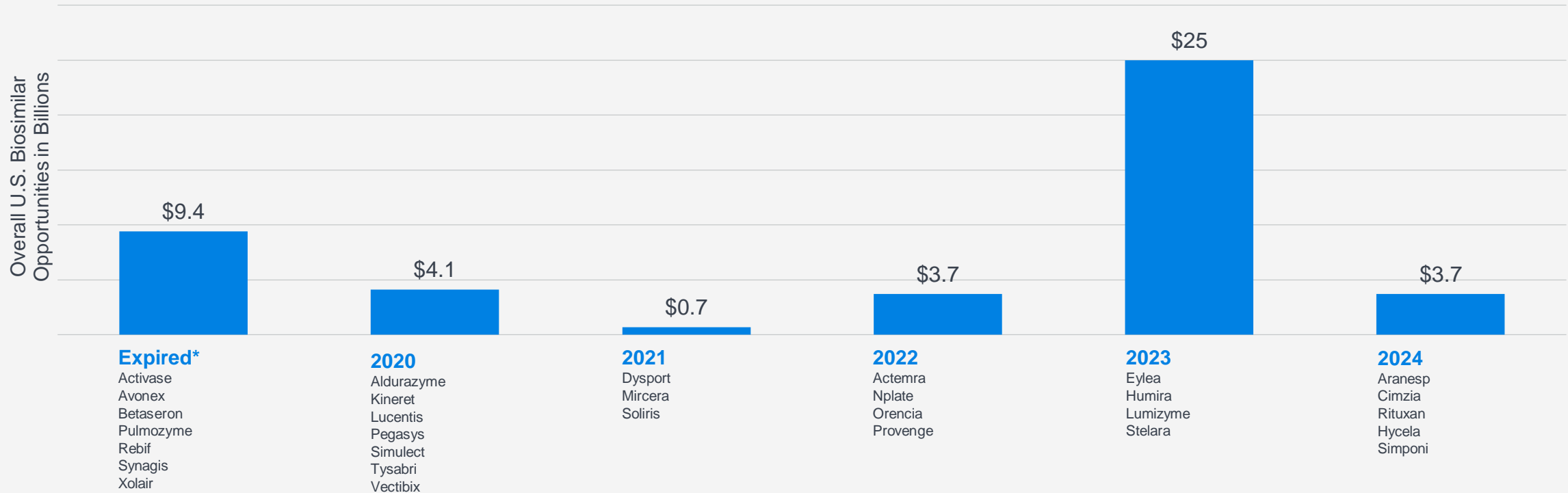
Reference Biologic	Annual U.S. Sales	Biosimilars (Brand Name – Manufacturer; Approval Date)
Neupogen (Amgen)	\$283 million	filgrastim-sndz (Zarxio - Sandoz; Mar. 2015) filgrastim-aafi (Nivestym - Pfizer; July 2018) infliximab-dyyb (Inflectra - Pfizer; Apr. 2016)
Remicade (Janssen)	\$5.2 billion	infliximab-abda (Renflexis - Merck/Samsung Bioepis; Apr. 2017) infliximab-qbtx (Ixifi - Pfizer; Dec. 2017) infliximab-axxq (Avsola - Amgen; Dec. 2019)
Enbrel (Amgen)	\$8 billion	etanercept-szsz (Erelzi - Sandoz; Aug. 2016) etanercept-ykro (Eticovo – Samsung Bioepis; Apr. 2019) adalimumab-atto (Amjevita - Amgen; Sept. 2016) adalimumab-adbm (Cyltezo - BI; Aug. 2017)
Humira (AbbVie)	\$18.3 billion	adalimumab-adaz (Hyrimoz - Sandoz; Oct. 2018) adalimumab-bwwd (Hadlima – Samsung Bioepis; July 2019) adalimumab-afzb (Abrilada - Pfizer; Nov. 2019) adalimumab-fkjp (Hulio - Mylan; July 2020)
Avastin (Genentech)	\$3 billion	bevacizumab-awwb (Mvasi - Allergan/Amgen; Sept. 2017) bevacizumab-bvzr (Zirabev – June 2019) trastuzumab-dkst (Ogivri - Mylan/Biocon; Dec. 2017)
Herceptin (Genentech)	\$3.1 billion	trastuzumab-pkrb (Herzuma - Celltrion/Teva; Dec. 2018) trastuzumab-dttb (Ontruzant - Merck/Samsung; Jan. 2019) trastuzumab-qyyp (Trazimera – Pfizer; Mar. 2019) trastuzumab-pkrb (Kanjinti – Amgen/Allergan; June 2019)
Epogen/Procrit (Amgen/Janssen)	\$2.4 billion	epoetin alfa-epbx (Retacrit - Hospira/Pfizer; May 2018)
Neulasta (Amgen)	\$4.2 billion	pegfilgrastim-jmdb (Fulphila - Mylan/Biocon; June 2018) pegfilgrastim-cbqv (Udenyca - Coherus; Nov. 2018) pegfilgrastim-bmez (Ziextenzo - Sandoz; Nov. 2019) pegfilgrastim-apgf (Nyvepria - Pfizer; June 2020)
Rituxan (Genentech)	\$4.3 billion	rituximab-abbs (Truxima - Celltrion/Teva; Nov. 2018) rituximab-pvvr (Ruxience – Pfizer; July 2019)

28 biosimilars received FDA approval for 9 different biologics

Only 18 of the approved biosimilars are available representing 7 different biologics

Future Biosimilar Opportunity

76 Patent Expirations with an estimated \$49B opportunity



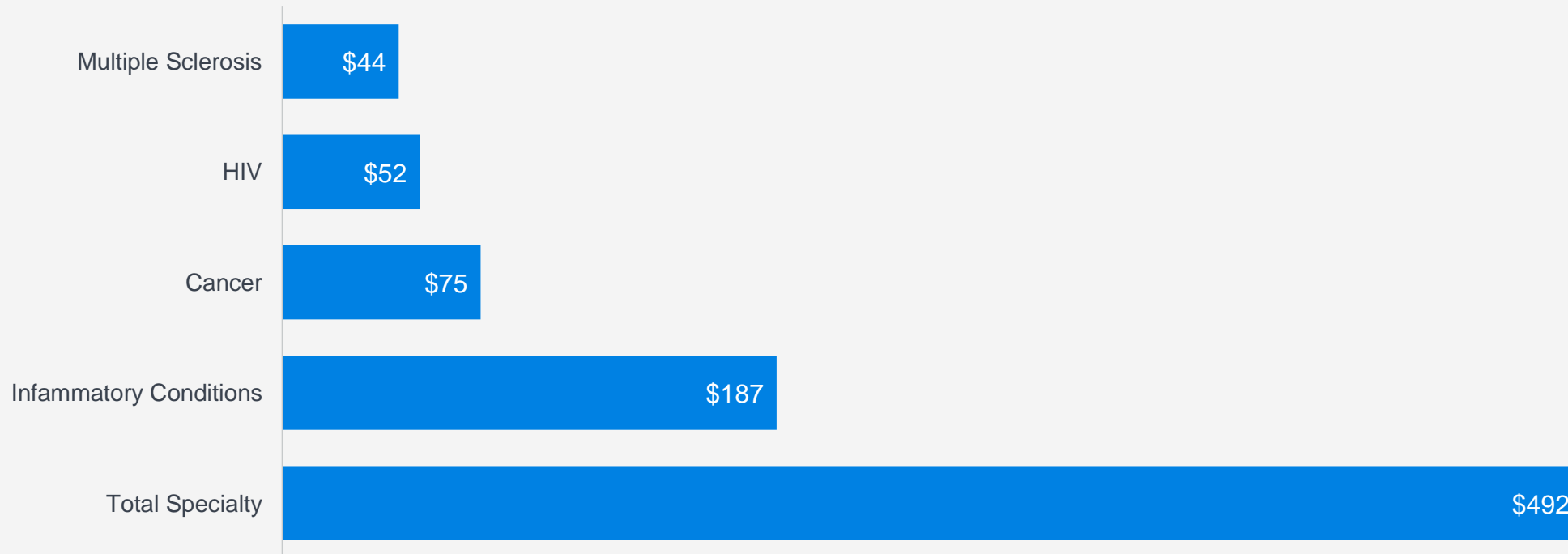
*Includes biologic drugs that have had key patents expire. Source: U.S. Drug spend estimates are based on IQVIA data for 2018. The patent expiration dates of the biologic products is current as of Jan. 2020. Patent expiration does not necessarily imply biosimilar availability. The availability of biosimilars is highly variable due to litigation, patent challenges, FDA's establishment of 351(k) pathway, or other factors. Trademarks are the property of their respective owners, brand names being used in this slide for illustrative purposes.

2021 Drug Patent Loss

Drug Class	Brand Name	Generic Name	Estimated Launch Date	PMPM*	Utilization per 1,000*
Irritable Bowel Syndrome- Constipation (IBS-C)	Amitiza	Lubiprostone	1/1/2021	\$0.06	2.048
Cancer	Thalomid	Thalidomide	1/1/2021	\$0.01	0.024
COPD	Daliresp	Roflumilast	1/23/2021	\$0.02	0.586
Antidepressant	Viibryd	Vilazodone Hydrochloride	3/1/2021	\$0.11	5.566
Fibromyalgia	Lyrica Cr	Pregabalin CR	4/11/2021	\$0.00	0.025
Migraine	Zomig Nasal	Zolmitriptan Nasal	5/1/2021	\$0.02	0.483
Iron toxicity	Ferriprox	Deferiprone	6/1/2021	\$0.01	0.010
COPD	Perforomist	Formoterol Fumarate	6/1/2021	\$0.01	0.090
HIV	Intelence	Etravirine	7/16/2021	\$0.02	0.204
Cancer	Sutent	Sunitinib	8/15/2021	\$0.08	0.079
Cardiovascular	Bystolic	Nebivolol	9/1/2021	\$0.22	19.364
HIV	Emtriva	Emtricitabine	9/1/2021	\$0.00	0.041
Multiple Sclerosis	Gilenya	Fingolimod	10/1/2021	\$0.86	1.352
COPD	Brovana	Arformoterol	11/1/2021	\$0.01	0.169
Anticoagulants	Pradaxa	Dabigatran	12/1/2021	\$0.07	2.195

Specialty Conditions

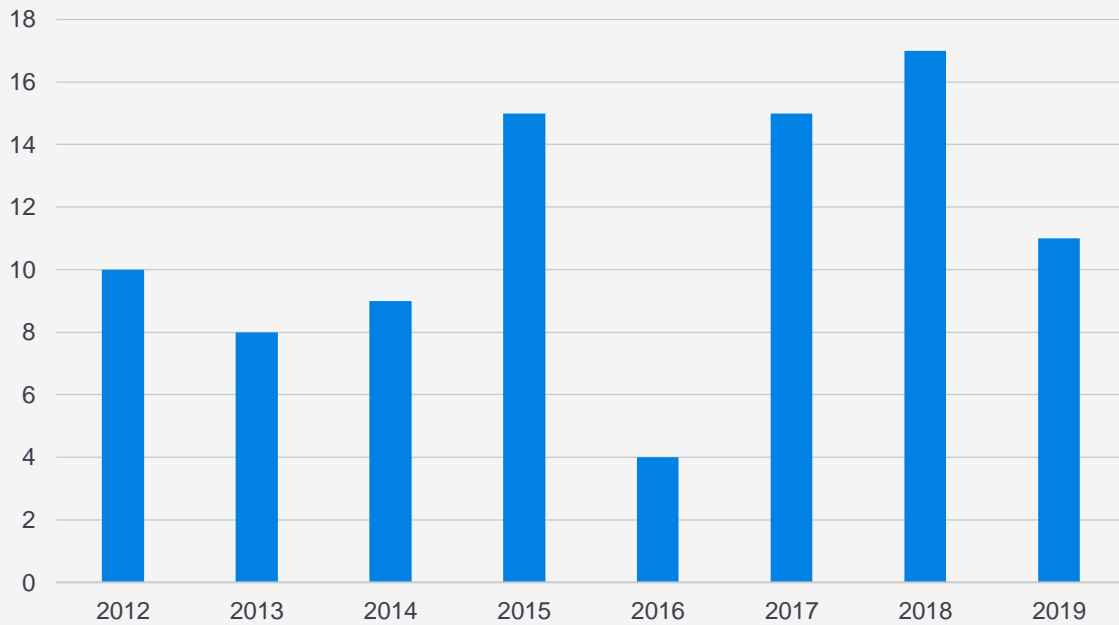
2019 PMPY



Express Scripts 2019 Drug Trend Report. <https://www.express-scripts.com/corporate/drug-trend-report#2019-in-review>. Accessed Oct. 25, 2020.

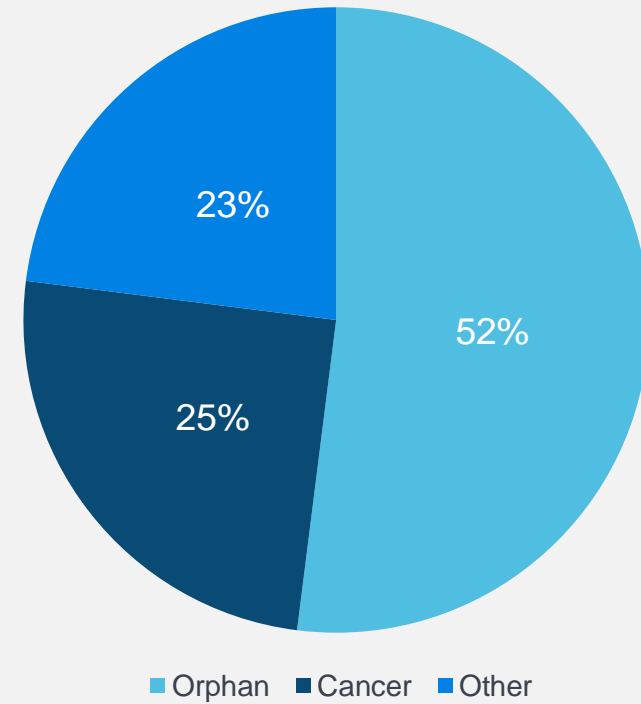
Cancer and Orphan Drug Development

Cancer Drug Approvals



<https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/>

Orphan Drug Development



2020 Specialty Drug Approval Timeline

2020 Specialty Drug Approvals



28 specialty drugs have been approved with 10 more estimated to be approved by the end of 2020

2021 Specialty Drug Pipeline

Drug Category	Drug Count
AADC Deficiency	1
Alzheimer's Disease	1
Atopic Dermatitis	5
Cancer*	9
Duchenne Muscular Dystrophy	2
Hemophilia	2
HIV	3
Hypercholesterolemia	1
Inflammatory	6
Multiple Sclerosis	1
NASH	1
Rare/orphan Disease	3
Grand Total	35

*Q1 2021 pipeline only

Cell and Gene Therapy Pipeline			
Drug Name	Manufacturer	Condition	Therapy Type
idecabtagene vicleucel	Bluebird Bio/BMS	Multiple Myeloma	Immunotherapy/CAR-T
SRP-9001	Sarepta	DMD	Gene Replacement
aglatimagene besadenovec	Advantagene	Prostate Cancer	Immunotherapy
ciltacabtagene autoleucel	Janssen	Multiple Myeloma	Immunotherapy/CAR-T
eladocagene exuparvovec	PTC Therapeutics	AADC Deficiency	Gene Replacement
etranacogene dezaparvovec	CSL Behring	Hemophilia B	Gene Replacement
nadofaragene firadenovec	Ferring	Bladder Cancer	Immunotherapy

2021 Specialty Drug Pipeline

Category	Drug Name	Manufacturer	Condition	Dosage Form	Approval
AADC Deficiency	eladocagene exuparvovec	PTC Therapeutics	AADC Deficiency	IV	2021
Alzheimer's Disease	aducanumab	Biogen/Eisai	Anti-amyloid beta antibody	IV	Mar. 7, 2021
Atopic Dermatitis	abrocitinib	Pfizer	Atopic Dermatitis	Oral (once daily)	Apr., 2021
Atopic Dermatitis	tralokinumab	LEO Pharma A/S	Atopic Dermatitis	SC (every 2 weeks)	May 9, 2021
Atopic Dermatitis	baricitinib (Olumiant)	Eli Lilly	Atopic Dermatitis	Oral (once daily)	2021
Atopic Dermatitis	ruxolitinib (Jakafi)	Incyte	Atopic Dermatitis	Topical (twice daily)	2021
Atopic Dermatitis	upadacitinib (Rinvoq)	AbbVie	Atopic Dermatitis	Oral (once daily)	2021
Cancer	dostarlimab	GlaxoSmithKline	Endometrial Cancer	IV	Jan. 14, 2021
Cancer	trilaciclib	G1 Therapeutics	Small Cell Lung Cancer	IV	Feb. 15, 2021
Cancer	umbralisib	TG Therapeutics	Marginal Zone Lymphoma & FL	Oral	Feb. 15, 2021
Cancer	tepotinib	EMD Serono	Non-Small Cell Lung Cancer	Oral	Feb. 25, 2021
Cancer	idecabtagene vicleucel	bluebird bio/BMS	Multiple Myeloma	IV	Mar. 27, 2021
Cancer	tivozanib	AVEO Oncology	Renal Cell Carcinoma	Oral	Mar. 31, 2021
Cancer	aglatimagene besadenovec	Advantagene	Prostate Cancer	Prostate injection	2021
Cancer	ciltacabtagene autoleucel	Janssen	Multiple Myeloma	IV	2021
Cancer	nadofaragene firadenovec	Ferring	Bladder Cancer	Intravesical	2021
Duchenne Muscular Dystrophy	casimersen	Sarepta Therapeutics	DMD Amenable to Exon 45 Skipping	IV	Feb. 25, 2021
Duchenne Muscular Dystrophy	SRP-9001	Sarepta Therapeutics	DMD Gene Therapy	IV	2021+

Cancer pipeline is only reported through Q1 2021

2021 Specialty Drug Pipeline

Category	Drug Name	Manufacturer	Condition	Dosage Form	Approval
Hemophilia	etranacogene dezaparvovec	CSL Behring	Hemophilia B	IV	2021
Hemophilia	fitusiran	Sanofi	Hemophilia A and B	SC	2021
HIV	cabotegravir	ViiV Healthcare	HIV	Oral	1Q: 2021
HIV	cabotegravir / rilpivirine	ViiV Healthcare/Janssen	HIV	IM	1Q: 2021
HIV	leronlimab	CytoDyne	HIV	SC	2021
Hypercholesterolemia	evinacumab	Regeneron	Angiopoietin-like 3 (ANGPTL3) inhibitor	IV	Feb. 11, 2021
Inflammatory	upadacitinib (Rinvoq)	AbbVie	Psoriatic Arthritis [†] ; AS [†]	Oral	Apr. 1, 2021
Inflammatory	bimekizumab	UCB	Psoriasis	SC	Jul. 22, 2021
Inflammatory	deucravacitinib	Bristol Myers Squibb	Psoriasis	Oral	2021
Inflammatory	mirikizumab	Eli Lilly	Psoriasis	SC	2021
Inflammatory	filgotinib	Gilead/Galapagos	Rheumatoid Arthritis	Oral	2021
Inflammatory	ozanimod (Zeposia)	Bristol Myers Squibb	Ulcerative Colitis [†]	Oral	2021
Multiple Sclerosis	ponesimod	Janssen	Multiple Sclerosis	Oral (once daily)	Mar. 18, 2021
NASH	obeticholic acid	Intercept Pharmaceuticals	NASH	Oral (once daily)	2021+
Rare/orphan Disease	pegunigalsidase alfa	Protalix BioTherapeutics	Fabry Disease	IV	Jan. 27, 2021
Rare/orphan Disease	arimoclomol	Orphazyme	Niemann-Pick Disease Type C	Oral	Mar. 17, 2021
Rare/orphan Disease	vosoritide	BioMarin	Achondroplasia	SC	Aug. 20, 2021

[†] New indication for a previously approved drug

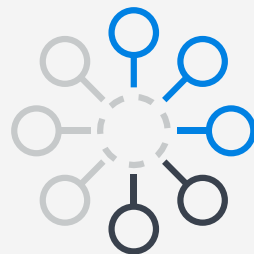
PBM contracts



Overview of a PBM Contract

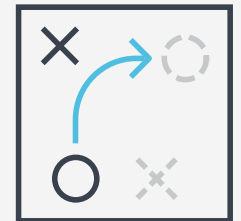
Layout

- Definitions
- Clauses / Scope / Legal
- Pricing
- Exclusions
- Administrative Services
- Performance Guarantees
- Supplemental Docs



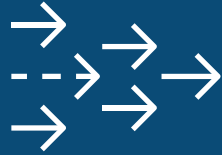
Navigation

- Ctrl + F is your friend
- Keywords:
 - Medi-Span® and FirstDataBank®
 - Termination
 - Market Check
 - Limited Distribution or LDD
 - PMPM or “per”



5 Things to Look for In Your PBM Contract

Here is what
to look for:



1

Definition of
Brand/Generic

2

Market Check
Clause

3

Pricing
Requirements

4

Exclusion
Categories

5

Admin Fees +
New Programs

5 Things to Look for In Your PBM Contract

1

Definition of Brand/Generic



1. Why does this matter?

1. Transparency
2. Pricing guarantees are contingent upon these classifications

2. Ideal Standard: Medi-Span.

1. Almost every PBM has their own unique definition
2. The goal here is to have this be auditable and transparent

3. How to treat Single Source Generics?

1. What are SSGs?
2. How do these impact pricing?

Definitions – Brand vs. Generic

	Total AWP	Discounted Price	Contracted Discount	Actual Discount
Brand	\$120,000	\$102,000	15%	15%
Generic	\$100,000	\$25,000	75%	75%
Single Source Generic	\$50,000	\$25,000	N/A	50%

	Total AWP	Discounted Price	Contracted Discount	Actual Discount
Brand	\$120,000	\$102,000	15%	15%
Generic (Includes SSG)	\$150,000	\$50,000	75%	67%

	Total AWP	Discounted Price	Contracted Discount	Actual Discount
Brand (Includes SSG)	\$170,000	\$127,000	15%	↓ 25%
Generic	\$100,000	\$25,000	75%	75%

	Total AWP	Discounted Price	Over / (Under) Performance	True Up Payment Owed
Total Cost (SSG as Brand)	\$270,000	\$152,000	(8%)	\$12,500
Total Cost (SSG as Generic)	\$270,000	\$152,000	0%	\$0

5 Things to Look for In Your PBM Contract

2

Market Check Clause



1. What is a market check?

2. **Ideal Standard: Once per year, but at least once per contract term.**

3. PBM Pricing Strategy

1. Most PBMs look at the contract term as a whole.
2. PBMs will lose money in early years and make it back in later years.
3. Conversely, pricing gets less competitive as the contract reaches maturity.

4. How does this impact your pricing?

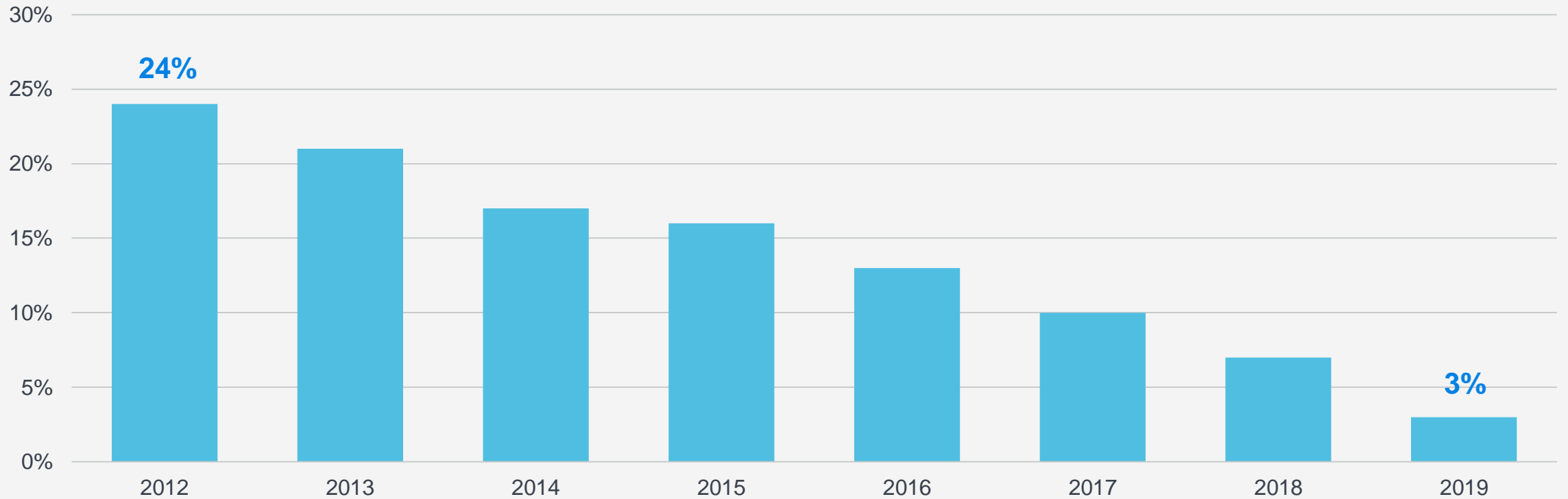
1. What happens if you delay and let the contract auto-renew?

5. Leveraging this option

1. Termination without cause.

Impact of Delaying Contract Pricing Updates

Illustrative Savings by Delaying Market Check



5 Things to Look for In Your PBM Contract

3

Pricing Requirements



1. Terms and Conditions that apply to your pricing metrics.

2. Examples:

1. Membership threshold – if membership changes by more than X% the PBM can alter the pricing guarantees or does not need to meet the existing guarantees.
2. Drug utilization threshold – if utilization of brands falls below X% the PBM can alter rebate guarantees.
3. Formulary adherence – pricing will only valid if the plan adheres to all UM criteria contained in formulary X.
4. Clinical program adoption – pricing will only be valid if you enroll in program X.

3. Ideal Standards:

1. Varies by category and by PBM.
2. Best to be made aware of all contingencies and how your plan may be impacted.

5 Things to Look for In Your PBM Contract

4

Exclusion Categories



1. What does an exclusion mean in a PBM Contract?
2. Ideal Standard: As few as possible.
3. Verify against your utilization.
4. Common types of exclusions (you can search for these)
 1. Vaccines
 2. Over the Counter (OTC)
 3. Compounds
 4. Limited Distribution
5. Pass-through vs Minimum Guarantees

Rebate exclusions

- Illustrative example of rebate exclusions
- PBM stated rebate exclusions:
 - Vaccines
 - OTCs
 - Compounds
 - Limited Distribution Drugs (LDDs)

Exclusion Category	Drug Channel	Brand Drug Count	% of Claims
Vaccines	Retail	200	5.0%
OTCs	Retail	100	2.5%
Compounds	Retail	50	1.3%
LDDs	Specialty	30	16.7%

Drug Channel	Quoted Rebate Guarantee	Effective Rebate Level
Retail	\$120	\$110
Specialty	\$1,500	\$1,250

5 Things to Look for In Your PBM Contract

5

Admin Fees + New Programs



1. Base admin fee vs ad hoc programs.

2. Ideal Standard: As many included in base admin fee as possible.

3. Some of the fees in the table can really add up.

4. Admin Fee Examples:

1. Prior Authorization (PA) fees
2. Subrogation / Coordination of Benefit (COB) fees
3. File transfer fees

5. New Program Examples:

1. Adding in a 90-day retail network.
2. Adding a specialty copay adjustment program.
3. Adding alternative payment structures outside of the standard discounts and rebates.



Thank you

Suzanne Taranto, EA, MAAA, suzanne.taranto@milliman.com

Brandy Millen, ASA, MAAA, brandy.millen@milliman.com

Dustin Pollastro, PHARMD, MBA, dustin.pollastro@milliman.com

Scott McEachern, FSA, MAAA, scott.mceachern@milliman.com