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Coding, Coverage, and Reimbursement

Considerations for Women's Health Access

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EXECUTIVE SUMMARY

Persistent gaps between men's and women's health research (WHR), innovation, and clinical outcomes are well documented.[1,2,3] Underinvestment in conditions that affect women uniquely, disproportionately, or differently led to renewed focus in recent years on advancing discoveries in women's health.[4,5,6,7] As a result, in 2024 health policymakers called for substantial federal funding to provide a "sustained commitment and prioritization" in research and workforce to improve health, quality of life, and treatment options for women in the United States across their lifespan.[8,9,10]

Increased investment in WHR will lead to innovations that may improve health. To deliver on this potential, women must be able to access care, including preventive, diagnostic, and therapeutic services and new technologies. Many factors limit access to care, including clinician workforce shortages, socioeconomic barriers, and the regulatory and legal landscape. Although access constraints, underrepresentation of women in medical research and outcomes are increasingly well-studied and reflected in the literature, less emphasis is placed on the role of coding, coverage, and reimbursement and whether male or female gaps exist in each of these key market access domains.

In the fee-for-service (FFS) healthcare ecosystem, insurance coverage and payment for a medical item or service in the United States is dependent on whether a code is available to report the service on healthcare claims. Though explicit coverage policy is not always necessary for items or services to be paid, noncoverage determinations, lack of transparency in coverage processes or coverage bias may prevent people from accessing care and technologies.[11] Even when accurate coding is available and patients have coverage, inadequate payment levels contribute to access constraints, limit investment in technology, and dampen market success. If this situation occurs differentially for services tailored to men compared with those unique to women, health gaps could be exacerbated and structurally incorporated into the US healthcare system.

The Advanced Medical Technology Association (AdvaMed) engaged Health Management Associates, Inc. (HMA), to investigate gaps in funding, coding, coverage, and reimbursement for women's healthcare services. We conducted a literature and landscape review, analyzed federal biomedical research funding and its relationship with disease burden, commercial payer claims data, Medicare payment rules, a sample of medical coverage policies, and coding structures. Despite the complexity of the topic and constraints of comparing women's and men's services, we explored where gap examples have been apparent and whether further gap observations are evident. We focused on AdvaMed's suggested topic areas of pelvic health, maternity care, and mental health. We synthesized publicly available information and performed an analysis of potentially analogous male to female services from payer snapshots to assess potential gaps in reimbursement.

Findings

Underfunded research on female-specific or dominant conditions is apparent. Federal funding for WHR is minimal relative to total budgets (less than 10%) and funding patterns favor the study of male-dominant conditions.[12,13] Our analysis of recent data suggests progress toward more equitable federal funding distribution; however, conditions affecting women, such as certain gynecologic cancers, remain underfunded compared to disease burden. Public reports also identify inadequate research funding for endometriosis, uterine fibroids, polycystic ovary syndrome (PCOS), pelvic floor disorders, postpartum depression, vulvodynia, and others.[14,15] Women's health is also among the most underfunded investment sectors, with venture capital in women's health cited at 2 percent of capital markets.[16]

The lack of investment and underrepresentation of women in clinical studies contributes to gaps in women's health. In 2025, reductions in federal funding for biomedical research, including biological sex-focused studies, may worsen these inequities. Canceled grants and reduced health-related funding could impede the investigation of diseases and conditions that uniquely or disproportionately affect women, as well as the scientific discovery of sex-based differences in health and treatment response. This situation may also delay the development of new therapies and technology solutions intended to improve health. The long-term effects of significant shifts in government priorities and defunding of research and the workforce are uncertain but will likely require greater reliance on private investment in women's health innovation.[17] Insufficient funding results in less evidence generation and affects coding, coverage, and reimbursement for medical services.

The coding structure in the United States that all payers use to reimburse for ambulatory care and physicians' services comprises more than 8,000 services and procedures. This coding system is predominately sex agnostic, making comparisons between services specific to one sex or another limited. A different coding system is used in the United States to report illness, injury, and inpatient procedures and contains more than 70,000 codes. We found that among other deficiencies it insufficiently captured endometriosis diagnoses—a significant health burden for women—for decades, potentially contributing to lack of disease awareness and treatment options for this condition.[18]

The development of new codes includes the assessment of clinical evidence, among other criteria, and medical community support. If a service meets a lower evidence bar, it may be assigned a temporary code for tracking, as is often the case for services that involve emerging technologies. Although assignment of a temporary code does not imply a lack of evidence to support clinical efficacy, safety, or applicability to clinical practice,[19] some payers interpret this coding classification as such, potentially introducing payer bias into the system. [20] Though these challenges are not exclusive to women's health technologies, chronic underfunding and underrepresentation of women in clinical data could exacerbate these barriers to the development of women's health technology solutions.

To date, gaps in traditional Medicare reimbursement to physicians for comparable male and female reproductive system procedures are subject to debate, with some experts finding no marked disparity in Medicare's valuation of clinician services and others arguing the Medicare physician reimbursement schedule embeds structural sex discrimination in the system.[21,22,23,24] Our analysis of a commercial payer dataset found evidence of differential reimbursement for male-centered services relative to the analogous female procedure, with national average commercial payments to clinicians higher for the majority of male-specific services analyzed. We also identified this occurrence in commercial payments to hospitals for inpatient stays as well as observations of commercial insurers paying a higher percentage of Medicare reimbursement for male-focused major diagnostic categories. Our analysis of Medicare hospital outpatient reimbursement found observations of higher paid male services, with technical methodology explaining some of this difference. Findings of higher payments for male-specific services contributes to perceptions of lesser value and lower return on investment for women's health care.[25]

Significant gaps in maternity care persist, with high rates of preventable maternal mortality, limited or inaccessible obstetric services, and inadequate perinatal insurance coverage.[26,27,28] Insufficient resources have hindered the adoption of innovative healthcare models and technology solutions to facilitate access and achieve improved maternal outcomes. Though factors contributing to maternal morbidity and mortality are multifactorial, experts have highlighted issues with coding and payment structures for maternity services, suggesting that lack of uniform definitions of severe maternal morbidity, as well as billing codes that do not fully reflect the practice of maternity care, contribute to multidimensional challenges. Efforts are under way, however, to update maternity services coding, which may facilitate improvements in clinician reimbursement.[29,30]

In the context of the women's healthcare landscape, signals of potential gaps in coding, coverage, and reimbursement—key market access levers—have been identified. Several issues stem from the healthcare system itself and may be the result of differences in methodology, resource consumption, or potential bias. Structurally low reimbursement disenfranchises patients and their care teams, as well as impedes access to services.[31] Fragmented coverage can contribute to undervaluation of codes and under-resourcing, less investment in innovation, and potentially reduce incorporation of best practices and new technology for women's health. At minimum, the gap indicators warrant further investigation, increased awareness of possible structural bias, and consideration of whether processes and criteria indirectly contribute to access barriers.[32]

Opportunities to align payment strategies to meet the needs of different patient populations and achieve better outcomes are core principles of value-based care.[33] At a macro level, continued shifts from transactional payment systems to value constructs must be part of the women's health equity solution; however, FFS remains the dominant form of payment within the US healthcare system[34] and is the underlying architecture for alternative models. Policy and advocacy efforts must be tailored to FFS.

Recommendations

We recommend that the medical technology community, clinicians, and patient advocates focus on establishing processes to raise awareness and facilitate further evaluation of potential gaps in coding, coverage, and reimbursement with the goal of making incremental changes over the coming years:

- Seek to establish a women's health coding committee within the entities that maintain the national code sets to expand expert contributions to coding processes with this lens as part of its charge. For professional services, it might entail expanding the Current Procedural Terminology ad hoc workgroup formed to evaluate codes for maternity care. Alternatively, it could be established as a women's health services coding and payment advisory group focused on identifying barriers and comprehensive solutions, like current initiatives concentrated on digital medicine.[35]
- Include a demographic review as part of this envisioned coding committee to better analyze and understand the populations for whom codes are reported and whether inadequate coding contributes to access challenges.
- Improve coding to facilitate billing and reimbursement of women's healthcare management services and/or patient navigation activities to facilitate screening, coordination and other care.
- Use federal notice of proposed rulemaking and comment periods to identify misvalued services and seek payment parity for analogous male and female procedures.
- Build on medical technology initiatives to expand transitional coverage for emerging technologies and provide more opportunities for new women's health technologies to be covered by Medicare.
- Work with the Centers for Medicare & Medicaid Services to establish a data-driven process to price emerging technology codes nationally rather than defaulting pricing decisions to local contractors where payment variability and uncertainty impedes access. Leverage this process to seek similar coverage and payment stability with other payers.
- Establish collaboratives to advance women's health policies in the private sector through partnerships with business roundtables, large employers, and associations that represent health plans.
- Collaboratives could also be helpful in raising awareness among national medical professional societies and coordinating the process to identify when outdated or incomplete clinical practice guidelines contribute to access barriers for women's health technologies.
- When consistent payer barriers are identified for women's health services or technologies, develop payer education campaigns or other toolkits for engaging commercial payers on unique challenges or considerations for women's health access.
- Promote diversity in clinical trials among developers of new technologies, disaggregation of research findings by sex, a focus on evidence to support clinical validity and utility, and further explore how real-world evidence could improve coding, coverage or reimbursement processes.
- Identify and disseminate best and promising practices for technology applications in maternity care. Use successful approaches in payer outreach to gain support and scale adoption.

Gender bias in medicine and medical research is evident[36,37] and may well be systematically incorporated into US coverage and reimbursement systems. Collaborative action to further investigate and address these issues is imperative and could be initiated through coding processes, payer reimbursement systems, and conveners of employer-sponsored healthcare plans. Commercial insurers will require a sustained and long-term approach to working with employers and plans to develop customized benefits for women's health. Sustainable reimbursement models and sufficient funding are needed to support the full range of services that contribute to better access and outcomes for women. Renewed efforts to raise awareness and educate policymakers, investors, and the private sector on the role these issues play in improving health is particularly critical to maintain progress in a rapidly changing federal landscape and healthcare workforce.

Stakeholders in Women's Health Say:

- Women's health is population health; it is not product or technology specific.
- Educate, raise awareness, and acknowledge women's health disparities.
- Underrepresentation of women in clinical trials limits the evidence base for diseases, conditions and interventions affecting women which in turn could impede successfully obtaining coding, coverage and reimbursement for women's health services.
- Coverage policy is a barrier to reimbursement, tends to favor male conditions or treatments (e.g., prostate cancer, sexual dysfunction vs. pelvic floor disorders).
- Women's health products and technologies are sometimes viewed as optional, left to consumer choice rather than a healthcare need, which influences coverage and treatment decisions.
- Disrupt the predisposition to focus research and analysis on men's health conditions.
- At minimum, help women better navigate their way into screening.
- Acknowledge limitations of Randomized Controlled Trial (RTC) inclusion criteria and generalizability to the population at large.
- Stop reliance on outdated research in clinical guidelines, coverage policy and practice patterns that can be problematic.
- Allow for real-world evidence to support performance.
- Social and healthcare stigma around women's health limits funding, coverage and direct-to-consumer advertising.
- Consider the whole woman perspective across her lifespan and quality of life.
- Direct research dollars toward patients with the greatest historic need.
- Women's health research, technology, and care are not components of a niche.

GAPS IN WOMEN'S HEALTH RESEARCH

Persistent gaps between men's and women's health research (WHR), innovation, and clinical outcomes are well documented.[38,39,40] Underinvestment in conditions that affect women uniquely, disproportionately, or differently led the Biden Administration, researchers, and business collaboratives to renew their focus on advancing discoveries in women's health in recent years.[41,42,43,44] This included calls in 2024 for substantial federal funding to provide a "sustained commitment and prioritization" in research and workforce to improve health, quality of life, and treatment options for women in the United States across their lifespan.[45]

Health gaps or disparities refer to differences in the quality of health and healthcare across groups—for example, between men and women, which is the focus of this work.[46] In the United States, gaps are evident across health domains and disease states, including heart disease, neurologic and brain conditions, lung and other cancers, immune and autoimmune conditions, osteoporosis, pain characterization and treatment, depressive disorders, and more.[47,48,49,50] Disparities may also present as lack of access to medical devices and in clinical outcomes.[51]

Women in the United States are more likely than men to have undiagnosed conditions, have a worse prognosis after acute events for certain conditions, experience more years in poor health or living with a disability,[52] be at risk of adverse events from drugs and high-risk medical devices, and expend more out-of-pocket costs.[53,54] Health disparities also exist among women based on race and ethnicity.

The root causes of disparities are multidimensional and outside the scope of this work. However, existing research teaches us that the causes of these variances include circumstances driven by geography, structural and social determinants of health, and other complex dynamics that contribute to health inequities and access challenges for women in the United States and globally.[55,56] See also Appendix 1 for additional background.

FUNDING

Research prioritization and funding allocation is critical to the development of new technologies and treatment options for all people. Because of historical and current disparities, however, targeted funding to fill established knowledge gaps in the prevention, diagnosis, and treatment of conditions that affect women only or differently than men is crucial. Funding and evidence generation is the foundation of evidence-based medicine, intersects with health policy, and ultimately influences access to medical technologies that advance women's health. Highlights from our analysis of funding for women's health research and innovations include:

- Of the more than $40 billion in federal funding for National Institutes of Health (NIH) research, less than 10 percent was allocated to WHR. This level of funding was relatively consistent over the last decade despite NIH budget increases.[57]
- Funding for conditions like endometriosis, fibroids, pelvic floor disorders, polycystic ovary syndrome (PCOS), postpartum depression, uterine cancer, vulvodynia, and others that are specific to women have remained low, and funding for these conditions has remained flat for over a decade.
- NIH funding patterns favor male-dominant conditions three to one, overfunding conditions that affect men primarily and underfunding conditions that afflict women primarily when taking disease burden into account.[58]
- Our update of this research methodology suggests recent progress toward more equitable funding distribution, with 10 out of 18 (56%) female dominant/semi-dominant conditions underfunded compared with 7 out of 14 (50%) of male conditions overfunded in the context of burden.[59]
- Progress is also occurring through the National Institute of Child Health and Human Development, with research into some women's health conditions taking place under this branch. These studies focus on topics such as maternal mental health, pregnancy complications, and the impact of health risks during pregnancy; however, it is unclear how recent NIH restructuring will affect these efforts.[60,61]
- Women's health is among the most underfunded investment sectors, with venture capital in women's health cited at 2 percent of capital markets.[62,63]
- High-impact investment collaboratives have recently been established to flow capital toward diagnostic, treatment, and preventive innovations for women, with the recognition that venture funding of health innovations is projected to grow from $41 billion in 2023 to $66 billion in 10 years.[64,65,66]

NIH Spending on WHR Is a Fraction of Overall Grant Allocation

In response to a request from Congress, the National Academies of Sciences, Engineering, and Medicine (NASEM) released an analysis in 2024 of NIH funding for research on conditions that are female-specific, more common among women, or that affect women differently.[67] NASEM found that NIH spending on women's health research was a fraction of overall grant spending from 2013 to 2023, comprising 8.8 percent ($33 billion) of all NIH research grant funding ($376 billion) over the 10-year timeframe of the study and ~8 percent ($3.4 billion out of $40.2 billion) in the most recent single year evaluated (2023). Conditions highlighted in the report include endometriosis, polycystic ovary syndrome, and uterine fibroids, as well as the health effects of menopause, associations between pregnancy complications and chronic conditions later in life, and women's more negative cardiac outcomes after heart attack or stroke relative to men's.

The authors argued for additional NIH funding of $15.7 billion over five years to elevate the Office of Research on Women's Health into a new institute to expand its scope and capacity, to establish a new fund to support interdisciplinary women's health research and expand related workforce.

The NIH responded to the NASEM report with a public statement supporting the critical need for women's health research, though noting that the NASEM analysis understates ongoing research through NIH institutes.[68] This discrepancy between NASEM findings and NIH statements on funding levels perhaps illustrates the challenge to accurately identify and assess biomedical research funding streams and topics studied.

NIH Funding Patterns Favor Conditions That Affect Men

The NASEM analysis of health grant funding highlighted the disproportionate allocation of funding in part by citing prior work that evaluated funding relative to disease burden. Across 34 conditions and diseases evaluated, almost three-quarters of the instances in which a disease primarily affects one sex, the funding pattern favored males, meaning either the disease impacts more women and is underfunded based on the burden of disease, or the disease has a great bearing on men and is overfunded (Figure 1).

Figure 1. Published Research Shows NIH Funding Patterns Favor Male Conditions

Allocation of NIH Research Funding Across Diseases

Female dominant diseases, such as chronic fatigue, migraines, anorexia, and endometriosis are among the most underfunded by the NIH.

Mirin, A. Gender Disparity in the Funding of Diseases by the U.S. National Institutes of Health. Journal of Women's Health. Volume 30, November 7, 2021. Gender Disparity in the Funding of Diseases by the U.S. National Institutes of Health (2021).

70-75%

Male favored diseases

25%

Female favored diseases

"In nearly three-quarters of the cases where a disease afflicts primarily one gender, the funding pattern favors males, in that either the disease affects more women and is underfunded (with respect to burden), or the disease affects more men and is overfunded"

2019 funding data
2015 U.S. disease burden data

Because the findings presented in Figure 1 were based on published research using 2015 disease burden and 2019 funding data, we attempted to update the NIH funding pattern research following a similar method using more recent data, 2023 NIH funding and 2021 disease burden metrics.[69,70,71] Similar to the published research approach, we normalized funding levels to disease burden using Disability Adjusted Life Years adjusted to 2023 U.S. Census Bureau population estimates. We focused on diseases with more recent available data for both metrics and assigned diseases to male-dominant/semi-dominant or female dominant/semi-dominant groupings consistent with the prior published work based on whether the disease is proportionately more prevalent among men or women,[72] though complete data were unavailable to fully replicate and update the prior study. A power-law regression analysis was used to model funding relative to disease burden. Our findings suggest progress with underfunded disease states (compared with burden) at a more similar proportion for male and female dominant/semi-dominant conditions. For the conditions with data available to analyze under this approach, our analysis suggests 56 percent of female dominant/semi-dominant conditions and 50 percent of male-dominant/semi-dominant conditions are underfunded compared to disease burden.

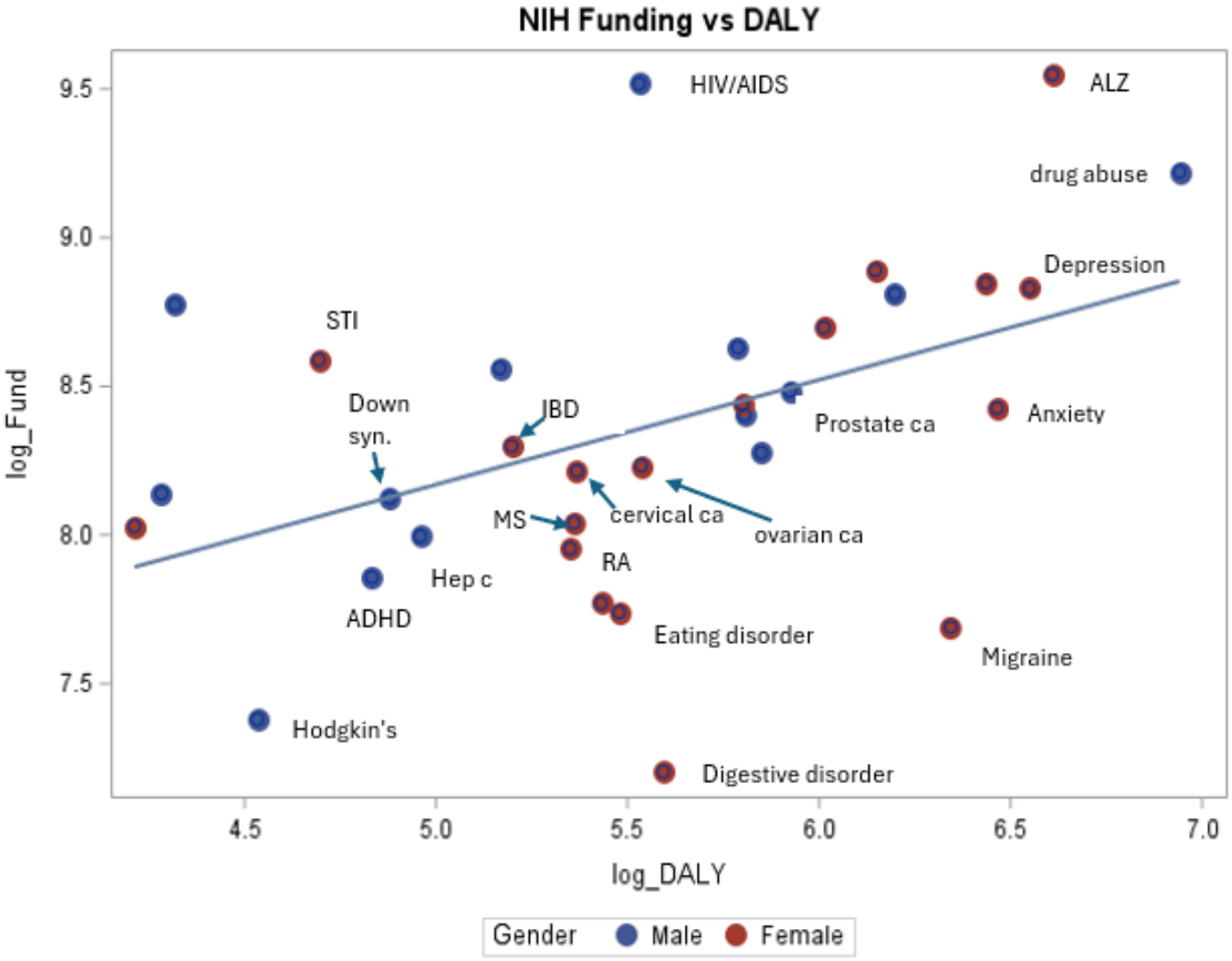
Table 1. Updated Data Suggest Funding Patterns Continue to Favor Men

Category	Female Count	Male Count
Total conditions captured	18	14
Conditions underfunded	10	7
Percent underfunded	56%	50%
Conditions overfunded	8	7
Percent overfunded	44%	50%

Source: HMA analysis of 2023 NIH funding data and 2021 disease burden data. Methodology adapted from: Mirin, A.

Figure 2 illustrates results from the funding allocation model compared to disease burden analysis. Those conditions falling under the line represent disease states that are underfunded benchmarked against burden following this approach. Conditions above the line reflect overfunded conditions in this paradigm.[73] Conditions that were classified in the original published work as male-dominant/semi-dominant are labeled with a blue dot in Figure 2, and those ascribed as female dominant/semi-dominant are identified in red based on which sex is more likely to experience the disease or condition.

Figure 2. Updated NIH Funding Allocation versus Disease Burden



Source: HMA analysis of 2023 NIH funding data and 2021 disease burden data. Methodology adapted from: Mirin, A.

Implications of 2025 NIH Funding Cuts and Restructuring Are Uncertain

Caps on federal payments for indirect costs of conducting research and grant reconsiderations or terminations in 2025 consistent with new federal government priorities may have disproportionate implications for clinical trials and medical research.[74] Executive orders that preclude federal funding for research-specific topics and major restructuring at the U.S Department of Health and Human Services (HHS) are likely to have significant, and still to be determined, impacts on women's health research and programs (see Appendix 2). In an already underfunded environment, these constraints could further challenge the study of women's health topics and inhibit breakthroughs intended to improve women's health, potentially making private sector investment pivotal to advancements.

Women's Health Market Is Projected to Grow

Women's health is among the most underfunded investment sectors, with venture capital in women's health cited at 2 percent of capital markets.[75] High-impact investment collaboratives have been established recently to direct capital toward diagnostic, treatment, and preventive innovation for women in recognition that venture funding of health innovations is projected to grow from $41 billion in 2023 to $66 billion in 10 years and is a sector to watch.[76,77,78,79] While the women's health sector has steadily grown since 2018, with significant expansion potential, sustained investment in women's health startups with continued and late-stage funding remains an ongoing challenge.[80] Funding options are often unavailable or structured in a way that makes it challenging to bring women's health innovations from an early stage all the way to commercialization. Early-stage and continued financing from government, venture capital, or private equity sources may be insufficient to bring companies to the point where they can be acquired or become public.[81]

CODING: THOUGH MOST SERVICE AND PROCEDURE CODING IS SEX AGNOSTIC, GAPS EXIST

Coding systems provide a uniform way to identify diagnoses, medical items, services, and procedures furnished in patient care. In the fee-for-service (FFS) healthcare ecosystem, a condition or service must be reportable to a health insurance company using a nationally recognized billing code before the healthcare clinician or provider such as a hospital can be reimbursed for providing that care and incurring expenses to do so. When a billing code is unavailable to report a service to a third-party payer, such as Medicare, Medicaid, or private insurance company, patients might pay out of pocket for care, limiting affordability, potential utilization, and realization of clinical benefit.

Highlights from our coding review include:

- Leveraging the national code set used to identify services and procedures on healthcare transactions has been raised by prominent clinicians as an opportunity to address health equity gaps.[82]
- Workgroups have been formed to rectify identified gaps in the maternity care professional services code set to better reflect the quantity and type of care provided throughout the course of a pregnancy, labor, and delivery management.[83,84,85]
- Recent efforts have expanded the diagnostic coding system to capture greater specificity, for example updating the codes to report an endometriosis diagnosis from one to several to reflect multi-organ manifestations and other variants, which will lead to improved tracking and research of this understudied condition.[86,87]
- Inaccurate or outdated diagnostic coding for female sexual health (FSH), vulvodynia and pelvic floor pain disorders also have been identified.[88]
- Challenges may exist for treatments of major conditions affecting women across the lifespan if coding does not sufficiently distinguish different approaches or technologies, thereby limiting reimbursement. For example, professional coding of laparoscopic endometriosis surgery has been raised in the public domain as an example in which a single code to report for any surgical method applied is insufficient.[89,90]
- The Centers for Medicare & Medicaid Services (CMS) also has recently sought to fill coding gaps in several areas, including for digital mental health treatment (DMHT) for software devices cleared by the Food and Drug Administration (FDA) with the goal of providing access to behavioral health services.[91] These efforts would benefit women, who disproportionately experience several common mental health conditions.
- The process and evidentiary standards to establish new codes for physicians' services and ambulatory procedures is viewed by innovators as a significant hurdle to commercialization and patient access to medical innovations with calls for more transparency, collaboration and predictability.[92]

Strong evidence requirements are an important safeguard in the coding system; however chronically underfunded women's health research leaves open the possibility that well-documented gaps in WHR could flow through to the code development process—a critical step for market access. Further, when a condition is understudied, clinicians may have a more limited understanding of the clinical manifestations of the disease, and payers may have inadequate information to reflect diagnoses in medical necessity criteria.

Process to Fill Coding Gaps Requires Clinical Evidence

The entities that maintain the nationally specified code sets generally rely on the medical community to identify gaps in classification and nomenclature for medical services and diagnoses and to seek coding changes to fill those gaps. This requires meeting evidentiary criteria. Under the Current Procedural Terminology (CPT®)[93] code set, which is used to report services and procedures that clinicians (i.e., professional services) and outpatient providers (e.g., hospital outpatient departments) furnish, evidentiary standards include well-designed studies published in peer review literature, a required number of studies with findings reported on different patient populations and with different authors, as well as demonstrated clinical efficacy expectations.[94] These requirements exist even when services and procedures using devices or other technologies have received FDA approval or clearance. The criteria are intended to ensure the service has proven clinical benefit and can be safely delivered. Other criteria to obtain a new CPT® code also include that the service is performed by many healthcare professionals in multiple locations (commonly referred to as the "widespread use" criteria). Services reported with codes that meet these requirements are referred to as "Category I".[95]

Services Not Meeting Evidence Requirements Are Reported with Temporary Codes

Avenues are in place for newer services and services involving emerging technologies that fall short of these evidentiary or widespread use criteria to obtain a temporary code to track utilization, support future research studies to demonstrate clinical efficacy and outcomes, and to seek reimbursement. These codes are commonly referred to as Category III, and FDA approval or clearance, when applicable, is unnecessary to obtain a new emerging technology code. Services reported with a Category III code do not automatically imply that there is a lack of findings to support clinical efficacy, safety, or applicability to clinical practice[96]; however, payers may interpret Category III as such, potentially introducing payer bias into the system. For Medicare, pricing of these services is left to Medicare Administrative Contractor discretion, which results in variability in payments.[97]

Code Sets Require Constant Updating and are Generally Sex Agnostic

Maintaining the national code sets depends on "constant updating to reflect changes in medical practice,"[98] understanding of clinical conditions, and new discoveries. Most of the more than 8,000 professional and outpatient services/procedure coding is sex agnostic, meaning the same code is used to report the service regardless of the recipient of the service. This situation leaves female-to-male comparisons primarily focused on reproductive or genital system procedures and areas unique to women, such as maternity care and delivery.

Diagnosis Coding Recently Improved for Endometriosis, but Other Gaps Remain

Coding of diseases, function, and disability often are referred to as diagnostic coding and is standardized in the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code set. Diagnosis codes reflect morbidity, mortality, and reasons for healthcare encounters. These codes are used to identify a person's condition, to track disease incidence and prevalence, to identify disparities through research, and, among payers, to specify when a condition, illness, or disease supports the medical necessity of a service or procedure.

CODING AFFECTS CARE

When a billing code is unavailable to report a service to a third-party payer, such as Medicare, Medicaid, or private insurance company, patients might pay out of pocket for care, limiting affordability, potential utilization, and realization of clinical benefit.

ICD-10-CM comprises more than 70,000 diagnosis codes, making it difficult to identify where gaps or underrepresentation of diseases exist.[99] Doing so requires clinical expertise, understanding of patient populations, details of the condition, clinical presentation, among others. Coding changes and updates are implemented twice a year and typically driven by the medical community. The process is coordinated through the HHS Interdepartmental ICD-10 Coordination and Maintenance Committee, with diagnostic coding issues led by the Centers for Disease Control and Prevention (CDC) and inpatient procedure coding matters led by CMS.[100] Although inpatient procedure coding influences reimbursement for hospital stays, diagnostic coding is the driver of case rate payments for acute hospital care. Requests for new codes or revisions also include an application process, discussion of clinical significance, rationale, and supporting evidence.

The significant expansion of endometriosis diagnostic coding in 2022 after 40 years of limited disease specification was characterized as a “historic development for endometriosis care” by advocates for improved funding and research of this condition, which affects up to 15 percent of reproductive age women in the United States and up to 5 percent of postmenopausal women.[101,102] In other areas, such as FSH, researchers identify incomplete, inaccurate or outdated diagnostic coding including for “vulvodynia” and pelvic floor pain disorders with some diagnoses grouped under general rather than specific classifications.[103]

COVERAGE: INSURER DECISIONS TO GRANT, RESTRICT, OR EXCLUDE SERVICES

Health insurance coverage broadly refers to contractual arrangements between a person or group paying premiums to a health insurance company, or through enrollment in a US government program, to help pay for the costs of receiving healthcare. Insurance companies can differ significantly in covered benefits and out-of-pocket cost sharing requirements. Insurance companies and government programs such as Medicare maintain processes and evidentiary requirements for making coverage determinations nationally or regionally. Though explicit coverage policy is not always necessary for items or services to be paid, noncoverage determinations, opaque processes, or coverage bias can prevent people from accessing care and innovative technologies. Highlights from a coverage perspective include:

- Health insurance coverage plays a central role in access to care; women with health insurance coverage are more likely to have better access to basic care and emerging advances.
- An estimated 10 percent of women in the United States are uninsured, compared with 13 percent of men, because women are more likely to have lower incomes and to qualify for Medicaid.[104]
- Medicaid covers more births (~41%) than any other US payer. Its enrollees are disproportionately women of reproductive age, and pregnancy may also be the reason a person qualifies for Medicaid.[105]
- Medicaid coverage gaps after giving birth have historically been common,[106] and most states (49) have expanded postpartum coverage from 60 days to one year to help address this disparity.[107] Coverage alone, however, does not guarantee continuity of care or robust postpartum supports.
- The potential of new technologies to reach more patients, monitor high-risk people for complications during pregnancy and postpartum, or to facilitate access to behavioral health treatments offers significant promise; however, commercial and Medicaid coverage for these technologies is highly variable.
- Coverage gaps also exist with established technologies. For example, coverage can be lacking for supplemental imaging for women with dense breasts who are at higher risk of developing breast cancer.[108]
- With 60 percent of women (ages 19–64) obtaining health insurance coverage through employer-sponsored plans,[109] commercial payer medical policy is highly relevant, particularly from a service or technology level perspective.
- There are examples of commercial payers classifying codes used to report emerging technology as investigational and not covered due to insufficient evidence.[110,111] While this affects coverage of emerging technologies for both men and women, gaps in women's health research may mean the evidence to support coverage is more limited, potentially exacerbating coverage restrictions for women or for conditions that disproportionately affect them.

Coverage Processes Lack Transparency and Consistency

For innovators of women's health technologies, developing robust data to meet health insurer coverage requirements may be particularly burdensome given challenges in securing funding and research prioritization. Insurance coverage, whether through Medicare, Medicaid, or private insurance companies, is contingent upon specific criteria. The evidence base must demonstrate clinical efficacy of a technology, a clear benefit to medical decision making, patient health or outcomes, and, for some payers, include other factors such cost-effectiveness.

Insurance companies often lack transparency in how they assess clinical data and make coverage decisions. Some insurers subscribe to outside technology assessment entities, while others conduct in-house reviews. Evidence-based clinical practice guidelines are often used in coverage decisions, rendering medical specialty society guidelines notably influential. Nevertheless, the criteria organizations use to endorse these guidelines and clinical recommendations are sometimes difficult to access.[112] Varying requirements, standards, and processes result in inconsistent coverage policies across plans.

Most Medicare coverage decisions are made by local administrative contractors through CMS's Local Coverage Determination (LCD) process, but the CMS National Coverage Determination (NCD) process significantly influences the health insurance coverage landscape. However, CMS's NCD process has been criticized by stakeholders in recent years for delays in coverage and a lack of transparency. Specifically, stakeholders have asserted that procedural delays, capacity constraints, and lack of transparency have caused CMS's NCD process to fail to keep pace with technological innovation.[113] Further, specific to the topic of this analysis, in the past five years, CMS's NCD process has generated no coverage determinations focused solely on women's health.

CMS has demonstrated a commitment to modifying agency coverage process to facilitate Transitional Coverage of Emerging Technologies, including the implementation of early NCD evidence reviews, the provision of opportunities for manufacturers to work with CMS to develop coverage evidence plans, and reduced uncertainty through expedited Medicare coverage of certain FDA-designated breakthrough devices.[114] The medical technology community has long supported improved processes to create clear and consistent coverage pathways for new and innovative medical technologies. These issues and solutions are not specific to women's health technologies but could be tailored to better address the unique challenges encountered by innovators of women's health technology. It could also include broader and regular consideration of the potential for bias in the assessment of clinical evidence for services and technologies specific to women.

Medicaid Coverage Discontinuity/Low Reimbursement Are Barriers to Improving Maternity Care

Medicaid has a unique role in this space because of its importance in coverage and payment for women's health services. Medicaid covers more births (~41%) than any other payer, and enrollees are disproportionately women of reproductive age.[115] Because of differing eligibility criteria, federally and among states for adults depending on whether they are pregnant, are parents, and how much time has elapsed postpartum, pregnancy may be the reason a person qualifies for Medicaid, until 60 days and (in most states) one year postpartum. A total of 41 states have expanded Medicaid eligibility to 138 percent of the federal poverty level, and 49 states have expanded postpartum coverage to a year rather than 60 days to address postpartum coverage gaps.[116]

Despite these positive steps, coverage discontinuities and low reimbursement in Medicaid remain barriers to improving maternity care outcomes and innovation in the program that covers more maternity care than any other, which has implications for perinatal care access and women's overall health. Even with expansions in place, gaps remain. For example, late entry to prenatal care because of a lack of coverage is an ongoing challenge. Low Medicaid payment rates contribute to poor provider access, exacerbating network adequacy challenges in maternity care, particularly for specialty care and behavioral health services. Postpartum coverage and service availability can be fragmented, especially once full-scope pregnancy Medicaid ends.

REIMBURSEMENT: OBSERVATIONS OF HIGHER PAID AMOUNTS FOR MALE SERVICES

Reimbursement refers to the amount an insurer such as a health plan, a state Medicaid agency, or traditional Medicare will pay to a physician or provider for the care furnished to patients. Payment amounts are based on rates set by the payer and other contractual agreements, with different methodologies used to set payment levels for different types of providers and payment structures. The general premise is that providers incur costs to furnish care and should be reimbursed for the time, skill, and resources expended. Inadequate reimbursement for care rendered contributes to access constraints, limits investment in technology and dampens market success. Highlights of reimbursement findings include:

- Reimbursement for healthcare products and services furnished in patient care is essential to market success and affordability.[117]
- Although most coding of healthcare services and procedures is sex agnostic, it is possible to make meaningful reimbursement comparisons between male and female reproductive system procedures.[118,119]
- Following this approach, we evaluated national average commercial payer reimbursement to physicians and found higher payment for the male procedure in 89 percent of the code pairs analyzed.
- A similar trend appears in Medicare payments to hospitals furnishing outpatient care with higher reimbursement to the hospital outpatient department (HOPD) for the male service in 73 percent of the code pairs analyzed; however, differences in rate setting methodology can explain some of this gap.
- Recognizing differences in Medicare hospital outpatient reimbursement may be driven by policies that package multiple services into a single payment, we also evaluated national average measures of hospital charges and found higher markups more often for male-related procedures than for the female counterpart.[120]
- From a hospital inpatient perspective, we see a similar trend among commercial payers with higher observed average allowed amounts per admission paid to acute care hospitals for diseases and disorders of the male reproductive systems than for the female.
- When compared with Medicare amounts, we also observe commercial inpatient average allowed amounts paid at a higher percent of Medicare for male reproductive system diseases and disorders.
- Base payment rates to inpatient hospitals for pregnancy, childbirth and the puerperium are the lowest across all major diagnostic categories (MDCs) for commercial payer data analyzed.
- Among Medicaid state agencies, reimbursement for labor and delivery can vary widely with over a decade of payment reforms intended to improve quality and safety; however, low reimbursement rates and insufficient operating margins contribute to declining availability of hospital obstetric care.[121]

Potentially Comparable Male and Female Procedures

When a single code is used to report a service (such as a physician office visit) or a treatment (such as vascular embolization to treat bleeding caused by uterine fibroids, to treat tumors or other conditions) there is no difference in payment when the service is provided to a man or a woman. This is the case for most codes in the CPT® coding system. Hence, comparisons are limited to services and procedures tailored to different anatomy when the service itself is generally analogous (e.g., biopsy of male versus female genitalia). We referenced prior published work using code pair comparisons, received guidance and insights from unofficial conversations with experts, and conducted our own coding assessment to identify potentially comparable code pairs for analysis. We state "potentially" comparable given that there could be clinical or other circumstances we are unaware of as part of this work that could limit the analogy between the code pairs selected. Using these sources, we identified 40 potentially analogous male/female (M/F) code pairs for analysis (Appendix 3), but not all pairs had sufficient data for payment comparisons and some codes may be used in more than one pair.

Differential Reimbursement Observations for Comparable M/F Procedures

Payment for Professional Services

Across all healthcare settings, physicians report the care they provide using the CPT® code set. In an FFS system, reimbursement (or payment) is made for each code submitted when medical necessity and coverage criteria are met. Reimbursement to healthcare professionals is referred to as the "professional fee" and is intended to pay the physician (or other qualified healthcare professional) for their time, intensity, mental effort and judgment, and costs incurred to provide care. Observations of gaps in traditional Medicare reimbursement to physicians for comparable male and female reproductive system procedures have been debated with some experts finding no marked disparity in Medicare's valuation of clinician services and others arguing the Medicare physician reimbursement system embeds structural sex discrimination in the system.[122,123,124, 125]

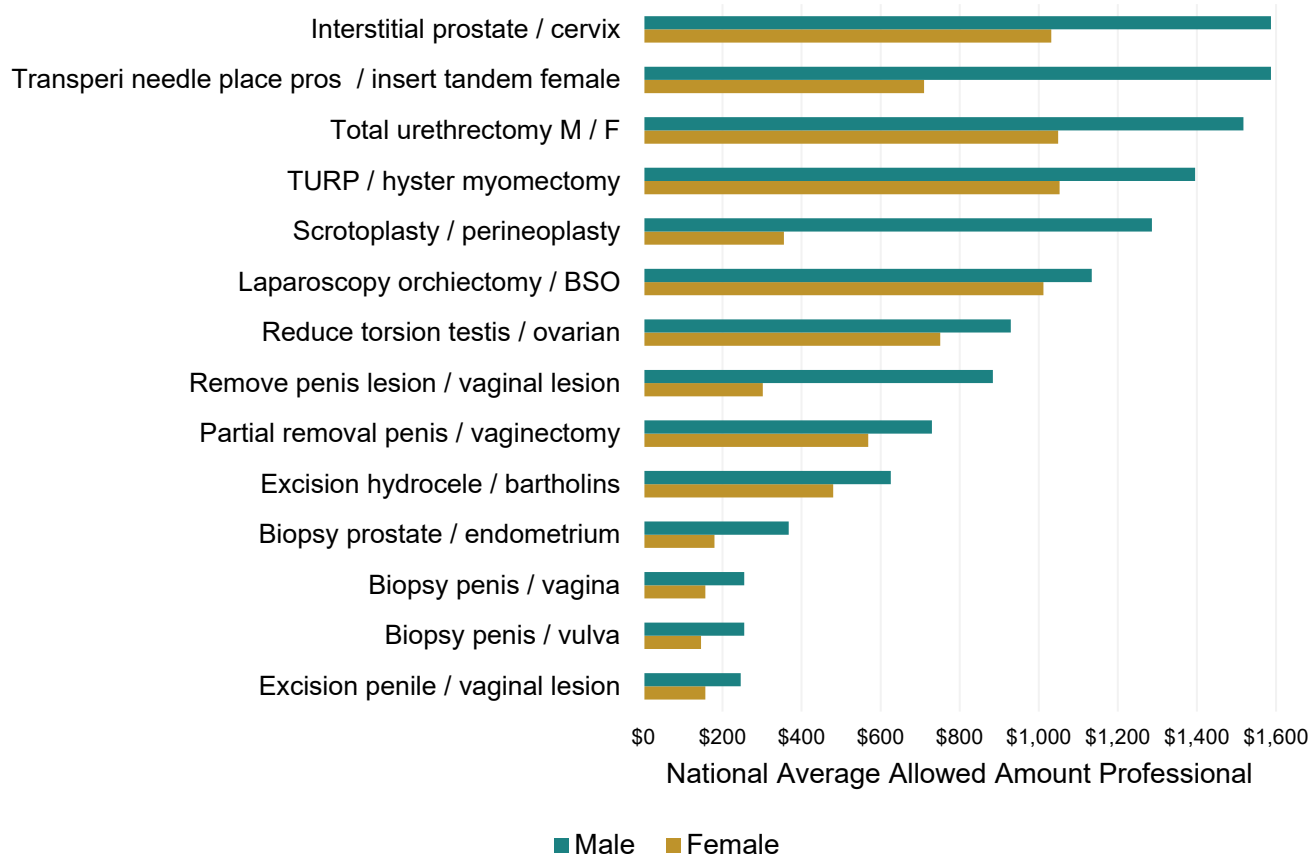
The Medicare physician fee schedule (PFS) is generally understood to be used by other payers as a baseline for establishing payments to clinicians (and therefore similar findings might be expected when analyzing other payer data), but commercial allowed amounts are driven by contract arrangements and other factors that extend beyond the Medicare PFS. We were accordingly interested in assessing allowed amounts paid by commercial insurance companies to professionals to determine whether observations of payment differentials between potentially analogous services are present. We present summary observations of average allowed payment amounts from a calendar year (CY) 2022 commercial payer dataset containing claims (in and out of network) for a nationally representative sample of age 65 and younger enrolled lives across different types of health plans.[126]

Commercial Payer[127] Snapshot of Average Allowed Amounts Paid to Professionals

89 Percent of Code Pairs Analyzed Reflect Lower Payment for the Female Procedure

Of the 40 potentially analogous code pairs identified, we evaluated commercial payer average allowed professional payment amounts in CY 2022 for 27 (68%) of them. If a code in a pair had no or low unit counts, we dropped it from the analysis out of concern that low volume may yield less reliable information on payment. Of the 27 code pairs analyzed, 24 (89%) reflect observations of lower national average allowed amounts for the female-focused service. This difference in national average allowed amounts between these male and female-focused services range from $67 to $1,593. Figures 3 illustrates the national average allowed amounts from analysis of 2022 commercial payer data for the potentially analogous male and female codes pairs with observations of higher payments for the male procedure.

Figure 3. National Average Allowed Amounts (Professional Fee) for Potentially Analogous M/F Services



Source: Analysis of 2022 Marketscan data, in- and out-of-network.

For example, biopsy of the penis is reported with code 54100, with a national average commercial payment amount to the professional of $255 in CY 2022, whereas biopsy of the vagina is reported with code 57100, with an observed national average payment amount to the professional of $157—an approximately 39 percent ($98) difference in the national average rate for the vaginal biopsy compared to the penile biopsy. Table 2 presents this information for three code pairs extracted as examples.

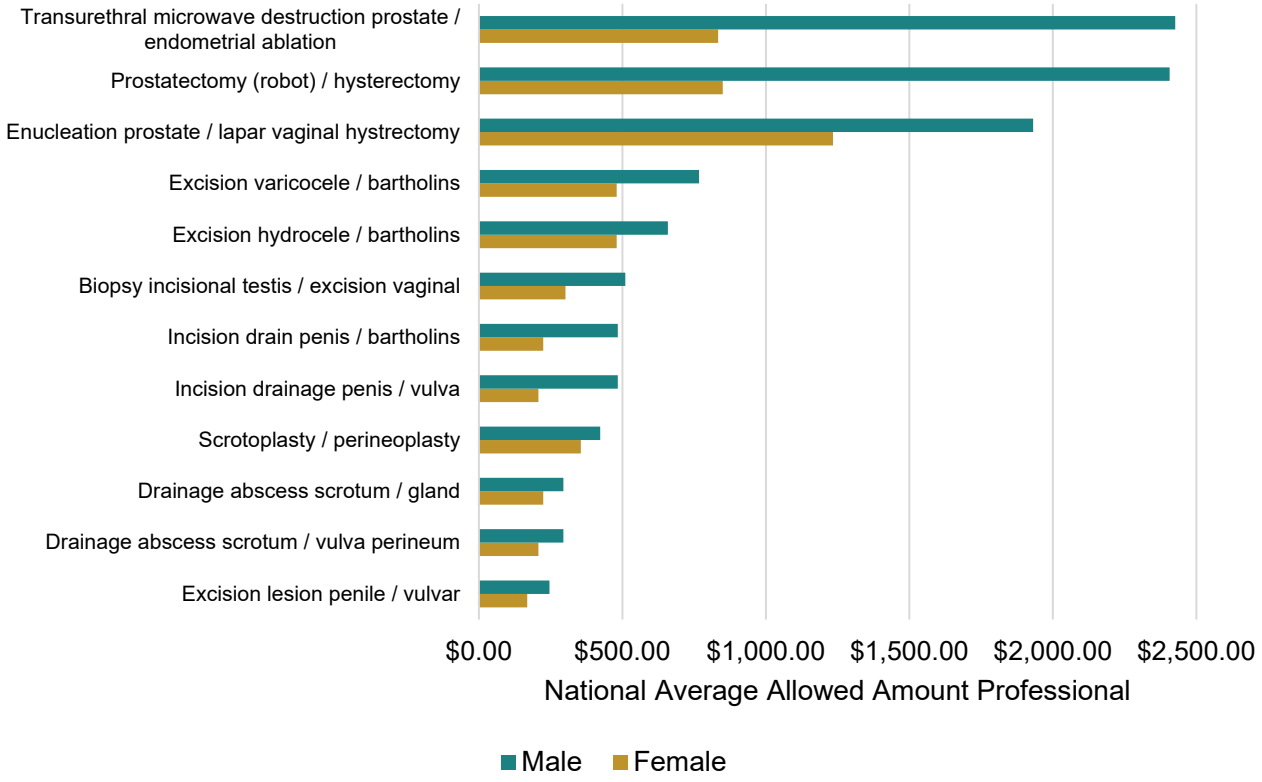
Table 2. National Average Allowed Amounts for Potentially Analogous M/F Services, Select Examples of Male Service Paid Higher than Comparable Female Service

Code	Lay Description	Avg MrktScan Allowed Amt	Total Units
54100	Biopsy penis	$255	821
57100	Biopsy vagina	$157	565
Difference		$98	
		-39%	
54060	Excision penile lesion	$246	241
57100	Excision vaginal lesion	$157	565
Difference		$89	
		-36%	
55700	Biopsy prostate	$368	10,086
58100	Biopsy endometrium	$180	41,392
Difference		$188	
		-51%	

Source: Analysis of 2022 Marketscan data. Values rounded, payment rates with decimal points were used to calculate percentages.

Figure 4 shows the national average allowed amounts for the remaining code pairs with observed higher national average commercial allowed amounts paid to professionals for the male-focused service compared with the potentially analogous female-centered procedure.

Figure 4. National Average Allowed Amounts (Professional Fee) for Potentially Analogous M/F Services, Additional Examples



Source: Analysis of 2022 Marketscan data in and out of network.

11 Percent of Code Pairs Analyzed Reflect Higher Payment for the Female Procedure

Of the 27 potentially analogous code pairs analyzed, three (11%) reflect higher national average payment to the professional from the commercial claims dataset for the female-focused procedure than for the male-specific service. The three pairs with higher national average professional payment amount for the female service are presented in Table 3.

Table 3. Code Pairs with Higher National Average Payment to the Professional for the Female Services (highest paid service listed first)

Code	Description	Avg MrktScan Allowed Amt	Total Units
56501	Laser vulva	$228	1,905
54057	Laser penis	$153	75
Difference		$75	
		-33%	
56620	Simple complete vulvectomy	$845	711
55150	Resection of (removal of) scrotum	$707	111
Difference		$137	
		-16%	
56515	Destruction vulvar lesions extensive	$339	708
54065	Destruction penile lesions extensive	$307	874
Difference		$31	
		-9%	

Source: Analysis of 2022 Marketscan data. Values rounded, payment rates with decimal points were used to calculate percentages.

Payment for Professional Services Commercial Payer Snapshot Limitations

Though we observed higher payment for the male service in most code pairs analyzed, the set of comparable services is limited. We removed services with no or very low volume from the analysis and note that the code pairs analyzed reflect relatively low volume services. Hence, the conclusions that can be drawn from these observations may not be generalizable. Details on the specific payer, population, or how the commercial payment amounts were established are unavailable. Findings have been presented as a reference point.

Hospital Providers of Outpatient Services

Payment for Hospital Outpatient Department Services, Medicare Snapshot

Hospital providers of outpatient services also report CPT® codes on healthcare claims. HOPD claims are typically filed every 30 days and may include multiple services; the combination of services on a claim may affect how the payment amount is calculated. Payment amounts referred to as the facility fee are intended to pay the hospital for costs incurred, such as for nursing staff, supplies, equipment, rooms, and other costs of furnishing care. Payments to hospitals for outpatient department services rendered to beneficiaries enrolled in the traditional Medicare program are established by the CMS Hospital Outpatient Prospective Payment System (OPPS).[128]

In the OPPS, codes are assigned to an Ambulatory Payment Classification (APC) based on clinical similarity and resource costs. CMS estimates costs using data from hospital cost reports and hospital charges recorded on claims. The payment rate assigned to an APC is based on the geometric mean (average) costs of all the services within the APC. Payment is made at the APC level, meaning all services in the APC are paid the same amount. The intent of the system is for hospitals to break even overall.

Several factors influence the assignment of an individual code to an APC, including clinical characteristics, hospital charging practices, CMS's estimation of cost, the frequency (volume) of the service, and of additional items (such as devices) used in combination with the service. These additional items may be incorporated into the average cost estimate. When multiple items and services are included in the estimate of the average cost of a service (such as the primary procedure), it is referred to as "packaged services" or "packaging," meaning that multiple costs are bundled into the ultimate payment rate calculated.

73 Percent of Code Pairs Analyzed Reflect Higher OPPS Payment for the Male Service

Using the potentially analogous M/F code pairs, we analyzed CMS OPPS payment rules and rates to identify if observations of differential reimbursement (gaps) between comparable M/F services are present in this payment system. We found 29 pair observations (73%) of the male service paid higher than the comparable female service; however, payment is based on the APC the code is assigned to, and we found significant technical differences in how those payment amounts are established, which drives differences in reimbursement levels.

Technical Differences in APC Assignment of Code Pairs Evaluated

Of the 40 code pairs evaluated, more than half (n = 23 or 58%) are assigned to an APC whose payment rate reflects significant packaging of multiple services into a single payment amount, referred to as a comprehensive APC (C-APC). This methodology makes comparisons of reimbursement amounts challenging and potentially unreliable because the comprehensive APC payment amount is based on multiple services reported with a primary procedure over a 30-day HOPD claim rather than on a single day for the specific service of interest.

Another eight code pairs (20%) reflect an OPPS payment situation in which one of the codes in a pair map to an APC with significant packaging policies such as a comprehensive APC and the other code does not. In these instances, the male service is consistently paid a higher rate; however, the male service is also assigned to a C-APC with significant packaging policies. This means the payment amount is intended to reflect the cost of more than just the procedure of interest. For this reason, CMS packaging policies could be the source of the payment rate differential.

Of the remaining code pairs evaluated from a hospital outpatient reimbursement perspective, seven (18%) map to the same APC making the payment amounts equal for each service in the pair. Another code pair (n = 1, 3%) is an inpatient only service not paid in the HOPD setting. The final code pair (n = 1, 3%) reflects a comparable situation in which both services are separately paid and significant packaging policies are not applied.

Code Pair Example Under Medicare Hospital Outpatient Prospective Payment System

As Table 4 shows, code 54060 is used to report an excision of a penile lesion. This code is placed in a skin procedures APC and paid a national average amount of $1,829 to the hospital outpatient department. A similar service performed on female anatomy is reported with code 57100 and is placed in a gynecologic procedure APC with payment to the hospital for the outpatient service at a national average amount of $871—less than half of what the male service is paid.

Table 4. CMS Payment to Hospital Outpatient Department, Separately Paid Pair Example

Code	Code Description	APC	APC Description	APC Payment
54060	Excision penile lesion	5054	Level 4 Skin Procedures	$1,829
57100	Excision vaginal lesion	5413	Level 3 Gynecologic Procedures	$871
Difference				$958
				-52%

Source: CMS CY 2025 OPPS, Status Indicator T (separate APC payment).

Cost reflects CMS calculation of geometric mean costs for each service.

APC CODE ASSIGNMENT

Several factors influence the assignment of an individual code to an APC, including clinical characteristics, hospital charging practices, CMS's estimation of cost, the frequency (volume) of the service, and of additional items (such as devices) used in combination with the service.

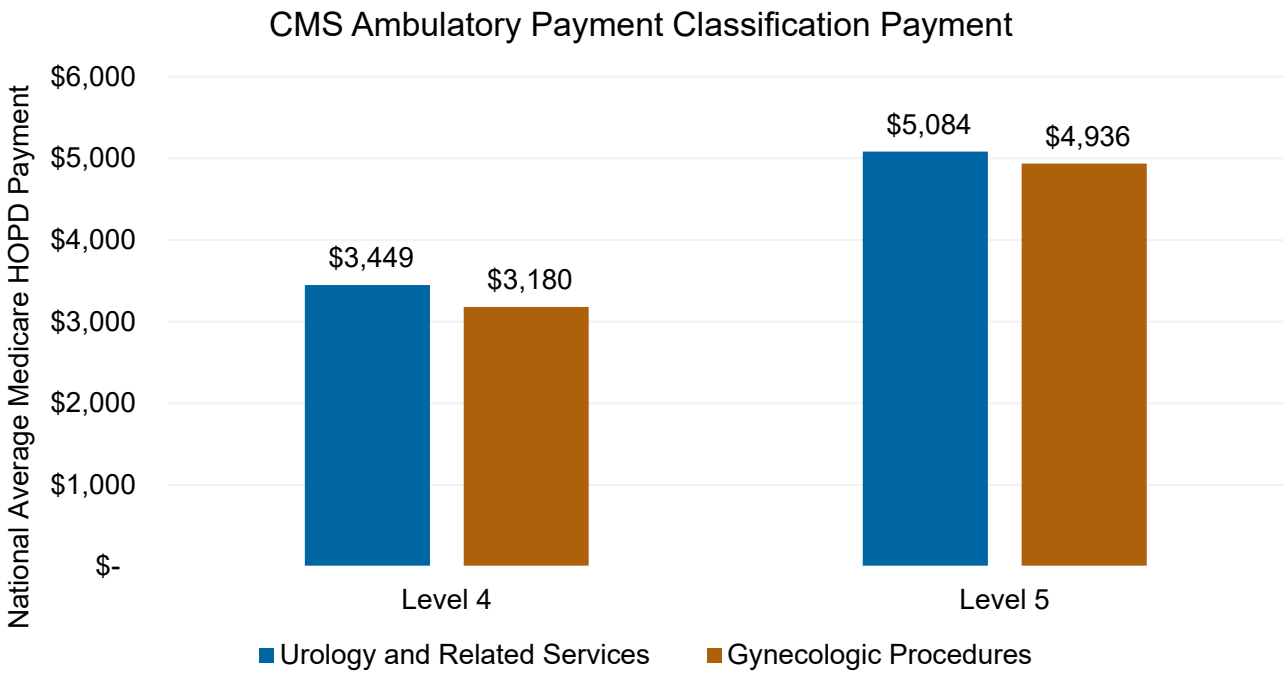
Though each service presented in Table 4 is paid separately under the OPPS, the payment level for the APC is established based on the geometric mean costs of all the services within the APC. In the above example, more than 80 services are included in the skin procedures APC the male procedure of interest is also assigned to, whereas only 10 services are assigned to the APC associated with the female procedure. These assignments make it difficult to compare payment for one discrete service with another as the APC payment rate is a function of all the services within an APC, the CMS derived cost of those services, and the volume associated with each. Therefore, the payment differential observed may be driven by the range of services and associated costs assigned to each APC rather than explicit difference between the code used to report excision of a penile lesion versus the code used to report excision of a vaginal lesion.

Nonetheless, these two codes could be placed in the same APC from a resource perspective. Advocates could use the comment period process associated with CMS annual rate setting rulemaking to bring this variance to the attention of Medicare officials for correction.

Ambulatory Payment Classification Example, Urology and Gynecologic APCs

Several of the code pairs evaluated are assigned to either the Urology and Related Services APC family (levels 1–8) or to the Gynecological Procedures APC family (levels 1–6). For example, in 10 pair examples, the male code maps to a level 4 Urology and Related Services APC and the corresponding female code maps to the level 4 Gynecologic Procedures APC, both are comprehensive APCs, meaning the payment amount reflects packaged services. The difference in payment for the level 4 urology C-APC and the gynecologic C-APC is $269, and the difference between the level 5 comparison is $147. These differentials could be driven by the frequency of additional packaged services (with costs that are bundled into the payment rate) and could be driven by hospital charging practices. Figure 5 presents the national average OPPS reimbursement amount for urology and related services and gynecological procedure APCs, with levels 4–5 as an illustration. Though the urology and related services APCs are presented because services of interest in this work fall into that classification, it should be noted that urology services are not exclusive to men.

Figure 5. CMS Payment to Hospital Outpatient Department, APC Example



Source: CMS OPPS CY 2025 addendum. Vales shown are rounded.

Urology and Related Services Code Level Example

One code pair of interest reflects a surgical procedure to remove the urethra (urethrectomy) and create an opening between the bladder and skin for drainage of urine (cystostomy). Separate codes are used for the male (53215) and female (53210) procedure. Under the OPPS, the male procedure is placed in a higher paid urology APC (level 5) and the female procedure is placed a level down (4) resulting in the female procedure paid, on average, 32 percent ($1,635) less than the analogous male service (Table 5). This placement is an artifact of the methodology used to calculate rates and how CMS estimates costs. Under the methodology, the male service has higher calculated costs than the female service, thereby driving the higher-level assignment. Because APC assignments are based on the geometric mean cost of services, if hospitals tend to bill more ancillary procedures or services alongside the male urethrectomy, those practices could also contribute to its placement in a higher APC group.

These services could, however, be placed in the same APC because they are clinically similar and are unaffected by any CMS rules that would prohibit classifying them in the same categories. Stakeholders could bring this possibility to the attention of the agency and request APC reassignment of the services to the same APC.

Table 5. CMS Payment to Hospital Outpatient Department, Urethrectomy Example

Code	Code Description	APC	APC Description	Cost	APC Payment
53215	Total urethrectomy male	5375	Level 5 Urology and Related Services	$6,030	$5,084
53210	Total urethrectomy female	5374	Level 4 Urology and Related Services	$4,777	$3,449
Difference					$1,635
					-32%

Source: CMS CY 2025 OPPS, Status Indicator J1 (paid through a comprehensive APC). Values are rounded.

Cost reflects CMS calculation of geometric mean costs for each service.

Generally Higher Hospital Outpatient Department Charging Practices for Male Services

As noted previously, rates paid under the OPPS are a function of several factors, including CMS's estimate of cost for items and services. CMS derives cost by applying a ratio of costs to hospital charges (cost-to-charge ratio, or CCR). Charges refer to hospital chargemaster fees recorded on a claim, whereas the CCR is derived from hospital cost reports for each individual cost center in a hospital's accounting system. The CCR reflects charges relative to costs. We analyzed the national average CCR for each code of interest and compared it across the M/F potentially analogous pairs. Our analysis shows that male-related codes tend to have lower CCRs than female-related codes suggesting that hospitals may apply higher fees to male-related services, which is consistent with an observation of higher reported charges for the male-related codes. Further investigation is needed before definitive conclusions can be made from these observations, as a CCR alone does not reflect the complexity of hospital billing practices, revenue centers, cost reports and how these factors feed into rate setting.

Hospital Inpatient Stays

Payment for Acute Care Hospital Inpatient Stays, Traditional Medicare Overview

When a traditional FFS Medicare beneficiary is admitted to the hospital, the facility is reimbursed for the patient's stay under the Medicare Inpatient Prospective Payment System (IPPS). The hospital receives a bundled payment for the entire hospitalization as per the case's Medicare Severity Diagnosis-Related Group (MS-DRG) assignment. Each hospitalization is assigned to a single DRG based on the patient's characteristics, the patient's diagnosis at discharge, and if applicable the major surgical procedure that occurred during the stay. The patient's condition(s) and any procedures performed are reported with the ICD-10 classification systems. The bundled payment is intended to provide reimbursement for the average cost of the case in the DRG rather than individual services. The system is designed to set rates prospectively using a rate setting process to establish the DRG payment amounts with the expectation that hospitals break even overall with some cases potentially over or under reimbursed.

Medicare IPPS New Technology Add-On Payment (NTAP)

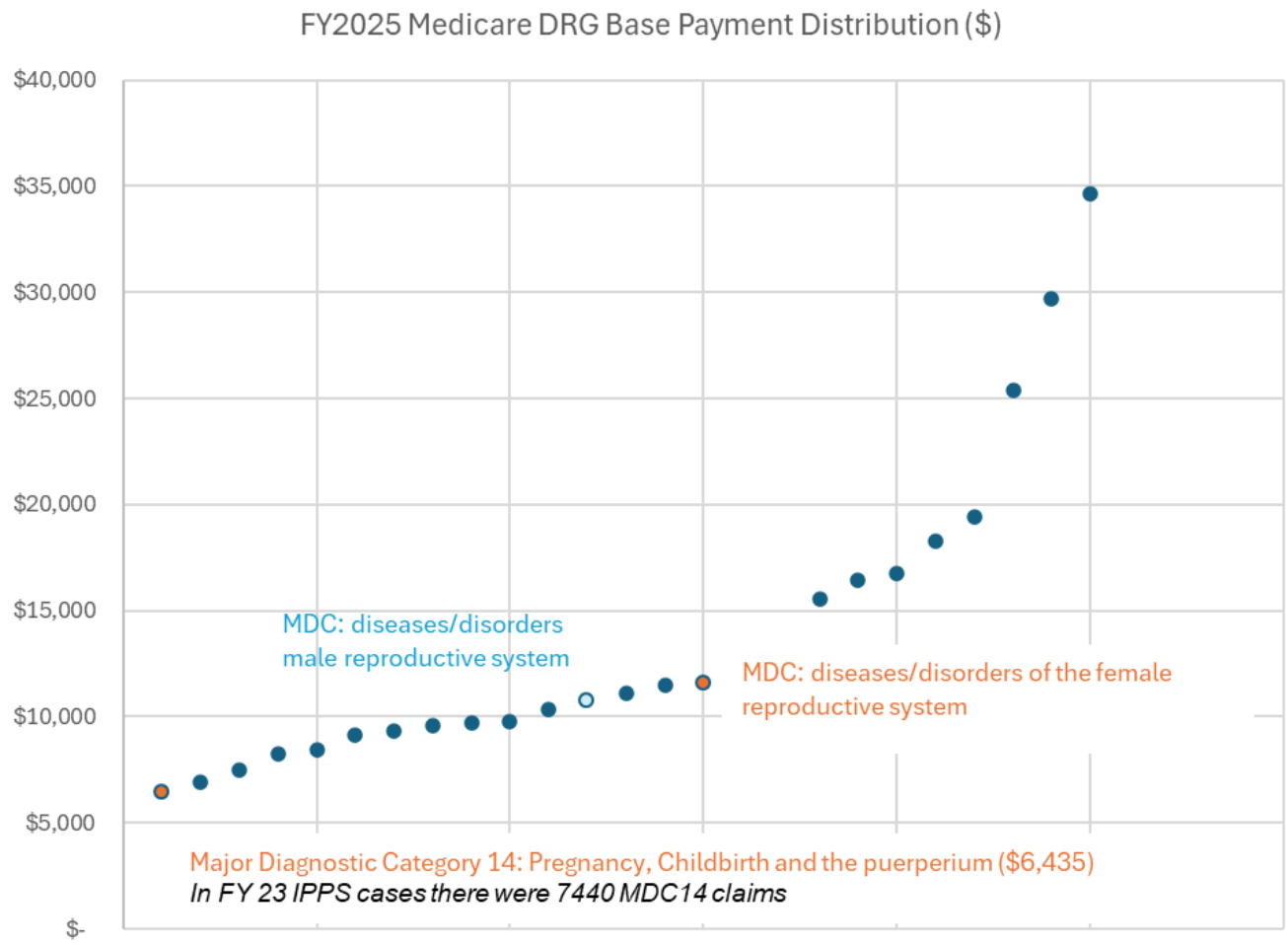
Most NTAPs granted are for new technologies used to treat both men and women. We conducted a high-level review of NTAP applications for fiscal years 2022–2026. We reviewed 172 applications,[129] two of which were for products designed specifically for women's healthcare, one of which is still in process,[130] and another an ovarian cancer indication.[131] From our high-level review, it appeared that no NTAPs were granted for products intended specifically for men's healthcare.

Items and procedures are not paid separately in the IPPS, except for certain new technologies that meet specific criteria. An application process is undertaken and may require evidence of substantial clinical improvement, among other criteria. Technologies with NTAP status are reported with ICD-10-PCS codes. When an NTAP is granted, a hospital may receive an additional payment if specific conditions are met. The patient must be a traditional FFS Medicare beneficiary (the NTAP program is inapplicable to Medicare Advantage), the hospital must report the appropriate code on the claim, and the cost of the claim must exceed the DRG payment amount. The additional payment amount is time limited, up to three fiscal years.

Payment for Acute Care Hospital Inpatient, Traditional Medicare Base Payment Distribution

The inpatient payment system is driven by the combination of diagnoses (up to 24 different diagnoses) and procedures reported on a claim for an inpatient case, as this determines DRG assignment, among other factors described above. Using case volumes and base payment amounts we aggregated DRGs into nationally recognized MDCs to present an average payment for all the DRGs within a category.[132,133] As Figure 6 indicates, the MDC pertaining to pregnancy, childbirth and the puerperium reflect the lowest average payment amount to hospitals across all DRGs (Appendix 5 presents each MDC and the FY 2025 IPPS base payment distribution). Though Medicare serves older adults, a beneficiary of childbearing age may qualify because of disability or other reason. While in this payer snapshot, the average DRG base payment for diseases and disorders of the female reproductive system is higher than the average base payment across all DRGs in the diseases and disorders of the male reproductive system MDC (Appendix 5), opposite findings were noted in analysis of average commercial allowed amounts as depicted in Figures 7 and 8.

Figure 6. FY 2025 Medicare DRG Base Payment Distribution by MDC

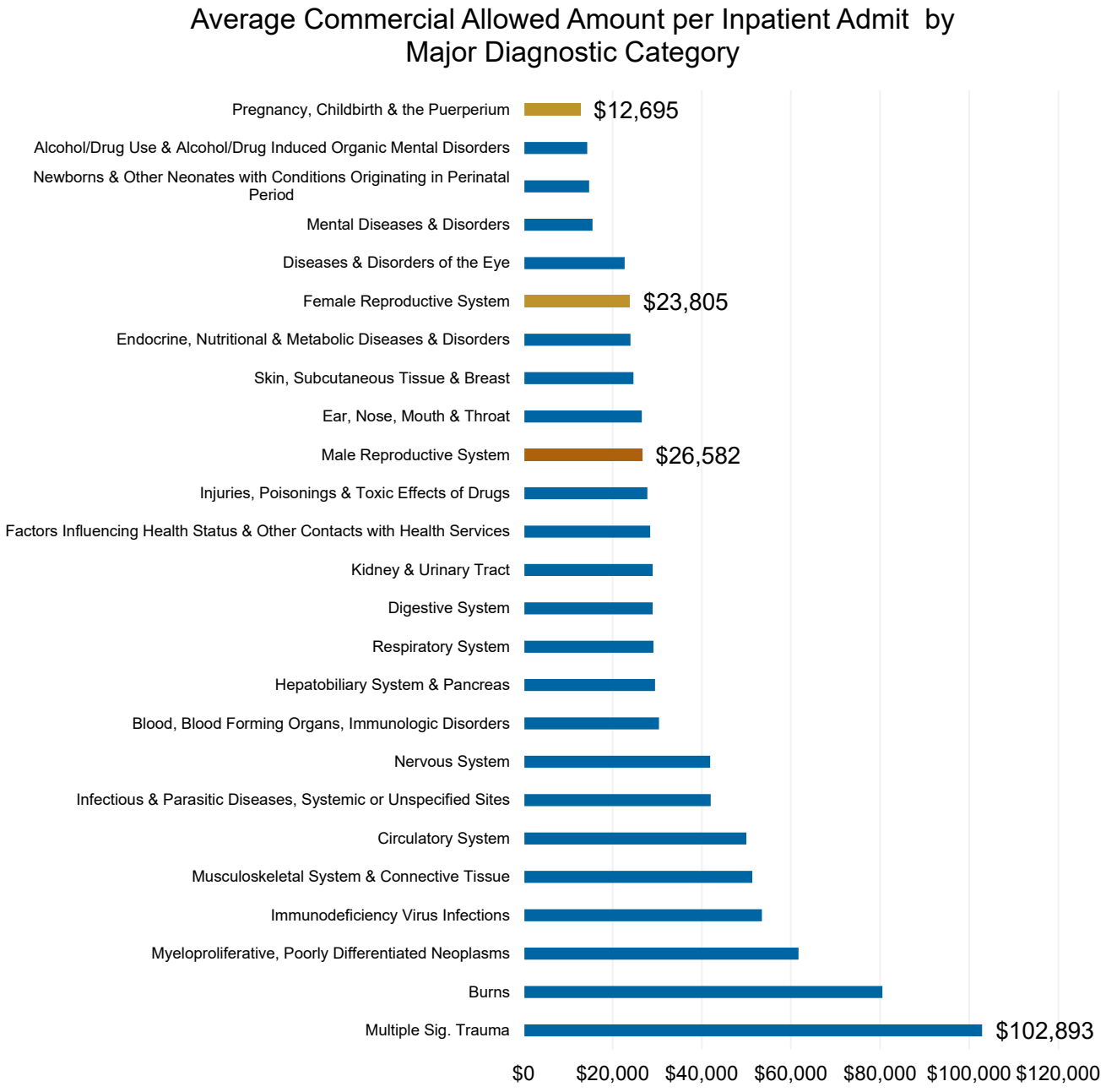


Source: HMA analysis of Medicare FY2025 IPPS Final Rule and MedPAR (FY2023 Claims).

Payment for Acute Care Hospital Inpatient Stays, Commercial Snapshot

Commercial insurer payments to hospitals for inpatient admissions may be structured differently than Medicare reimbursement for acute care stays and could be based on DRGs, per diems, or other commercial contracts arrangements. To gain a sense of commercial payments for hospital admissions we analyzed 2022 commercial payer data containing claims for inpatient admissions, which includes a DRG assignment on the submitted claim.[134] We used the DRG on commercial claims and mapped it to the applicable MDC for comparison. We evaluated national average payment amounts from commercial payers to hospitals at the MDC level to compare rates across major categories. As Figure 7 demonstrates, across all major categories, average commercial allowed amounts per inpatient admission are lowest for the pregnancy, childbirth, and the puerperium MDC.

Figure 7. Average Allowed Commercial Reimbursement by MDC, Showing Low Reimbursement Levels for Perinatal Care



Source: Analysis of 2022 Marketscan data in and out of network.

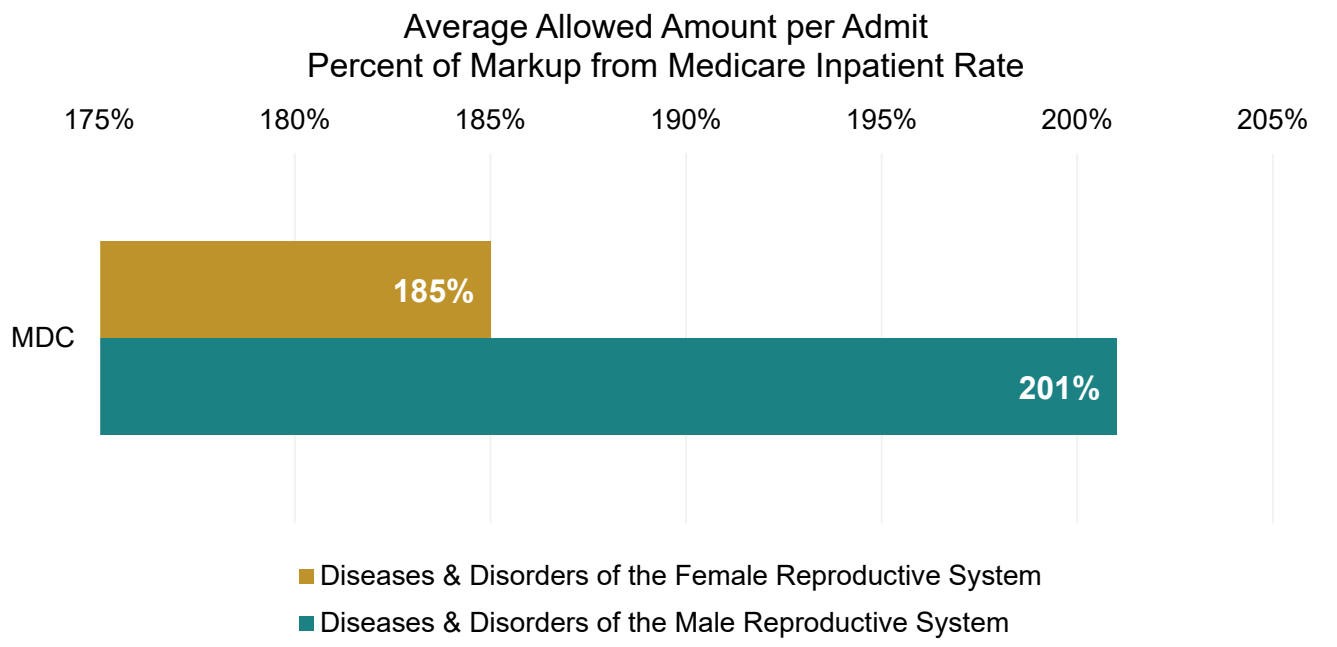
Payment for Hospital Inpatient Maternity Care

Low reimbursement levels and relatively limited payment innovation persist in maternity care, in both commercial markets and Medicaid. Among commercial inpatient payment rates, perinatal care is the lowest of any MDC at a national average allowed amount of $12,695 according to our analysis (see Figure 7), with Medicaid payment substantially below that total.[135]

Commercial Payment for Diseases and Disorders of the Male/Female Reproductive System

As Figure 7 also demonstrates, the average commercial allowed amount per inpatient admission for cases classified under the male reproductive system MDC is a national average of $26,582 versus $23,805 for cases assigned to the female reproductive system MDC. This amount reflects an approximate 10 percent ($2,777) difference between average payment amounts for hospital inpatient reproductive system services for the male MDC and the female category. When commercial average amounts are compared with Medicare MS-DRG amounts,[136] we also observe payment at a higher percent of Medicare for cases assigned to the male-focused MDC (see Figure 8), though we are unable to access data that can be used to determine why this occurs.

Figure 8. Average Allowed Commercial Markup by Major Diagnostic Category



Source: Analysis of 2022 Marketscan data in and out of network.

RECOMMENDATIONS

We recommend the medical technology community and patient advocates initially focus on establishing processes to raise awareness and facilitate further evaluation of potential gaps in coding, coverage and reimbursement with the goal of making incremental changes over the coming years. Examples outlined in this work could be used to prompt discussions with stakeholders, policy makers, and payers about the problem of how to improve policies and remove barriers for better access to services and technologies that address women's health. Collaborative action to further investigate and address these issues must occur and could be initiated through coding processes, payer reimbursement systems, and conveners of employer-sponsored healthcare:

- Seek to establish a women's health coding committee within the entities that maintain the national code sets to expand expert contributions to coding processes with this lens as part of its charge.
    - Evaluate the evidentiary criteria that must be met to obtain new Category I codes and suggest whether modifications or clarifications may be appropriate for code change applications in instances where the service and/or technology may be useful in addressing chronically under-resourced, under-studied, and under-accessed healthcare services.
    - Alternatively, seek to establish women's health advisory groups within prominent medical professional associations to further identify barriers to women's access to services and technology solutions in the coding, coverage and payment domains, and develop comprehensive solutions to integrate these technologies into clinical practice through these pathways. The American Medical Association Digital Medicine Payment Advisory Group was convened with a similar objective and could serve as a model to establish a collaborative, multidisciplinary initiative focused on advancing coding, coverage and reimbursement pathways for women's health access.
- Enhance coding for effective billing and reimbursement of women's health management and patient navigation services to facilitate screening, coordination and other services.
    - A viable model for this approach is the code set CMS established to reflect care management and principal illness navigation services, which could be tailored to the unique challenges of women.
- Include a demographic review as part of this envisioned coding committee or advisory group with a focus on CMS misvalued services initiatives to better analyze and understand the populations for which codes are reported and whether inadequate coding contributes to access challenges.
- Collaborate with CMS to establish a data-driven process to price emerging technology codes nationally rather than defaulting pricing decisions to local contractors where payment variability and uncertainty impedes access. Leverage this process to seek similar payment stability for emerging technology services with other payers.
- Use CMS notice of proposed rulemaking comment periods to raise examples of differential reimbursement for clinically similar male and female services and seek payment corrections through this process.

- Build on medical technology initiatives to expand transitional coverage for emerging technologies and provide more opportunities for new women's health technologies to be covered by Medicare.
- Establish collaboratives to advance women's health policies in the private sector through partnerships with business roundtables, large employers, and associations that represent health plans to raise awareness, educate, and advance gap consideration from a coding, coverage, and reimbursement perspective.
- Identify and disseminate best and promising practices for technology applications in maternity care. Apply successful approaches in payer outreach to gain support and scale adoption.
- Track noncoverage in the commercial sector for specific technologies to identify trends and better evaluate potential gender bias in a systematic way.
- When consistent payer barriers are identified for women's health services or technologies, develop payer chief medical officer education campaigns to raise awareness on the issues and gaps of concern.
- Promote diversity in clinical trials for new technologies, disaggregation of research findings by sex, a focus on evidence to support clinical validity and utility, and further exploration of where real-world evidence could improve coding, coverage, or reimbursement processes.

As new opportunities arise and payment policies develop, identify lessons learned or success stories and promote incorporation of those findings into traditional payment systems similar to how CMS has incorporated findings from accountable care organizations and other alternative payment methodologies into Medicare FFS programs.

FINDINGS

In the context of the women's healthcare landscape, signals of potential gaps in coding, coverage, and reimbursement—key market access levers—have been identified.

CONCLUSION

Investing in women's health yields physical, socioeconomic, population-level benefits and fiscal returns with estimates suggesting billions in reduced healthcare and caregiving costs attributable to improvements in women's health.[137] Developing robust data to support clinical practice guideline development, to meet coding criteria, and health insurer coverage requirements, can be particularly challenging for innovators of women's health technologies given difficulties in securing funding and research prioritization. Allocating funds to women's health research will drive innovation in technologies that benefit women's health; however, with an uncertain federal funding and workforce outlook in 2025, private investors in women's health companies may become increasingly important.

Though funding and representation in clinical research is paramount to the development of new discoveries in women's health, access to innovations used in direct patient care is facilitated or dampened by coding, coverage, and reimbursement policies in the US healthcare system. Even when codes are available, lack of coverage or inadequate reimbursement limit access and technology adoption. Although these dynamics are applicable to all new technologies, if they affect services unique to women or tailored to women's health needs differently than those for men, health disparities could be perpetuated. Observations of potential gaps in coding, coverage and reimbursement, in the context of overall women's health, suggest that improvements could be made in these areas to enhance women's health, access to care, and outcomes. Although these issues are systemic, awareness campaigns, support resources, and incremental process changes can have a significant impact over time.

APPENDIX 1. ADDITIONAL BACKGROUND ON WOMEN'S HEALTH EQUITY

Women's health includes conditions, biological and reproductive processes that are unique to women, as well as health concerns that may impact women differently or disproportionately. Among these are conditions unique to women such as maternity-related health needs, conditions that are more common in women such as urinary incontinence, and those that affect women differently than men, such as cardiovascular disease, where symptoms manifest differently.[138,139] Disparities in women's health include less funding for conditions primarily impacting women, lack of representation in clinical research, lack of equity centered data analysis, and worse health outcomes.

Snapshot of Women's Health in the United States

Women's health has gained greater public attention in recent years as health disparities between men and women across the lifespan have been documented more clearly. For example, women spend an average of 18 percent more years experiencing poor health than men.[140] Compared with other high-income countries, American women have the lowest life expectancy at 80 years and the highest rate of avoidable deaths at 270 per 100,000.[141] A multitude of societal factors contribute to these disparities. Lack of access to needed healthcare because of a variety of economic and social factors play a role. According to survey data from the Centers for Disease Control and Prevention (CDC), women were more likely than men to report delays in healthcare access, inability to see a doctor due to cost, and not following a prescribed course of medication because of its cost. Underrepresentation of women in clinical trials and under-diagnosis of certain common diseases, like cardiovascular disease, may also play a role. For example, women accounted for 38 percent of cardiovascular health study participants between 2010 and 2017, even though they are "more likely than men to die from a heart attack or develop heart failure within five years after discharge from a hospital."[142] These systemic issues underscore the need for targeted interventions to address gender disparities in healthcare.

What Is Women's Health Equity?

Health equity is "the state in which everyone has a fair and just opportunity to attain their highest level of health."[143] Achieving women's health equity would mean that there were no differences in health outcomes for women attributable to structural inequities in research, innovation, and care delivery; however, underrepresentation in clinical trials and funding imbalances have long constrained advancement and innovation in women's health. For instance, women account for only about one-third of participants in many cardiovascular device trials despite these devices being used to treat conditions prevalent in women.[144]

It is critical to recognize the differences between equality and equity and how pursuing equity can address the systemic shortcomings in women's health. Equality is when everyone is treated the same regardless of their differences, whereas equity means everyone receives what they need—in this context, to achieve optimal health. As the CDC noted, "Achieving health equity requires valuing everyone equally with focused and ongoing efforts to address avoidable inequalities and injustices, and the elimination of health and healthcare disparities".[145] Many cardiovascular devices have been developed and tested primarily on men but prescribed for men and women. Equity would require that devices be developed and tested, taking into consideration differences in cardiovascular disease for women.[146] Centering equity will include strategies, such as diversity and representation in research, tailored technologies, and investment across all stages of women's lifespan.[147]

Health, Wellness, and Women's Health

The World Health Organization defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity," whereas wellness is a less clearly-defined concept that often includes the role of personal agency in progressing toward a desired state.[148,149] Stakeholders interviewed as part of this project indicated that women's health products and technologies are sometimes viewed as optional treatments and should be left to consumer choice. These perceptions may influence coverage and treatment decisions in the healthcare system.

Historical Exclusion of Women from Clinical Research

Gaps in WHR and women's health reflect decades of exclusion or underrepresentation in clinical trials, as well as inattention to studying risk factors, function, anatomy, and physiological differences between the sexes. Research has historically favored studying male-specific over female-specific health conditions and the male body as typical despite women comprising more than half of the US population. Strategies to correct these limitations are under way with emphasis on disaggregating research data to report clinical research findings by sex, including for device development, performance, and to foster innovation for conditions prevalent among women.[150]

Click for a history of key federal agency events affecting women's health research and innovation →

Growing Focus on Increasing Research Funding and Clinical Trial Participation

At least part of the inclusion gap in women's health research can be attributed to a 1977 policy guidance from the FDA, which requires clinical researchers to exclude "women of reproductive potential" from Phase 1 and 2 clinical trials. The FDA developed this policy in part because of the negative impacts of the morning sickness medication thalidomide, which led to more than 10,000 deaths and birth defects in Europe and Australia in the 1960s.[151] Though the policy was intended to prevent pregnancy complications, clinical researchers excluded nearly all premenopausal women, including those on birth control and abstaining from sex. Although the FDA reversed this policy in 1993, women are still underrepresented in key research areas decades later.

Throughout the past four decades, the NIH and the FDA have made numerous efforts to improve the inclusion of women in clinical trials. In 1986 the NIH enacted the Inclusion of Women and Minorities in Clinical Research policy, it's first attempt to encourage clinical researchers to include women in their studies.[152] The NIH Revitalization Act of 1993 cemented women's health research as a policy priority by mandating the inclusion of women and minorities in NIH funded research, creating programs to recruit women and minorities, and requiring clinical trials to study additional variables like gender and race.[153] Since the NIH Revitalization Act, the NIH and the FDA have updated their guidance to require evaluation of sex differences in clinical studies to better understand how biological sex may impact clinical outcomes.[154,155] Initially released in 2015 and updated in 2024, the FDA's Women's Health Research Roadmap indicates an ongoing commitment to advancing women's health.[156]

Support for Women's Health Research and Recognition of Gaps

In recent years, growing efforts have been made at the federal level to address these disparities and prioritize women's health research. Policymakers, agencies such as the NIH, and advocacy groups have sought to raise awareness, promote inclusion in clinical trials, and support research specifically focused on women's health issues. The Biden Administration elevated women's health as a national priority. In 2024, The White House Initiative on Women's Health Research was established, the Advanced Research Projects Agency for Health's (ARPA-H) Sprint for Women's Health was launched, and the president issued an Executive Order to direct actions toward assessing unmet need, advancing research, and improving women's health. This included requiring federal research grant applicants to describe how their project considers women's health and providing grant funding to small businesses focused on women's health.[157] Subsequent grantmaking efforts from HHS and the Department of Defense were also intended to provide millions of dollars in funding for women's health.[158,159] These actions raised visibility and increased efforts to advance new discoveries, but ongoing attention and additional resources are necessary. Nonetheless, women's health research still faces significant gaps, underscoring the need for continued efforts to ensure women are equitably represented in clinical studies. Further, it remains to be seen whether any of these grant initiatives will be affected by the Trump Administration's review of covered contracts and grants in 2025.[160]

APPENDIX 2. MAJOR RESTRUCTURING OF HHS

Major restructuring and staff cuts at the U.S. Department of Health and Human Services (HHS), including changes announced March 27, 2025, are likely to have significant and still to be determined impacts on women's health research and programs.[161,162] Staff of the Division of Reproductive Health within the Centers for Disease Control and Prevention were eliminated as part of major reductions in staff across federal agencies, and significant cuts were made to the Health Resources and Services Administration, an operating division of HHS that houses the Maternal and Child Health Bureau. The entire staff of the Pregnancy Risk Assessment Monitoring System was also put on leave.[163]

Within NIH, the directors of the National Institute of Child Health and Human Development and the National Institute on Minority Health and Health Disparities were placed on leave, in addition to two other chiefs of institutes and centers within the agency.[164] It is unclear what impact, if any, the reorganization and cuts will have on the Office of Research on Women's Health within the NIH Office of the Director. The administration also said it would shut down offices of minority health within the Centers for Medicare & Medicaid Services and HHS.[165] The newly created Administration for a Healthy America (AHA) will include maternal and child health programs, but the full scope of the changes is uncertain.

APPENDIX 3. ADDITIONAL BACKGROUND ON UNIQUE ISSUES AFFECTING WOMEN

Funding and evidence generation intersect with health policy and access to services. Coverage, coding, and reimbursement are major levers to facilitate improved access to services and medical technologies that address women's health issues. Three areas that advocates suggest are ripe for improvements in coding, coverage, and reimbursement include maternity and postpartum care, mental health, and pelvic health.

Maternal Health

The United States continues to have high rates of preventable maternal and infant morbidity and mortality relative to other high-income countries, as well as deep and persistent racial inequities in outcomes.[166, 167, 168, 169] In recent years, healthcare providers, payers, and state and federal governments have heightened efforts to improve these outcomes and address racial disparities, including through increased research focus, coverage expansion (such as postpartum Medicaid coverage extensions to one year[170]), clinical quality improvement, health plan provider payment incentives and care management programs, and, in some cases, payment reforms that support innovative models of care. Challenges that contribute to poor outcomes are wide-ranging and include factors that extend beyond individual healthcare access, pregnancy, and the postpartum period. However, coverage and care discontinuities that are specific to perinatal care, low reimbursement, and the limited impact of payment innovation thus far contribute to poor birth outcomes and inadequate postpartum support.

Recent research reviewing advances in digital health as part of prenatal care suggests that its use is increasing in the United States and other high-income countries, primarily for "patient-provider consultations, remote monitoring, and health education, complementing in-person visits or as a substitute when necessary," with "high levels of acceptance and satisfaction" among users. "These interventions primarily targeted general maternal care (28.57%), gestational diabetes mellitus (15.07%), and mental health (13.49%) while also addressing gestational weight management, hypertensive disorders, high-risk pregnancies and maternal education. The findings demonstrated positive outcomes in managing clinical conditions, enhancing knowledge, promoting birth preparedness, and improving antenatal care access and utili[z]ation."[171] Access to these technologies is substantially influenced by coverage and payment policies.

THREE AREAS WITH OPPORTUNITY FOR IMPROVEMENT IN CODING, COVERAGE & REIMBURSEMENT

Maternity care
"Over 35 percent of counties are considered maternity care deserts" (March of Dimes). "There's little mystery why providers shutter labor and delivery units: they make comparatively little money, and, in some cases, they lose a lot of it" (TIME).

Mental Health
"Recent research has identified disparities between men and women in regard to risk, prevalence, presentation, course and treatment of mental disorders" (American Psychiatric Association).

Pelvic Health
"Conditions such as endometriosis, fibroids, pelvic floor disorders, polycystic ovary syndrome, vulvodynia have no obvious home" within NIH (National Academies of Sciences).

Sources: endnote

Maternity Health Reimbursement Challenges and Innovations, Medicaid Overview

Historically, payment structures for maternity care delivered to Medicaid enrollees were not aligned to support the best outcomes; for example, only in recent years have payers begun to address unintended incentives for cesarean and early elective deliveries, which occur at higher rates in the United States than medically necessary and create unnecessary risks to mothers and infants.[172] State and CMS recognition of challenges has led to payment innovations, such as episode-based payments, add-on "kick" payments for delivery to prevent Medicaid health plans from avoiding pregnant enrollees, payment carve-outs to enable access to long-acting reversible contraceptives postpartum, and non-payment for elective cesarean sections, among other examples.

Payer use of quality measures tied to payment have sought to incentivize providers to ensure that postpartum visits are accessible and timely; however, additional effort is needed to address the burden of complications during delivery and the postpartum period, including persistent racial inequities in birth outcomes. Sustainable payment models remain limited and underdeveloped, which can inhibit adoption of innovative models, such as group prenatal care, support from navigators, community health workers, and doulas, maternity care homes, and other customized models intended to improve birth outcomes.

Despite more than 15 years of efforts to change payment structures to support better outcomes and models of care that better meet women's needs, innovative models are still in limited use and have had limited impact. For example, only an estimated 3 percent of births take place in programs that use an episode of care payment model.[173] Despite growing interest and funding from the federal government via the Center for Medicare and Medicaid Innovation (Innovation Center)[174] in recent years, care models that require non-traditional reimbursement and that can be tailored to address inequities continue to face sustainability challenges and are in limited use.

Mental Health

Significant gender disparities in mental health are apparent, with women disproportionately affected by certain conditions such as post-traumatic stress disorder (PTSD), anxiety, and depression. The Substance Abuse and Mental Health Services Administration's annual national survey found that women are more likely than men to have a mental illness (26.4% versus 19.0%).[175] The American Psychological Association's 2023 Stress in America survey found that women reported a higher average level of stress than men (5.3 versus 4.8 out of 10) and were more likely to rate their stress levels between 8 and 10 (27% versus 21%), a pattern the organization observed has been consistent over time.[176] A 2017 study estimates the lifetime prevalence of PTSD to be about 10–12 percent in women and 5–6 percent in men.[177]

Moreover, childbirth can be a traumatic experience; between 9 and 44 percent of women report giving birth as a traumatic experience, and 3 percent of women develop a form of PTSD following childbirth.[178] Postpartum depression also is a public health concern, affecting at least 14 percent of new mothers.[179] Estimated medical and economic costs related to perinatal or postpartum mood and anxiety disorders, including those related to the health of both mothers and infants from birth to age five, have been estimated at $32,300 per dyad (mom-baby pair).[180] Gaps in screening for perinatal depression and connection to appropriate services persist, as do racial and ethnic disparities in care.[181] Most women with perinatal depression do not receive appropriate treatment, even if they are identified through screening.[182] Women are also two to three times more likely than men to meet criteria for generalized anxiety disorder and about twice as likely as men to develop depression.[183, 184]

Digital mental health technology (DMHT) offers potential to improve access to mental health services including screening, diagnosis, and treatment of these conditions. Recognizing this opportunity, in calendar year 2025 CMS established billing codes for clinicians to report and receive reimbursement for services related to a patient's use of an FDA approved or cleared DMHT device intended to treat or alleviate a mental health condition. CMS requires that the device be used in conjunction with an ongoing behavioral health treatment plan and intends to monitor how DMHT devices are used as part of overall care moving forward.[185] Current use cases include for insomnia, substance use disorders, depression, and anxiety.[186] As DMHT devices evolve, stakeholders have identified reimbursement as key to adoption and have called for improved clarity and guidance from payers on evidence requirements to obtain positive coverage.[187]

Pelvic Health

Pelvic health encompasses the proper functioning of the pelvic floor muscles, ligaments, and connective tissues that support the pelvic organs, including the bladder, uterus, and rectum. Pelvic floor disorders may arise when these structures are weakened or impaired, leading to conditions such as urinary incontinence, fecal incontinence, and pelvic organ prolapse.[188]

Pelvic floor disorders are prevalent among women. Studies indicate that approximately one in four women in the United States are impacted by one or more pelvic floor disorder. Urinary incontinence (17%) is the most common pelvic floor disorder reported among women in the United States, followed by fecal incontinence (9.4%) and prolapse (2.9%).[189]

While the risk of developing a pelvic floor disorder increases with age, many young women develop them as well. [190] The postpartum period can leave women at higher risk for a pelvic disorder resulting from hormonal and physical changes.[191] Despite their prevalence, there is a lack of awareness and research around pelvic health disorders; pelvic floor disorders are both underdiagnosed and undertreated.[192] In addition, studies note that stigma and access are contributing factors to women's ability to seek healthcare support. Stigma includes insecurity, embarrassment, and lack of knowledge and awareness. [193]

At present, treatment for pelvic floor disorders typically includes pelvic floor therapy and sometimes medication or surgery; however, advancements in technology and medical devices could significantly enhance the diagnosis and treatment of pelvic health conditions. Innovative technologies include digital therapeutic devices, remote monitoring, and telehealth physical therapy.[194,195]

Taking a Life Course Perspective on Women's Health

Women's health is sometimes viewed through a narrow lens that considers only major reproductive health needs, when there are milestones and health needs across a woman's lifespan. It is critical to recognize that at each stage women have distinct health concerns and needs, from menstrual health in adolescence to bone health in post menopause. The hormonal lifecycle stages for women include adolescence, reproductive years, perimenopause, menopause, and post menopause, each marked by significant hormonal changes.

During adolescence, rising estrogen and progesterone levels trigger menstruation and physical development. The reproductive years are characterized by regular menstrual cycles, fertility, pregnancy, and postpartum hormonal fluctuations. Perimenopause, a transitional phase, involves fluctuating hormones and associated symptoms in the period before menopause. Menopause marks the end of menstruation because of a significant decline in estrogen and progesterone, bringing symptoms such as hot flashes and increased risks of osteoporosis and cardiovascular disease. Post menopause results in stable low hormone levels, with heightened risks for long-term health issues like osteoporosis and heart disease. These stages collectively shape a woman's health journey.

As digital health technologies (DHTs) expand with the potential to improve women's health, evidence generation to understand the health benefits and impact on women's access to healthcare will be important. Examples of stage-specific DHTs for women's health solutions include:

- Adolescence: Devices for menstrual tracking, acne treatment, and educational tools
- Reproductive years: Fertility monitors, contraceptive devices, pregnancy and postpartum care devices (e.g., remote monitoring of conditions)
- Perimenopause: Devices for symptom monitoring, hormone level testing, and sleep aids
- Menopause: Bone density monitors, cardiovascular health trackers, and vaginal health devices
- Post menopause: Long-term health management tools like bone health devices and cardiovascular screening

APPENDIX 4. POTENTIALLY ANALOGOUS CODE PAIRS[196]

Sex	HCPCS	M/F Pair Lay Description	M/F Code Pair	HCPCS Short Descriptor
M	54100	Biopsy penis/vagina	54100_57100	Biopsy of penis
F	57100	Biopsy penis/vagina	54100_57100	Biopsy vaginal mucosa simple
M	54110	Remove penis lesion/vaginal lesion	54110_57135	Treatment of penis lesion
F	57135	Remove penis lesion/vaginal lesion	54110_57135	Excision vaginal cyst/tumor
M	54060	Excision penile/vaginal lesion	54060_57100	Excision of penis lesion(s)
F	57100	Excision penile/vaginal lesion	54060_57100	Biopsy vaginal mucosa simple
M	55040	Excision hydrocele/bartholins	55040_56740	Removal of hydrocele
F	56740	Excision hydrocele/bartholins	55040_56740	Exc bartholins gland/cyst
M	54360	Scrotoplasty/perineoplasty	54360_56810	Penis plastic surgery
F	56810	Scrotoplasty/perineoplasty	54360_56810	Perineoplasty rpr per nonob
M	55875	Interstitial prostate/cervix	55875_55920	Transperi needle place pros
F	55920	Interstitial prostate/cervix	55875_55920	Place needles pelvic for rt

Sex	HCPCS	M/F Pair Lay Description	M/F Code Pair	HCPCS Short Descriptor
M	55875	Transperi needle place pros/insert tandem female	55875_57155	Transperi needle place pros
F	57155	Transperi needle place pros/insert tandem female	55875_57155	Insert uteri tandem/ovoids
M	53215	Total urethrectomy M/F	53215_53210	Removal of urethra
F	53210	Total urethrectomy M/F	53215_53210	Removal of urethra
M	54120	Partial removal penis / vaginectomy	54120_57106	Partial removal of penis
F	57106	Partial removal penis / vaginectomy	54120_57106	Vagnc prtl rmvl vag wall
M	54690	Laparoscopy orchiectomy / BSO	54690_58661	Laparoscopy orchiectomy
F	58661	Laparoscopy orchiectomy / BSO	54690_58661	Laparoscopy remove adnexa
M	54600	Reduce torsion testis / ovarian	54600_58920	Reduce testis torsion
F	58920	Reduce torsion testis / ovarian	54600_58920	Partial removal of ovary(s)
M	54100	Biopsy penis / vulva	54100_56605	Biopsy of penis
F	56605	Biopsy penis / vulva	54100_56605	Biopsy of vulva/perineum
M	55700	Biopsy prostate / endometrium	55700_58100	Biopsy of prostate

Sex	HCPCS	M/F Pair Lay Description	M/F Code Pair	HCPCS Short Descriptor
F	58100	Biopsy prostate / endometrium	55700_58100	Biopsy of uterus lining
M	52601	TURP / hyster myomectomy	52601_58561	Prostatectomy (turp)
F	58561	TURP / hyster myomectomy	52601_58561	Hysteroscopy remove myoma
M	55720	Drain abscess prostate / ovaria	55720_58820	Drainage of prostate abscess
F	58820	Drain abscess prostate / ovaria	55720_58820	Drain ovary abscess open
M	55530	Excision varicocele / bartholins	55530_56740	Revise spermatic cord veins
F	56740	Excision varicocele / bartholins	55530_56740	Exc bartholins gland/cyst
M	55500	Excision hydrocele / bartholins	55500_56740	Removal of hydrocele
F	56740	Excision hydrocele / bartholins	55500_56740	Exc bartholins gland/cyst
M	55175	Scrotoplasty / perineoplasty	55175_56810	Revision of scrotum
F	56810	Scrotoplasty / perineoplasty	55175_56810	Perineoplasty rpr per nonob
M	54015	Incision drainage penis / vulva	54015_56405	Drain penis lesion
F	56405	Incision drainage penis / vulva	54015_56405	I & d of vulva/perineum

Sex	HCPCS	M/F Pair Lay Description	M/F Code Pair	HCPCS Short Descriptor
M	54060	Excision lesion penile / vulvar	54060_11403	Excision of penis lesion(s)
F	11403	Excision lesion penile / vulvar	54060_11403	Exc tr-ext b9+marg 2.1-3cm
M	54015	Incision drain penis / bartholins	54015_56420	Drain penis lesion
F	56420	Incision drain penis / bartholins	54015_56420	Drainage of gland abscess
M	54505	Biopsy incisional testis / excision vaginal	54505_57135	Biopsy of testis
F	57135	Biopsy incisional testis / excision vaginal	54505_57135	Excision vaginal cyst/tumor
M	55100	Drainage abscess scrotum / vulva perineum	55100_56405	Drainage of scrotum abscess
F	56405	Drainage abscess scrotum / vulva perineum	55100_56405	I & d of vulva/perineum
M	55100	Drainage abscess scrotum / gland	55100_56420	Drainage of scrotum abscess
F	56420	Drainage abscess scrotum / gland	55100_56420	Drainage of gland abscess
M	55866	prostatectomy (robot) / hysterectomy	55866_58541	Laps surg prst8ect rpbic rad
F	58541	prostatectomy (robot) / hysterectomy	55866_58541	Lsh uterus 250 g or less
M	53852	Transurethral RF destruction prostate / remodeling female bladder neck	53852_53860	Prostatic rf thermotx

Sex	HCPCS	M/F Pair Lay Description	M/F Code Pair	HCPCS Short Descriptor
F	53860	Transurethral RF destruction prostate / remodeling female bladder neck	53852_53860	Transurethral rf treatment
M	53850	Transurethral microwave destruction prostate / endometrial ablation	53850_58353	Prostatic microwave thermotx
F	58353	Transurethral microwave destruction prostate / endometrial ablation	53850_58353	Endometr ablate thermal
M	52649	Enucleation prostate / lapar vaginal hystrectomy	52649_58553	Prostate laser enucleation
F	58553	Enucleation prostate / lapar vaginal hystrectomy	52649_58553	Laparo-vag hyst complex
M	54057	Laser Penis / Vulva	54057_56501	Laser surg penis lesion(s)
F	56501	Laser Penis / Vulva	54057_56501	Destroy vulva lesions sim
M	55150	Resection Scrotum / vulvectomy	55150_56620	Removal of scrotum
F	56620	Resection Scrotum / vulvectomy	55150_56620	Vulvectomy simple partial
M	53442	Revise remove sling M /F	53442_57287	Remove/revise male sling
F	57287	Revise remove sling M /F	53442_57287	Revise/remove sling repair
M	54065	Destruction lesion penile / vulvar	54065_56515	Destruction penis lesion(s)
F	56515	Destruction lesion penile / vulvar	54065_56515	Destroy vulva lesion/s compl

Sex	HCPCS	M/F Pair Lay Description	M/F Code Pair	HCPCS Short Descriptor
M	55705	Incision prostate / conization	55705_57520	Biopsy of prostate
F	57520	Incision prostate / conization	55705_57520	Conization of cervix
M	55810	Radical prostatectomy / hysterectomy	55810_58210	Extensive prostate surgery
F	58210	Radical prostatectomy / hysterectomy	55810_58210	Extensive hysterectomy
M	52275	cystourethro w urethrotomy M/F	52275_52270	Cystoscopy & revise urethra
F	52270	cystourethro w urethrotomy M/F	52275_52270	Cystoscopy & revise urethra
M	53440	Sling operation urinary incontinence M/F	53440_57288	Male sling procedure
F	57288	Sling operation urinary incontinence M/F	53440_57288	Repair bladder defect
M	55867	Laparoscopy surgical prostatectomy robotic / Laparoscopy ablation uterine fibroids	55867_58674	Laps surg prst8ect smpl stot
F	58674	Laparoscopy surgical prostatectomy robotic / Laparoscopy ablation uterine fibroids	55867_58674	Laps abltj uterine fibroids
M	0714T	Laser ablation BPH >50ml / Destruction vaginal lesions extensive	0714T_57065	Tpla b9 prst8 hyprplsa<50ml
F	57065	Laser ablation BPH >50ml / Destruction vaginal lesions extensive	0714T_57065	Destruction vag lesion xtnsv

Sex	HCPCS	M/F Pair Lay Description	M/F Code Pair	HCPCS Short Descriptor
M	0867T	Laser ablation BPH<=50ml/Transcervical ablation uterine fibroids	0867T_58580	Tpla b9 prst8 hyprplsa>=50ml
F	58580	Laser ablation BPH<=50ml/Transcervical ablation uterine fibroids	0867T_58580	Transcrv abltj utrn fibrd rf
M	52700	Drain prostate abscess / ovarian	52700_58820	Drainage of prostate abscess
F	58820	Drain prostate abscess / ovarian	52700_58820	Drain ovary abscess open

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APPENDIX 5. FY 2025 MEDICARE IPPS DRG BASE PAYMENT DISTRIBUTION BY MAJOR DIAGNOSTIC CATEGORY

MDC	Title	FY 2025 DRG Base Payment Distribution
14	Pregnancy, childbirth and the puerperium	$ 6,435
23	Factors influencing health status and other contacts with health services	$ 6,918
2	Diseases and disorders of the eye	$ 7,472
20	Alcohol or drug use or induced organic mental disorders	$ 8,227
3	Diseases and disorders of the ear, nose, mouth and throat	$ 8,413
10	Endocrine, nutritional and metabolic diseases and disorders	$ 9,145
9	Diseases and disorders of the skin, subcutaneous tissue and breast	$ 9,342
16	Diseases and disorders of blood, blood forming organs and immunologic disorders	$ 9,569
12	Diseases and disorders of the male reproductive system	$ 9,674
11	Diseases and disorders of the kidney and urinary tract	$ 9,763
19	Mental diseases and disorders	$ 10,326
4	Diseases and disorders of the respiratory system	$ 10,736
6	Diseases and disorders of the digestive system	$ 11,072
13	Diseases and disorders of the female reproductive system	$ 11,510
7	Diseases and disorders of the hepatobiliary system and pancreas	$ 11,580
21	Injuries, poisonings and toxic effects of drugs	$ 12,705
1	Diseases and disorders of the nervous system	$ 12,761
5	Diseases and disorders of the circulatory system	$ 15,524

MDC	Title	FY 2025 DRG Base Payment Distribution
18	Infectious and parasitic diseases, systemic or unspecified sites	$ 16,415
8	Diseases and disorders of the musculoskeletal system and connective tissue	$ 16,747
25	Human immunodeficiency virus infections	$ 18,252
17	Myeloproliferative diseases and disorders, poorly differentiated neoplasms	$ 19,419
24	Multiple significant trauma	$ 25,380
15	Newborns and other neonates with conditions originating in perinatal period	$ 29,682
22	Burns	$ 34,655

Data Sources:

1. *DRG standard base payment rate from the FY 2025 final rule, Table 1.*
2. *DRG weights from the FY 2025 final rule Table 5.*
3. *DRG distribution in each MDC from the FY 2025 final rule MedPAR (FY 2023 claims).*

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[126] Certain data used in this study were supplied by Merative. Any analysis, interpretation, or conclusion based on these data is solely that of the authors and not Merative. Analysis of 2022 MarketScan Data: Professional conducted by Wakely, an HMA Company. Observations presented in this report prepared by HMA as a point of reference and do not reflect a position of HMA. The assumptions and resulting estimates included in this analysis are inherently uncertain. Users of the results should be qualified to use it and understand the results and the inherent uncertainty. Actual results may vary, potentially materially, from our estimates. Wakely does not warrant or guarantee the projected values included in the analysis. It is the responsibility of the organization receiving this output to review the assumptions carefully and notify Wakely of any potential concerns.

[127] Analysis of 2022 MarketScan Data: Professional conducted by Wakely, an HMA Company. All claims (in-and out-of-network) were included in these tabulations. Some code pairs included a code with very small unit counts, the credibility of codes with a very low number of claims in the data may be less reliable. We utilized CMS's threshold of less than 11 claims to identify services with very low units, 9 codes had less than 11 units. Code pairs with a service missing data were not included in summary observations. Some codes are used in multiple pairs as relevant comparators. Certain data used in this study were supplied by Merative. Any analysis, interpretation, or conclusion based on these data is solely that of the authors and not Merative.

[128] We selected Medicare for this hospital outpatient department payment rate snapshot because payers' reimbursement to hospitals may involve methodologies that bundle payment for multiple items or services into a single payment amount and the rules and methods used by CMS to do so are publicly available.

[129] Note that this does not mean that there were 172 different products. An applicant can re-submit an application if they don't gain NTAP status in a prior year's application. Also, an applicant can apply for NTAP for multiple indications.

[130] The Emily's Care Nourish Test System (Model 1) is an FDA Approved Breakthrough Device. It is an analytical system designed to measure the concentration of fat, carbohydrates (lactose), and protein in human milk at point of care using an enzyme-based test strip and a smartphone camera with an associated application. 2026 fiscal year application, no further information available at this point in time.

[131] Cytalux® (pafolacianine) - Targeted intraoperative molecular imaging agent for ovarian cancer. 2024 application. CMS granted NTAP status for this indication and again for an indication for lung cancer.

[132] MedPAR file (FY 2023 claims) published with the FY2025 IPPS Final rule.

[133] We utilized the MedPAR file (FY2023 claims) published with the FY2025 IPPS Final Rule to determine the average DRG base payment by MDC. This analysis was confined to IPPS claims only. The DRG payment was computed by multiplying the FY2025 DRG base rate ($7117.02) by the weight of each DRG. The MDC-level average payment was then calculated and weighted by the distribution of the DRGs within each MDC

[134] Analysis conducted by Wakely, an HMA Company. The assumptions and resulting estimates included in this analysis are inherently uncertain. Users of the results should be qualified to use it and understand the results and the inherent uncertainty. Actual results may vary, potentially materially, from our estimates. Wakely does not warrant or guarantee the projected values included in the analysis. It is the responsibility of the organization receiving this output to review the

assumptions carefully and notify Wakely of any potential concerns. Certain data used in this study were supplied by Merative. Any analysis, interpretation, or conclusion based on these data is solely that of the authors and not Merative.

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