PARTNERING TO ADVOCATE FOR IMPROVED CARDIOVASCULAR HEALTH: IT TAKES A TEAM

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DISCLOSURES (CONSULTANT / ADVISORY BOARD)

- Amgen
- Janssen and Janssen
- Astra Zeneca
- Esperion
- Boheimer Ingelheim
- Novo Nordisk
- Medtronic

OVERVIEW

- PCSK9 story
- Policy that affects access to Prescribed Therapy
- Payers Perspective
- Mini Act
- Advocacy Wins

What is Advocacy?

Advocacy is Part of the Prescription

CARDIOVASCULAR NURSING SYMPOSIUM

Why You Need to Advocate

Advocacy is Part of the Prescription

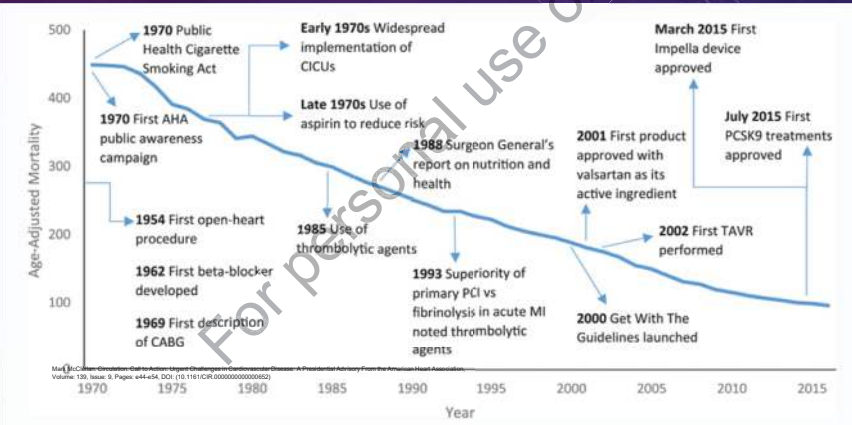
Never before has the clinician (ahem – the nurse's!) voice been more important

GALLUP

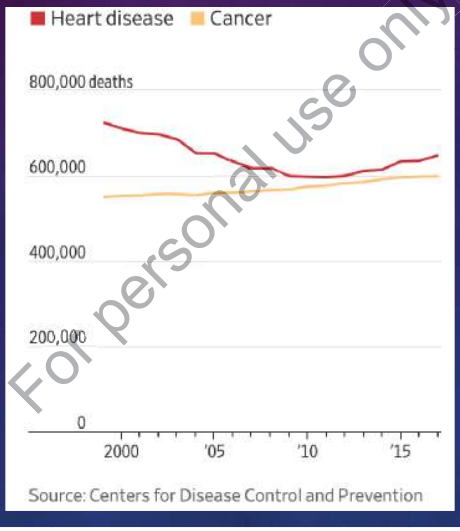
Nurses remain the most trusted profession, with 78% of U.S. adults currently believing nurses have high honesty and ethical standards.

https://news.gallup.com/poll/608903/ethics-ratings-nearly-professions-down.aspx

The CVD Challenge



The CVD Challenge



The CVD Challenge

Forecasting the Burden of Cardiovascular Disease and Stroke in the United States Through 2050-Prevalence of Risk Factors and Disease: A Presidential Advisory From the American Heart Association

"Clinical and public health interventions are needed to effectively manage, stem, and even reverse these adverse trends."

The best person to deliver message of change is the person that the public TRUSTS

NURSES!

The CVD Challenge

Forecasting the Burden of Cardiovascular Disease and Stroke in the United States Through 2050-Prevalence of Risk Factors and Disease: A Presidential Advisory From the American Heart Association

"The prevalence of many cardiovascular risk factors and most established diseases will increase over the next 30 years."

"Most adverse trends are projected to be worse among people identifying as American Indian/Alaska Native or multiracial, Black, or Hispanic."

https://pubmed.ncbi.nlm.nih.gov/38832505/

CARDIOVASCULAR NURSING SYMPOSIUM

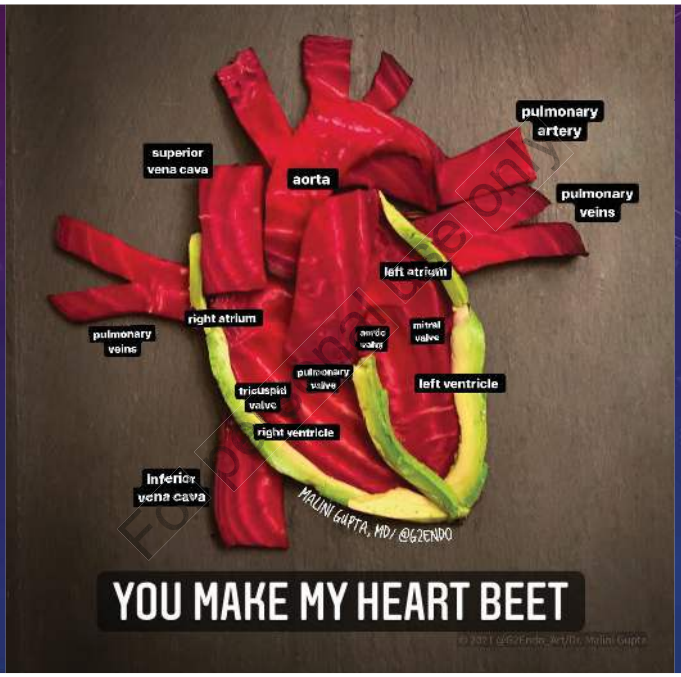
Agent	Mechanism of Action	Main Lipid Lowering Effect	Administration Scheme	Side-Effects	Comment
Statin	HMG-CoA inhibition	LDL - C	1x/day p.o.	Myopathy, increased liver enzymes	Side-effects are rare, novel statins like rosuvastatin and atorvastatin can be taken in the morning because of long t 1/2
Ezetimibe	NPC1L1 protein inhibition	LDL-C	1x/day p.o.	Diarrhoea	Side-effects are rare
PCSK9i (alirocumab/ evolocumab)	PCSK9 inhibition	LDL-C	2x/month (1x/ month) s.c.	Injection site reactions	Side-effects are rare, not more than placebo
Inclisiran	siRNA targeting mRNA PCSK9	LDL-C	2x/year s.c.	Injection site reactions	Side-effects are rare, not more than placebo (still under investigation)
Bempedoic acid	Inhibiting ACL and AMPK	LDL-C	1/day p.o.	Not greater than placebo	Alternative to SAMS?
Icosapent ethyl	LPL?	TGs	1/day p.o.	?	Benefit of long-term use of this agent still needs to be proven; many pleiotropic effects
Volanesorsen	Antisense oligonucleotide to apo C-III	TGs	2x/year s.c.	Thrombocytopenia and injection-site reactions	Treatment of ultra rare LPL deficiency
ANGPTL3	Monoclonal anti-ANGPTL3 antibody and ASO	TGs, LDL-C	2x/year s.c.?	Not yet fully determined	Studies are ongoing
Pemafibrate	Peroxisome proliferator-activated receptor alpha modulator	TGs	1/day p.o.	Liver enzymes?	Clinical data as well as long-term efficacy and safety need to be investigated
Pelacarsen	ASO to apolipoprotein(a)	Lp(a)	2x/year s.c.?	?	The agent is in phase III trial

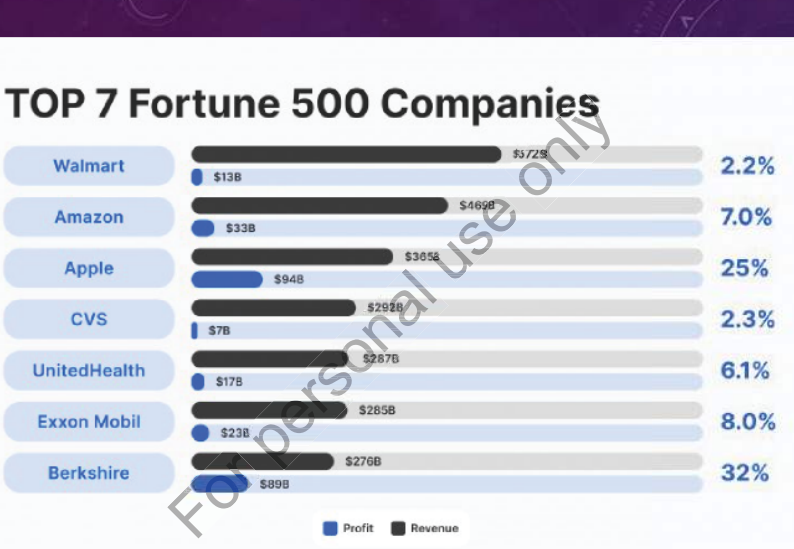
Abbreviations: HMG-CoA, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; LDL-C, Low density lipoprotein cholesterol; NPC1L1, Niemann-pick-C1 like-1 protein; PCSK9, inhibitor of proprotein kexin serin convertase type 9; p.o., peroral therapy; s.c., subcutaneous therapy; ACL, Adenosine triphosphate-citrate lyase; AMPK, adenosine monophosphate-activated protein kinase; SAMS, statin associated muscular symptoms; TGs, Triglycerides; LPL, lipoprotein-lipase; Apo-C-III, Apolipoprotein CIII; ANGPTL3 Angiopoietin-like 3; ASO, anti sense oligonucleotide; Lp(a), lipoprotein (a).
Note: ? indicates unknown side effects.

THERAPIES / POTENTIAL THERAPIES FOR LIPID MANAGEMENT

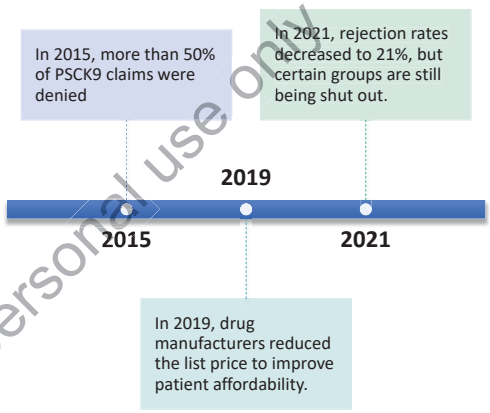
CURRENT LIPID LANDSCAPE

New and innovative therapeutics are great – but only if patients have access.



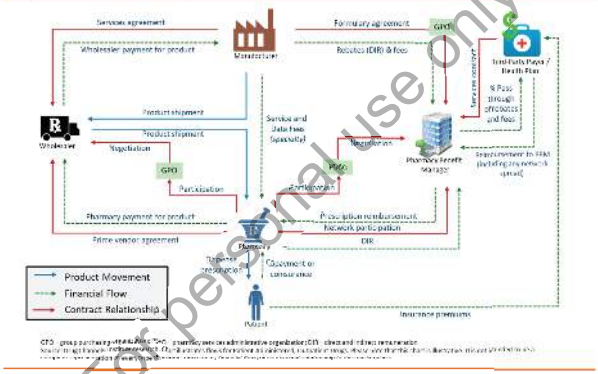


PCSK9I STORY



The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers

The U.S. Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Brand-Name Drugs

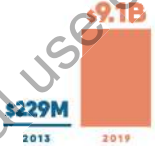


The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers discusses and analyzes the key channel flows illustrated above:

The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers
Adam J. Fein, Ph.D. Drug Channels Institute March 202

PHARMACY BENEFIT MANAGERS

The **3 biggest PBMs** controlled roughly **77%** of all U.S. prescription drug claims in 2020.[1]



PBM fees charged to pharmacies grew from **$229 million** in 2013 to an estimated **$9.1 billion** in 2019.[2]

PBMs pocketed more than **$450 billion** in revenue in 2020 – up from less than $300 billion eight years ago.[3]

The 3 largest PBMs excluded **846 FDA-approved drugs** from their formulas in 2020, denying patients access to more medications than ever before."[4]

[1] https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbm.html
[2] https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.html
[3] https://fortune.com/2021/08/06/pharmacy-benefit-manager-claims-auditing-pbm/
[4] https://www.fiercehealthcare.com/payer/study-drug-utilization-costs-health-industry-93b-a-year-patients-bearing-most-cost

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For Release

FTC Launches Inquiry Into Prescription Drug Middlemen Industry

Agency to Scrutinize the Impact of Vertically Integrated Pharmacy Benefit Managers on the Access and Affordability of Medicine

June 7, 2022

Tags: Competition | Office of Policy Planning | Nonmerger | generic drugs | Pharmacy Benefits Managers (PBM) | Health Care | Drug Stores and Pharmacies | Prescription Drugs

The Federal Trade Commission announced today that it will launch an inquiry into the prescription

Related actions

Statement of Chair Lina M. Khan Regarding 6(b) Study of Pharmacy Benefit Managers

POLICY THAT AFFECTS ACCESS TO PRESCRIBED THERAPY

Policy Made at Many Levels

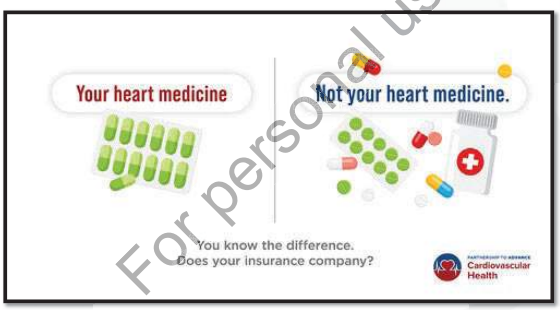
Medical Society Guidelines
Health Plan Formularies and Policies
Economic Assessments (ICER)
Agency Rulemaking
State and Federal Legislation
Enforcement in the Executive or Bureaucracy

Policies We Track

Prior Authorization
Non-medical Switching
Step Therapy
Co-Pay Accumulators
Formulary Tiering and Placement
Formulary Exclusion

Challenges in CV Advocacy

Non-Medical Switching



CARDIOVASCULAR NURSING SYMPOSIUM

Challenges in CV Treatment

CVS Caremark Formulary Change Freezes Out Apixaban

Patrice Wendling
January 13, 2022

In a letter to CVS Caremark backed by 14 provider and patient organizations, the nonprofit Partnership to Advance Cardiovascular Health (PACH) calls on the pharmacy chain to reverse its "dangerously disruptive" decision to force stable patients at high risk of cardiovascular events to switch anticoagulation, without an apparent option to be grandfathered into the new plan.

PACH president Dharmesh Patel, MD, Stern Cardiovascular Center, Memphis, Tennessee, called the formulary change "reckless and irresponsible, especially because the decision is not based in science and evidence, but on budgets. Patients and their health care providers, not insurance companies, need to be trusted to determine what medication is best," he said in a statement."

https://www.medscape.com/viewarticle/966588?form=fpf

Challenges in CV Treatment

Challenges in CV Treatment

Apixaban Returned to CVS Caremark Formulary After Outcry

"…Because of a significant backlash from various clinician and patient advocacy groups, apixaban was re-added to the formulary in July 2022."

WHAT IS PRIOR AUTHORIZATION (PA)?

What began as a safeguard against unnecessary drug spending has become a **significant barrier** to patient access.

It's the process whereby **insurance companies must approve a physician-prescribed medicine**, procedure, or test before a patient can get coverage.

Insurers and PBMs are increasingly imposing utilization management protocols, especially prior authorization, to reduce and deny patients access to life-saving treatments.

BURDEN OF PRIOR AUTHORIZATIONS

- A **2021 survey from the American Medical Association** states that:
  - **93% of physicians** report that prior authorizations **delay access** to necessary care
  - **82%** said that problems related to prior authorizations result in patients abandoning treatment
  - More than **1/3 of physicians** reported that the process led to a **severe adverse event**
  - **24% of physicians** report that prior authorization has led to a patient's **hospitalization**
  - On average, practices complete **41 prior authorizations per week** and dedicate **13 hours each week** to complete the paperwork, with 88% describing the burden as extremely high

American Medical Association 2021

Challenges in CV Treatment

Figure 3. Change in PA for Single-Source Brand Drugs in the Commercial Market by TA,[a] 2014–2020

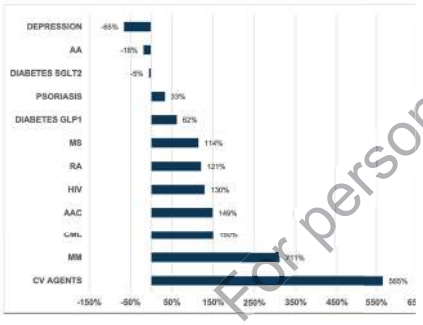
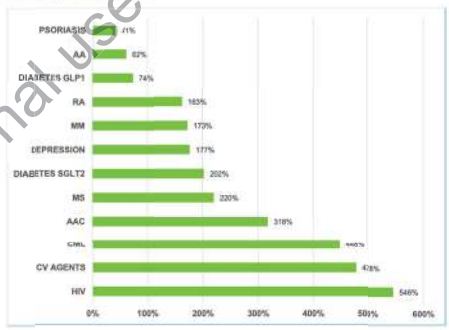
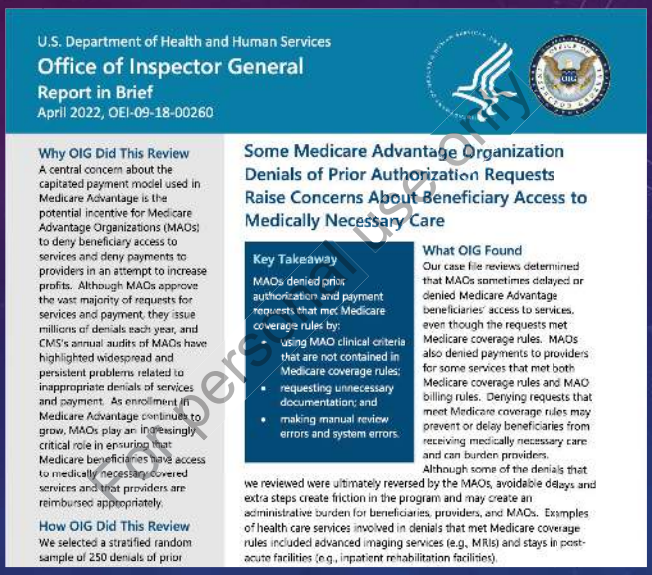


Figure 4. Change in ST for Single-Source Brand Drugs in the Commercial Market by TA,[a] 2014–2020



https://avalere.com/wp-content/uploads/2021/11/UM-Trends-in-the-Commercial-Market.pdf



U.S. Department of Health and Human Services

Office of Inspector General

Report in Brief

April 2022, OEI-09-18-00260

Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care

Why OIG Did This Review

A central concern about the capitated payment model used in Medicare Advantage is the potential incentive for Medicare Advantage Organizations (MAOs) to deny beneficiary access to services and deny payments to providers in an attempt to increase profits. Although MAOs approve the vast majority of requests for services and payment, they issue millions of denials each year, and CMS's annual audits of MAOs have highlighted widespread and persistent problems related to inappropriate denials of services and payment. As enrollment in Medicare Advantage continues to grow, MAOs play an increasingly critical role in ensuring that Medicare beneficiaries have access to medically necessary covered services and that providers are reimbursed appropriately.

How OIG Did This Review

We selected a stratified random sample of 250 denials of prior

Key Takeaway

MAOs denied prior authorization and payment requests that met Medicare coverage rules by:

- using MAO clinical criteria that are not contained in Medicare coverage rules;
- requesting unnecessary documentation; and
- making manual review errors and system errors.

What OIG Found

Our case file reviews determined that MAOs sometimes delayed or denied Medicare Advantage beneficiaries' access to services, even though the requests met Medicare coverage rules. MAOs also denied payments to providers for some services that met both Medicare coverage rules and MAO billing rules. Denying requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically necessary care and can burden providers. Although some of the denials that we reviewed were ultimately reversed by the MAOs, avoidable delays and extra steps create friction in the program and may create an administrative burden for beneficiaries, providers, and MAOs. Examples of health care services involved in denials that met Medicare coverage rules included advanced imaging services (e.g., MRIs) and stays in post-acute facilities (e.g., inpatient rehabilitation facilities).

SUCCESSFULLY NAVIGATING THE PA

- Start with a **thorough template letter** addressing the patient's high-risk status and proven data supporting the medication to lower LDL.
- Know the **current guidelines and coverage criteria** for approvals.

PCSK9s

- Atherosclerotic Cardiovascular Disease (ASCVD)
- LDL-C ≥ 190 mg/dL (including polygenic hypercholesterolemia, HeFH, and the HoFH phenotype)
- Very High-Risk/Statin Intolerance

Bempoic Acid

- For the treatment of an adult patient with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease
- Prescribed as an adjunct to maximally tolerated statin therapy
- The patient requires additional lowering of low-density lipoprotein cholesterol (LDL-C)

COMPLETE PATIENT INFORMATION

More than half of denials are attributed to incomplete paperwork

- Indication and documentation of **patient's medical conditions** and needs
- A **recent lipid panel** (< 30 days old)
- FH Documentation, when applicable
- **Statin history**
- Explain **step therapy** or failed medications
- **LDL-C Goal** and how they did not reach the goal on a statin
- **Adjunctive Therapy** - this can include patients' efforts to lower LDL w/ diet and exercise and any appointments with nutritionists.

BEST PRACTICES FOR PA APPROVALS

- **Persistence matters**.
- Suggest the patient try a **specialty pharmacy**; there has been a greater success with less paperwork.
- Train **staff and assign one person as the point person** for submissions. Experience helps for a smooth approval process.
- **Manufacturers' field access specialists** may be helpful.

PA APPEAL PROCESS

You can appeal the initial rejection.

- Either a **letter or peer-to-peer discussion** is next
  - The letter is used to fill in the gaps omitted from the first request
  - Peer-to-peer is typically a brief phone call with a better success rate for approvals
- A **secondary appeal** can be requested - or a medical review

KEYS TO SUCCESSFULLY NAVIGATING PCSK9

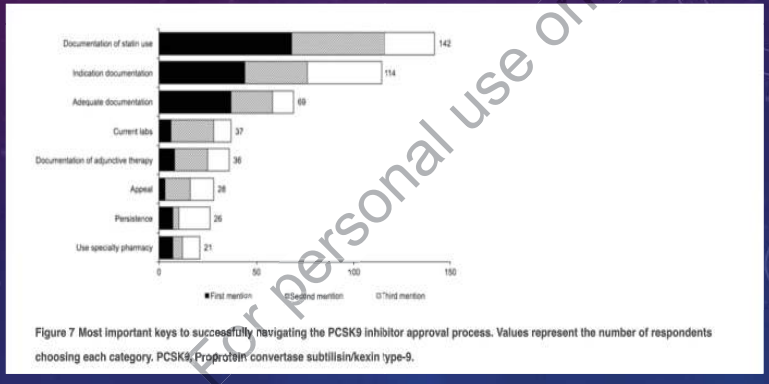


Figure 7 Most important keys to successfully navigating the PCSK9 inhibitor approval process. Values represent the number of respondents choosing each category. PCSK9, Proprotein convertase subtilisin/kexin type-9.

Barriers to PCSK9 inhibitor prescriptions for patients with high cardiovascular risk: Results of a healthcare provider survey conducted by the National Lipid Association
Jerome D. Cohen, MD Journal of Clinical Lipidology May 24, 2017

DIFFERENT PAYER APPEALS

- **Medicare** - The appeals process has five levels. If you disagree with the decision made at any process level, you can generally go to the next level. The last step is a federal court district review - which is costly for the patient.
- **Commercial** - If patients are denied after the second appeal, they can file a formal complaint with the state insurance commissioner. The payer is obligated to inform the patient why they are denied.

BE A VOICE FOR PATIENTS

Get involved with organizations like NLA /ACC/PACH to elevate the physician's voice and make guideline changes.

Suggestions for streamlining the PA process:

- A unified prior authorization form encourages efficiency.
- Electronic submission and response should be standard - it's tough to keep up with communications that aren't in one centralized location - telephone, fax, and email.
- Considerations of prior authorization requests should adhere to a uniform timeline.
- Patients deserve a straightforward appeal process.
- Digitally-focused strategy that emphasizes brand awareness and ease of prescribing in the EHR

FORMULARY EXCLUSIONS

Market-wide trends

In 2022, 1,156 unique prescription medicines were excluded from the standard formularies of at least 1 of the 3 PBMs, a 961% increase from 2014, when 109 medicines were excluded (**Figure 1**).* From 2014 to 2022, the number of medicines excluded by 1 or more PBM increased by an average of 34% per year.

Figure 1. Number of prescription medications excluded from 1 or more PBM formulary, by year

* In 2014, medicines were either excluded from CVS Caremark, Express Scripts, or both. OptumRx did not begin excluding medicines from its formulary until 2016.

FORMULARY EXCLUSIONS BY THERAPEUTIC AREAS

Table 1. Therapeutic areas for medicines excluded from 1 or more PBM formulary, 2014–2022

Rank	Therapeutic area	# of medicines excluded*	% of total exclusions
1	Autonomic and central nervous system	225	16.6%
2	Diabetes, endocrine, metabolic, and weight loss	209	15.4%
3	Dermatologics	151	11.1%
4	Oncology, hematological, and antineoplastic/immunosuppressant	117	8.6%
5	Cardiovascular	109	8.0%
6	Gastrointestinal	82	6.0%
7	Musculoskeletal, rheumatology, and osteoarthritis	80	5.9%
8	Respiratory	78	5.7%
9	Obstetrical and gynecological	65	4.8%
10	Ophthalmic	64	4.7%
11	Antivirals and anti-infectives	61	4.5%
12	Ear/nose/throat/mouth and allergies	32	2.4%
13	Urological	26	1.9%
14	Inflammatory conditions	20	1.5%
15	Hepatitis	17	1.3%
16	Immunomodulators and transplant	9	0.7%
17	Nephrology and renal disease	5	0.4%
18	Hepatology	2	0.1%
Total		1,357	100%

* Unique medicines excluded for current plan year by 1 or more PBM

AmerisourceBergen Xcenda May 2022

STEP THERAPY

- time-consuming from a physician and patient standpoint
- is more expensive from a direct and indirect out-of-pocket cost perspective
- denies patients the drugs they need when they need
- allows payers to practice medicine without a license.
- Creating additional barriers, leading people to forgo needed medications
- Possibly causing patients' medical conditions to deteriorate, increasing the need for later medical intervention in the future, thus making patients require increasingly-costly medical care
- Increasing frustration and incidents of depression
- Increasing the risk of non-compliance and self-medication

PAYERS PERSPECTIVE

- PA -effectively help avoid inappropriate drug use and promote the use of evidence-based drug therapy
- Reduce off-line indication
- Medical Economics
- Control Costs

JAMA. | Original Investigation

Cost-effectiveness of PCSK9 Inhibitor Therapy in Patients With Heterozygous Familial Hypercholesterolemia or Atherosclerotic Cardiovascular Disease

Dhruv S. Kazi, MD, MSc, MS; Andrew E. Moran, MD, MPH; Pamela G. Coxson, PhD; Joanne Penko, MS, MPH; Daniel A. Ollendorf, PhD; Steven D. Pearson, MD, MSc; Jeffrey A. Tice, MD; David Guzman, MSPH; Kirsten Bibbins-Domingo, PhD, MD, MAS

IMPORTANCE Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors approved for lowering low-density lipoprotein cholesterol in heterozygous familial hypercholesterolemia (FH) or atherosclerotic cardiovascular disease (ASCVD) have potential for broad ASCVD prevention. Their long-term cost-effectiveness and impact on health care spending are uncertain.

OBJECTIVE To estimate the cost-effectiveness of PCSK9 inhibitors and their impact on US health care spending.

DESIGN, SETTING, AND PARTICIPANTS The Cardiovascular Disease Policy Model of US adults aged 35 to 94 years, was used to evaluate cost-effectiveness of PCSK9 inhibitors or ezetimibe in heterozygous FH or ASCVD. The model incorporated PCSK9 inhibitor costs of $14 360 (based on mean wholesale acquisition cost) and clinical trial data and concurrently adopted a health-system perspective. Lifetime horizon, 2015 US dollars, probabilistic sensitivity analyses to explore uncertainty.

EXPOSURES Statin therapy compared with addition of ezetimibe or PCSK9 inhibitors.

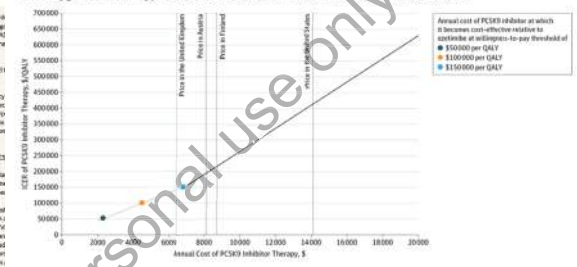
MAIN OUTCOMES AND MEASURES Lifetime major adverse cardiovascular events (MACE), cardiovascular death, nonfatal myocardial infarction, or stroke), incremental cost-effectiveness ratios, quality-adjusted life-year (QALY), and total effect on US health care spending.

RESULTS Adding PCSK9 inhibitors to statins in heterozygous FH was estimated to prevent 39 300 MACE at a cost of $908 000 per QALY gained compared with statins (80% uncertainty interval [UI], $490 000-$1 737 000). In ASCVD, adding PCSK9 inhibitors to statins was estimated to prevent 4.3 million MACE compared with statins plus ezetimibe at $414 000 per QALY (80% UI, $277 000-$1 329 000). Reaching costs to $4536 per patient or less would be needed for PCSK9 inhibitor therapy to cost at less than $100 000 per QALY. At 2015 prices, PCSK9 inhibitor use in the US was estimated to reduce cardiovascular care costs by $29 billion over 5 years. Increased by an estimated $992 billion (a 38% increase over 2015 prescription drug expenditures). In contrast, initiating statins in these high-risk populations and in individuals who are not currently using statins was estimated to save $1

CONCLUSIONS AND RELEVANCE Assuming 2015 prices, PCSK9 inhibitor therapy for heterozygous FH or ASCVD did not meet generally acceptable incremental cost-effectiveness thresholds and was estimated to increase US health care costs substantially. Achieving drug prices from more than $14 000 to $4536 would be necessary to meet commonly used $100 000 per QALY thresholds.

JAMA. 2016;316(7):743-753. doi:10.1001/jama.2016.11004

Figure 2. Incremental Cost-effectiveness Ratio (ICER) of PCSK9 Inhibitor Therapy Among Patients With Heterozygous Familial Hypercholesterolemia or Atherosclerotic Cardiovascular Disease



The ICER for proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor therapy increases with the annual cost of PCSK9 inhibitor therapy. Blue, orange, and black data markers indicate the price at which PCSK9 inhibitor therapy would become cost-effective in the United States at willingness-to-pay thresholds of $150 000 per quality-adjusted life-year (QALY) ($6810), $100 000 per QALY ($4536), and $50 000 per QALY ($2261), respectively. In the base case, status quo statin plus PCSK9 inhibitor therapy is compared with status quo statin plus ezetimibe (black line). When PCSK9 inhibitor therapy costs less than $7049 per year (inflection in the graph), ezetimibe is eliminated by extended dominance and status quo statin plus PCSK9 inhibitory therapy is compared directly with status quo statin therapy (gray line). For reference, vertical lines include the list price of a 1-year supply of evolocumab in the United States and 3 European countries.

Cost-effectiveness of PCSK9 Inhibitor Therapy in Patients With Heterozygous Familial Hypercholesterolemia or Atherosclerotic Cardiovascular Disease

Dhruv S. Kazi, MD, MSc, MS[1,2,3,4,5]; Andrew E. Moran, MD, MPH[6,7]; Pamela G. Coxson, PhD[1,2,8]; et al Joanne Penko, MS, MPH[1,2]; Daniel A. Ollendorf, PhD[9]; Steven D. Pearson, MD, MSc[9]; Jeffrey A. Tice, MD[2]; David Guzman, MSPH[1]; Kirsten Bibbins-Domingo, PhD, MD, MAS[1,2,3,8]
Author Affiliations Article Information

JAMA. 2016;316(7):743-753. doi:10.1001/jama.2016.11004

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

- Independent nonprofit research institute -produces reports analyzing the evidence on the effectiveness and value of drugs and other medical services
- evidence-based calculations of prices for new drugs that accurately reflect the degree of improvement expected in long-term patient outcomes, while also highlighting price levels that might contribute to unaffordable short-term cost growth for the overall health care system

ICER RECOMMENDATIONS

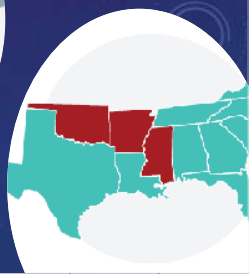
HEALTH-BENEFIT PRICE BENCHMARKS

What is a fair price for these therapies based on its value to patients and the health care system?

	Annual or Estimated Price	Annual Price to Achieve $100,000 - $150,000 cost-effectiveness threshold range	Change from WAC Required to Reach Threshold Prices	Estimated Net Price within or below range?
Bempedoic acid	$4,018	$1,600 to $2,600	Discounts of 36%-60%	NO
Inclisiran	$5,644 (assumed price)	$3,600 to $6,000	Nodiscount required at placeholder price	YES

PAYER RESISTANCE DISPARITIES

- **Women are 21% more likely to be rejected** than men, and it's worth noting that one in four women does not have a PCSK9 inhibitor covered by her health plan.
- **Black patients are rejected at a 20% higher** rate than white patients
- **Hispanic patients are rejected at a 25% higher** rate than white patients
- **Southern States Have Higher Rejection Rates**



Challenges in CV Treatment: R&D

"One of America's greatest achievements over much of the past century has been a huge decline in death rates from heart disease and strokes…."

"…Now, progress has stalled. That's helping drive down life expectancy in the U.S. after decades in which each generation of Americans could expect to live longer than the one that came before."

"Heart experts say they need new tools and approaches, because today's cardiovascular disease patients differ from those of past…"

Challenges in CV Treatment: R&D

Will We Get Those New Treatments?

Challenges in CV Treatment: R&D

- CV trials are larger
- Phase 3 clinical trials take longer
- Upfront investment is large and high risk
- Uptake of new therapy is slow
- Guidelines updating is slow
- 9 v 13: 80% of CV therapies are classified small molecule (including MABs)

5 of 10 drugs up for first-round negotiation were CV therapies

Challenges in CV Treatment: R&D

Impact of Medicare Drug Price Negotiation on Cardiovascular Disease Product Development and Patient Access

Avalere

CARDIOVASCULAR NURSING SYMPOSIUM

Challenges in CV Treatment: R&D

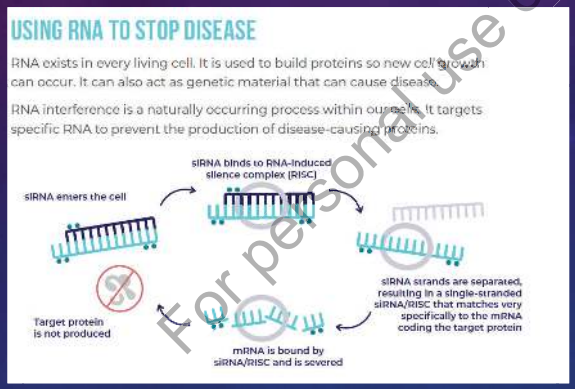
- ✓ **Larger study enrollment:** Phase III CVD trials averaged 67% greater enrollment than respiratory disease trials and 107% greater enrollment than metabolic disease trials
- ✓ **Longer clinical trials:** Phase III CVD trials took 28%–32% longer to complete than metabolic and respiratory disease trials
- ✓ **More trial sites:** The average number of sites per trial was more than 40% greater for phase III CVD trials than it was for respiratory or metabolic disease trials
- ✓ **Lower success rates:** The likelihood of success from phase I trial to FDA approval was 150% greater for respiratory disease and 300% greater for metabolic disease than for CVD; CVD trials had the second-lowest likelihood of success among the conditions analyzed

Challenges in CV Treatment: R&D

Figure 1. Illustrative Impact of Medicare Negotiation on Additional Indications

MINI Act

Genetically Targeted Technologies: siRNA and ASO



MINI Act
Maintaining Investment in New Innovation Act

MINI Act
Maintaining Investment in New Innovation Act

LP(a)
Hypertension
Cholesterol (inclisiran)

Moves the timeline for this small group of medicines to the 13 year price setting timeline to encourage continued investment in CV R&D

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	$113.00	$527.00	79%	$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	$119.00	$495.00	76%	$3,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$178.50	$556.00	68%	$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355.00	$7,106.00	67%	$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	$197.00	$573.00	66%	$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695.00	$13,836.00	66%	$2,988,560,000	23,000
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197.00	$517.00	62%	$6,309,766,000	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231.00	$521.00	56%	$18,275,108,000	3,928,000
Entresto	Novartis Pharms Corp	Heart failure	$295.00	$628.00	53%	$3,430,753,000	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319.00	$14,934.00	38%	$2,371,858,000	17,000

Note: Numbers other than prices are rounded to the nearest thousands. List prices are rounded to the nearest dollar and represent the Wholesale Acquisition Costs (WACs) for the selected drugs based on 30-day supply using CY 2022 prescription fills. Drug companies' participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.

THE RISE OF ADVOCACY

- PACH (Partnership to Advance Cardiovascular Health)
- National Lipid Association Advocacy
- American Society of Preventative Cardiology Advocacy
- American College of Cardiology Advocacy
- Preventative Cardiology Nursing Association

- January 2021: Blue Shield of CA Standard commercial formulary removed both PCSK9i products (all NDCs/formulations)

- February 2021:
  - AfPA CV WG launches sign-on letter to Blue Shield
  - PACH pushes out media release and informs coalition
  - PACH contacts ACC Advocacy

- **June 7, 2021: Blue Shield reverses its decision**

"Outrageous…how can we be moving backwards after all these years?"

COLLABORATE WITH PATIENT GROUPS

The Partnership to Advance Cardiovascular Health (PACH) raised this issue directly with health insurers in states with the highest rejection rates.

Results: PCSK9 rejection rates decreased, and patients began receiving life-saving medications.

- Within three months, BCBS of Alabama announced **it would cover PCSK9s** for patients with high cholesterol.
- BCBS of Florida **removed a step edit** and increased the duration of the PCSK9 therapy to increase patient access.
- BCBS of Mississippi **lifted the block on the PCSK9s** within 15 months.
- In only six months, Blue Shield of California **reversed its decision** to remove PCSK9s from its formulary.

CONCLUSIONS

Agreements to expand PCSK9I access occurred two-to-three years after the drugs entered the market. Stakeholders should seek to iron out the details of innovative payment agreements closer to a drug's launch to avoid long delays in patient access.

Ultimately, if patients are truly to benefit from innovative therapies, all stakeholders—including manufacturers, payers, and providers—must engage in efforts to ensure appropriate drug pricing, utilization management, and prescribing

PA is not the answer – transparent guideline driven process by physicians and professional societies should form the basis for developing mechanisms to minimize wasteful spending without compromising the quality of care

Advocacy Works !

Challenges in CV Treatment

Utilization Management

Research and Development for New Therapeutics

CARDIOVASCULAR NURSING SYMPOSIUM

Making the Difference


Memphis
THANK YOU !