MANAGING THE SPECIALTY DRUG PIPELINE: A DATA-DRIVEN CLINICAL APPROACH

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SPEAKERS

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PAYERS' TOP SPECIALTY DRUG MANAGEMENT GOALS FOCUS ON COST CONTAINMENT

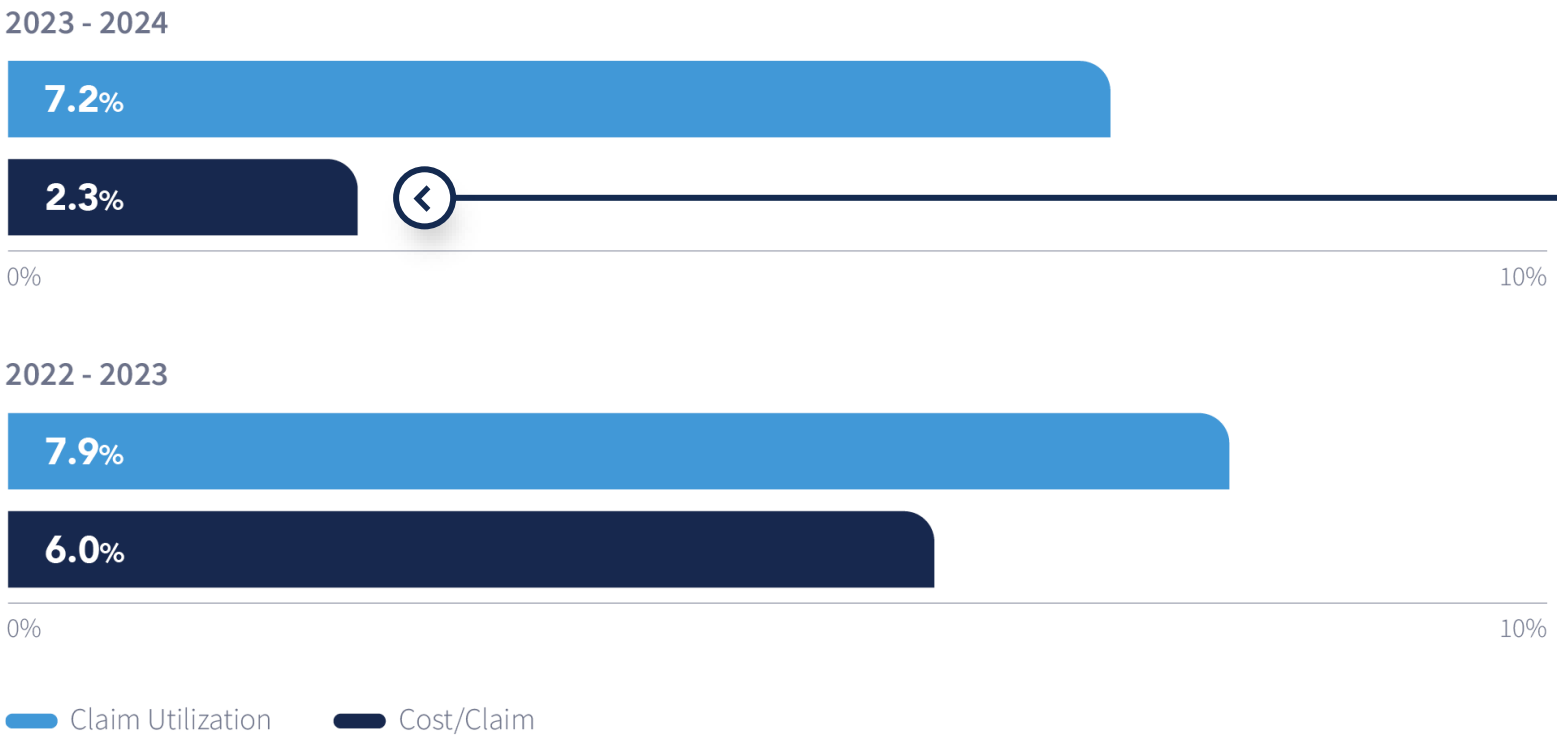
Table 1 Specialty Management Top Goals *(n=226)*

Specialty Management Goals	Ranked 1st	Ranked 2nd	Ranked 3rd
Manage Overall Specialty Trend/Specialty Drug Costs	43%	30%	12%
Manage Total Cost of Care	41%	23%	16%
Reduce Patient Out-of-Pocket Costs	5%	5%	13%
Reduce Inappropriate Utilization	4%	21%	23%
Increase Transparency	4%	7%	5%
Improve Patient Satisfaction	2%	5%	9%
Manage Site of Care/Place of Service	1%	4%	10%
Improve Specialty Drug Adherence and Persistency	1%	4%	14%

Pharmaceutical Strategies Group. 2025 Trends in Specialty Drug Benefits Report. Dallas, TX: PSG.

INCREASED CLAIM UTILIZATION IS THE PRIMARY DRIVER OF SPECIALTY TREND

Figure 2 Drivers of Increased Specialty Drug Trend



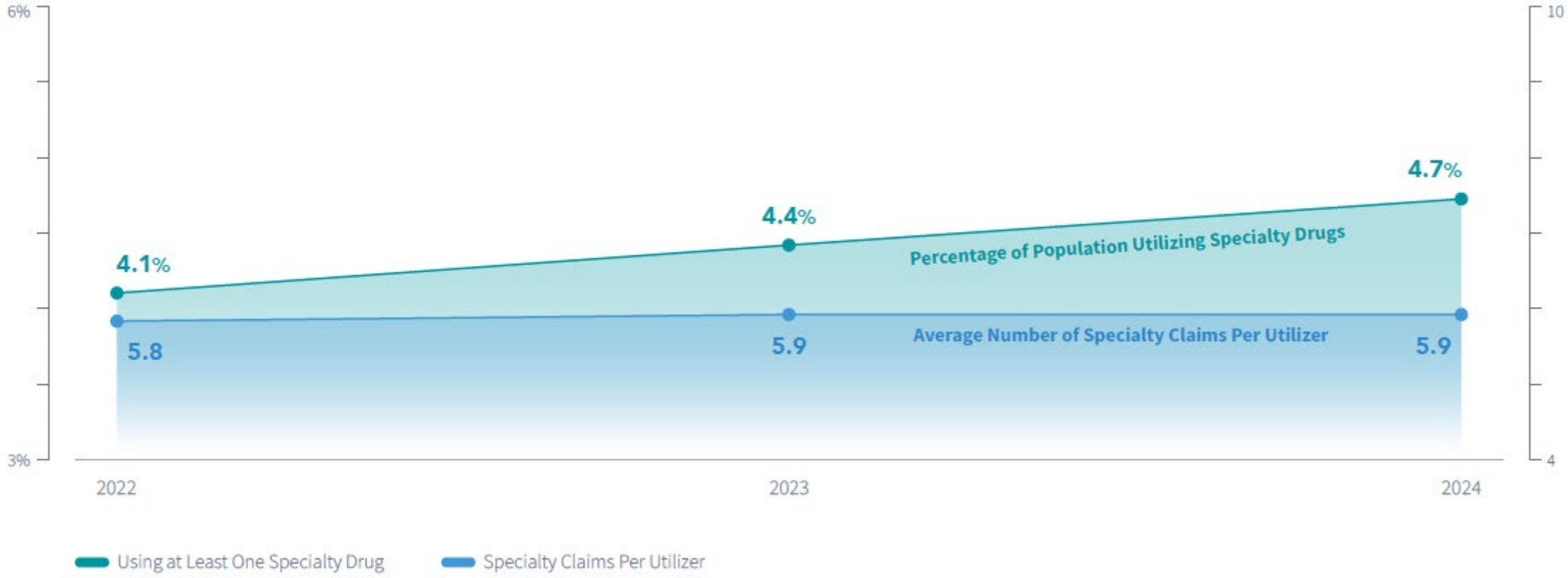
Additional analysis revealed no difference in cost per claim trend in 2023 compared to 2024 if biosimilars are excluded, so the decrease in cost per claim trend is due primarily to uptake of biosimilars.

Note: Percentages in the chart add up to slightly less than the overall trend shown on the prior page because cost per claim applicable to new claim volume also makes a small contribution to overall trend.

Pharmaceutical Strategies Group. 2025 Artemetrx State of Specialty Spend and Trend Report. Dallas, TX: PSG.

NUMBER OF SPECIALTY DRUG UTILIZERS CONTINUES TO INCREASE

Figure 3 Percentage of Population Using at Least One Specialty Drug and Average Number of Specialty Claims Per Utilizer



Pharmaceutical Strategies Group. 2025 Artemetrx State of Specialty Spend and Trend Report. Dallas, TX: PSG.

INFLAMMATORY CONDITIONS CONTINUE TO DRIVE TOP DRUGS, WITH SKYRIZI, DUPIXENT, AND RINVOQ ON THE RISE

Table 4 Top 10 Specialty Drugs by Spend

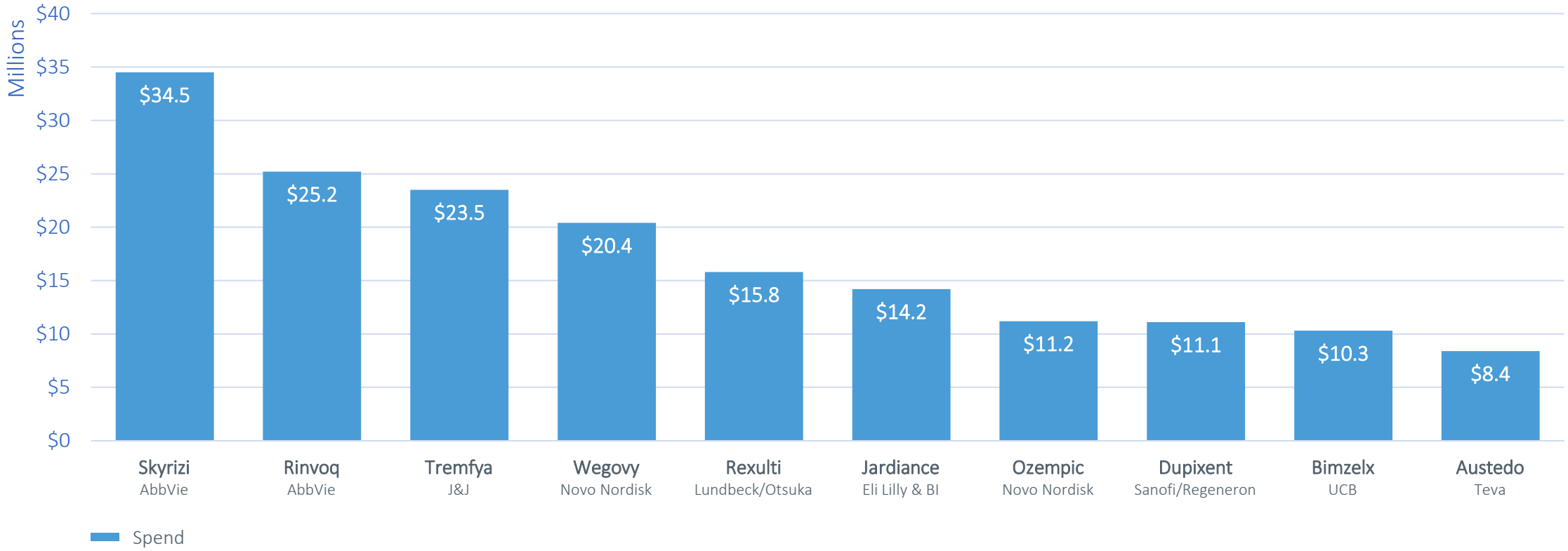
	Top Drugs	Avg 2024 Cost/Rx*	2023 Rank	Utilization Trend	Cost/Claim Trend	Cost PMPY Trend
1	**Humira** (Inflammatory Disorder)	$8,073	1	-18.6%	-1.5%	-19.8%
2	**Stelara** (Inflammatory Disorder)	$12,703	2	-2.2%	6.3%	4.0%
3	**Skyrizi** (Inflammatory Disorder)	$8,093	3	39.3%	9.2%	52.1%
4	**Dupixent** (Inflammatory Disorder)	$3,864	4	28.3%	7.5%	38.0%
5	**Keytruda** (Oncology)	$17,260	5	11.4%	4.4%	16.3%
6	**Tremfya** (Inflammatory Disorder)	$6,887	8	12.5%	3.1%	16.0%
7	**Ocrevus** (Multiple Sclerosis)	$37,542	6	-1.3%	5.8%	4.4%
8	**Enbrel** (Inflammatory Disorder)	$7,095	7	0.3%	5.1%	5.4%
9	**Rinvoq** (Inflammatory Disorder)	$6,514	13	53.6%	4.2%	60.0%
10	**Taltz** (Inflammatory Disorder)	$7,438	10	13.2%	3.2%	16.8%

**Normalized to 30-day equivalents*

Down from 2023 Up from 2023 Same rank from 2023

Pharmaceutical Strategies Group. 2025 Artemetrx State of Specialty Spend and Trend Report. Dallas, TX: PSG.

TOP SPEND PHARMA TV ADS - AUGUST 2025



Bimzelx new at #9, Dupixent down to #8, many list NFL Network as top TV network for spend

DRUGS TO WATCH 2025 current as of 09/15/2025

Drug (Manufacturer)	U.S. Prevalence	Route	Use	Est. Approval	Notes
Revascor (rexlemestrocel-L) (Mesoblast)	6.7M - heart failure 40%-50% - reduced ejection fraction	Intra-myocardial	Heart Failure	Submitting for review in 2025	• Potential first cell therapy to treat cardiovascular disease • Estimated cost $300K - $500K, one-time dose
JOURNAVX (suzetrigine) Vertex	80M use drugs for acute pain	Oral	Acute Pain	Approved 1/30/2025	• Approved for treatment of adults with moderate-to-severe acute pain • First new medication class for acute pain in more than 2 decades
Ekterly (sebetralstat) KalVista Pharmaceuticals	1 in 50,000 or 7,000	Oral	HAE – on-demand treatment	Approved 7/7/2025	• First-in-class oral therapy for on-demand HAE attacks
Andembry (garadacimab) CSL Behring	1 in 50,000 or 7,000	SQ	HAE – prophylactic treatment	Approved 6/16/2025	• Potential self-administered following provider-administered loading dose. Dosed once monthly
Vanrafia (atrasentan) (Novartis)	1 in 100,000	Oral	IgA nephropathy	Approved 4/3/2025	• Potential to provide benefit in multiple chronic kidney diseases • Estimated cost $100K - $200K , WAC per year
Dawnzera (Donidalorsen) Ionis Pharmaceuticals	1 in 50,000 or 7,000	SQ	HAE – prophylactic treatment	Approved 8/21/2025	• Potential for self-administration, RNA-targeted • Dosed once monthly or every 2- months
Cardamyst (Milestone Pharmaceuticals)	2M	Nasal Spray	PSVT	FDA denied 3/28/2025	• Short-acting calcium channel blocker for paroxysmal supraventricular tachycardia (PSVT)
Brinsupri (brennsocatib) Insmed	350,000 – 500,000 adults	Oral	Non-cystic fibrosis bronchiectasis (NCFB)	Approved 8/12/2025	• Currently no FDA-approved drugs for NCFB
Deutivacftor/tezacaftor/vanzacaftor – Alyftrek, (Vertex)	40,000 individuals	Oral	Cystic Fibrosis	Approved 12/20/2024	• Vertex will likely try to transition patients from Trikafta • Non-inferior to Trikafta, greater reduction in sweat chloride levels
Azemiglitazone (Cirius Therapuetics)	22M	Oral	NASH/MASH	Moving to Phase 3 trials	• 2nd generation insulin sensitizer, studied in MASH, pre-T2D, T2D • Estimated cost $20K - $50K per year
Qfitlia (fitusiran) (Sanofi/Alnylam)	Hem A – 1 in 5600 male births Hem B – 1 in 19K male births	SQ	Hemophilia A & B	Approved 3/28/2025	• New way to treat with potentially less dosing (6 doses per year) • Eliminates risk of inhibitors, estimated annual cost $500K - $750K

CLINICAL UPDATES – NEW DRUG APPROVALS

Ekterly Early Demand – FDA approved at beginning of July, the first oral on-demand drug for treatment of HAE acute attacks is off to a fast start. KalVista reported $1.4M in net revenue in its first quarter, post-Ekterly's approval suggesting it's driven by "strong early demand" reporting submission of 460 start forms in the first 8 weeks since the drug launched.

Wegovy for MASH Physician Enthusiasm – according to Spherix Global Insights, expectations are Wegovy's expanded indication for MASH will "be greeted by" enthusiasm among physicians and "swift" adoption.

- They suggest Rezdiffra "has built a strong adoption base" since its approval in March 2024
- Survey results following 1 week after Wegovy was approved for MASH, showed 42% of specialists (hepatologists & gastroenterologists) reported awareness, but 65% of physicians said they expect to prescribe Wegovy in the next three months
- Doctors surveyed two different drug approaches "could be favorable to different patient profiles"
  - 43% suggested preference for Wegovy in patients with moderate fibrosis (F2), 33% sided with Rezdiffra
  - For patients with advanced fibrosis (F3), suggestions were made to consider a combination of both options, with 43% of physicians doubting the "ability of monotherapy alone in the high-risk population"

Source: Novo's Wegovy in line for a 'swift' adoption in MASH: Spherix

DRUGS TO WATCH 2025 – EXPANDED INDICATIONS, NEW FORMULATIONS

current as of 09/15/2025

Drug (Manufacturer)	U.S. Prevalence	Route	Use	Expected Approval	Notes
Ozempic (Novo Nordisk)	30% to 40% of T2D	SQ	CKD in T2D	Approved 1/28/2025	• Approved to reduce kidney disease worsening, kidney failure (ESRD) and death due to CV disease in adults with T2D and CKD
Wegovy (Novo Nordisk)	22M adults in US	SQ	NASH/MASH	Approved 8/15/25	• Phase 3 study results appear to be comparable to Rezdiffra • Could be used in combination with Rezdiffra for more severe disease
Zepbound (Eli Lilly)	50% of patients with heart failure	SQ	HFpEF	Withdrawn	• Studied in patients with and without T2D but all had obesity
Dupixent (Regeneron/Sanofi)	300,000 individuals	SQ	Chronic spontaneous urticaria (CSU)	Approved 4/18/2025	• Will compete with Xolair – currently only drug approved for CSU • Also being studied for chronic pruritus of unknown origin and chronic inducible urticaria which there are no treatments
Nucala (GSK)	15M US population	SQ	COPD	Approved 5/22/2025	• Add-on therapy for treatment of eosinophilic phenotype COPD
Tremfya (J&J)	1M US population	IV/SQ	Crohn's Disease	Approved 3/20/2025	• Annual cost $90,000 - $180,000
Omvoh (Eli Lilly)	1M in US population	IV/SQ	Crohn's Disease	Approved 1/15/2025	• Estimated cost $100,000 - $200,000 annual WAC (maintenance)
Leqembi (Eisai/Biogen)	5.8M	IV/SQ	Early Alzheimer's	IV approved 1/26/2025, SC approved 8/29/2025	• Once monthly IV maintenance dosage after 18 months of every 2 week dosing • Once weekly maintenance dose
Rexulti (Lundbeck/Otsuka)	1 in 11 individuals	Oral	PTSD	First half 2025	• Could be used in combination with sertraline, convening an advisory committee, review date is delayed
Amvuttra (Alnylam)	> 120K US adults with 5K – 7K new cases diagnosed annually	SQ	ATTR-CM	Approved 3/20/2025	• Currently approved for hATTR-PN • Will compete with Vyndaqel/Vyndamax but double the cost

SPOTLIGHT – MASH

Dan Marino, ex-NFL player, reveals he has MASH and is campaigning with Novo Nordisk, the manufacturer of Wegovy, which received the expanded indication for treatment of MASH in adults on August 15th

- TV Advertisement campaign began during September 14th NFL schedule followed by media publications.
- 1 in 20 in the U.S. have fatty liver disease and 15M have MASH- he's partnered with Novo Nordisk as part of an awareness campaign to encourage people to see their doctors and get treated, as the condition is reversable.

SPOTLIGHT - HAE

Hereditary Angioedema (HAE) is a rare, genetic disorder in which patients experience recurring episodes of severe swelling caused by a deficiency in a protein called C1 esterase inhibitor (C1-INH) that is responsible for controlling inflammation. In its absence the body can over-produce inflammatory substances which results in swelling.

- Estimated 6,000 in the U.S. with HAE
- Since 2008, the FDA has approved 11 drugs for HAE **(3 approved in 2025)** making it a competitive market.
  - For prophylaxis, Cinryze & Haegarda originally had the market until Takhzyro became more commonly used in 2022, followed by oral Orladeyo which is less effective in reducing acute attacks and difficult to tolerate due to GI issues
  - Newer drugs offer different way to treat HAE and improved dosage forms and frequency
- The U.S. Hereditary Angioedema Association (HAEA) Medical Advisory Board has published guidelines for HAE treatment which include the following:
  - All patients with confirmed HAE should have “at least 2 standard doses” of an FDA approved on-demand treatment available for treatment of acute attacks
- In real-world utilization of HAE drugs, especially on-demand treatment, egregious quantities that lead to increased spend, wasted dollars and possible inappropriate use
  - i.e., member filling 32 Ruconest (enough to treat 16 attacks) $240k, appropriate quantity 4 (treat 2 attacks) $30K , appropriate quantity 8 (treat 4 attacks) $60K

SPOTLIGHT - HAE

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  - Newer drugs offer different way to treat HAE with improved dosage forms and frequency
- HAE treatment guidelines
  - Published by the U.S. Hereditary Angioedema Association (HAEA) Medical Advisory Board
  - All patients with confirmed HAE should have “at least 2 standard doses” of an FDA approved on-demand treatment available for treatment of acute attacks
- Egregious utilization quantities
  - Increased spend, wasted dollars, and possible inappropriate use
  - Example: Member filling 32 Ruconest (enough to treat 16 attacks) costing $240k. Appropriate quantity of 4 (to treat 2 attacks) costing $30K, or appropriate quantity of 8 (to treat 4 attacks) costing $60K

SPOTLIGHT – HAE ON-DEMAND DRUGS FOR TREATMENT OF ACUTE ATTACKS

Drug	Manufacturer	Mechanism of Action	Dosage Form	Dosing	Estimated Cost Per Dose
Berinert	CSL Behring	C1 esterase inhibitor	IV	20u/kg	$12,813 (3 vials)
Ruconest	Pharming Americas B.V.	C1 esterase inhibitor	IV	<84kg 50u/kg ≥84kg 2 vials	$16,150 (2 vials)
Kalbitor	Takeda	Kallikrein inhibitor	SC injection (MD)	30mg SC (3 x 10mg inj.)	$17,119
Firazyr	Takeda	Bradykinin B2 receptor antagonist	SC injection (self)	30mg SC	$11,147
Icatibant	Teva & others	Bradykinin B2 receptor antagonist	SC injection (self)	30mg SC	$3,049
Ekterly	KalVista	Kallikrein inhibitor	Oral tablet	600mg	$16,720

There are now **6 FDA approved drugs** for HAE prophylaxis

Drug	Manufacturer	Mechanism of Action	Dosage Form	Dosing	Estimated Annual Cost
Cinryze	Takeda	C1 Esterase inhibitor (C1-INH)	IV infusion	Every 3 or 4 days	$550K
Haegarda	CSL Behring	C1-INH	SC injection	Twice weekly, every 3-4 days	$509K - $679K
Takhzyro (lnadelumab)	Takeda	Kallikrein inhibitor	SC injection	Every 2 or 4 weeks	$266K - $534K
Orladeyo (Berotralstat)	Biocryst	Kallikrein inhibitor	Oral capsule	Once daily	$310K
Andembry (Garadicimab)	CSL Behring	FXIIa inhibitor	SC injection	Once monthly	$685- $742K
Dawnzera (Donidalorsen)	Ionis Pharma	Prekallikrein inhibitor	SC injection	Every 4 or 8 weeks	$747K

Questions?

Four Annual Market Research Reports

PBM Customer Satisfaction Report Webinar

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