OPINION PAPER

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What is the status of insurance coverage for fertility services in the United States by large insurers? A patchwork system in need of repair

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Health and well-being are fundamental rights for all people. Assurances that these rights are fulfilled result from a complex skein of political, clinical, and business debates ending with what is referred to as *health insurance*. And *health insurance* can be like tickets to a hot Broadway play: much discussed but difficult to secure. The issues that surround healthcare coverage reach new levels of complexity in the USA, best profiled as variable, multilayered and unevenly distributed. The Affordable Care Act (ACA) was a stellar achievement and a start toward expanded coverage. But the U.S. stands out from most advanced societies in not offering across-the-board, universal health insurance. At best, crafting a cost-effective path to deliver healthcare is tricky business. It is a delicate, high wire act to expand coverage yet contain costs. That balance of forces remains a work in progress and out of pocket costs remain prominent for many patients. Even those with insurance still can face large and variable out-of-pocket expenses. The upper end of the distribution of these costs may dwarf the resources of many U.S. households, meaning that many people faced with a significant illness (read: expensive treatments) may also find themselves in financial trouble. Frameshift now to the issue of fertility benefits and the finances and out-of-pocket expenditures attendant to this care (a conversation all too familiar to those in the ART/IVF space) and the coverage patchwork is even more bewildering for patient and provider alike. Benefits are variable and inconsistent, the result of several factors intrinsic to the system of purchasing healthcare plans but also driven by an against-the-tide struggle to have infertility understood as a disease by insurers. Understanding the landscape is essential.

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Most U.S. healthcare coverage is through an employer and subject to what a company can afford. This affordability is very frequently dictated by the size of the company's labor force and the status of an individual's employment: part-time or full time. Many U.S. employers by dint of size simply cannot offer nor subsidize access to insurance policies. Continuous employment is a frequent prerequisite for coverage and part-time employment is a non-starter for full healthcare benefits let alone fertility coverage. Adding to this complexity is the persistent and unfounded dogma that fertility is not really a disease worth covering but an elective, nice-to-have and very expensive option. Falsehoods and half-truths persist and adversely influence drafting thoughtful, effective, and caring policies. The misperception that these technologies add significantly to the cost remains embedded in the decision-making process across all levels of industry and government despite adequate data to suggest otherwise. As an example, and to highlight these concerns, the following was one of several conclusions at the end of a 2021 draft of the mandated benefit review in Washington state in an otherwise tightly drafted iteration of the proposal: infertility treatments are expensive and require a significant investment in resources for patients who choose to pursue them to have biologically related children. It is likely that insurance premiums will rise as a result of requiring coverage for these treatments. The financial protection that many (but not all) insurance policies provide through fertility benefits remains patchy and often out-of-date. This status exists in the face of expanding technology that translates to higher success and of changing demographics that will increase demand dramatically making it essential that adequate and complete fertility benefits be available. These factors create a trifecta of increased demand, more effective technology and a glaring coverage gap that needs to be filled.

Consider these trends. Family building trends suggest that increased demands loom just over the horizon. Fertility rates hit a record low in the United States 58.2 births per year

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per 1000 women between the ages of 15 and 44 (2019 data reported in 2022) [1]. Bottom line: 12% of women experience difficulties becoming pregnant and 33% access fertility treatments. The reasons are complicated and varied but suggest that the demand for interventions using reproductive technologies is likely to increase. This expansion does not include the fertility preservation requests that are now one of the more common indications for patients to seek care at fertility centers. But without adequate and carefully drafted policies, a population will be priced out of these treatments and lose the opportunity for family building. Even if a patient has a "fertility benefit", coverage may be filled with gaps leaving even "covered" patients facing significant outof-pocket expenses. The circumstances beg for a universal definition of fertility coverage that offers patients assurances that their journey to family building does not carry the risk of financial ruin.

Taking into perspective the national scene for coverage and fertility benefits, just how diverse are current policies from major carriers? Details can clarify the discussion and draw into sharper focus precisely where we are. The article by Finkelstein et al. entitled In vitro fertilization: a crosssectional analysis of 58 United States insurance companies is eye-opening and warrants a close look from those in the business of providing fertility services [2]. The article highlights the policy profiles, stipulations and gate keeping in place among major medical insurers. The study evaluated 58 companies of which 51 had a publicly available policy describing fertility benefits and services. The authors used this open database for its analysis. The major insurers are not the only players in the fertility space but are significant due to their marketplace heft. The companies are presented in tabular form with immediate name recognition. The list is comprehensive and consistent with up-to-date listings of major insurers [3]. The policies described in this article represent the current state of affairs for large insurers that offer fertility coverage in the USA. The article describes a patchwork of coverage with unintended negative consequences and barriers to coverage that are dated, losing relevance to contemporary clinical care and may have the unintended and ironic consequences of adding to costs and complexity. The shortcomings of this study are its cross-sectional design and as such a one-point-in-time assessment, but the conclusions should interest every practitioner of assisted reproductive technologies. The reality that this article reveals is that even under the auspices of having "fertility coverage" and what patients at times perceive as "really good coverage", policies are often inadequate and subject to change and conditions. It is an oft told story familiar to any practitioner: a family or individual presents with the impression that their employer provides full infertility coverage when in fact considerable limitations exist that constrain covered care as this article reveals.

The benefit restrictions among the various companies studied include such things as precluding IVF for a patient with a previous tubal ligation or in one instance denying coverage if an individual has had three live births by any means within their lifetime. Both appear on the surface as arbitrary and insensitive to the realities patients face. The authors also identified 6% of the policies that list exposure to DES as a qualifying condition and risk factor that improves the likelihood of IVF coverage (dated and hardly relevant since DES has been off the market since the 1970s making most patients exposed in utero in their 50-60 s, hardly IVF candidates). One of the key takeaways from the article is that the varying coverage, stipulations, and restrictions for accessing fertility coverage ultimately translates to creating as they suggest an artificial barrier to receiving care and at times encouraging practices such as multiple embryo transfers that place patients at risk and ironically can result higher overall costs when NICU care is factored into the equation.

The manuscript prompts a step-back and take-stock pause to review coverage as it stands and explore models of how fertility care can be provided in a more complete, caring, and effective manner. The study prompts three critical questions that should be posed as we move forward. These questions include: how dated and static are fertility benefits and requirements to access these benefits by major insurers; how far are we from adequate, universal, and effective fertility and family building benefits; and finally, are there more effective models that could better inform and guide coverage?

Regarding the first question about current benefits and gatekeeping requirements for accessing the services: the shadow of the age-old treatment crescendo-style plan of a simple start and progression through medicated cycles to adding IUIs to finally (when all else has failed), a consideration of IVF lurks in many insurance policies. This dated approach risks reducing success and adding to costs. Current techniques such as IVF, preimplantation genetic testing and cryopreservation of embryos, sperm, or oocytes enable families to fulfill present and future family building options and at times are best first line treatments. Insurance policies should be updated to offer these options at the start rather than as last resort. But good care should go beyond these technologies and extend to making sure that patients have the security that they can exercise these options without facing significant out-of-pocket expenses. Even when offered and regardless of adequacy of coverage, requirements that insurers have in place to access benefits remain problematic and in dire need of change. Our specialty is changing in both small and significant ways and in its current evolution, two aspects of current policies outlined in this article are in this need-to-change category and should be addressed: clinical staff and the embryology lab. The concept that fertility care will be provided only by reproductive endocrinologists (as is stipulated by several companies) is rapidly

changing as reality sets in and we learn that clinical decisions can very frequently be made by non-fellowship trained practitioners. The simple need to deliver services and meet demand will preclude our ability to fulfill these practitioner requirements with fellowship trained REIs. Make no mistake about it: fellowship training is an essential cornerstone to delivering high-quality care but in many circumstances using nurse practitioners, skilled gynecologists and other non-REI practitioners will fill a gap without sacrificing quality of care. Second, inclusion of performance standards for the embryology lab is critical. The two most prominent thresholds for coverage are pregnancy rates and recommendations for single embryo transfers. These modifications are clearly a step away from the requirements described in this article and would require insurance companies to evaluate on an ongoing basis technology, practice trends and lab efficiencies and enable insurers to deliver coverage that is up-to-date and cost-effective.

Second, how far are we from adequate universal fertility benefits: we are getting closer, but coverage remains a patchwork of plans with far too many gaps that risk patients falling through the cracks. Encouraging signs are emerging with both employers recognizing the value of fertility benefits and legislative action for state mandates [4]. As noted, benefits can depend on place and status of employment. Throughout the 2010s, fewer than a fourth of large employers i.e., those with 500 or more employees offered employer-sponsored health plans that included IVF. That number rose to 27% in 2020 and to 36% in 2021 [5]. Among very large employers defined as those with 5000 or more employees 70% offer this coverage. This may be in part a reflection of the competition that large companies face for talent: if one company offers a benefit such as IVF, talent is likely to trend toward that company. The other significant finding among companies offering fertility benefits is that 97% reported that adding coverage did not result in significant increased medical costs. But what about those not employed in a sector or company size likely to offer the benefit? How can inclusivity be expanded? State mandated coverage is one option gaining increasing attention with 19 states with mandates in effect. These mandates have shown to increase IVF uptake threefold but leave unaddressed the depth and completeness of coverage which can vary markedly state by state [6]. The support for such mandates continues to grow to assure coverage and access. Senator Tammy Duckworth (D-IL) put forward a Senate bill to protect access to IVF and other fertility treatments that contains broad definitions, a step in the right direction to protect these options [7]. A universal definition of coverage and safeguards to protect these rights (as this bill suggests) is a worthy goal to assure that a patient can transition from the start of evaluation to the end point of having the family they want regardless of treatment needed.

Though the enthusiasm regarding mandates is well placed and suggests an awakening regarding this coverage, caution is needed. Mandates may be subject to challenge and repeal throwing the hard work of politicking and arm twisting back to the starting line. In the current political and legislative environment, court challenges could render even the most tightly drafted legislation worthless. This trend to challenge health guidelines is increasingly becoming a path for repealing mandates for insurance benefits with the most recent example in the Braidwood Management Inc. v. Becerra, a decision which successfully challenged the ACA recommendations that insurers follow and pay for preventative guidelines as suggested by United States Preventive Services Taskforce [8]. This decision and other similar challenges are relevant to the issue of fertility benefits and reproductive technologies for the application of religious freedom as a basis for the litigation and denial of previously mandated benefits for health and wellbeing. A post Dobbs era suggests that possible challenges may be in the offing. Bottom line: while the work in grinding forward to achieve these mandates to ensure fertility benefits is laudatory, vigilance is required to safeguard access after enactment. Given current trends and the shadows that surround reproductive issues, mandates for IVF may be vulnerable to change and possibly reversal.

And finally, are there more effective models that could better inform effective coverage? Two models emerge as possible options toward the goal of universal and complete family building coverage: value-based care and specialty vendor benefit administrators. Value-based models or value-based care align preventive care with payment plans to achieve clinical goals and have been successful in other settings and specialties [9]. Outcomes and quality of care drive payments. The model leverages technology with care and benefits, attractive options as fertility drives forward with expanding technology such as artificial intelligence and increasingly sophisticated platforms for preimplantation genetics. Fertility benefits could be viewed through this lens of clinical outcomes such as pregnancy rates and rate of multiples among other factors. This model could also focus on prevention of infertility with increased awareness of the impact of age on outcomes (for example) and offering interventions earlier in the treatment plan with an eye to both present and future family building options. Specialty vendors to provide or administer fertility services is another path forward enabling a focus on a single set of benefits in the narrow space of fertility. Programs that offer specific fertility benefit packages to large corporations are paths forward that can be flexible and pivot quickly to respond to changes in technology. This model also can offer opportunities to monitor results to assure the most cost-effective tools are in use and that outcomes are state of the art. Twelve percent of large companies use a specialty vendor to administer these benefits.

The impact of a failure to provide comprehensive benefits so that an individual or family can realize both the present and future family building is profound. Many would-be patients continue to slip through the cracks in the current system and find themselves without the necessary financial support to pursue assisted reproductive technologies. For many patients and especially for marginalized populations, the cost of the process and lack of coverage magnify the emotional impact doubling down on the negative aspects of this journey. Until we have more effective standards of what is considered true fertility coverage and the means of enforcing these policies whether by federal or state regulations, a patchwork of coverage for fertility services will prevail. It is time that fertility care is no longer considered as "nice coverage if you can get it" but placed squarely in the framework for what it really is: a human right and step away from the concept that assisted reproductive technologies are expensive and ineffective in achieving this right.

This article provides context and not only highlights the current state of affairs among major insurers, but a betweenthe-lines read suggests there is an opportunity to explore where we can improve insurance coverage and what the future could hold. The authors define a starting point for a more informed discussion among shareholders. As a point-in-time analysis and within the limits of the study design, the authors offer an opportunity to open the discussion and define a path forward to assure patients that their healthcare coverage will not be gap ridden and leave them abandoned in their pursuit of their family building dreams.

Declarations

Conflict of interests The author declares no conflict of interest.

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