MILKEN INSTITUTE

AUGUST 2026

Coverage and Reimbursement Roadmap for Women's Health Innovation

Abigail Humphreys, PhD
Jenica Patterson, PhD
Esther Krofah, MPP
Lee Fleisher, MD

About the Milken Institute

The Milken Institute is a nonprofit, nonpartisan think tank focused on accelerating measurable progress on the path to a meaningful life. With a focus on financial, physical, mental, and environmental health, we bring together the best ideas and innovative resourcing to develop blueprints for tackling some of our most critical global issues through the lens of what's pressing now and what's coming next.

MILKEN INSTITUTE HEALTH

Milken Institute Health develops research and programs to advance solutions in biomedical innovation, public health, healthy aging, and food systems.

Women's Health Network

The Women's Health Network, convened by the Milken Institute, is a global, cross-sector collaborative bringing together leaders from research, health systems, investment, industry, philanthropy, and community organizations to accelerate progress in women's health. The Network addresses longstanding gaps in women's health and underinvestment by breaking down silos and turning collaboration into action. Its work centers on three core efforts: a shared digital platform to enable data, resource, and knowledge exchange; a catalytic philanthropic fund to deploy capital toward high-impact women's health solutions; and practical, proof-of-concept initiatives that strengthen research, access, and care. Together, these efforts align stakeholders, mobilize resources, and drive measurable progress across the women's health ecosystem.

Contents

Introduction

The Milken Institute Women's Health Network bridges gaps in innovation and health care for conditions that impact women exclusively, differentially, or disproportionately. With more than 170 diverse stakeholders across industry, clinical care, research, investment, employers, and advocacy, the Network brings together cross-sector stakeholders to drive progress in women's health. Through its convening strength, the Milken Institute aligns priorities, clarifies evidence needs across the ecosystem, and builds the structures necessary to accelerate and scale women's health innovations.

On February 19, 2026, the Women's Health Network's Coverage and Reimbursement Working Group convened experts in a workshop to examine the fundamental coverage challenges and barriers affecting women's health innovation in the United States. Nine key barriers emerged from the in-depth discussion: the persistent undervaluation of women's health products and services; fragmented and inconsistent payer pathways; a lack of billing codes and reimbursement mechanisms; delayed payer engagement that results in misaligned evidence generation; gaps in sex-specific evidence that complicate coverage decisions; reimbursement uncertainty that deters investment; and administrative burdens, including complex coding requirements, prior authorization processes, and limited clinician adoption.

This Innovator Roadmap is designed to guide women's health innovators (hereafter referred to simply as innovators) through the reimbursement landscape by outlining key considerations, optimal timing, and the critical steps associated with the three primary pathways toward commercialization: self-pay, commercial payer coverage, and public programs (Medicare and Medicaid).

Predevelopment Considerations for Women's Health Innovators

To lay the groundwork for success, all innovators should assess several foundational elements prior to the development process to avoid common pitfalls and thereby save time and resources. Innovators developing women's health diagnostics, therapeutics, and technologies (hereafter referred to as innovations or products) face additional challenges because many of the conditions that exclusively, differentially, or disproportionately affect women are underdiagnosed and lack both established clinical trial endpoints or comparators and standardized diagnostic criteria. Therefore, innovators may need to rely on real-world evidence in study designs when traditional evidence is limited due to delayed diagnosis or heterogeneous patient populations. By understanding these foundational barriers and the potential pathways around them, innovators can more effectively plan their development strategy to ensure that early decisions on study design, endpoints, and evidence generation align with both clinical realities and payer expectations.

CONSIDERATION 1. COMMERCIALIZATION: PAYER COVERAGE VS. SELF-PAY

A critical decision for innovators during the commercialization process is whether to pursue payer coverage for their innovation or to opt for a direct-to-market (i.e., self-pay) approach. This decision should be made early because transitioning between pathways can present significant challenges. In particular, transitioning from a self-pay pathway to a payer coverage pathway may require substantial product modifications to align with payer expectations and standards. Table 1 summarizes the key advantages and disadvantages of each pathway.

Table 1. Advantages and Disadvantages of Self-Pay Compared to Coverage

	Pros	Cons
Self-Pay	• Direct to consumer • Immediate revenue generation • No payer approval timeline • Pricing control • Lower evidence threshold	• Excludes Medicaid population • Reverting to a coverage-based model is difficult and may require innovation redesign or repositioning to meet payer requirements • Challenges to provider integration • Equity limitations
	Pros	**Cons**
Coverage	• Increased accessibility • Broader access and adoption • Greater market scale and revenue stability • Stronger clinical credibility • Health system integration (if successful) • Greater equity and reduced disparities	• Longer time to market • Pricing pressure by payers • Administrative complexity (billing codes, claims submission) • Uncertain coverage determinations • Fragmented payer landscape • Slower iteration • Dependence on provider behavior (risk of underutilization)

Source: Milken Institute (2026)

CONSIDERATION 2. CLINICIAN ENGAGEMENT

Innovators frequently overlook the importance of involving clinicians from the outset of the development process. Early and active clinician engagement is a key to ensuring that the innovation integrates smoothly into existing clinical workflows and practices. Clinicians operate under significant time pressure, so innovations that disrupt workflow or add steps often struggle to gain adoption, regardless of coverage status. Innovators should engage a diverse group of clinicians—primary care, OB/GYNs, midwives, behavioral health specialists, and others—to capture the full spectrum of care settings as well as to clarify which clinical endpoints the innovation will address to support future payer engagement.

CONSIDERATION 3. PAYER ENGAGEMENT

By engaging payers early, innovators can clarify the specific evidence requirements for coverage and reimbursement, setting expectations from the outset. To foster this engagement, innovators can initiate targeted conversations with medical directors, policy analysts, and payer advisory boards; share preliminary clinical data and product concepts; and request feedback on preferred study designs, endpoints, and economic analyses.

Several payers have dedicated teams and contact points for innovation, pilot programs, and mentorship opportunities. Innovators can connect with these teams by exploring payer websites, subscribing to innovation newsletters, attending industry conferences, or leveraging LinkedIn and professional networks to identify relevant contacts who may help arrange an appropriate meeting. During these discussions, it is crucial for the innovator to discern which outcomes are viable for reimbursement, demonstrate economic value and clinical utility, and address potential coverage variability across the life cycle. Leveraging payer insights during product development ensures that evidence generation aligns with payer standards and supports future coverage decisions.

Notably, payers will require different evidence packages than the Food and Drug Administration (FDA). Innovators often become so focused on securing FDA approval that they overlook payer requirements. Innovators should seek opportunities to design clinical trials that satisfy both FDA and payer standards, minimizing the need for additional studies and avoiding delays in coverage. Proactive alignment of study designs with payer expectations streamlines the path to reimbursement.

In addition, neither commercial nor public payers will cover products marketed as wellness or lifestyle enhancements. Innovators should use language that emphasizes “treatment of disease” rather than “general wellness” to qualify for reimbursement and avoid unnecessary obstacles.

Although payers may focus on covering innovations deemed necessary within a beneficiary’s enrollment period, innovators should not be discouraged from pursuing evidence of longer-term outcomes. Evidence of the effectiveness of women’s health innovations is often demonstrated over many years, and that long-term evidence remains valuable. Innovators should be aware that the typical duration of a beneficiary’s enrollment in a health plan (approximately 14 to 18 months[1]) can make it easier and less costly to generate shorter-term evidence, but this is a practical consideration, not a ceiling. Projects to generate evidence on clinical utility should be designed with both time frames in mind, recognizing that longer-term studies may be necessary to fully demonstrate a product’s value.

CONSIDERATION 4. CODING

When seeking payer coverage, innovators should establish a comprehensive coding strategy during the proof-of-concept or feasibility stage. The latest point to address coding is Technology Readiness Levels 5 and 6, where the product is tested in clinical trials and laboratory settings. During this time, the coding approach must be finalized to avoid setbacks, such as revisiting clinical endpoints for payer alignment, which can lead to significant delays and increased costs.

Current Procedural Terminology (CPT) codes, which are developed and maintained by the American Medical Association (AMA), describe medical, surgical, and diagnostic services performed by health-care providers and are a key element of the process for reimbursing medical services and procedures.[2] The Healthcare Common Procedure Coding System (HCPCS) codes extend this framework, with Level I comprised of CPT codes and Level II describing products, supplies, and services not captured by CPT codes. HCPCS codes are maintained by the Centers for Medicare & Medicaid Services (CMS).[3]

A key challenge in women's health innovation is the lack of appropriate billing codes. Innovators typically have two options: Use an existing code that may not accurately reflect the innovation's value or apply for a new code. The former option can facilitate earlier adoption but may trigger payer review or reimbursement limitations, while the latter option is a lengthy process that can last up to three years.

To apply for a new CPT code, innovators must submit a Code Change Application (CCA) to the AMA. This formal process enables stakeholders to propose additions, deletions, or revisions to the existing CPT code set.[4] To support applicants, the AMA has developed a series of six instructional webinars on its website that guide innovators through each step of the CCA process.[5]

Innovators should also consider how their innovation may fit within existing payment sets, such as preventive care bundles. If an innovation is expected to markedly expand the use of a code and increase CMS spending, the code may be flagged for review by the Center for Program Integrity, creating additional barriers and delays. If an innovation is truly novel or clearly superior to existing options, pursuing a new code from the outset may be the most strategic approach. In the interim, unlisted or Category III CPT codes may be used while building the clinical and economic evidence needed to support eventual transition to a permanent Category I CPT code.

Successful women's health innovation hinges on early, strategic planning across multiple domains—from evidence generation to clinician and payer engagement to regulatory approval and coding strategy. By proactively addressing the unique challenges of women's health innovation, such as limited clinical endpoints, diagnostic variability, and gaps in existing coding infrastructure, innovators can build a strong foundation for product development and align both clinical and payer requirements to ensure a more cost-effective path to commercialization.

Development Stage

Clinical Trials

Historically, women were excluded from participating in clinical trials until 1993, when Congress passed the NIH [National Institutes of Health] Revitalization Act, mandating the inclusion of women in NIH-sponsored studies.[6] Despite this progress, pregnant women continue to be excluded from clinical trials because of ethical and safety concerns, which has led to their underrepresentation in research on medical interventions for this population. Several barriers contribute to the ongoing exclusion of women in clinical trials. These barriers include the responsibility to protect the reproductive systems of women of childbearing potential and their fetuses, the fear of legal liability if harm to a fetus is suspected, the challenge of recruiting cohorts who are compliant and at high risk for study endpoints, the availability of identifiable and convenient cohorts, and well-known variations in hormonal status that can affect laboratory test results and treatment inferences.[7]

For medical devices, innovators must obtain an Investigational Device Exemption (IDE) to begin clinical trials. However, some studies may be exempt from this requirement, such as those involving devices that have already received FDA clearance or diagnostic devices that are not invasive or pose minimal risk.[8] For drugs and biologics, the process starts with the submission of an Investigational New Drug (IND) application. Clinical trials are essential for determining whether a medical product is safe and effective, and the underrepresentation of women has led to a massive gap in data about what is safe and effective for women.

FDA Authorization

Regardless of the commercialization pathway, an innovation will require FDA approval if it meets the FDA's definition of a medical device, drug, or biological product. Medical devices are products intended for use in the "diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body and is not dependent upon being metabolized for the achievement of its primary intended purposes."

Drugs are defined as "articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and intended to affect the structure or any function of the body of man or other animals."

Biologics meet the definitions of either a drug or device and are defined as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[9]

While the FDA may exercise enforcement discretion for diagnostic tests, many products may enter the market based on published data rather than full FDA approval.

MEDICAL DEVICES

The nature of the innovation dictates the appropriate FDA premarket submission pathway. For medical devices, the premarket submission pathway depends on the device's class. There are three classes, each reflecting increasing risk to the patient.[10] Class I or II devices generally require a 510(k) submission, while Class III devices require Premarket Approval (PMA). The FDA's classification database is a valuable resource for determining device class.[11]

510(k) submissions require new devices to be substantially equivalent to a predicate device, that is, as safe and effective as a legally marketed device with the same intended use. Because of the evidence gap in women's health research and consequent delays in innovation, novel devices often lack a substantially equivalent predicate, and many will not qualify for 510(k) clearance.[12] In such cases, innovators should consider submitting a De Novo Classification Request, either after receiving a Not Substantially Equivalent (NSE) determination on a 510(k) submission or proactively through the De Novo pathway. Applying for a Q-Submission (Q-Sub) meeting is recommended because innovators can meet with FDA reviewers to discuss evidence requirements for their device and seek advice on approaches to obtaining FDA approval.[13] The timeline for medical device review depends on the submission pathway. Innovators should anticipate approximately 6 months for 510(k) clearance, 6–12 months for De Novo Classification, and approximately one year for PMA.[14]

Additionally, innovators developing medical devices should consider applying to the FDA's Center for Devices and Radiological Health Total Product Life Cycle Advisory Program (TAP) pilot. The TAP pilot is designed to accelerate patient access to innovative medical devices by providing early, frequent, and strategic communications with the FDA and other non-FDA stakeholders.[15] To be eligible for TAP enrollment, innovators must first request either Breakthrough Device Designation or participation in the Safer Technologies Program (STeP) through the Q-Sub Program. Once Breakthrough Designation or STeP acceptance has been granted, innovators can apply for TAP by submitting an amendment to the original Q-Sub application that specifies the subject heading "TAP Pilot Request for Enrollment," the device sponsor's name and address, and the original Q-Sub number.[16]

Innovators with digital health devices targeting cardio-kidney-metabolic, musculoskeletal, or behavioral health conditions may consider enrolling in the FDA's Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot. This program is a collaborative initiative between the FDA and the CMS Innovation Center (CMMI), specifically under the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model. Under the TEMPO pilot, innovators test their devices through the ACCESS model while collecting, monitoring, and reporting real-world data. These data help CMS to assess how digital technologies perform and improve outcomes for individuals with chronic conditions.

To participate, innovators must submit a letter of intent to FDA-TEMPOPilot@fda.hhs.gov. While devices ideally should already be FDA-approved for their intended use, innovators can ask the FDA to exercise enforcement discretion, that is, to not enforce certain regulatory requirements while their device is being offered to CMMI ACCESS participants. Requirements may include premarket authorization, IDE, and institutional review board requirements under 21 CFR parts 50 and 56.[17] The FDA will work with pilot participants to determine where enforcement discretion is appropriate.

Devices eligible for the TEMPO pilot must focus on one or more of the following clinical areas:

- Early cardio-kidney-metabolic conditions (hypertension, dyslipidemia, obesity or overweight with central obesity, or prediabetes)
- Cardio-kidney-metabolic conditions (diabetes, chronic kidney disease, or atherosclerotic cardiovascular disease)
- Musculoskeletal conditions (chronic musculoskeletal pain)
- Behavioral health conditions (depression or anxiety)

The submission email, titled "Statement of Interest for Participation in the TEMPO Pilot," should include:

- The manufacturer's name, device details, and any current authorizations or FDA interactions with relevant submission numbers
- An indications for use statement explaining how the device will improve patient outcomes in one of the specified clinical areas
- A request for the FDA to provide a statement confirming that it does not intend to enforce certain legal requirements

Additional helpful information may be included as relevant to the device:

- A description of the device, including proposed indications for use that clearly identify how it is intended to improve patient outcomes within the CMMI ACCESS model
- Data demonstrating the device's safety and functionality, and supporting a reasonable expectation of patient benefit (e.g., bibliographies, publications, and summaries of unpublished safety information)
- Information about the manufacturer's quality management system
- A plan to mitigate patient risks and to collect, monitor, analyze, and report real-world performance data
- Proposed performance goals and a statistical analysis plan for patient outcomes
- A timeline for data collection and submission of a premarket notification (510(k)) or other applicable marketing submission for the device's intended use
- An interim reporting plan, including reporting frequency (such as every six months), covering adverse events, new risks, and progress related to established timelines

The TEMPO pilot is currently accepting statements of interest, and space is limited. Innovators are encouraged to submit their applications as soon as possible to ensure consideration.[18]

Innovators developing Class II or III medical devices for the Medicare population should consider the upcoming Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway. RAPID is a joint FDA-CMS initiative designed to engage innovators earlier in the technology development process so that evidence generated for FDA review can also support Medicare coverage decisions. To qualify, a

device must have Breakthrough Device designation and address an unmet need for Medicare beneficiaries. The pathway is available to Class II devices participating in TAP and to Class III devices regardless of TAP participation. Eligible devices must also be the subject of an IDE study that enrolls Medicare beneficiaries and evaluates clinical outcomes agreed upon by both the FDA and CMS.

Under RAPID, CMS issues a proposed National Coverage Determination (NCD) on the same day the device receives FDA market authorization, immediately initiating the 30-day public comment period and significantly accelerating the coverage timeline. Through this pathway, Medicare coverage may be available as soon as two months after market authorization, much sooner than the typical timeline of one year or more.[19]

DRUG DEVELOPMENT

When pursuing FDA approval for drug development, innovators must navigate several pathways. The process begins with submitting an IND application to initiate clinical trials for a new drug or biologic. Next, innovators should evaluate two main New Drug Application (NDA) pathways as they advance toward FDA approval: 505(b)1 and 505(b)2.

The 505(b)1 pathway is used for new drugs that are novel to the market and have not been previously studied or approved. This pathway requires the innovator to conduct comprehensive studies to demonstrate safety and efficacy.[20] Although costly and time-consuming, this pathway is often necessary for women's health innovations with limited prior evidence.

The 505(b)(2) pathway maintains safety and efficacy standards identical to those of the 505(b)(1) pathway but allows innovators to leverage previously established research on the active ingredient when creating new drug products. This pathway can reduce cost and time, but it hinges on the availability of preexisting evidence, which is often lacking in women's health innovation.

Finally, for generic drugs, the Abbreviated New Drug Application (ANDA) 505(j) pathway is used. This pathway does not require independent clinical investigations to meet evidence standards; instead, innovators must demonstrate bioequivalence to the reference listed drug (RLD).

The FDA review timeline for new innovations is an important consideration for innovators. For standard drug applications, the process typically lasts 10–12 months; however, priority review can shorten the timeline to 6–8 months.[21]

Self-Pay Roadmap

The self-pay roadmap is a direct-to-consumer approach. Innovators may opt for self-pay for consumer products, such as wearables, digital health apps, over-the-counter or at-home testing products, supplements, and subscription services. To enhance affordability for consumers, these innovations can be positioned as eligible for Flexible Spending Accounts (FSA) or Health Savings Accounts (HSA), thereby broadening access and reducing out-of-pocket costs.

Successful navigation of the self-pay roadmap requires determination and resilience. Innovators should proactively recruit experienced business professionals to strengthen their leadership and operational capabilities. They should also establish connections with peers who have previously pursued the direct-to-consumer pathway and can provide valuable guidance on overcoming challenges and achieving market success. By ensuring that a direct-to-consumer expert is a part of the team, innovators can better position themselves for strategic growth and effective market engagement.

STEP 1. DEMAND

Before launching an innovation, innovators should confirm that the product addresses a genuine need and that women are willing to pay for it directly. This step may involve the following actions:

- Identify and define the target audience, such as reproductive-age women, menopausal women, postpartum individuals, or those with chronic conditions, to ensure that the innovation is aligned with their specific needs and demands.
- Validate that the product solves a real problem by conducting surveys, interviews, and focus groups.
- Conduct a competitive analysis to identify similar products and clarify how the innovation stands apart.
- Establish a pricing strategy and prepare a clear rationale for self-pay. Use methods such as pre-orders and pilot programs to test willingness to pay.
- Engage patient communities, virtual forums, and advisory boards focused on the targeted women's health condition to better understand consumer needs, preferences, and factors that support long-term retention.

STEP 2. REGULATORY AND LEGAL ASSESSMENT

Innovators of medical devices, drugs, or biologics (as defined above) should determine whether FDA regulation and approval are necessary. This step may involve the following actions:

- Confirm that no intellectual property (IP) barriers exist, such as patents or trademarks, and initiate the process of securing appropriate protections. This step should be among the first taken by innovators of technology products and should be regularly revisited throughout development, because IP issues are often a major challenge to bringing new tech to market.
- For digital health products, including apps and diagnostics, prioritize privacy and data compliance from the outset.
- Establish clinical validation, even with small-scale studies, to build credibility and trust.
- Leverage real-world data to refine marketing strategy and messaging.
- Ensure robust safety protocols by providing clear disclaimers and implementing adverse event reporting processes, as appropriate.

STEP 3. GO-TO-MARKET STRATEGY

A robust go-to-market strategy for women's health innovations should leverage direct-to-consumer channels by utilizing social media, forming influencer partnerships, investing in paid advertising, and participating in community forums to maximize reach and engagement. Emphasis should be placed on education and integrating the product into consumers' lifestyles to foster adoption. This step may involve the following actions:

- Engage in content marketing, with blog posts, webinars, and podcasts focused on women's health topics, to build awareness and credibility.
- Launch an early adopter program by offering pilot access at a discounted rate to generate valuable testimonials and real-world data, further strengthening market positioning.
- To establish and maintain brand credibility, engage clinical advisors or board members, showcase user testimonials and case studies, ensure transparency, and pursue third-party validation when appropriate.
- Employ experienced business and marketing executives at the C-suite or board level to further strengthen organizational leadership and support strategic growth.

This multifaceted approach will help drive adoption, trust, and long-term growth in the women's health market.

WOMEN'S HEALTH–SPECIFIC CHALLENGES IN SELF-PAY

The self-pay pathway provides a direct route to market for women's health innovations, but it also presents significant challenges that must be carefully considered. Exclusive reliance on self-pay can restrict access for women with low income and those in the Medicaid population—groups who often experience the most pressing unmet health needs. This limitation can inadvertently widen health disparities, as these populations may be unable to afford out-of-pocket costs for new innovations.

Direct-to-consumer marketing is another hurdle because it tends to be costly and requires ongoing investment. Establishing trust with consumers takes time, especially in the women's health sector, where education and behavioral change are often prerequisites for adoption. The need for extensive educational initiatives increases overall marketing expenditures, and consumer engagement may diminish rapidly if results are not immediate or tangible.

Price sensitivity is heightened in the self-pay pathway unless the value proposition is clearly and effectively communicated. Therefore, strategic pricing and value articulation are essential to sustain consumer interest and drive adoption. From a clinical standpoint, integrating self-pay products into existing care pathways can be challenging, leading to fragmented care and limiting their acceptance among health-care professionals.

In health care, coverage is often associated with legitimacy. Clinicians may question the value of products that payers do not cover. In addition, if innovators later decide to pursue coverage, they may need to modify their innovations to meet payer and clinical requirements.

These considerations underscore the importance of strategic planning when pursuing the self-pay pathway for women's health innovation.

Commercial Payer Coverage Roadmap

Commercial payers are focused on streamlining care delivery for clinicians and mitigating costs. Thus, to achieve commercial coverage, innovators must demonstrate that their products will be readily and easily adopted by providers, will not create additional unnecessary hurdles, and will offset costs. Private payers are frequently willing to collaborate with innovators via pilot programs. However, innovators should engage with payers only after generating early outcome data that demonstrate measurable medical necessity and clinical utility outcomes, obtaining FDA approval for the innovation's intended use, and establishing its economic viability prior to initiating coverage discussions.

Employers are a strategic channel for advancing commercial coverage of women's health innovations. As the primary purchasers of private health insurance, employers have significant influence over benefit offerings and are motivated to provide comprehensive coverage for their workforce.[22] Innovators should actively engage with employers and health plan sponsors to position them as champions for coverage, recognizing that expanding women's health benefits often comes at the expense of budgets allocated to other benefits. Thus, to encourage employers to approach private payers for coverage, innovators must have an FDA-approved product and clearly articulate the measurable, evidence-based outcomes of their product that translate into improved employee productivity and cost-effectiveness for employers. By aligning product benefits with measurable business outcomes, innovators can strengthen their position and drive adoption within the commercial payer landscape.

Finally, women's health innovation competes for attention within CMS alongside other health-related areas. Therefore, private payers closely monitor CMS' evolving priorities. Innovators should be mindful of this broader landscape and position their evidence accordingly.

STEP 1. DEFINE COVERAGE STRATEGY

In the context of women's health innovation, products typically fall into three primary benefit categories: medical, pharmacy, and digital health. Some innovations may cross into multiple categories—for instance, fertility treatments may include medical procedures, pharmacy benefits for hormone therapies, and digital platforms for care navigation. Innovators should be prepared to clearly articulate how their innovation fits within these benefit categories to help employers and payers understand its value and coverage potential.

STEP 2. COLLECT EVIDENCE TO SUPPORT COMMERCIAL PAYER COVERAGE

To gain the attention of commercial payers and establish a strong case for coverage, innovators must proactively gather and present rigorous, quantitative data. While qualitative data are important, payers tend to prioritize quantitative metrics in their decision-making. Evidence presented to payers follows a hierarchy, with clinical utility taking top priority, followed by market potential, integration capabilities, and regulatory compliance.

Clinical Utility and Workforce Impact

To determine clinical utility, payers typically evaluate four key factors: real-world effectiveness, impact on clinical decision-making, patient outcomes, and comparative value relative to existing alternatives. Innovators should provide evidence of measurable improvements in patient outcomes, reduced symptoms, or decreased complication rates. Additionally, they should connect these outcomes to real-world impacts, such as enhanced employee productivity or reduced absenteeism if presenting to an employer. For instance, if an innovation helps to alleviate menopausal symptoms, innovators should quantify how this outcome reduces absenteeism. Similarly, innovators can highlight how better identification and management of underdiagnosed conditions, such as endometriosis, can benefit both employees and employers by improving health and productivity.

Market Size, Prevalence, and Utilization Forecast

Commercial payers are more likely to consider innovations for coverage when the intended market is clearly defined, sizable, serviceable, and obtainable. To build a compelling case for coverage, innovators should offer strong evidence on the prevalence of the targeted condition, ensuring that the data are tailored to the specific geographic region within which the payer's network operates and to relevant demographic profiles. Because plans, provider networks, and premium structures vary by area and must adhere to state-level regulations, these local and demographic nuances are critical. In addition, innovators should account for under- and delayed diagnoses, which may affect the actual utilization of the innovation within the intended population.

By demonstrating both the size and relevance of the market, innovators can provide payers with a clear understanding of coverage potential and anticipated demand. Payers can then market the innovation to the populations most likely to benefit, thereby maximizing utilization among people with the greatest need. When an innovation is covered but not utilized, commercial payers are discouraged from supporting future innovations.

Demonstrated Market Interest and Strategic Partnerships

Evidence of investors signals to payers that the product is viable and valued in the marketplace. In addition, exploring and documenting strategic partnerships, such as collaborations with clinician networks or integration with virtual women's health platforms, can demonstrate broader reach, scalability, and ease of adoption. These partnerships reinforce the innovation's credibility and highlight its potential for seamless implementation within existing care models.

Regulatory Compliance and Approval Status

Regulatory requirements must be addressed early in the process. Commercial payers typically restrict their coverage to products that have received FDA approval. By securing necessary approvals before approaching payers, innovators can avoid delays and strengthen their case for inclusion in medical benefit designs. Proactive compliance demonstrates a commitment to quality and safety, making it easier for payers to justify coverage.

STEP 3. UNDERSTAND EMPLOYER COVERAGE MODELS FOR WOMEN'S HEALTH INNOVATION

Employers consider two main types of coverage models: (1) medical benefits covered under employer health plans and (2) employer benefits through direct contact with an innovator.

Medical Benefits Covered Under Employer Health Plans

Employers have considerable flexibility in designing their benefit offerings, with the ability to add or remove benefits unless the state mandates coverage of certain services. Optional benefits may include treatments such as in vitro fertilization (IVF), menopause support programs, and GLP-1 medications, while mandated benefits typically encompass core services such as well-woman visits, contraception, and mammograms.

To qualify for coverage under employer health plans, innovations must comply with rigorous clinical and regulatory requirements. Coverage is restricted to medical technologies and procedures deemed medically necessary in accordance with established clinical policy. The essential criteria include a focus on prevention, diagnosis, or treatment of disease, not simply information utility. In addition, all innovations must have final FDA approval for the innovation's intended purpose. For instance, although testosterone is FDA-approved for men, it is not approved for women and therefore cannot be covered for female employees.

Importantly, innovations must demonstrate an improvement in net health outcomes and be at least as beneficial as any established alternative. This standard may pose challenges in women's health, where comparators and standard-of-care options are limited.

The evidence standards applied to coverage decisions by employer health plans are stringent:

- Scientific evidence must be sourced from peer-reviewed, published medical literature, such as articles indexed in the PubMed database, rather than small, localized studies. Randomized prospective trials are considered the gold standard; however, well-designed cohort studies may also be acceptable when appropriately conducted.
- A comprehensive review of regulatory status by the relevant authority, such as FDA or CMS, is necessary to confirm compliance and safety.
- Review of evidence-based clinical practice guidelines from relevant professional societies (e.g., American College of Obstetricians and Gynecologists [ACOG], Society for Maternal-Fetal Medicine [SMFM], National Comprehensive Cancer Network [NCCN]) and technology assessments conducted by authoritative bodies, including the Agency for Healthcare Research and Quality (AHRQ), National Institute for Health and Care Excellence (NICE), or Cochrane, are also considered to validate clinical effectiveness and safety.
- When necessary, opinions from relevant clinical experts may be solicited to supplement the evidence base.

All of the above criteria and findings are consolidated into clinical policy bulletins or guidelines and are accessible online. These documents present data both for and against coverage and outline innovations deemed medically necessary. Policies are reviewed annually in accordance with National Committee for Quality Assurance (NCQA) standards and include the dates for the next review. Innovators seeking evaluation of their innovations by the clinical policy committee should consult these bulletins to determine the dates for the next review window.

Triggering a review outside of the annual schedule is often challenging and generally discouraged. However, updates to professional society guidelines, emerging evidence, changes in national standards, significant safety incidents, or formal requests from professional organizations may warrant consideration of new innovations and trigger a review cycle.

Employer Direct Contact with Innovator

The second approach to obtaining coverage through an employer is through direct contact. In these cases, employers may purchase supplemental women's health solutions either directly from specialized vendors such as Progyny, Carrot Fertility, or Sword Health, or through health plans and pharmacy benefit managers that partner with vendors such as Maven Clinic, Midi Health, and Oshi Health.

These solutions are typically structured as employer-sponsored benefit carve-outs or wraparound services rather than fully integrated insured medical benefits. As a result, they may use Alternative Payment Models, such as per-member-per-month reimbursement, in which innovators receive a fixed, negotiated monthly payment for each patient or consumer, or engaged reimbursement models.

Employer benefits do not always follow traditional medical claims pathways, though some vendors support or process claims based on the model. Member cost sharing varies based on the employer's plan design, the level of integration with the underlying health plan, and the vendor's reimbursement structure.

WOMEN'S HEALTH–SPECIFIC CHALLENGES IN COMMERCIAL PAYER COVERAGE

Innovators face several significant challenges when seeking commercial coverage for their products. One primary obstacle is the fragmentation across benefit categories and care settings, which complicates reimbursement. Innovations often do not fit neatly into a single category, making it difficult to navigate coverage pathways.

Employers play a pivotal role in determining what is covered by health plans. Their influence, combined with variability in how they prioritize women's health, results in inconsistent access to and utilization of new products. This discrepancy can limit the adoption of innovations. Innovators must not only produce robust evidence that demonstrates the clinical utility and economic value of their products but also persuasively communicate why their innovation deserves a place within the employer's limited benefits budget. This task is complicated by fierce competition from other innovations and disease categories outside of women's health, all vying for scarce resources.

A final challenge stems from the historically male-centered approach to medical research. As a result, clinical guidelines specific to women's health are often lacking, complicating coverage decisions and delaying the approval process.

Public Program Roadmap

Pursuing coverage through public programs demands patience and persistence, but it offers innovators the opportunity to reach the broadest possible population, including lower-income and older adults who often experience the greatest unmet needs in women's health. The pathway is lengthy and highly regulated, so innovators should enter it with realistic timelines and a long-term strategy. The effort can also pay dividends beyond the public programs themselves: because commercial payers frequently model their coverage criteria, coding, and reimbursement rates on Medicare and Medicaid policy, achieving public program coverage can set a precedent that strengthens an innovator's position in subsequent negotiations with private payers.

STEP 1. LEARN THE BASICS: CMS COVERAGE AND PAYMENT PROCESSES

CMS serves as the federal authority overseeing health coverage for more than 160 million Americans across Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace. Medicare is designed for individuals aged 65 and older, as well as those with specific disabilities. Medicaid operates as a collaborative federal–state program targeting eligible low-income populations. CHIP provides coverage for children in families whose income exceeds Medicaid thresholds, while the Health Insurance Marketplace offers subsidized plans under the Affordable Care Act.

Innovators seeking coverage through public programs must carefully evaluate how women's health populations are distributed across these offerings. For instance, those developing products for pregnancy or postpartum care should consider Medicaid, which covered 41 percent of births in 2021.[23] Conversely, innovations targeting reproductive-age women may benefit from evaluating the intersection between the Health Insurance Marketplace and commercial payers.

CMS encompasses several distinct groups responsible for policy, coding, and payment processes, yet women's health does not align exclusively with any single group.[24] As a result, advancing women's health innovation often requires coordinated engagement across divisions such as the Center for Clinical Standards and Quality (CCSQ) and CMMI.

Medicare and Medicaid, established in 1965, operate under laws that have remained largely unchanged for more than 50 years.[25] Updating these statutes is complex because the government must carefully consider unintended consequences that may undo progress for other populations and collaborate with the US Department of Health and Human Services (HHS) Office for Civil Rights. As a result, women's health policy is frequently influenced by implicit or "silent policy," leading to uncertainty about what is considered "normal aging" versus a distinct women's health issue, such as menopause. The interpretation of policy can differ from claim to claim and by locality, creating inconsistent experiences for both patients and providers.

MEDICARE OVERVIEW

Medicare is organized into four distinct parts—A, B, C, and D—each covering specific aspects of care. Part A encompasses inpatient hospital care, skilled nursing facility stays, hospice services, and home health care. Part B provides reimbursement for outpatient prescription drugs and biologics administered by health-care providers. Part C, known as Medicare Advantage, consists of private plans that integrate coverage for Parts A and B, and often Part D, while offering supplemental benefits. Part D covers self-administered outpatient prescription drugs through private plan networks.

Innovators should identify which Medicare Part applies to their product. For example, breast cancer screening and treatment are typically covered under Part B, osteoporosis therapies may be covered by Part D, and postmenopausal care could involve both Parts B and D.

Each Medicare Part features unique reimbursement policies and payment methodologies. Part A relies on Diagnosis-Related Groups (DRGs), which assign hospitals a fixed payment per discharge based on the patient's diagnosis. While DRGs are essential for managing acute care efficiency, they often fail to account for underlying biological differences in treatment response and disease presentation when considering the complexities and intersectionality of women's health conditions.[26]

Part B reimbursement is guided by the physician fee schedule or the hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System. Providers receive payment based on relative value units, which reflect the resources, such as time, expertise, risk, and physical assets, required for specific procedures and services as described in CPT codes, with adjustments for geographic variation.[27] Under OPPS, hospital outpatient services are grouped into Ambulatory Payment Classifications (APCs), and CMS assigns HCPCS codes to APCs, updating them at least annually.[28]

Reimbursement for Parts C and D is determined by private plans, which use formularies and typically apply tiered cost-sharing structures.

Medicare restricts coverage for new innovations to those that have received FDA approval, ensuring that only products deemed safe and effective for their intended use are considered. In addition, eligibility for Medicare coverage is determined by the requirement that interventions must be "reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member," as specified by Social Security Act 1862A1A.[29]

This strict interpretation means that certain women's health innovations may be classified as nonessential, lifestyle-related, or insufficiently medically necessary. As a result, they can be excluded from Medicare coverage. Therefore, innovators must be able to demonstrate that their product is medically necessary health care.

MEDICAID OVERVIEW

Medicaid accounts for approximately 20 percent of health-care expenditures in the United States and is a critical program for women's health, especially in the case of maternal care.[30] The program comprises state initiatives administered through managed care organizations operating within broad federal guidelines, with joint funding from both states and the federal government.

Each state's Medicaid program is distinct, with varying eligibility requirements, benefits, payment models, and delivery systems; thus, innovators are advised to strategically select a limited number of target states when initially pursuing coverage.

When pursuing Medicaid coverage, innovators must tailor their product's value proposition to the specific state rather than the broader population. Each state establishes distinct three- and five-year priorities, so the innovation's alignment with these objectives should be demonstrated. In addition, innovators should familiarize themselves with the state's payment and benefit structures, including applicable rubrics, classifications, and billing codes. Understanding state-level reimbursement guardrails, often based on Medicare's, is essential. Innovators should also become acquainted with the state's fee-for-service rates and the evaluation and decision-making processes to ensure that their innovation fits within the established framework.

Identifying a champion within the state's agency is highly recommended. By fostering relationships with key contacts, innovators can gain valuable insights and assistance to overcome potential barriers. These relationships may also facilitate receipt of guidance from Medicare Administrative Contractors (MACs) and involvement with state advisory and advocacy groups. Innovators should be prepared to engage at multiple levels within the state's health-care ecosystem.

Of note, some innovations may require federal authorization, and the decision-making process may extend beyond the state level. For pilot programs, innovators should explore relevant waivers, such as Waiver 1115, which can exempt them from certain requirements. Reviewing waiver timelines and engagement processes will help to determine the optimal moment to initiate action.

STEP 2. NAVIGATE COVERAGE DETERMINATIONS AND CODING PATHWAYS

Medicare coverage is limited to innovations that are deemed reasonable and necessary for the diagnosis or treatment of an illness or injury.[31] To secure Medicare coverage, innovators must ensure that their product falls under an existing NCD or Local Coverage Determination (LCD) or submit a request for a new one. NCDs apply nationwide and are developed by CMS based on clinical evidence, technology assessments,

and input from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).[32] An NCD request must meet several criteria to be considered:

- be submitted in writing, clearly labeled as "A Formal Request for a National Coverage Decision," and not marked as a draft;
- specify the statutorily defined benefit relevant to the innovation;
- provide sufficient evidentiary documentation;
- describe the medical benefits and impact on the Medicare population; and
- thoroughly explain the design, purpose, and intended use of the product.

Early engagement with a MAC, often facilitated through advising firms, can help innovators understand the clinical evidence threshold required for Medicare coverage.

Upon gathering the required documentation, innovators should email their submission to NCDRequest@cms.hhs.gov.[33] CMS reviews standard requests within six months. If the request requires an external technology assessment or expert consultation, the review period may extend to nine to twelve months. The determination will then be posted on CMS's website for a 30-day public comment period. After collecting public feedback, CMS reviews the comments and provides a final decision no later than 60 days after the comment period ends.[34]

Regional MACs establish LCDs. To initiate this process, innovators are encouraged to meet informally with the MAC to ensure that all relevant information is available before submitting a formal review request. Contact details and scheduling procedures can be found on the MACs' websites. A formal LCD request must meet several criteria to be considered:

- be submitted via email, facsimile, or written letter;
- specify the statutorily defined benefit under which the innovation falls, along with a justification for its assignment;
- clearly outline the desired language for the LCD and include peer-reviewed evidence, with full copies of published articles attached (Any request lacking such documentation will be invalidated.);
- articulate the relevance, usefulness, clinical health outcomes, and medical benefits of the product or service; and
- thoroughly explain the design, purpose, and methodology.

The MAC will review the submission within 60 calendar days to assess completeness. If any information is missing, the MAC will respond with guidance on required additions. Once the request is deemed complete, the MAC supplements its review with clinical guidelines, consensus documents, and expert consultations. Each state's Contractor Advisory Committee, comprising medical association representatives, beneficiary advocates, and health-care professionals, contributes additional expertise to ensure an impartial evaluation of the innovation.

Following its determination, the MAC opens a public comment period of at least 45 days, during which open meetings are held to discuss the rationale for the proposed LCD with stakeholders. Innovators may prepare brief presentations for these meetings. All formal comments must be submitted in writing to the MAC. MACs also keep innovators informed of related proposed LCDs.

After the public comment period and open meetings conclude, the MAC publishes the final LCD and Response to Comments on the Medicare Coverage Database. There is a minimum 45-calendar-day waiting period before the LCD takes effect.[35]

LCDs can be a more practical entry point for innovators because they are often faster and more flexible than NCDs. LCDs may be more willing to consider real-world evidence and can be useful for regional pilot programs as innovators build the clinical evidence base needed to request an NCD.

Innovators must recognize the significant downstream effects of the NCD and LCD request processes on women's health. Many women's health innovations lack robust clinical evidence and are often categorized as "lifestyle" or "wellness" rather than medical, which can hinder coverage. Examples of categories that often fall under "wellness" are fertility services, sexual dysfunction, and some pelvic health therapies.

While advocacy is needed to shift perceptions, innovators must present compelling arguments that their innovations are reasonable and necessary for improving women's health conditions, employing clear clinical framing. Treatments, such as menopause symptom management or sexual health therapies, may be deprioritized unless they are positioned as medical necessities rather than quality-of-life enhancements. Ultimately, expanding the number of NCDs and LCDs is essential for advancing women's health innovation and improving access to care.

Innovators should consider a claim-by-claim adjudication strategy while building the evidence base needed to pursue an LCD and reduce the risk of an early noncoverage determination. Under this approach, MACs review each claim individually to confirm that CMS requirements have been met before issuing payment. To support providers, innovators should make the process as straightforward as possible by supplying clear coding, billing, and clinical documentation toolkits aligned with the MAC's "reasonable and necessary" standard, including peer-reviewed publications, FDA approval materials, and relevant society guidelines. Innovators could also provide a sample letter of medical necessity, prior authorization or pre-claim guidance, and a checklist outlining which clinical notes and lab results should accompany each claim. When used effectively, a claim-by-claim approach can also help generate real-world utilization data before pursuing an LCD.[36]

STEP 3. APPEALS PROCESSES

Both NCDs and LCDs provide appeals processes for innovators to challenge coverage determinations. The NCD appeals pathway follows federal legal procedures, requiring innovators to submit new evidence for reconsideration through an Administrative Law Judge review. Statutory timelines govern this process and can be complex, often resulting in lengthy review periods.[37] LCDs can be appealed through an LCD Reconsideration Request, which must include new evidence and proposed changes. The reconsideration process for LCDs is typically shorter, with reviews generally completed within 60 calendar days.[38]

WOMEN'S HEALTH–SPECIFIC CHALLENGES IN PUBLIC PROGRAMS

As innovators explore pathways for women's health coverage under public programs, they must recognize several persistent challenges that shape the landscape. Medicaid serves as a crucial program for low-income women, particularly during pregnancy. However, because Medicaid is administered at the state level, coverage options and access to care can vary significantly across states, resulting in unequal support for women's health needs. Additionally, CMS, as a government program, ties innovation and coverage decisions to current policy priorities. If a new product or service does not align with these priorities, innovators may find it difficult to gain recognition and support for their innovations.

Moreover, women's health services are often bundled in coding structures, such as well-woman visits. Historically, maternity care has been bundled, but it will be unbundled starting in January 2027.[39] This bundling approach can limit incremental reimbursement for new products, making it difficult for innovators to introduce advances that fall outside of established categories.

A further hurdle is demonstrating medical necessity for conditions primarily driven by symptoms. For example, alleviating menopause symptoms is often not classified as medically necessary, making it more difficult to meet coverage criteria and secure payment from public programs.

Finally, a consistent theme in women's health is the lack of robust evidence supporting many conditions. This limited evidence base increases payer reluctance to cover new innovations, creating additional barriers for innovators seeking to improve women's health care.

Conclusion

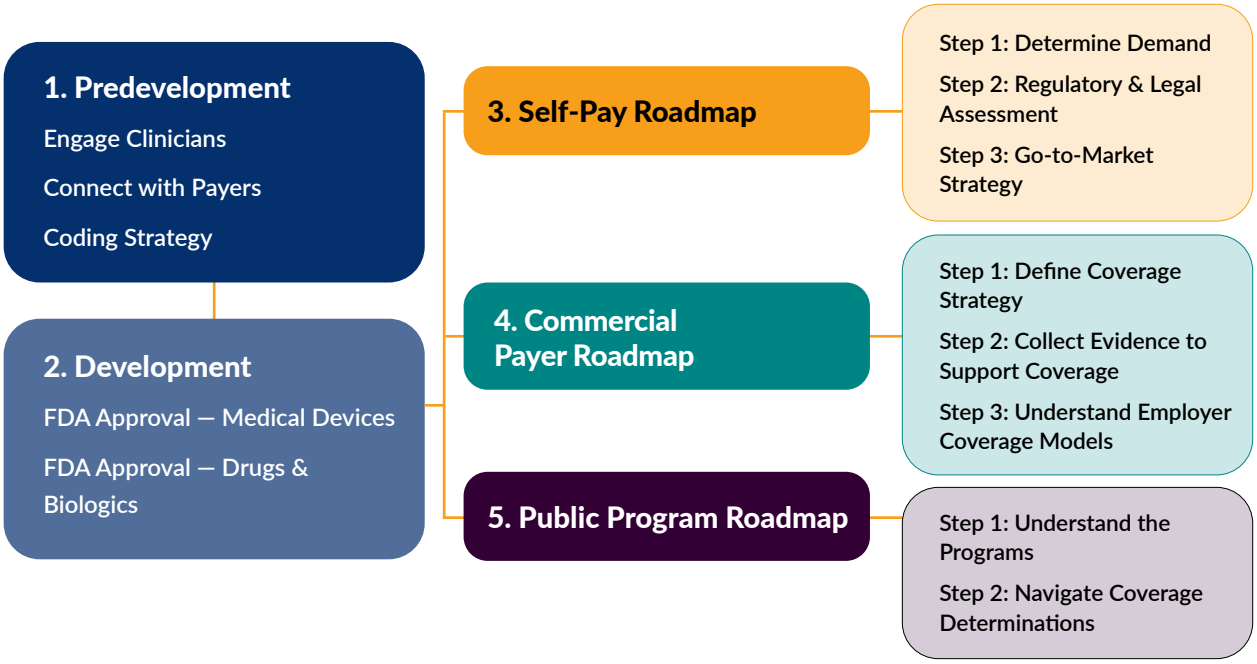
Navigating coverage and reimbursement for women's health innovations is a complex, multifaceted journey that demands strategic foresight, collaboration, and adaptability. As detailed throughout this report, innovators face persistent challenges—from evidence gaps and coding limitations to payer engagement and regulatory hurdles. Yet, by leveraging the outlined roadmaps for self-pay, commercial payer, and public program pathways, and by proactively engaging clinicians, payers, and regulatory bodies, innovators can build a strong foundation for market access.

Success in advancing women's health innovations requires not only robust clinical and economic evidence but also an understanding of payer requirements, benefit structures, and the nuances of policy interpretation. Innovators must frame their products as medically necessary, demonstrate real-world impact, and anticipate challenges unique to women's health. Ultimately, both government and commercial payers are seeking innovations that meaningfully advance clinical *and* cost outcomes. In an increasingly strained health-care system, the ability to demonstrate real-world value and cost savings is no longer optional, but essential. Through persistence, thoughtful planning, and a commitment to improving care for women, innovators can drive meaningful progress in women's health for generations to come.

Appendix: Innovator Roadmap

WOMEN'S HEALTH INNOVATOR ROADMAP

From predevelopment through regulatory approval to public programs, commercial payer, and self-pay pathways



Predevelopment and Development

Predevelopment Stage

Engage clinicians to ensure integration into existing workflows.

Connect with payers

- Determine viable endpoints.
- Discuss evidence packages for coverage.

INNOVATOR ALERT

Evidence packages for payers are different from those for the US Food and Drug Administration (FDA). Design clinical trials that will satisfy both requirements to save time and resources.

Coding — Options

- **Use existing code or fit innovation into an existing bundle.** Facilitates earlier adoption but may trigger payer review
- **Request new code.** Time intensive

INNOVATOR ALERT

It is essential to finalize a coding strategy in this stage to avoid revisiting clinical endpoints for payer alignment.

INNOVATOR ALERT

For innovators with technology products, intellectual property barriers are among the main challenges of getting new tech to market. It is essential to regularly check for patents and trademarks.

Development Stage

FDA Approval — Medical Devices

Step 1
Investigational Device Exemption (IDE) application

Step 2

- **510(k) submission** — Class I, Class II devices
- **Premarket Approval (PMA)** — Class III devices

Timeline

- 510(k): 6 months
- De Novo: 6–12 months
- PMA: 12+ months

INNOVATOR ALERT

Due to the evidence gap in women's health research, many devices may not meet the substantially equivalent predicate requirement. Consider submitting a De Novo Classification Request for novel devices.

Pilots

- Total Product Life Cycle Advisory Program (TAP) pilot
- Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices pilot
- Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway

Centers
Center for Devices and Radiologic Health (CDRH)

FDA Approval — Drugs and Biologics

Step 1
Investigational New Drug (IND) application

Step 2 — New Drug Applications (NDA)

- **505(b)1** — Novel drugs where the innovator conducts comprehensive studies to demonstrate safety and efficacy
- **505(b)2** — Previously established research on the active ingredient is used to demonstrate safety and efficacy

Abbreviated New Drug Application (ANDA) for Generic Drugs

- **505(j)** — evidence demonstrating bioequivalence to the reference listed drug

Timeline

- Standard Review: 10–12 months
- Priority Review: 6–8 months

Centers
Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER)

Self-Pay Roadmap

Step 1 • Determine demand

- Identify the target audience.
- Conduct a comparative analysis to identify similar innovations.
- Establish a pricing strategy using pre-orders, landing pages, and pilot programs to test willingness to pay.
- Actively engage in patient communities, virtual forums, and advisory boards to understand consumer needs.

Step 2 • Regulatory and legal assessment

- Ensure relevant regulatory approvals are acquired.
- Confirm there are no existing intellectual property barriers, such as patents or trademarks, and initiate the process of securing appropriate protections.
- Establish clinical validation with small-scale studies.
- Implement robust safety protocols with clear disclaimers and adverse event reporting.

Step 3 • Go-to-market strategy

- Hire an experienced business and marketing executive at the C-suite or board level.
- Emphasize education and integration into consumers' lifestyles to foster adoption.
- Utilize social media, paid advertising, and influencer partnerships.
- Conduct webinars and podcasts focused on women's health topics to build awareness and credibility.
- Engage with clinical advisors and board members frequently to maintain brand credibility.
- Pursue third-party validation when appropriate.

Commercial Payer Roadmap

Step 1 · Define coverage strategy

Where does the innovation fit in benefits?

Common women's health benefit categories
Medical, pharmacy, and digital health

Step 2 · Collect evidence to support coverage

Quantitative evidence to present

- **Improvements in patient outcomes:** symptom reduction, decreased complication rates
- **Market size and utilization forecast:** serviceable obtainable market, tailored to geographic region and relevant demographic profiles
- **Demonstrated market interest:** early investments and partnerships
- **Regulatory status:** FDA approval

INNOVATOR ALERT
Recognize that expanding women's health benefits comes at the expense of other benefits and be prepared to make a financial case for coverage.

INNOVATOR ALERT
Employers are the primary purchasers of private health plans and determine what is covered. Innovators should actively engage with employers and health plan sponsors to position them as champions for coverage.

INNOVATOR ALERT
Connect outcomes to real-world impacts, such as workforce productivity and decreased absenteeism, if presenting to an employer.

Step 3 · Understand employer coverage models

Benefits covered under employer health plans
Coverage is restricted to innovations in accordance with the payer's established clinical policy. Policies are reviewed annually, and innovators are encouraged to provide evidence at the review to support coverage.

Clinical policy guidelines compile and publish the following evidence justifying coverage decisions:

- Peer-reviewed, published medical literature, such as articles indexed in the PubMed database
- Review of evidence-based clinical practice guidelines from relevant professional societies (e.g., ACOG, SMFM, NCCN)
- Technology assessments conducted by authoritative bodies, including AHRQ, NICE, or Cochrane
- Opinions from relevant clinical experts

Direct contact with employer
Employer-sponsored benefit carve-outs rather than fully integrated medical benefits; often use Alternative Payment Models (APMs) in which innovators receive a fixed, negotiated monthly payment for each patient or consumer, or engaged reimbursement models

Public Program Roadmap

Step 1 · Understand the public programs and where the innovation fits

Medicare

National program organized into four distinct parts.
Population: 65+

- **Part A:** Inpatient hospital care, skilled nursing facility stays, hospice services, home health care.
  Reimbursement: Diagnosis-Related Groups (DRGs)
- **Part B:** Outpatient prescription drugs and biologics administered by health-care providers
  Reimbursement: Guided by physician fee schedule, Outpatient Prospective Payment System (OPPS), and Ambulatory Surgical Center (ASC) payment system; payment based on relative value units (RVUs)
- **Part C (Medicare Advantage):** Private plans integrating services in Parts A, B, and D
  Reimbursement: Determined by private plans
- **Part D:** Self-administered outpatient prescription drugs.
  Reimbursement: Determined by private plans

Medicaid

Joint state-federal program consisting of state initiatives administered through Managed Care Organizations (MCOs).
Population: low-income

INNOVATOR ALERT — MEDICARE
Medicare restricts coverage for new products and services to those that have received FDA approval *and* are "reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member" *(Social Security Act 1862A1A).*

INNOVATOR ALERT — MEDICAID
Each state's Medicaid program is distinct, with varying eligibility requirements, benefits, payment models, and delivery systems; thus, innovators are advised to strategically select a limited number of target states when initially pursuing coverage.

Step 2 · Navigate coverage determinations

Determine whether the innovation is covered by an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) or request a new one.

NCD submission requirements
Must be a formal written request labeled "A Formal Request for a National Coverage Decision" (not a draft), specify the relevant Medicare benefit category, and include evidence, clinical benefit, and a clear description of the innovation's design and intended use.

How to submit & review timeline
Send to NCDRequest@cms.hhs.gov; CMS review typically takes about 6 months, or up to 9 months if an external technology assessment or expert input is needed.

Decision process
CMS posts a proposed decision for a 30-day public comment period, then issues a final decision within 60 days after comments close.

Initiating an LCD
Managed by regional MACs; innovators should start with an informal MAC meeting, then submit a formal request (email/fax/letter) specifying the Medicare benefit category, proposed LCD language, justification, and full peer-reviewed evidence.

Review process
MACs review completeness within about 60 days, may request additional information, then evaluate using clinical guidelines, expert input, and Contractor Advisory Committee (CAC) feedback; CAC includes clinicians, associations, and beneficiary representatives.

Decision timeline
Proposed LCD is subject to a 45-day public comment period and open meetings; final LCD and response to comments are posted on the Medicare Coverage Database, followed by a ≥45-day waiting period before it becomes active.

INNOVATOR ALERT
Consider a claim-by-claim adjudication strategy while gathering sufficient evidence to apply for an NCD or LCD.

Endnotes

1. Emory Wolf et al., "Assessment of Churn in Coverage Among California's Health Insurance Marketplace Enrollees," *JAMA Health Forum* 3, no. 12 (December 2, 2022): e224484, https://pmc.ncbi.nlm.nih.gov/articles/PMC9719048/; Haechung Chung et al., "Health Plan Enrollment and Disenrollment of Individuals With and Without Established Chronic Disease in a US Commercially Insured and Medicare Advantage Population," *Journal of Managed Care & Specialty Pharmacy* 25, no. 5 (May 2019): 612, https://pmc.ncbi.nlm.nih.gov/articles/PMC10398183/.

2. "CPT Code Set Overview," American Medical Association, January 23, 2026, https://www.ama-assn.org/practice-management/cpt/cpt-code-set-overview.

3. "Healthcare Common Procedure Coding System (HCPCS)," Centers for Medicare & Medicaid Services, accessed June 17, 2026, https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system.

4. "The CPT Code Process," American Medical Association, January 22, 2026, https://www.ama-assn.org/about/cpt-editorial-panel/cpt-code-process.

5. "CPT Code Change Applications via the CPT SmartApp," American Medical Association, February 3, 2026, https://www.ama-assn.org/practice-management/cpt/cpt-code-change-applications-cpt-smart-app.

6. US Institute of Medicine Committee on Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies, *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*, vol. 1, ed. Anna C. Mastroianni, Ruth Faden, and Daniel Federman (Washington, DC: National Academies Press, 1994), https://www.ncbi.nlm.nih.gov/books/NBK236531/.

7. US Institute of Medicine Board on Health Sciences Policy, *Inclusion of Women in Clinical Trials: Policies for Population Subgroups* (Washington, DC: National Academies Press, 1993), https://www.ncbi.nlm.nih.gov/books/NBK221285.

8. "Investigational Device Exemption (IDE)," US Food and Drug Administration, August 22, 2024, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide.

9. "Classification of Products as Drugs and Devices and Additional Product Classification Issues," US Food and Drug Administration, July 12, 2018, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-products-drugs-and-devices-and-additional-product-classification-issues.

10. "Classify Your Medical Device," US Food and Drug Administration, January 15, 2026, https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

11. "Product Classification," US Food and Drug Administration, accessed June 17, 2026, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm.

12. "De Novo Classification Request," US Food and Drug Administration, accessed June 17, 2026, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request.

13. "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program," US Food and Drug Administration, accessed June 17, 2026, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

14. "De Novo Classification Request."

15. "Total Product Life Cycle Advisory Program (TAP)," US Food and Drug Administration, April 23, 2026, https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap.

16. "TAP Pilot Enrollment Expansion," US Food and Drug Administration, April 23, 2026, https://www.fda.gov/medical-devices/total-product-life-cycle-advisory-program-tap/tap-pilot-enrollment-expansion.

17. "21 CFR Part 50—Protection of Human Subjects and Institutional Review Boards," Electronic Code of Federal Regulations, accessed June 17, 2026, https://www.federalregister.gov/documents/2022/09/28/2022-21088/protection-of-human-subjects-and-institutional-review-boards; "21 CFR Part 56—Institutional Review Boards," Electronic Code of Federal Regulations, https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56.

18. "Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot," *Federal Register*, December 8, 2025, https://www.federalregister.gov/documents/2025/12/08/2025-22190/technology-enabled-meaningful-patient-outcomes-tempo-for-digital-health-devices-pilot.

19. "CMS and FDA Announce Rapid Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices," Centers for Medicare & Medicaid Services, April 23, 2026, https://www.cms.gov/newsroom/press-releases/cms-fda-announce-rapid-coverage-pathway-accelerate-patient-access-life-changing-medical-devices.

20. "505(b)(1) Versus 505(b)(2): They Are Not the Same," Premier Research, March 18, 2022, https://premier-research.com/perspectives/505b1-versus-505b2-they-are-not-the-same/.

21. "Development & Approval Process | Drugs," US Food and Drug Administration, accessed June 17, 2026, https://www.fda.gov/drugs/development-approval-process-drugs.

22. Gary Claxton et al., "Employer-Sponsored Health Insurance 101," KFF, April 15, 2026, https://www.kff.org/health-costs/health-policy-101-employer-sponsored-health-insurance/.

23. Claudia P. Valenzuela and Michelle J.K. Osterman, "Characteristics of Mothers by Source of Payment for the Delivery: United States, 2021," NCHS Data Brief no. 468 (Hyattsville, MD: National Center for Health Statistics, May 2023), https://www.cdc.gov/nchs/products/databriefs/db468.htm.

24. "Overview of CMS Groups," Centers for Medicare & Medicaid Services, accessed June 17, 2026, https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/getting-started/overview-cms-groups.

25. "Medicare and Medicaid Act (1965)," National Archives, accessed June 17, 2026, https://www.archives.gov/milestone-documents/medicare-and-medicaid-act.

26. Bridget Balch, "Why We Know So Little About Women's Health," AAMC, March 26, 2024, https://www.aamc.org/news/why-we-know-so-little-about-women-s-health.

27. "Understanding Relative Value Units (RVUs)," American Medical Association, December 5, 2025, https://www.ama-assn.org/practice-management/cpt/understanding-relative-value-units-rvus.

28. Teri U. Guidi, "Medicare's Hospital Outpatient Prospective Payment System: OPPS 101 (Part 1 of 2)," *Journal of Oncology Practice* 6, no. 6 (November 2010): 321–324, https://pmc.ncbi.nlm.nih.gov/articles/PMC2988668/.

29. "Compilation of the Social Security Laws: Exclusions from Coverage and Medicare as Secondary Payer (§1862)," Social Security Administration, accessed June 17, 2026, https://www.ssa.gov/OP_Home/ssact/title18/1862.htm.

30. Elizabeth Williams et al., "Medicaid Financing: The Basics," KFF, March 4, 2026, https://www.kff.org/medicaid/medicaid-financing-the-basics/.

31. "Medicare Coverage Determination Process," Centers for Medicare & Medicaid Services, accessed June 18, 2026, https://www.cms.gov/medicare/coverage/determination-process.

32. "Medicare Evidence Development and Coverage Advisory Committee," Centers for Medicare & Medicaid Services, accessed June 17, 2026, https://www.cms.gov/medicare/regulations-guidance/advisory-committees/evidence-development-coverage.

33. "Coverage Determination Process: How to Request an NCD," Centers for Medicare & Medicaid Services, accessed June 29, 2026, https://www.cms.gov/medicare/coverage/determination-process/request.

34. "Medicare Coverage Determination Process," Centers for Medicare & Medicaid Services, accessed June 17, 2026, https://www.cms.gov/medicare/coverage/determination-process.

35. "Medicare Program Integrity Manual, Chapter 13—Local Coverage Determinations," Centers for Medicare & Medicaid Services, accessed June 17, 2026, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

36. Lee A. Fleisher and Tamara Rook, "How Claim-by-Claim Payments for Novel Devices Can Actually Save You from the 'Valley of Death'," Reasonable & Necessary (Substack), April 28, 2026, https://leeafleishermdml.substack.com/p/how-claimbyclaim-payments-for-novel.

37. "42 CFR § 426.340—Procedures for Review of New Evidence," Legal Information Institute, Cornell Law School, accessed June 17, 2026, https://www.law.cornell.edu/cfr/text/42/426.340.

38. "Local Coverage Determination (LCD) Reconsideration Process—Medical Policy Article," Article A52842, Medicare Coverage Database, Centers for Medicare & Medicaid Services, revised January 1, 2024, https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52842.

39. "After Years of ACOG Advocacy, AMA Releases New Obstetric Codes," American College of Obstetricians and Gynecologists, April 23, 2026, https://www.acog.org/news/news-releases/2026/04/ama-releases-new-obstetric-codes.

Acknowledgments

This report emerged from the Coverage and Reimbursement workshop convened by the Milken Institute's Women's Health Network Coverage & Reimbursement Working Group. We are grateful to the many individuals who generously contributed their time, expertise, and perspectives to this effort.

We extend special thanks to the workshop cochairs, DeChane Dorsey, JD, and Trish Stroman, for their leadership and guidance throughout this work.

We are also grateful to the speakers, workshop attendees, and working group members listed below, whose insights and expertise directly informed this report:

Speakers

Ashley Abel, PhD

Joanne Armstrong, MD

Kristine Cecchetti

Ing-Jye Cheng

Natalie Davis

Trena Depel

Chad Hoskins

Hilary Imai

Tamara Syrek Jensen, JD

Emily S. Lau, MD

Courtney H. Lias, PhD

Liz Powell, JD

Erica Spatz, MD

Michelle Tarver, MD, PhD

Sharon Woda

Workshop Attendees

Lori Bernstein

Heather Bowerman

Tania Calle

Laura Cohen, JD

Meg Eckenroad

Autumn Enhow

Jessica Foley, PhD

Ruth Frey

Claire Gill

Millicent Gorham, PhD

Christine Jarjour

Georgie Kovacs

Oriana Kraft

Geraldine McGinty, MD

Erika Miller, JD

Nikki Modi

Jodi Neuhauser

Barrett Pignone

Neda Razavi

Mandy Sandkuhler

Rachel Braun Scherl

Randi Seigel, JD

Ben Swanson, DDS, PhD

Sarah Temkin, MD

Pam Traxel

Deidre Washington, PhD

Working Group Members

Eliza Chin, MD

Lindsay Davis

Vrunda Desai, MD

Megan Dover

Kara Egan

Autumn Enhow

Ruth Farrell, MD

Juan Camilo Arjona Ferreira, MD

Jessica Grossman, MD

Martha Gulati, MD

Christina Han, MD

Nada Hanafi

Alessandra Henderson

Colby Holtshouse

Louise King, MD, JD

Georgie Kovacs

Oriana Kraft

Mitzi Krockover, MD

Madeleine Livingston

Geraldine McGinty, MD

Erika Miller, JD

Miller Morris

Jodi Neuhauser

Luba Perry, PhD

Liz Powell, JD

Soum Rakshit, PhD

John Scalon

Randi Seigel, JD

Lisa Suennen

Sarah Temkin, MD

Deidre Washington, PhD

Jocelyn Wittstein, MD

We thank the Institute's Women's Health Network team for convening the workshop and bringing this report to fruition.

The findings and conclusions presented here are those of the authors and do not necessarily represent the views of the workshop participants or their organizations.

About the Authors

Abigail Humphreys, PhD, is a senior associate on Milken Institute Health's Research team, where she works on projects spanning women's health access, coverage, and reimbursement. Prior to joining the Milken Institute, she was part of the Colorado Fertility Project and was affiliated with the CU Population Center at the University of Colorado Boulder. There, she conducted research on public health and contraceptive access. Her research has been published in the peer-reviewed journals *JAMA Network Open* and *Contraception*, and she has presented at the Population Association of America's annual meeting. Humphreys received her PhD in health economics from the University of Colorado Denver in 2024 and holds a BA in economics from Binghamton University.

Jenica Patterson, PhD, is senior director of the Women's Health Network at the Milken Institute, where she leads a global initiative to accelerate innovation, investment, and cross-sector collaboration in women's health. She works at the intersection of science, commercialization, and capital, mobilizing leaders across industry, government, philanthropy, and finance to advance scalable solutions and strengthen the ecosystem needed to bring women's health innovations to market and scale. In this role, Patterson focuses on unlocking key system barriers to growth, including investment gaps, regulatory and reimbursement pathways, and barriers to access and awareness, helping translate scientific advances into real-world impact at scale.

Prior to joining the Milken Institute, Patterson served as a portfolio lead at the Advanced Research Projects Agency for Health (ARPA-H) within the Office of Commercialization. She led the agency's first Sprint for Women's Health, a $113 million initiative to catalyze innovation and accelerate the commercialization of high-impact technologies. She also directed the Small Business Program and Launchpad Accelerator, advancing transition pathways and product readiness across ARPA-H's portfolio. Earlier in her career, Patterson held roles at the Defense Advanced Research Projects Agency and the National Institutes of Health (NIH), where she advanced translational programs spanning therapeutics and diagnostics, including contributions to the Rapid Acceleration of Diagnostics initiative. Patterson earned her PhD in neuroscience and completed her postdoctoral training within the NIH Intramural Research Program. She is based in Washington, D.C.

Esther Krofah is the executive vice president of health at the Milken Institute, leading FasterCures, Public Health, the Future of Aging, and Feeding Change. A recognized expert in health policy, biomedical innovation, and clinical research, Krofah has extensive experience shaping health initiatives that unite diverse stakeholders, foster collaboration, and motivate action toward shared goals. Under her leadership, the Milken Institute formed multisectoral coalitions with hundreds of participating organizations to advance clinical trials through the Enabling Networks of Research Infrastructure for Community Health Through Clinical Trials (ENRICH-CT), Project Prevent, and the Milken Institute Women's Health Network.

Before joining the Milken Institute, Krofah was the director of public policy at GlaxoSmithKline, where she led engagement with the US Department of Health and Human Services (HHS) and relevant executive branch agencies. She also served as a political appointee to President Obama as deputy director of HHS' Office of Health Reform, led work with state governments on health policy at the National Governors Association, and served in management consulting at Deloitte Consulting LLP. Krofah received a BA from Duke University and a master's degree in public policy from the John F. Kennedy School of Government at Harvard University.

Krofah is an active member of several advisory boards informing work on health policy, innovation, and effective multistakeholder strategies for health transformation. She is the immediate past president of the Alliance for a Stronger FDA, a member of the National Academy of Medicine Drug Forum, a member of the editorial advisory board for the *Therapeutic Innovation & Regulatory Science* (official journal of the Drug Information Association), and a member of the board for Clinical Trials Transformation Initiative, Duke Margolis Institute for Health Policy, Eshelman Institute for Innovation, i-Cubed Duke Clinical Research Institute, Global Liver Institute, Medical Device Industry Consortium, Protas, Reagan Udall Foundation for the FDA, and Seed Global Health.

Lee Fleisher, MD, is emeritus professor of anesthesiology and critical care at the University of Pennsylvania Perelman School of Medicine and continues to practice clinically. He is also the founding principal and CEO at Rubrum Advising, LLC. He serves as a senior advisor of the Bipartisan Policy Center and FasterCures of the Milken Institute, and visiting fellow of the Duke-Margolis Center. He is a member of the Steering Committee of Coalition of Health AI and of the Health Information Technology Advisory Committee of the Office of the National Coordinate for Health IT.

From July 2020 to July 2023, he was the chief medical officer and director of the Center for Clinical Standards and Quality for the Centers for Medicare & Medicaid Services. In this capacity, he was responsible for executing all national clinical, quality, and safety standards for health-care facilities and providers, as well as establishing coverage determinations for items and services that improve health outcomes for Medicare beneficiaries. From 2004 through July 2020, he was the Robert D. Dripps Professor and chair of anesthesiology and critical care and professor of medicine at the University of Pennsylvania. In 2007, he was elected to membership of the National Academy of Medicine (NAM) of the National Academies of Sciences, Engineering, and Medicine and served on committees including the NAM Board of Health Services.

LOS ANGELES | WASHINGTON | NEW YORK | MIAMI | LONDON | ABU DHABI | SINGAPORE