Point32Health, parent company of
Harvard Pilgrim Health Care & Tufts Health Plan
ETHICS ADVISORY GROUP (EAG)

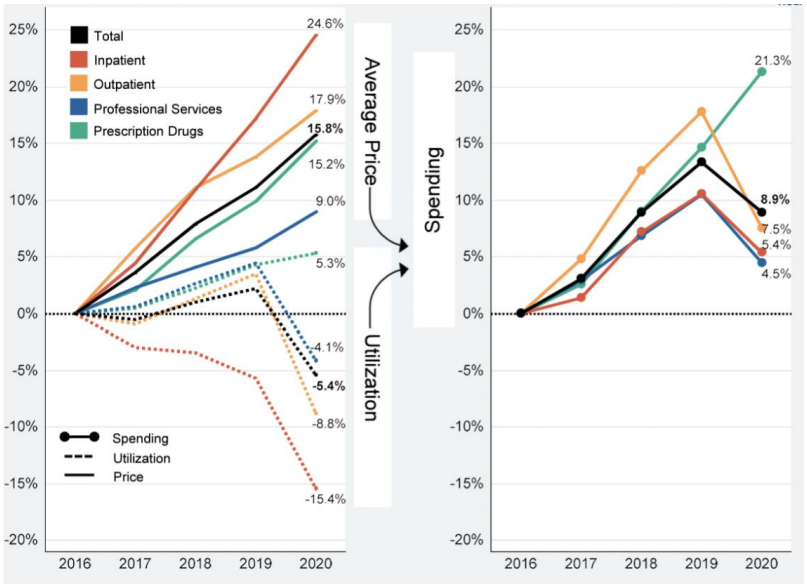
Consultation Report
<u>Affordability of New Therapies - Principles for Health Plan Communication</u>
January 9, 2023

Purpose
To seek input from the multi-stakeholder Ethics Advisory Group (EAG) on principles leaders of a health plan might consider for communicating with members, clinicians, and others about societal tradeoffs, including threats to affordability of health insurance, posed by increasingly expensive therapies.

Customers for the Ethics Advisory Group and Expert Guest
The Point32Health customers for the EAG meeting were Michael Sherman, MD, MBA, Chief Medical Officer and Gail Ryan, PharmD, Director, Pharmaceutical Transformation. Stuart Altman, PhD, the Sol C. Chaikin Professor of National Health Policy at Brandeis University offered introductory remarks. Among many other responsibilities, Dr. Altman has acted as advisor to five U.S. presidential administrations and served as chair of the Massachusetts Health Policy Commission.

Background
<u>Prescription drug prices</u>
Prescription drug spending is the major contributor to rising health care costs in the US (Figure 1), and prescription drug prices are the major contributor to increasing drug spending which exceeded $500 Bn in 2020.[1] Prescription drug spending is driven by highly priced brand name drugs for which manufacturers freely set prices after receiving regulatory approval by the Food and Drug Administration (FDA).

Figure 1. Price, utilization, and spending on health care (HCCI 2022)

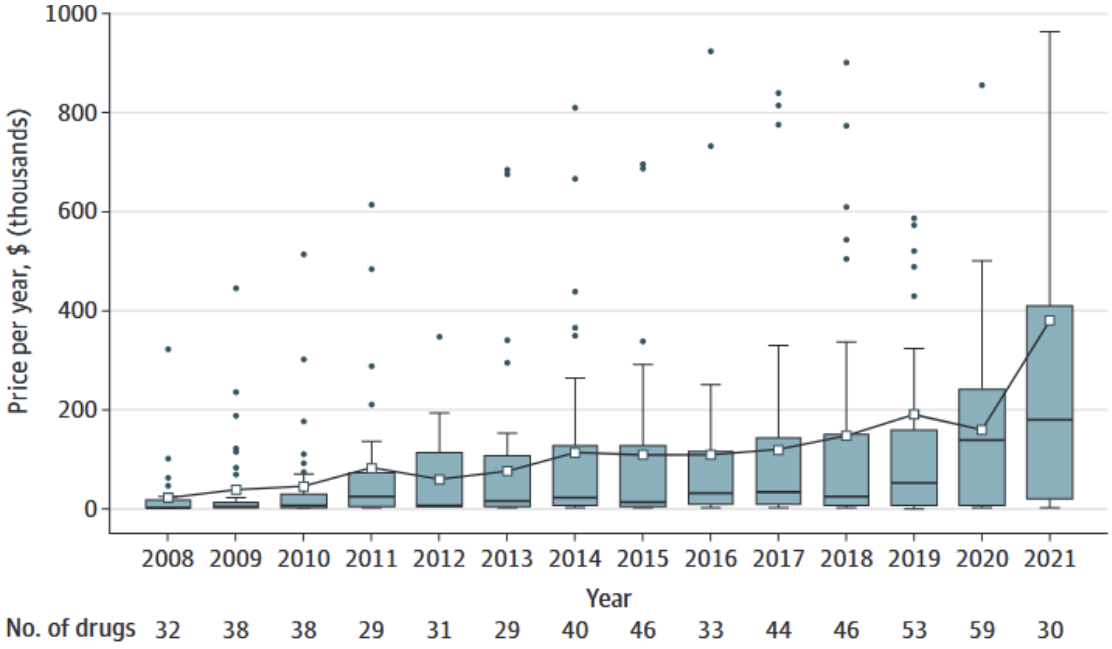


Launch prices of newly FDA-approved drugs have increased exponentially in the past decade. Figure 2 shows that median launch prices of new to market drug therapies per year increased from $2115 in 2008 to $180007 in 2021. The proportion of drugs priced at $150000 per year or more was 9% in 2008-2013 and 47% in 2020-2021.[2] For 13 drugs for chronic conditions launched between January and mid-August 2022, the median price per year of treatment was $257,000.[3]

In August 2022, Congress passed the Inflation Reduction Act that allows Medicare to start negotiating prices of selected drugs after 7 years on the market and that includes a cap on annual drug price increases.

Because the bill does not limit launch prices, experts expect that manufacturers will continue to raise launch prices of new drugs.[4]

Figure 2. Launch prices of 548 drugs approved between 2008 and 2021 (Rome et al, 2022)



More advanced therapies

A rising proportion of new therapies are cell, gene, and mRNA therapies, also called regenerative or advanced therapies. These new therapies are expected to halt progression of, or potentially cure, previously untreatable serious conditions, including some rare genetic conditions. Of note, the drug price calculations for Figure 2 exclude 6 such therapies[a] approved between 2015 and 2021 with launch prices exceeding $1 million per patient per year.[2]

In August 2022, the FDA approved betibeglogene autotemcel marketed by bluebird bio Inc. as Zynteglo for the treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell transfusions.[5] Beta thalassemia is an inherited blood disorder that affects red blood cells which transport oxygen through the body, resulting in chronic anemia. Beta thalassemia affects approximately 1 in 100,000 individuals. Severely affected patients must receive regular blood transfusions to survive. An estimated 2,600 individuals in the US have transfusion dependent thalassemia. bluebird bio set the price for Zynteglo at $2.8 million per patient, the highest price for a single-dose therapy in the US at the time.[6] Then, in September 2022, the FDA approved elivaldogene autotemcel for a rare (about 700 individuals in the US), debilitating neurological disorder called cerebral adrenoleukodystrophy. The single-dose therapy has a list price of $3 million per patient. Hemgenix (etranacogene dezaparvovec), a single dose therapy approved in

[a] sebelipase alfa [Kanuma, 2015; $1.2 million per year], inotuzumab ozogamicin [Besponsa, 2018; $1.0 million per year], tagraxofusp-erzs [Elzonris, 2019; $2.2 million per year], onasemnogene abeparvovec [Zolgensma, 2019; $2.2 million per year], naxitamab-gqgk [Danyelza, 2021; $3.2 million per year], and asparaginase erwinia chrysanthemi-rywn [Rylaze, 2021; $1.6 million per year]

November 2022 for treatment of severe hemophilia B, a rare bleeding disorder, is priced at $3.5 million per patient.

Approved gene and cell therapies to date are indicated for rare diseases. Accordingly, total spending on these expensive therapies is still limited by relatively low numbers of eligible patients and concentrated in areas with specialized treatment centers administering advanced therapies (including Massachusetts). However, as of 2019, more than 1000 clinical trials of advanced therapies were under way, for rare and for common diseases, with most (62%) for treatment of cancers.[7] FDA estimated in 2019 that by 2025, it will be approving 10 to 20 cell and gene therapy products a year.[8] Two treatments for sickle cell disease are expected to be approved in 2024. There are about 58,000 potential patients, most of whom are Medicaid beneficiaries. It has been estimated that a $1.85 million sickle cell gene therapy administered to only 7% of eligible patients annually would create an average one-year budget impact per state Medicaid program of nearly $30 million.[9] With more advanced therapies for more common diseases, global spending on advanced therapies is predicted to increase from $6 billion in 2021 to $19.6 billion in 2026.[10]

Uncertain duration of benefits of new therapies

The FDA approves most new therapies, including those designated as regenerative medicine advanced therapies (RMAT)[11] via expedited pathways requiring less rigorous evidence to make promising treatments available to patients while evidence regarding clinical benefits is still in development.[12] Especially for gene and cell therapies, data on the durability of effects are limited at the approval stage. In setting the price for Zynteglo, bluebird bio assumed that the treatment will offset costs for transfusions and associated care for patients with beta thalassemia which it estimated to exceed $6 million over a patient's life time.[6] Approval of the drug was based on single-arm, open-label, 24-month Phase 3 studies among 41 patients aged 4 to 34 years of whom 36 could be evaluated. Eighty-nine percent (32/36) of patients achieved transfusion independence during the 24-month study period, which was defined as no longer needing red blood cell transfusions for at least 12 months. The longest follow up was 4 years and observed duration of transfusion independence ranged from 12.5 to 39.4 months at the time of approval.[13] Of note, European payers' concern about the evidence gap led to a lower price offering by the German government ($790,000 for each patient between November 2020 and September 2022 to be increased to nearly $950,000 if all patients did no longer need chronic blood transfusions), half the price the company sought to negotiate in Germany ($1.8 million/patient, payable over 5 years).[14] In response, bluebird bio took Zynteglo off the German market in April 2021.[15]

Payment models for gene and cell therapies

Realizing the budget impact of highly priced advanced therapies, life science companies and payers are exploring different payment models, including outcomes-based contracts. bluebird bio announced that it will reimburse contracted commercial and government payers up to 80% of the cost of the therapy if a patient fails to achieve and maintain transfusion independence up to two years following infusion.[13]

Challenges of rising drug prices and spending for payers, insured members, workers, and society

Insurers of fully insured commercial members (for whom the health plan bears financial risk) have two mandates: they need to pay for medically necessary therapies for individual members and they need to steward resources wisely to ensure sustainability of health insurance coverage for all members. To meet these mandates, commercial insurers have essentially 2 options: 1) they may increase out-of-pocket cost share for care, including for new therapies, to be paid by the members who receive the care. And/or 2) they may raise premiums to cover increasing costs of health care, including highly priced therapies, through higher premiums paid by all members. Self-insured employers (who bear the financial risk and are not subject to the same coverage mandates as commercial health plans for fully insured members) may decide

to not cover expensive therapies.[16] Employers need to weigh rising health insurance premiums and health care costs against salary increases and other benefits.

Strategies to pay for increasing health care costs have societal opportunity costs. Increasing out-of-pocket payments increase *under*insurance, that is, the proportion of insured members who spend more than 10% of their income (or 5% if low-income [<200% of poverty]) on health care (over and above insurance premiums). Higher premiums increase *un*insurance rates when premiums become so expensive that small employers or employees may not be able to afford health insurance.

Figure 3 illustrates that more than 2 in 5 working age adults in the US were inadequately insured in 2022.[17] Individuals had continuous insurance coverage over the past year but were underinsured (23%), were insured with gaps in coverage (11%), or were uninsured at the time of the survey in the first half of 2022 (9%).[17]

Figure 3. Underinsurance and uninsurance rates, 2022 (Commonwealth Fund, 2022)

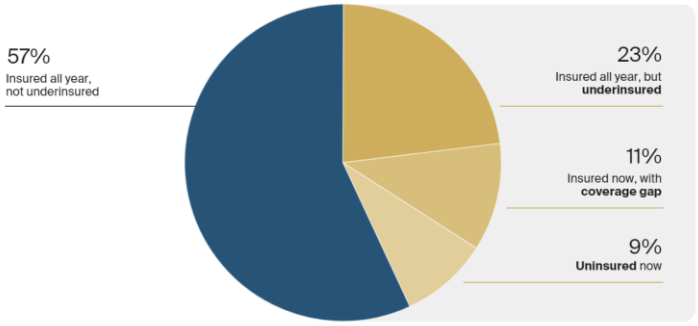
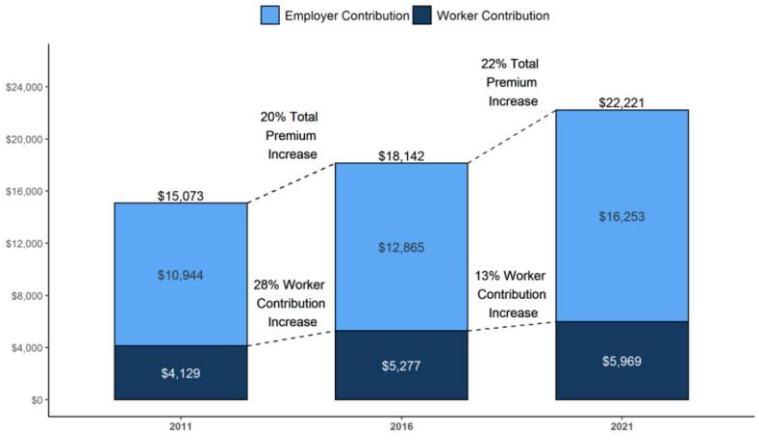


Figure 4 shows that in 2021, the average annual premium for employer-sponsored health insurance was $22,221 for family coverage. The average premium for family coverage has increased 22% over the last five years and 47% over the last ten years.[18] A 2019 analysis found that the cost to families for health coverage and care has risen more than 2 times faster than wages and 3 times faster than inflation over the last decade.[19]

Figure 4. Premium rises 2011-2021 (Kaiser Family Foundation, 2022)



Rising health care spending, including pharmaceutical spending, also stresses state and federal budgets. Public payers, e.g., state Medicaid programs, need to balance budgets. That is, they can either raise taxes

or shift spending from paying for common goods such as maintaining infrastructure and supporting public education.

In the US, the combination of increasing drug approvals via expedited pathways combined with unregulated drug prices and insurance coverage mandates contributes to rising health care spending and societal tradeoffs for drugs with uncertain benefits, at a time of depleted resources for most due to impacts of the COVID-19 pandemic and high inflation. Advanced therapies, if they fulfil their promise of cures, may offset some of the future time and financial costs of care for individuals with serious illnesses and improve the quality of life of both patients and their care givers. However, as Dr. David Rind from the Institute for Clinical and Economic Review states "if you think of the cost offsets for this expensive disease, [Zynteglo's price] is giving all of that to the manufacturer and none back to society."[6]

Financial pollution in the US health system

In a highly fragmented health care delivery and payment system, the interconnectedness of drug regulation, pricing, reimbursement, insurance affordability, wages, and public goods is not easily seen. Researchers at Point32Health's academic Harvard Pilgrim Health Care Institute have termed "financial pollution"[20] the insidious harm of high prices and other sources of harmful health care spending that increase premiums, erode wages, threaten employer-based insurance coverage, and deplete resources for common goods. As with environmental pollution, financial pollution harms vulnerable populations most.

Similar to environmental pollution, financial pollution and associated harms are not apparent to most who are affected. Increasing premium payments typically occur invisibly as regular payroll deductions. Rising Medicare and Medicaid expenditures lead to higher taxes, larger budget deficits, or a reduction in government services. Many people are unlikely to appreciate the relationship between, for example, exorbitantly priced health services and wage stagnation or tax increases. Thus, financial pollution is largely unnoticed.

What is the role of a health insurer in ensuring affordability of care and insurance?

The status quo raises questions: Based on which principles should a health insurer use its voice to discuss societal affordability of care? How should it advance literacy among its constituents about documented and potential benefits, high prices, and societal trade-offs of extraordinarily highly priced gene and cell therapies? How could health plan discussions of affordability with prescribers and members serve as levers in price negotiations with manufacturers? What are the risks of such discourse and how could they be mitigated?

Related Prior Ethics Advisory Group (EAG) Deliberations

Since 1998, more than 10 EAG deliberations have focused on pharmaceuticals. Until 2017, the deliberations mostly addressed questions of how the health plan should best balance its responsibility to cover costly drugs for individual members against its responsibility to ensure sustainably affordable coverage for all its members. Deliberations addressed ethical questions around incentives for members and prescribers toward most cost-effective alternatives. In 2017, in a deliberation[b] on the increasing proportion of (specialty) pharmaceutical spending of the health plan,[21] participants discussed, for the first time, questions around not covering a drug based on costs. At that time, the "*EAG recognized that some new agents provide outcomes not achievable by other means. At the extreme, a new drug may cure an*

[b] A Framework of Values for Dealing with High Drug Prices. Consultation report of the Harvard Pilgrim Health Care Ethics Advisory Group deliberation. October 17, 2017. Available from anita_wagner@hms.harvard.edu.

otherwise fatal disorder. Patients expect to have access to these life-changing benefits. Saying "no" to a breakthrough drug would be clinically and morally repugnant to a health plan. But the ever-escalating cost of health care creates its own form of harm to the public. Not covering a valuable agent versus contributing to access-preventing health care cost increases is a lose/lose situation." In 2021, following FDA approval of a highly priced drug lacking evidence of benefit (aducanumab), EAG participants acknowledged that a payer should provide member and clinician education about evidence of benefits and risks of rapidly approved drugs lacking evidence of benefit and publicly advocate for system change. *"In this way, a payer demonstrates consistently its efforts as an "honest broker" in a complex system."*[c] In all EAG deliberations on pharmaceuticals and other highly priced technologies, participants advised the health plan to provide physicians and members with information about drug prices. They also suggested that the health plan work with other stakeholders to promote public understanding of (a) the fact that health care costs trade off against other desirable social goals and (b) the health plan's ethical imperative to manage care and costs. Provider, member, and public education by the health plan were seen as necessary to support reforms of the pharmaceutical system.

Questions for the Point32Health Ethics Advisory Group Deliberation

On January 9, 2023, the Ethics Advisory Group was asked to deliberate on the following questions: In light of the pipeline of gene and cell therapies expected to be approved and coming to the US market at extremely high prices, some for prevalent conditions such as cancers,

1. Should a health plan surface questions about affordability of highly priced therapies and associated potential health care and societal trade-offs?
2. If yes, *how* should a health plan communicate about affordability of care? *Which constituencies* should it prioritize?
3. If no, *why should a health plan not communicate* about affordability of care? *What risks* would it incur? *How could risks be mitigated*?

Summary of the January 9, 2023, Point32Health Ethics Advisory Group Deliberation

Almost 90 individuals from within and outside of Point32Health participated in the discussion. Customers Drs. Gail Ryan and Michael Sherman and invited expert Professor Stuart Altman highlighted key background points for the discussion:

- As a health insurer, Point32Health is obligated to cover medically necessary treatments and to steward resources wisely. The organization is committed to promoting health equity.
- Health insurers have no leverage over drug approvals or drug prices. Exponentially increasing drug prices and the marketing of more enormously highly priced advanced therapies indicated for more and for more common diseases will continue to present challenging trade-offs for health insurers, employers, and for society at large. Trade-offs of increasing pharmaceutical spending occur in the form of higher insurance premiums and less affordability of insurance, stagnating wages, and shifts away from investment in common goods. The trade-offs affect vulnerable populations most, increasing inequities.
- Public and private sector health spending are connected. It is to be expected that the Inflation Reduction Act of 2022 which includes some provisions to lower prescription drug costs for individuals

[c] Accelerated Drug Approvals: Roles and Responsibilities of a Health Insurer. Consultation report of the Point32Health Ethics Advisory Group deliberation. October 15, 2021. Available from anita_wagner@hms.harvard.edu.

with Medicare and reduce drug spending by the federal government[22] will increase launch prices of drugs[4] and increase drug spending by private payers, further decreasing commercial insurance affordability for members and employers.

EAG participants discussed whether trade-offs required to pay for increasingly extraordinarily highly priced advanced therapies should be addressed "behind closed doors" of the health plan or "made visible" in discussions of the health plan with its stakeholders. Most EAG participants agreed *that the health plan should communicate with its stakeholders about affordability and trade-offs* (Table).

Table. EAG participants' poll responses (n=48)

Do you think a health plan should communicate about trade-offs that highly priced therapies require with:	Yes (%)	Not sure (%)	No (%)
Contracted clinicians	94	4	2
Contracted clinicians who prescribe highly priced therapies	98	2	0
Employers	92	6	2
Members	77	19	4

EAG participants offered these reasons for the health plan to engage with its stakeholders about trade-offs:

- Trade-offs required by pharmaceutical spending constitute a national problem. Educated discussions at different levels are needed to collectively identify comprehensive solutions.
- Health plan constituents, including prescribing clinicians, are not aware of the trade-offs.
- Given the information it has and the policy dilemmas it faces due to increasing drug spending, Point32Health is an expert on the issues. It is able to draw attention to affordability challenges and trade-offs required by paying for highly priced advanced therapies by providing evidence. It can help create common understanding for a much-needed societal conversation. Not fulfilling this role would be considered irresponsible by at least one participant.
- In communicating about impacts of increasing pharmaceutical spending with its stakeholders, Point32Health would add its important voice to that of other organizations that discuss harms of high drug prices and seek to change the status quo (e.g., Families USA, Patients for Affordable Drugs, the American Association of Retired Persons, the Institute for Clinical and Economic Review, the Massachusetts Health Policy Commission). Health plan communications could also spark conversations among constituents for the health plan's benefit.
- Fostering communication on trade-offs was seen as an important attempt to counteract powerful efforts of the pharmaceutical industry which is consistently among the top lobbying spenders.[23]
- Point32Health's engagement with stakeholders in affordability discussions was seen as consistent with the organization's position as a national leader. EAG participants recalled a 1998 pharmaceutical policy dilemma – the trade-offs incurred by paying for Viagra, a drug for erectile dysfunction. The Boston Globe then wrote favorably about Harvard Pilgrim Health Care's approach to covering Viagra which was preceded by an open, inclusive discussion.[24,25]
- Clear communication about trade-offs was considered necessary to foster understanding of coverage limits when those are implemented.

EAG participants saw limited risk in engaging with stakeholders in discussions of trade-offs (see below). They acknowledged that trade-off discussions are challenging because the topic is technical and requires understanding of complex health care regulatory and financing systems.

A question was raised regarding *which trade-offs* the health plan should communicate about. European payers pay lower prices for advanced therapies than US payers because European countries have different drug pricing and reimbursement laws than the US where prices are not limited, and reimbursement mandates exist. While important, global drug price differences seemed a lesser priority for health plan discussions with stakeholders than national and local trade-offs.

EAG participants agreed that the primary questions to focus on are *with which stakeholders* and *how the health plan communicates about trade-offs*. They suggested that providers, members, and employers should be brought into tailored discussions. Providers were considered the primary target for such trade-off discussions since, according to the opinion of participants, they are generally unaware of the costs of novel treatments and are on the front lines when it comes to patient education and treatment recommendations. Given limited member co-payments, and the complex relationships of health care spending, premiums, and salaries, members are not likely to be aware of trade-offs required by increasing drug spending. Such awareness was seen as needed, and member conversations were considered most challenging. Communications with members need to avoid potential misunderstandings of prioritizing individuals with certain diseases over others.

Communications about trade-offs with all constituencies will need to consider the lack of an accepted social compact in the US for discussing individual and community needs and benefits. All discussions must avoid being perceived as self-serving for the health plan or interfering with provider-patient relationships.

EAG participants suggested a public page on the health plan's website with information on pharmaceutical spending and the trade-offs it requires. Such a webpage would also allow highlighting efforts Point32Health leaders make to rein in pharmaceutical spending through outcomes-based payment contracts and contributions of health plan leaders to the discourse in national insurance provider fora. While reporting on egregious drug pricing issues has sparked public outcry, EAG participants agreed that sensational reporting should be left to others.

In summary, EAG participants suggested a need for and responsibility of the health plan to engage with all its stakeholders proactively and visibly about the trade-offs that are required, locally and nationally, by increasing pharmaceutical spending. This communication should include a focus on equity and will require a long-term strategy to be effective.

This report is respectfully submitted, with gratitude to Point32Health leaders, the expert guest, and all who generously shared their perspectives for making this important and timely Point32Health EAG conversation possible.

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