Resources for pharmacy program members

www.vizientinc.com/PharmacySolutions

We are here to help

Visit our pharmacy webpage for webbased resources and the latest updates

Log into My Dashboard on our website to access

Contact us at PharmacyQuestions@vizientinc.com







Pharmacy Solutions

Sourcing, clinical and ambulatory support



Analytics

Drug spend and clinical analytics platform



Consulting Services

Operations, ambulatory, 340B, clinical



Aggregation Groups

Pharmacy group purchasing & oncology network





Pharmacy Market Outlook Winter 2024

Keeping you at the forefront of drug price projections and market developments

Vizient Pharmacy Solutions January 31, 2024



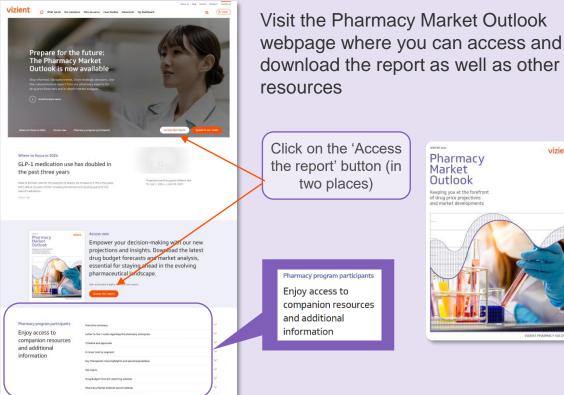
Housekeeping

- This call is being recorded
- Because of the large number of participants, all lines will be kept in listen-only mode
- Questions will be managed through the Q & A box





Access & download







info.vizientinc.com/ pharmacy-marketoutlook-memberdetails

From this page, you can also access the latest Budget Impact Projections report related to the healthcare supply chain.

Gain insight on anticipated price changes over the next 18 months and plan for them now to lessen the impact of 2024 inflation.



Additional resources

Drug Budget Forecast

Vizient Savings Actualyzer – Pharmacy

Personalizes the projections with your own spend data

- High level projection analysis and overview
- Detailed report with data filters and dynamic fields ۰
- Editable within portal and exportable ۰

izient. Savings Actualyzer Ph armacy Scorecard Explore M					- 0				pharmacy program							
My Drug Budget Forecas	st			System: Facility: Multiple Facilit Date Range: Apr 2019 - Ma		nths)					\subseteq		_	0	_	
Total Spend Analyzed Spend \$176,240,032 \$149,457,461	Analyzed Spend % 84.80%	Projected inflati \$5,320,		vizien	t. sa	avings Actualyzer Ph	harmacy							+	• 11	
Top 10 Therapeutic Class by Total Spend	*	My Percent of	Pr			d Explore ug Budget Forecast Budget Foreca		τοοίδοκ		System:						
Enhanced Therapeutic Class	Total Spend	Total Spend	In	-	Deriview	Details	ISC			Facility: Multi Date Range: Apr 2		12 Months)				
Antineoplastics	\$56,461,987	32.04%	51		Total Spend \$176,240,03		Analyzed Spo 84.80%		d Inflation Imp \$5.320,265	act Projected In 3.561		sted Analyz \$154,777;		Total Projected S \$181,560,29		
Biologicals	\$15,015,850	8.52%	\$4	Filters * * Account Type (0 of 3)	DEF Details								_			
Endocrine	\$14,784,981	8.39%	55	¹ Account Type (0 of 3) ² Search Account Type	NDC	NEC Description	Total Spend	Analyzed Spend	Analyzed Spend S	Override Spend	Spend Variance	Inflations	Override Inflation%	Projected Inflation Impact	Projected Inflation	Projected Analyzed Spend
Hematological Agents	\$12,440,481	7.05%	52	* Account Number (0 of 198)	00000312(02	NL WALLIF, PIF, OUTER, SUV	\$1,662,573	\$1.662,573	100.00%		1	5.00%	-	\$83,125	5.00%	\$1,745,78
			-	^Q Search Account, Nambor	57094000103	STELARA (ustationaread) 50 MGAL SYRINGE 1 X 1 ML SYRINGE PJF, SINGLE DOSE	\$1,595,195	\$1,095,195	100.00%			1.00%		\$127,516	8.00%	\$1,722.81
				¹⁰ Class of Trade (0 of 5) ¹⁰ Search Class of Trade	00074055402	HUMIRA PCN (adakmarvah) 40MG/0.4NL PEN U KIT 1.X 2 CT KIT LATEX-FREE, SUY, P/F	\$1,405,503	\$1,406,503	100.00%	÷	1	1.20%		887,222	6.20%	\$1,494,82

Letter to the C-suite

Describes the most consequential issues confronting pharmacy

Letter to the C-suite regarding the pharmacy enterprise

Pharmacy Market Outlook Winter 2024

As a result, investment in phermacy (pharmacids and technicians) as well as analysticidata scientists and their accompanying technologies and information sections will be recessary to ensure financial with being in a highly consertitive market.

Quick market update

Available to all

organizations

that participate

in the Vizient

The pharmaceutical industry continues to change ofer the concerns about thus expenditures. The initial work on dr The phenomenolisis installary contrasts to share given the users and ding expenditures. The investigation of the strength of t

The battle over site of care

As described in previous versions of the Pharmocy Market Outlook, growth in pharmacy p

(A). This tool enables you to determine which



nt relations and physician leadership

ments for rare diseases approved by the FDA - all which cost \$2.2M or more. Given nail populations in which they are used, the cost impact has been spread over

prificantly change in 2024 as the number of approved gene therapies could

k closely with the physician specialists likely to prescribe these agents and t

will remain unlattle due to increasing concern about the cost of about

t of important steps that you as leadership should consider as you build a

ding to purchase these treatments. In addition, these medicatio

If you answered "no" to any of these questions and/or would like more information from Vizient, including other phy



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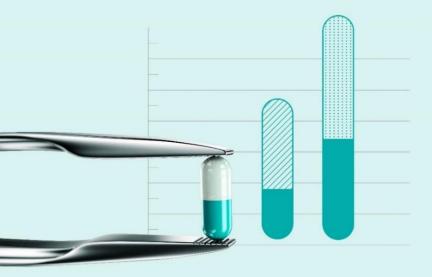
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Webinar for financial leaders

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Join us for an exclusive perspective designed for financial leaders in your organization

Wednesday, Feb. 28 – 1:00 p.m. CT



Find more information on vizientinc.com/PharmacySolutions



Today's presenters



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Methodology and overall numbers



Price projection methodology overview

Based on Vizient pharmacy program participant data

- Projections 6 to 18 months forward; for price only
- Overall summary, therapeutic class, generic
- Query purchase and price history of member facilities
 - Inclusions: All classes of trade
 - Exclusions: 340B, direct purchases, nondrug purchases
- Determine top 85% of products, based on aggregate spend
- Team makes projections at national drug code (NDC) level
 - Contract products and noncontract products from contract manufacturers: assigned to portfolio executives
 - Other noncontract products: outside data sources



Overview by the numbers

	July 2023	January 2024			
# NDC initial data pull	58,188	57,958			
# NDC without exclusions	32,858	32,821			
# NDC in top 85%	1,308	1,274			
Highest projected Inflation	10% (etoposide, morphine, phenobarbital)	20% (iohexol & sodium phosphate)			
Greatest projected deflation	-50% (regadenoson)	-69% (IV acetaminophen)			
Number of NDC in both editions	1,166 (92%)				
Number of NDC no longer in top 85%	102				
Number of NDC new to top 85%	113				



Projected drug price inflation July 1, 2024 through June 30, 2025

This is our highest projected inflation rate since the July 2019 edition (January 2020 – December 2020 prediction window)

Several factors drive the trend of increasing inflation:

- · Increase in specialty and ultra-specialty approvals
- Additional indications for previously approved medications, increasing utilization
- Products with higher-than-customary price increases
- Payer restrictions influencing site of care and class of trade implications for pharmacy services

3.80% Projected overall drug price inflation rate



Key therapeutic class highlights

Therapeutic classes	Key products in class	Est. price change
Autoimmune and inflammatory conditions	Humira, Stelara, Entyvio, Skyrizi, Dupixent	3.72%
Biosimilars	Inflectra, Truxima	0.55%
Cardiometabolic diseases	Ozempic, Eliquis, Mounjaro	3.41%
Infectious diseases	Biktarvy, Veklury	4.05%
Neurology	Ocrevus, Botox, Kesimpta, Tysabri	4.60%
Oncology	Keytruda, Opdivo, Darzalex Faspro	3.89%
Pediatrics	Unituxin, Asparlas	3.65%
Plasma critical care	Albumin, Immune globulin intravenous	3.63%
Radiopharmaceuticals	Omnipaque, Visipaque	10.36%



Percent of spend captured by top 15 drugs: **25.77%**

ranked by spend

Semaglutide jumps from #10 to #5; Risankizumab-rzaa jumps from #12 to #6

Top 15 drugs

Remdesivir falls out of the top 15 for the first time; Secukinumab new to the list

Rank	Generic name	Brand name	Previous rank
1	Adalimumab	Humira	1
2	Immune globulin, intravenous	Gammagard, Gamunex, Privigen	2
3	Ustekinumab	Stelara	3
4	Pembrolizumab	Keytruda	4
5	Semaglutide	Ozempic, Rybelsus, Wegovy	10
6	Risankizumab-rzaa	Skyrizi	12
7	Dupilumab	Dupixent	9
8	Ocrelizumab	Ocrevus	6
9	Etanercept	Enbrel	8
10	Denosumab	Prolia, Xgeva	5
11	Nivolumab	Opdivo	7
12	Daratumumab-hyaluronidase-fihj	Darzalex Faspro	11
13	Bictegravir / emtricitabine / tenofovir alafenamide fumarate	Biktarvy	14
14	Vedolizumab	Entyvio	15
15	Secukinumab	Cosentyx	



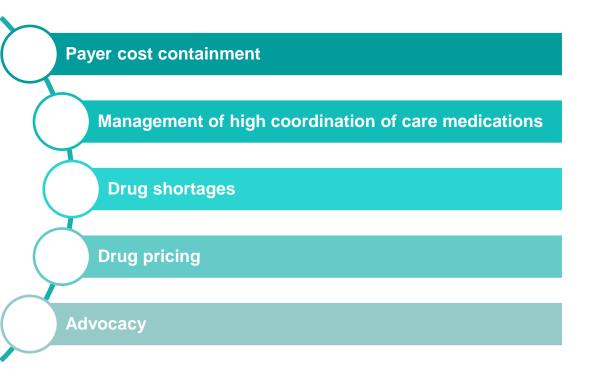


Top drugs by retrospective price increase

Generic name	Brand name	WAC price change (%)	% of total aggregate spend
Fludarabine	Fludara	653.7%	0.01%
Cefepime in D5W	Maxipime	22.9%	0.07%
Ceftolozane / tazobactam	Zerbaxa	15.3%	0.10%
Denosumab	Prolia, Xgeva	10%	1.16%
Remdesivir	Veklury	9.9%	0.78%
Dinutuximab	Unituxin	9.9%	0.24%
Venetoclax	Venclexta	9.7%	0.25%
Human prothrombin complex concentrat	te Kcentra	9.6%	0.43%
Secukinumab	Cosentyx	9.1%	0.81%
Daratumumab Daratumumab-hyaluronidase-fihj	Darzalex Darzalex,	9.0%	0.10% / 1.08%
Adalimumab	Faspro Humira	8.0%	4.46%



Focus for 2024









Non-acute care highlights

Biosimilars

505(b)(2) approvals

GLP-1 therapies

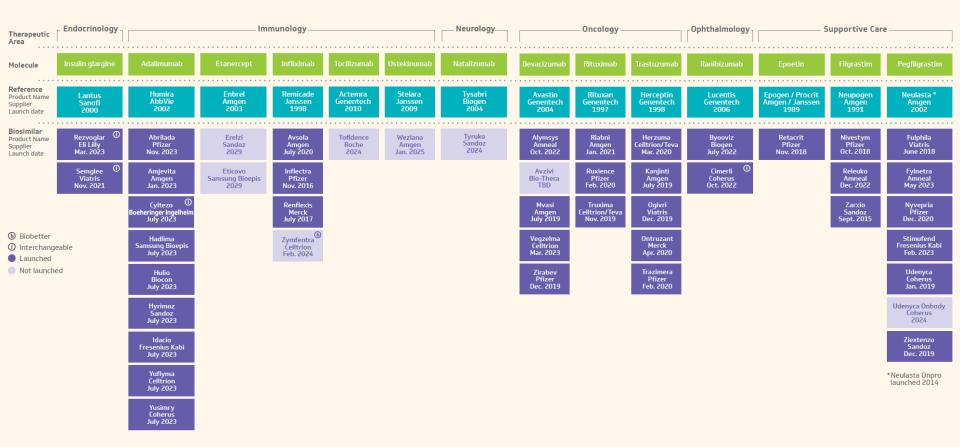
Gene therapies

Site of care considerations





Biosimilar approvals and launches



505(b)(2) considerations

- Cost / reimbursement analyses
- Charge master updates
- Formulary evaluations
- Payer coverage
- Prior authorization considerations
- Supply chain / purchaser education

	Approval type	Studies conducted	HCPCS Code	Example
NDA [505(b)(1)]	New (small) molecule	Full safety and efficacy	Reference listed drug	J9056 Inj, bendamustine, 1 mg
ANDA [505(j)]	Generic	Bioequivalence	Generic molecule (share w/other generics & [505(b)(1)]	J9056 Inj, bendamustine, 1 mg
505(b)(2)	Different characteristics	PK, bioavailability	Unique to approval (by manufacturer)	J9036 Inj belrapzo/ bendamustine
351 (a)	Reference biologic	Full efficacy, safety and purity	Biologic molecule	J1745 Infliximab not biosimil 10 mg
351 (k)	Biosimilar	PK, PD, immunogenicity	Unique to each biosimilar	Q5103 Injection, inflectra

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505(b)(2) resources

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Minute Market Insights

Minute Market Insights are intended to highlight changes that may impact drug product selection, drug product utilization or patient care. Background

505(b)(2) Products and Reimbursement

The 505(b)(2) New Drug Application (NDA) approval pathway allows

pharmaceutical manufacturers to bring drugs to market more efficiently than

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505(b)(2) pathway. for HCPCS codes by NDC.

Drugs approved via the 505(b)(2) pathway are not generic molecules of the reference or brand mane drug and have distinct NDCs. 505(b)(2) drugs are not considered therapeutically equivalent by the FDA but may have similar clinical effects and place in therapy to the lated drug.

What is new? For Medicare reimbursement, 505(b)(2) products each have unique Healthcare Common Procedure Coding System (HCPCS) codes and payment varies depending on the drug's Average Sales Price (ASP). In January 2023, the Centers for Medicare & Medical Services (CMS) made several coding changes.

Additional Resources · 505/bir2) Prequently Asked · Applications Covered by 505(b)(2)

· Coding for 505(b)(2) drugs

· Vigent has subject matter expents

available to answer questions

 Since 505(b)(2) products are approved under separate NDAs and are not rated as therapeutically equivalent by the FDA Orange Book, they are Because 505(b)(2) products are considered single source drugs, there is a
programmatic need for each product to have a <u>prices billing and perment</u>

· When products do meet the statutory definition of a generic or multiple source drug and are rated as therapeutically equivalent in the FDA Orange Book, CMS is removing brand names from any existing HCPCS codes as needed (eg. removal of "Velcade" from JS041)

What is the impact?

Billing errors can prove if \$25(b)(2) products and formulary decisions are not incorrectly coded charges may need to be credited and rebilled.

å

Minute Market Insights



505(b)(2) New Drug Application

Frequently Asked Questions

What are the 3 types of new drug applications described under Section 505 of the Federal Food, Drug, and Cosmetic Act?

- . An application that contains full reports of investigations of safety and effectiveness (505(b)(1))
- · An application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2).

· An application that contains information to show that the proposed product is identical in active inprecient. dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)).

Why did the Centers for Medicare and Medicald (CMS) establish new HCPCS Level II codes to separately identify products under the 505(b)(2) New Drug Application (NDA) or the Biologics License Application (BLA) pathways?

In the 3rd quarter of the 2022 HCPCS Coding Cycle, CMS reviewed its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS codes, CMS is made several code changes effective January 1, 2023:

. Due to rating of 'not therapeutically equivalent' to the reference listed drups and consideration as single source products, assignment of manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways.

· Removal of the brand name from existing HPCPS codes when products meet the statutory definition of a multiple source drug to accommodate any associated generic products that are rated as therapeutically equivalent.

How do I know if a medication has been approved through the 505(b)(2) pathway?

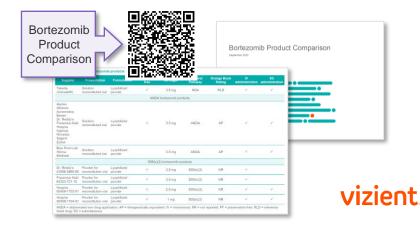
There are proprietary subscription-based services that can provide this information, or it can be found on the Drugs @FDA: FDA-Approved Drugs webpage by searching by drug name, active ingredient, or application

Go to the Drug Approval Package by clicking on "Review" under Approval Date(s) and History. Letters, Labels Reviews for NDA. The Administrative Document(s) and Correspondence PDF includes the type of exclusivity determination needed (See Part I).

Bendamustine Product Comparison	39



Table 1. FDA-approved bendamustine products as of April 2023 NDA ANDA Formulation Vial Type Strength Approva Date SDV NDA RLD March 2008 Bendam ustine SDV ANDA AP Dec. 2022 SDV ANDA NR Feb. 2023 Breckenridge Bendamustine AP Dr. Reddy's* Bendamustine SDV ANDA AP NR Dec. 2022 Eagle (Teva) Bendeka Solution MDV 100 mg/4 mL 505(b)(2) NR Dec. 2015 Eagle MDV 100 mg/4 mL 505(b)(2) NP May 2018 NDA 212209 100 mg/4 mL 505(b)(2) NR Dec. 2022 Solution MDV 100 mg/4 mL 505(b)(2) NR 30 minutes Dec. 2022 ANDA = abbreviated new data application: AP = therapeutically equivalent: IV = intravenous: NR = not reported; PF = preservative (see: RLD = reference listed Hours - accordance in the upgraphication, Re - deteropedically equivalent, IV - and remote, NK - IO reported, PI - preservative see, RGD - I drug; SC + subordaneous "Dr. Reddy's gained FDA approval in December 2022 and Brockenridge in February 2023 but neither have launched their product as of 4/23/23.



Gene therapy: approvals and pipeline



https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products https://clinical-pipeline.ipdanalytics.com/



Challenges related to gene therapy

Access

 Qualified Treatment Centers (QTCs)

Cost

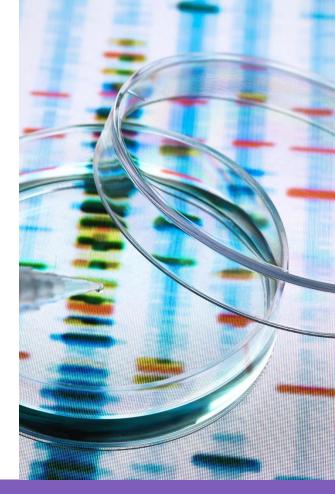
- \$2 million or greater
- Availability of patient assistance programs

Reimbursement

- Single-case agreements
- Outcomes-based agreements

Operations

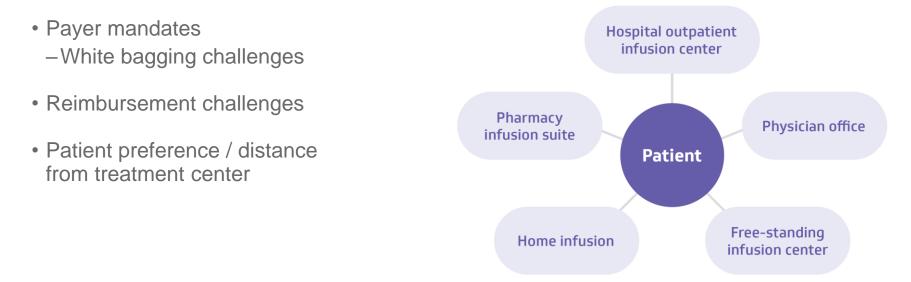
- Cold chain storage
- Biohazard and safety precautions





Site of care considerations

Maximizing different sites of care to meet patient needs





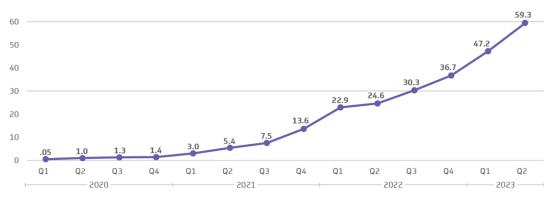
Source: Vizient pharmacy program participant data, Oct. 2022-Sep. 2023

Acute care Medications that are more than 88% acute care spend

Top acute care medication spend

Rank	Generic name	Brand name
1	Remdesivir	Veklury
2	Sugammadex sodium	Bridion
3	Alteplase	Activase, Cathflo Activase
4	Human prothrombin complex concentrate (PCC)	Kcentra
5	Albumin	AlbuRx, Albutein, Flexbumin
6	Anti-thymocyte globulin (rabbit)	Thymoglobulin
7	Coagulation factor VIIa (recombinant)	NovoSeven
8	Bupivacaine liposomal	Exparel
9	lohexol	Omnipaque
10	Tenecteplase	TNKase

Proportion of ischemic stroke cases using tenecteplase



Source: Vizient Clinical Data Base/Resource Manager

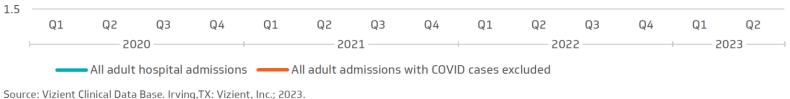




Inpatient acuity

CMI trend for inpatient hospital admissions, 2020-2023

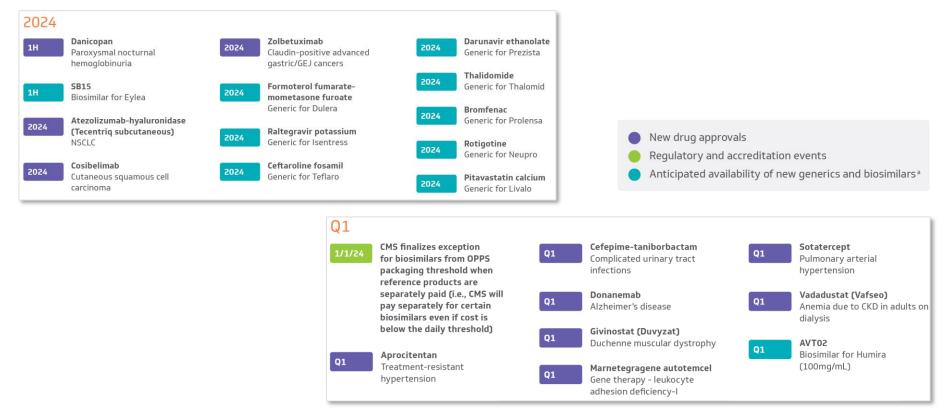




Q1 2020 – Q2 2023, COVID: Any ICD-10 diagnosis = U071.

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Projected timeline and approvals



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New and noteworthy approvals Autoimmune and inflammatory diseases

Drug	Route	MOA	Indication(s)	What's new?
Bimekizumab (Bimzelx)	SUBQ	IL-17 antagonist	Plaque psoriasis	Inhibits both IL-17A and IL-17F
Etrasimod (Velsipity)	Oral	S1PR modulator	UC	2nd in class. No dose titration
Infliximab-dyyb (Zymfentra)	SUBQ	TNF-a inhibitor	Crohn's disease, UC	1st SUBQ formulation of infliximab
Mirikizumab (Omvoh)	IV, SUBQ	IL-23 antagonist	UC	1st IL-23 inhibitor approved
Natalizumab-sztn (Tyruko)	IV	Anti-a4-integrin antibody	Crohn's disease, MS	1st biosimilar for Tysabri
Roflumilast (Zoryve)	Topical	PDE4 Inhibitor	Plaque psoriasis	Expanded to children 6–11 yrs
Secukinumab (Cosentyx)	IV	IL-17 antagonist	PsA, AS, nr-axSpA	New route of administration
Tocilizumab-bavi (Tofidence)	IV	IL-6 receptor antagonist	RA, JIA	1st biosimilar for IV Actemra
Ustekinumab-auub (Wezlana)	SUBQ	IL-12 and IL-23 antagonist	Plaque psoriasis, PsA, Crohn's disease, UC	1st [interchangeable] biosimilar for Stelara; launch anticipated January 2025
Vedolizumab (Entyvio)	SUBQ	Integrin receptor antagonist	UC	1st SUBQ formulation
Zilucoplan (Zilbrysq)	SUBQ	Complement inhibitor	gMG	1st once-daily, self-administered therapy for gMG



Advocacy in action

Public policy topics

- Biosimilars
- Drug Pricing
- Innovative Payment Models (e.g., CMS Innovation Center)
- Reimbursement
- 340B
- White bagging and other payor-mediated influences
- Drug shortages
- Pandemic-related updates

A busy 2023...

- Developing policy concepts to address drug shortages
- Sharing recommendations related to the 340B remedy repayments
- Supporting policies to increase competition by easing barriers related to biosimilars
- Urging action be taken to address white bagging and other payer-mediated policies
- Opposing site neutral payment policy for certain drug administration services

For more information

 Visit our Public Policy and Government Relations <u>webpage</u>

> vizientinc.com/aboutus/public-policy

 Visit our pharmacy member policy <u>webpage</u>

vizientinc.com/our-solutions/pharmacysolutions/member-programs/payerpolicy-members





Advocacy remains a priority in 2024

Upcoming

- Elections
- Congressional Activity (e.g., funding the government)
- Implementation of the Inflation Reduction Act
- Implementation of the remedy from the 340B Supreme Court decision
- Annual rulemaking



Questions?

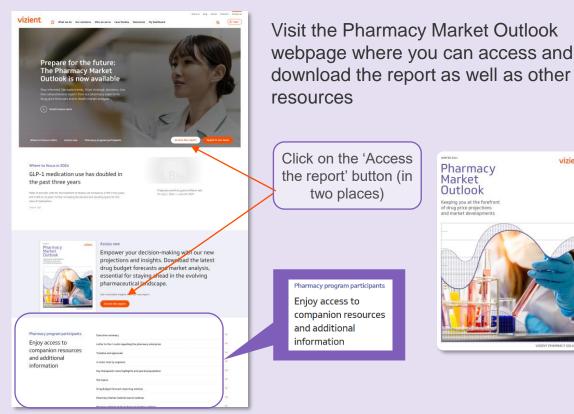




Pharmacy program resources



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izient. Savings Actualyzer Pha armacy Scorecard Explore M	onitor Toolb	юх					. 0	•						rma		
Date Range Selection > Drug Budget Forecast My Drug Budget Forecas Overview Details	t			System: Facility: Multiple Facilit Date Range: Apr 2019 - Mar		antha)						4		grar	n	
Total Spend Analyzed Spend \$176,240,032 \$149,457,461	Analyzed Spend % 84.80%	Projected inflati \$5,320		vizient	t. s	avings Actualyzer P	harmacy							+	• 11	1
Top 10 Therapeutic Class by Total Spend	•					rug Budget Forecast		loolbox								
Enhanced Therapeutic Class	Total Spend	My Percent of Total Spend	Pr In	-	ly Drug	Budget Foreca	ast			System: Facility: Mult Date Range: Apr		[12 Months]				
Antineoplastics	\$50,401,987	32.04%	51		Total Spen \$176,240.0		Analyzzd Sper 84.80%		d Inflation Impa \$5,320,265	t Projected in 3.56		ected Analyz \$154,777;		Total Projected S \$181,560,29		
Biologicals	\$15,015,850	8.52%	\$4	Filters *	DEF Details											
Endocrine	\$14,784,981	8.39%	55	¹⁴ Account Type (0 of 3) ¹³ Search Account Type	NDC	NDC Description	Total Spend	Analyzed Spend	Analyzed Spend S	Override Spend	Spend Variance	Inflation%	Override Inflation's	Projected Inflation Impact	Projected Inflation	Projected Analyzed Spend
Hematological Agents	\$12,440,481	7.05%	52	* Account Number (0 of 1980)	00000312002	NU VIAL LIF RIF OUTER, SUV	\$1,662,573	\$1,662,573	100.00%	-	100	5.00%	-	\$83,125	5.00%	\$1,745,765
and an array of the second	F10,400,401	1.00.0	-	^Q Search Account: Number	57894010103	STELARA (ustalityme) 90 NGAL SYRINSE 1X1 MLEVEINGE PF. SINGLE DOSE	\$1,595,195	\$1,095,195	100.00%			1.00%		\$127.516	8.00%	61,722,81
				² Class of Trade (0 of 5) ⁽³⁾ Search Class of Trade	00174055402	HUMRAPCN (adakmanab) doMG/0-4NL PEN U KIT 1 X 2 CT KIT LATEX-FREE, SUV.	\$1,405,313	\$1,405,502	100.00%			1.215		887.222	6.20%	\$1,494,02

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Letter to the C-suite regarding the pharmacy enterprise

Pharmacy Market Outlook Winter 2024

As a result, investment in phermacy (pharmacids and technicians) as well as analysticidata scientists and their accompanying technologies and information sections will be recessary to ensure financial with being in a highly consertitive market.

Quick market update

The pharmaceutical industry continues to change often the concerns about thus expenditures. The initial work on dry The phenomenolisis installary contrasts to share given the users and ding expenditures. The investigation of the strength of t

The battle over site of care

As described in previous versions of the Pharmocy Market Outlook, growth in pharmacy p

(A). This tool enables you to determine which



nt relations and physician leadership

ments for rare diseases approved by the FDA - all which cost \$2.2M or more. Given nail populations in which they are used, the cost impact has been spread over

prificantly change in 2024 as the number of approved gene therapies could

k closely with the physician specialists likely to prescribe these agents and t

will remain unlattle due to increasing concern about the cost of about

t of important steps that you as leadership should consider as you build a

ding to purchase these treatments. In addition, these medicatio



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