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



# Deliberation Report <u>Fertility Care – Considerations for Health Plans</u> April 14, 2023

## Purpose

To seek input from the multi-stakeholder Ethics Advisory Group (EAG) on health plan considerations for coverage of fertility care.

# **Customers for the Ethics Advisory Group and Expert Guests**

The Point32Health customers for the EAG meeting were <u>Claire Levesque</u>, MD, Chief Medical Officer, Commercial Products and <u>Patrick Cahill</u>, JD, President of Commercial Markets. <u>Brent Monseur</u>, MD, reproductive endocrinologist at Stanford University School of Medicine, offered introductory remarks.

# Background

Many people require fertility assistance to reproduce, either due to a diagnosis of infertility, or because they are in a same-sex relationship or single. Since the mid-1990s, societal understanding of family building and reproductive technology have changed dramatically. However, health insurance coverage of assisted reproductive services currently varies widely.

In this context, questions arise about the use of medical necessity as the standard for these benefits. Historically, health plan coverage of infertility has been based on definitions of medical necessity, with a focus on physiological infertility. Questions under discussion now include whether, from a health equity perspective, health plans should consider broadening infertility coverage to include coverage for relational infertility or social infertility, which typically would fall outside the existing definitions of medical necessity and would extend coverage beyond coverage mandated by most states that provide for some aspect of infertility coverage today. Below we lay out background information for the discussion.

# Brief history and definitions

Societal and medical technology changes over time prompt questions faced today. In December 1948, the United Nations General Assembly published the Universal Declaration of Human Rights.<sup>1</sup> For the first time, "rights inherent to all human beings, regardless of race, sex, nationality, ethnicity, language, religion, or any other status," including the right to "medical care" were declared as fundamental human rights.<sup>1</sup> In 1994, the International Conference on Population and Development in Cairo considered reproductive rights under the human rights obligations.<sup>2</sup>

At least since the 1970s, when a same-sex couple attempted to pursue marriage through higher courts in the US, the LGBTQ+ community has made progress toward equal rights.<sup>3</sup> Massachusetts became the first state to legalize same-sex marriage in 2003, and the US Supreme Court made same sex marriage legal in all 50 states in 2015. Lastly, following disputes during the Trump administration, the Office for Civil Rights enforces since 2022 Section 1557 of the 2010 Affordable Care Act, the first federal civil rights law to prohibit discrimination in health care on the basis of sex, including pregnancy, sexual orientation,

gender identity, and sex characteristics.<sup>4,5</sup>

## Infertility

In 2009, the World Health Organization and the International Committee for Monitoring Assisted Reproductive Technologies defined infertility as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse."<sup>6</sup> The American Medical Association supported the WHO definition in 2017.<sup>7</sup> The Centers for Disease Control defines infertility as "not being able to get pregnant (conceive) after one year (or longer) of unprotected sex".<sup>8</sup> The American Society of Reproductive Medicine defines infertility as "the result of a disease (an interruption, cessation, or disorder of body functions, systems, or organs) of the male or female reproductive tract which prevents the conception of a child or the ability to carry a pregnancy to delivery. The duration of unprotected intercourse with failure to conceive should be about 12 months before an infertility evaluation is undertaken, unless medical history, age, or physical findings dictate earlier evaluation and treatment."9 "Unprotected intercourse" in these definitions refers to vaginal-penile intercourse, and the definition of *infertility* due to a medical condition (e.g., low sperm count, blocked fallopian tube, also called "physiological infertility"<sup>10</sup>) applies to individuals in heterosexual, cisgender relationships. This implies that due to their relationship status individuals who do not have unprotected heterosexual intercourse, that is heterosexual single cisgender individuals and LGBTQ+ individuals and couples cannot be diagnosed and treated as infertile.

## Fertility

Fertility assistance needs of single individuals and LGBTQ+ couples are due to relationship structures (although their needs have also been categorized **as** "*relational infertility*" or "social infertility"<sup>10</sup>). Individuals can have both social infertility and physiological infertility. For example, a lesbian woman can be socially infertile because she is in a same sex relationship and be physiologically infertile due to endometriosis.

## Assisted human reproductive technology

Since in vitro fertilization (IVF) led to the birth of Louise Brown in 1978 in the UK, biomedical research rapidly developed assisted human reproductive technology (ART), and the first American IVF clinic opened in Virginia in 1980.<sup>11,12</sup> Dr. Robert Edwards, who, together with Dr. Patrick Steptoe, pioneered IVF research, is said to have "essentially changed the rules for how people can come into the world". He received the Nobel Prize in Physiology or Medicine in 2010 and was knighted by Queen Elizabeth II for "services to human reproductive biology".<sup>13</sup> Today, ARTs allow individuals who do and do not meet definitions of (physiological) infertility to have children.

An estimated 10%-15% of heterosexual couples experience infertility.<sup>14</sup> In general, infertility estimates do not consider LGBTQ+ or single individuals who seek fertility care. Figure 1 illustrates reasons for seeking fertility assistance.

#### Figure 1. Reasons for seeking fertility assistance<sup>10</sup>



## Types and cost of assisted reproductive technologies

ARTs comprise diagnostic, treatment, and fertility preservation services (Table 1). Most ARTs are expensive, and for individuals with insurance coverage, out-of-pocket costs vary widely, .<sup>10,15,16,17</sup>

#### Table 1. Common assisted reproductive technology services<sup>10</sup>

Service category	Service
Diagnostic services	Lab Tests (e.g., progesterone, ovarian reserve, thyroid studies, prolactin) Semen Analysis Imaging (e.g., pelvic ultrasound, hysterosalpingogram (HSG))
	Diagnostic procedures (e.g., laparoscopy, hysteroscopy)
Treatment services	Medications (e.g., Clomid/clomiphene citrate)
	Surgery (e.g., laparoscopy, hysteroscopy)
	Intrauterine insemination (IUI) [also known as "artificial insemination"]
	In vitro fertilization (IVF) [a type of assisted reproductive therapy (ART)]
Fertility preservation	Cryopreservation [also known as egg/sperm/embryo "freezing"]

Note: Services used for infertility diagnosis and treatment and for fertility assistance

Table 2.	Nationa	l estimates of	f costs of	assisted	reproductive	technology	and related	services <sup>17</sup>

Service	Cost estimate (\$)			
Costs before procedure (non-donor IVF)				
Base fee (typically includes monitoring appointments, egg retrieval, embryo creation and fresh embryo transfer)	12,000 – 14,000			
Fertility assessment	250 - 500			
Semen analysis	200 - 250			
Injectable medications	3,000 - 6,000			
Monitoring appointments	Typically included in base fee			
Cost of embryo retrieval and fresh embryo transfer				
Egg retrieval	Typically included in base fee			
Anesthesia (during egg retrieval)	Included in base fee to 725			
Donor sperm	300 - 1600			

Service	Cost estimate (\$)
Intracytoplasmic sperm injection (ICSI)	Included in base fee to 2,000
Mock embryo transfer	240 - 500
Fresh embryo transfer	Typically included I base fee
Costs of frozen embryo transfer	
Embryo cryopreservation	1,000 - 2,000
Embryo storage	350 – 6,000/year
Genetic testing	1,800 - 6,000
Frozen embryo transfer	Included in base fee to 6,400
Medication for frozen embryo transfer	300 - 1,500
IVF costs	
Mini IVF with medications	5,000 – 6,000 plus medications
	from 50 – 2,000
Frozen donor egg IVF base cycle	14,000 - 20,000+
Fresh donor egg IVF base cycle	27,000 - 47,000+
Gestational carrier or surrogate costs	
Legal fees and medical expenses	60,000 - 150,000+

Note: Not all services are used by an individual and not all used services are listed; estimates by Forbes Health, March 7, 2023.<sup>17</sup>

#### Fertility services as a workplace benefit

To recruit and retain top talent in a tight labor market, foster inclusivity, and be recognized as a family friendly employer, employers increasingly offer benefits that meet employees' needs in their lives outside of work. With employee interest in fertility benefits growing, employers are increasingly considering workplace benefits to help build a family, regardless of an employee's gender, sexual orientation, or medical condition, or whether they are single or partnered. Benefits that employers consider can include IVF treatment, elective egg freezing (for future family planning), as well as surrogacy and adoption support and reimbursement allowances.<sup>18</sup> From 2015 to 2020, large employers' coverage of fertility benefits has grown (Table 3).<sup>18</sup>

Table 3. Employer coverage of fertility benefits, by employer size<sup>18</sup>

Service		Employers with 500 or		Employers with 20,000	
	more		or more		
	employees		employees		
	2015	2020	2015	2020	
Evaluation by a reproductive endocrinologist or infertility specialist	54%	58%	70%	73%	
Drug therapy	32%	33%	44%	53%	
In vivo fertilization (intrauterine insemination)	23%	28%	34%	38%	
In vitro fertilization	24%	27%	36%	42%	
Egg freezing	5%	11%	6%	19%	
No coverage provided	40%	39%	23%	23%	

#### Insurance coverage of infertility services

Insurance coverage of ART services for infertility treatment varies widely by state, type of insurance, size of employer, type of service, and individual eligibility (Figure 2).<sup>10,19</sup> Disparities therefore exist in access to infertility services, by state of residence, insurance plan, income level, race/ethnicity, sexual

orientation and gender identity.<sup>10</sup> As of June 2022, 20 states have infertility insurance coverage laws, 14 states include IVF coverage, 12 states include preservation for iatrogenic infertility.<sup>20</sup> All 5 states in which Point32Health does business, Connecticut, Maine, Massachusetts, New Hampshire and Rhode Island, have infertility coverage laws. Mandated coverage differs across these states. Different from Connecticut, Massachusetts, New Hampshire and Rhode Island, the Maine law (effective January 1, 2024) explicitly includes fertility coverage, in addition to infertility coverage. It covers physiological infertility and also covers "an individual unable to conceive as an individual or with a partner because the individual or couple does not have the necessary gametes for conception".<sup>20</sup>

The Massachusetts statute remains one of the most inclusive examples of assuring coverage for infertility services in the United States. The "Massachusetts Infertility Insurance Mandate", signed into law in 1987, defines infertility as a disease and declares the treatment of infertility an eligible health benefit that must be covered by state-licensed private health insurance plans.<sup>21</sup> However, the Massachusetts insurance mandate does not apply to all individuals. State and federal statutory exemptions exclude individuals in self-insured, employer-sponsored health plans, reproductive-age women enrolled in MassHealth and/or Medicare, active duty service and civilian employees of the US military, and certain federal employees.<sup>21</sup> A recent study estimated that between 2016–2019, only 26.2%–36.0% of state-based reproductive-age women were eligible beneficiaries of the Massachusetts Infertility Insurance Mandate.<sup>21</sup> Similarly, state mandates in Maine, New Hampshire, Connecticut, and Rhode Island do not apply to all individuals.

#### Point32Health infertility benefits

The Point32Health policies<sup>22</sup> for covering ART services for Harvard Pilgrim Health Care Commercial products, Tufts Health Plan Commercial products, and Tufts Health Direct plans go beyond the Massachusetts state mandate. ART/infertility services are those services that are "medically necessary for all members (male, female, and other gender identities) when criteria in this policy are met". Of note, the plan's medical necessity guideline applies to LGBTQ+ individuals. It specifies that "[f]or the purposes of this guideline, the term biological female refers to an individual having ovaries and a uterus and includes other gender identities."<sup>22</sup> The guideline also includes ART services often excluded by other payers, such as cryopreservation and IVF.





#### What is the role of a health insurer in covering fertility care?

Medical necessity<sup>23</sup> determination is intended to help a health insurer balance its obligation to cover services consistent with accepted standards of medicine for individual members with its obligation to steward resources for its members. Different payers use different approaches for medical necessity determination. In the majority of states that mandate infertility care, medical necessity determinations set the floor for insurance benefits. When a payer covers more services than mandated and commonly considered medically necessary, they risk adverse selection: Individuals with health care needs met by only one payer in a market may seek health insurance by that payer. The payer is then potentially liable for large health care expenditures for a high-need population, risking premium increases and affordability and sustainability of insurance.

#### Ethical questions related to health plan fertility benefits

Ethical considerations start with the *organization's values*. Point32Health is dedicated to delivering "accessible and affordable quality health care to everyone – no matter their age, health, race, identity, or income".<sup>24</sup> It seeks to "support and guide members and communities to their best version of well-being" and to "improve health outcomes, increase affordability, impact policy, and help more people".<sup>24</sup> As a non-profit insurer and *responsible steward of health resources*, Point32Health considers which services it provides to increase individual and community well-being, including, for example, preventive services, food security or family building programs balanced against the responsibility to manage the cost of insurance.

Given its values, Point32Health offers programs that are "intended to deliver additional care and services to health plan members seeking to grow, build or nurture their families, no matter how that family is defined".<sup>25</sup> Despite additional family building care navigation support, an inclusive definition of infertility, and coverage of a wide range on ARTs for commercially-insured members, member access to covered reproductive services differs across states, insurance products, and fully and self-insured

employers. These differences raise questions of *equity and transparency*.

Inequity in insurance coverage is a characteristic of the US health system. In this context, what can a health plan do to make reproductive care access *equitable* for every member when decisions about coverage of fertility services depend on state mandates and employer choices? What should be the outcome a health plan strives to facilitate equitably? Would the outcome be trials of IVF, achieving a pregnancy, having a genetically related child, having a family regardless of genetic ties? To what extent is promoting equitable access for every member the *responsibility of the health plan* under its medical benefits versus the responsibility of employers under workplace benefits? Given the nuances in coverage, how should a health plan dedicated to promoting inclusive family building *transparently and trustworthily communicate* about its reproductive services coverage? Answering these questions requires considering that different coverage for different individuals is a characteristic of the system yet may be perceived as inconsistent with the health plan's proclaimed *values*, and that expanding fertility coverage could lead to *trade-offs at the member population level* in the form of fewer other well-being services, and/or increasing premiums for all members which could result in underinsurance.

# Selected Related Prior Ethics Advisory Group (EAG) Deliberations

In the November 2019 discussion on "Compassion in Health Care – The Roles of a Health Plan", <sup>a</sup> EAG participants affirmed compassion as a key value and the default frame for actions of a health plan. They highlighted that a plan's compassionate responses to an individual's suffering must also consider the plan's responsibilities to fairness, equity, and fiscal stewardship within the complex health system. EAG participants also suggested that simplifying health plan policies and procedures as permitted by law and accreditors, combined with support for members and others in navigating the increasingly complex health system, reflects a plan's focus on compassion. They affirmed that a well-documented and publicized focus on compassion is an important aspect of the reputation of the organization.

In April 2022, the EAG discussed ""Gender-Affirming Care - Roles and Responsibilities of a Health Insurer".<sup>b</sup> Participants agreed that health plans have important roles in the care of gender-diverse individuals. Because the needs of gender-diverse individuals differ widely, and because navigating a fragmented, unjust, stigmatizing health system can further harm vulnerable individuals, EAG participants suggested that health plans fill gaps in the system. They highlighted the role of health plans as care navigators for individual members. On the population level, they suggested engaging communities of gender-diverse individuals, their clinicians, and advocates in adapting health plan policies, to understand different needs from those with lived experience.

## Questions for the Point32Health Ethics Advisory Group Deliberation

On April 14, 2023, the Ethics Advisory Group was asked to deliberate on the questions below.

Differences across state laws, common definitions of infertility in medical necessity guidelines, and employer choices create inequity in access to assisted reproductive services. In this context,

1. How should a health plan committed to promoting family care, diversity, equity, and inclusivity advance its policies for infertility coverage?

<sup>&</sup>lt;sup>a</sup> EAG report available from anita\_wagner@hms.harvard.edu

<sup>&</sup>lt;sup>b</sup> EAG report available from anita\_wagner@hms.harvard.edu

- 2. What principles should a health plan consider for funding fertility services outside mandated infertility coverage when that funding competes with funding of other individual and community well-being services?
- 3. How should the health plan discuss its fertility services support and infertility services coverage with members, employers, and the public?

#### Summary of the April 14, 2023, Point32Health Ethics Advisory Group Deliberation

More than 60 individuals from inside and outside of Point32Health joined the conversation. Participants summarized the following points regarding fertility services and insurance coverage.

- Societal, including legal, and medical technology advances in the past decades, have changed the composition of families, and made it possible for any individual, regardless of having the organs to reproduce, to have genetically related or unrelated children. For some individuals, less costly interventions, for others more expensive technologies may be needed and desired to build a family. Individuals or couples who need another person (a gestational carrier or surrogate) to carry a pregnancy are likely in need of the most expensive assisted reproductive technologies (see Table 2 above).
- 2. Health insurance is a benefit that a group of members (and their employers or the government) buy to pay for *medically necessary interventions* of *individual members* (not couples, not a third person like a surrogate), with the objective to share risk among members, so that individual members in need of medical care are not harmed by the expenses of that care. As increasingly expensive medical technologies exist, many legally mandated to be covered by health plans, health insurance in the US becomes less affordable, especially for lower income households.<sup>26</sup> Assisted reproductive technologies are not currently legally mandated medically necessary interventions for most individuals in most states.
- 3. In the US, inequity in access to health care in general, and access to fertility services, is structural, based on current laws and public policy:
  - a. Treatment for infertility is <u>not</u> one of the 10 essential benefits and infertility services coverage is not mandated by the ACA or any other federal law.<sup>27</sup>
  - b. 30 US states currently do not have infertility care coverage laws.<sup>20</sup>
  - c. Among the 20 states that do, definitions of who is covered and covered services differ.<sup>20</sup> With few exceptions, mandates are designed around heterosexual cisgender couples who are trying to conceive through intercourse.
  - d. In the states that have infertility coverage mandates, state mandates only apply to state-regulated plans, which include health plans that individuals and businesses purchase from an insurance company. Mandates generally do not apply to individuals insured by self-insured employers and public plans. Nearly 2/3 of individuals with employer-sponsored health insurance are covered by self-insured plans. This means that even in states with infertility coverage mandates, infertility services coverage may not be available to many people with employer-sponsored coverage.<sup>27</sup> In 2020, only New York specifically required their Medicaid program to cover fertility treatment (limited to 3 cycles of fertility drugs) and no state Medicaid program covered artificial insemination (IUI), IVF, or cryopreservation.<sup>10 (Appendix 2)</sup> The Medicaid program's lack of coverage of fertility assistance is one reason for unequal use of fertility services by age,

race, ethnicity, and income. Most women seeking fertility assistance tend to be 35+ years old, White, with higher incomes and privately insured.<sup>10</sup>

Given these societal and medical changes and structural inequities, ethical dilemmas arise for a health plan that is committed to promoting equity, including equity in family building. The responsibility to provide sustainable, affordable health insurance equitably (that is, prioritizing the worst off) for all members, within the boundaries of federal and state insurance mandates and medical necessity guidelines, competes with a commitment to undoing structural inequities.

When a health plan covers care for which no coverage mandates exist and covers care that goes beyond what health plans usually cover (medically necessary care for an individual), the health plan makes itself vulnerable to attracting a larger share of members who seek the plan's more generous coverage (called "adverse selection"). Adverse selection risks higher premiums. Higher premiums may make the plan unaffordable for members, especially lower-income members, and potentially unsustainable. In addition, resources for family planning services not considered medically necessary by current standards compete with resources for other services not considered medically necessary, such as healthy food access.

This reality makes it challenging for a health plan to be a leader on values and a responsible steward of health care dollars. A forward-looking health plan committed to promoting equity, including equity in family building, needs to fulfill competing economic and ethical responsibilities. Economically and ethically, it needs to consider risks for the plan's affordability and sustainability when offering fertility care to all who need it (regardless of mandates and medical necessity guidelines). Ethically, it needs to act according to its values. In addition, by pioneering equitable fertility care for its members, the health plan may impede collective legal and public policy actions needed to change federal and state coverage mandates as members and their families with access to fertility care may not perceive a need for grassroots advocacy. Universal coverage mandates could benefit more individuals and would make it less risky for an individual plan to provide coverage equitably.

EAG participants highlighted further points for consideration.

*Inclusivity, equity*: It is important to ensure that policies are transparent, are not based on incorrect assumptions, and do not discriminate based on sexual orientation. Older cisgender heterosexual women may require more expensive reproductive interventions than single young cisgender heterosexual or lesbian women. Some reproductive technologies can only support family building for individuals with a uterus. For individuals without access to a uterus, family building requires surrogacy. This need exists for individuals with physiologic infertility (females after hysterectomies) and for individuals with relational infertility (single or gay male individuals). Participants stressed that any reproductive technology services a health plan covers should be covered for all members, regardless of physiologic or relational infertility.

*Ethical decision-making processes*: Whatever policy a health plan institutes at a given time to prioritize health care dollar spending, it is important that the processes for arriving at the policy are fair. Fair priority setting requires deliberation by all 'fair-minded' stakeholders including those affected by the decision, transparency of the decision and reasons behind it, and mechanisms through which stakeholders can appeal a decision and it can be revised.<sup>28,29</sup> Participants acknowledged the value of this EAG deliberation for informing ethical decision making.

*Goals for equity of covered fertility benefits*: There were different perspectives on what should be processes or outcomes related to fertility care that a health plan committed to promoting family care, diversity, equity, and inclusivity should seek to facilitate equitably (Table 4). More than 90% of participants answering the poll question agreed that a health plan should cover IVF for all members, regardless of state mandates. About half of participants voting indicated that a health plan should seek to facilitate family creation with or without genetic ties.

Do	you think a health plan should seek to:	Yes (%)	Not sure (%)	No (%)
1.	cover IVF equitably for all its members (regardless of state mandates)?	91	9	0
2.	facilitate achieving a pregnancy equitably for all its members (regardless of state mandates)?	78	20	2
3.	facilitate a genetically related child equitably for all its members (regardless of state mandates)?	53	35	12
4.	facilitate family creation regardless of genetic ties equitably for all its members (regardless of state mandates)?	49	35	16

Table 4. EAG participants' poll responses (n=43)

*Incremental versus step-change toward equity*: Participants discussed the benefits and challenges of a health insurer's incremental versus step change approaches toward facilitating equitable fertility services access. Incremental change would be more prudent given the financial and ethical risks of adverse selection. Higher risk step-change of expanded coverage might be considered a more visible implementation of policies consistent with the organization's family building values.

*Concerns about the business of fertility care*: There are growing concerns about the quality, transparency, and practices of a rapidly growing reproductive services industry that creates and meets demands and is not well-regulated.<sup>30,31,32</sup> More than 440 clinics in the US are part of a multi-billion dollar assisted reproduction industry. Compared to other countries, there is little regulation of the American reproductive industry which has been called "a Wild West of procreative possibilities".<sup>33</sup> Participants mentioned the important role of a payer in ensuring quality of care of its contracted fertility care providers.

*Universality of benefits*: Participants discussed whether a health insurer should make provision of ART coverage part of all commercial plan employer contracts (that is, potentially increasing premiums for employers and members in fully insured employer-sponsored plans) or allow employers to opt into the benefit (with additional costs for the added benefit and the choice to not pay for care for which coverage is not mandated in a state).

*Education and advocacy*: Participants mentioned the health plan's opportunity to drive change through education and advocacy. Generally, existing state infertility laws do not apply to the worst off, individuals with Medicaid insurance.<sup>10</sup> This presents an opportunity for a health plan committed to fostering family building equity to advocate for expanding infertility coverage mandates to benefit the Medicaid population.

In summary, this EAG deliberation highlighted the ethical complexity of decisions to facilitate equitable access to reproductive technologies in a structurally unequal health care and health financing system. Ultimately, society must decide whether building a family is a universal human right and who is responsible for paying for increasingly available reproductive technologies that facilitate family building, and at what cost. In this changing societal and medical landscape, a health plan committed to promoting equity will need to facilitate access to services equitably and set limits fairly, by engaging in deliberations with stakeholders, making rationales for its decisions transparent, and revising its policies as needed.

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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