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U.S. Real-World Prescribing Patterns of Mixed Gonadotropin Ovarian Stimulation Protocols: A Claims-Based Analysis

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OBJECTIVE

To evaluate U.S. real-world prescribing patterns for mixed gonadotropin ovarian stimulation protocols.

KEY TAKEAWAYS

1. In this large U.S. claims-based study (2019–2025), co-prescription of rFSH and HP-hMG was the predominant strategy for ovarian stimulation, with stable year-over-year prescribing patterns, suggesting that "mixed" protocol in U.S. practice specifically reflects combination of these two distinct gonadotropin preparations.
2. Co-prescribed rFSH and HP-hMG corresponded to an approximate 3:1 combined FSH-to-LH labeled bioactivity ratio, likely reflecting a consistent real-world gonadotropin prescribing approach.
3. Claims-based data enable large-scale quantification of dispensed gonadotropin volume and labeled bioactivity balance, providing a foundation for future evaluations of stimulation strategy, resource utilization, and clinical and economic outcomes.

Abbreviations

COS, controlled ovarian stimulation; **ART**, assisted reproductive technology; **rFSH**, recombinant follicle-stimulating hormone; **HP-hMG**, highly purified-human menopausal gonadotropin; **LH**, Luteinizing hormone; **SD**, standard deviation.

References

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4. Follistim AQ (follitropin beta injection) [prescribing information]. Jersey City, NJ: Organon USA Inc.; 2023.

Disclosures

KC, UR, WZ, and KB are an employee of Ferring Pharmaceuticals Inc., Parsippany, NJ, USA

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BACKGROUND

- Controlled ovarian stimulation (COS) is a central component of IVF/ICSI, in which exogenous gonadotropins are administered to promote multi-follicular development, primarily through follicle-stimulating hormone (FSH) bioactivity, and frequently, supplementation with luteinizing hormone (LH) bioactivity from highly purified-human menopausal gonadotropin (HP-hMG).
- The ovarian stimulation strategies may involve recombinant follicle-stimulating hormone (rFSH) monotherapy, HP-hMG monotherapy, or mixed regimens combining rFSH and HP-hMG within the same cycle.[1]
- In the U.S., "mixed" gonadotropin protocol is the predominant ovarian stimulation strategy[1]; however, the definition of "mixed" in real-world practice has not been well characterized.
- rFSH provides consistent FSH bioactivity without LH activity, while HP-hMG preparations are labeled as containing 75 IU FSH and 75 IU LH bioactivity per vial (1:1 FSH-to-LH ratio).[2-4]
- Using a large U.S. Rx claims database, we characterized real-world gonadotropin prescribing patterns to define what "mixed" stimulation means in practice and to quantify the relative FSH and LH bioactivity balance of dispensed gonadotropins at the cycle level.

METHODS

- Using IQVIA Longitudinal Access and Adjudicated Data (LAAD), a large US pharmacy and medical claims database, the present study characterizes gonadotropin utilization patterns from 2019 through 2025.
- Women aged ≥18 years with at least one gonadotropin dispensing claim were eligible for inclusion. Gonadotropins were identified using National Drug Codes and included follitropin-alfa and follitropin-beta preparations (rFSH)[3-4] and menotropins (HP-hMG).[2]
- Ovarian stimulation cycles were defined as 30-day treatment episodes beginning on the index gonadotropin dispensing date.
- Dose calculations were derived from pharmacy claims using dispensed quantity and labeled IU strength per vial. To standardize dosing comparisons across products and strengths, all vials were normalized to 75-IU equivalents according to label.
- The FSH-to-LH bioactivity ratio was computed as the ratio of total dispensed FSH IU to total dispensed LH IU.
- Descriptive statistics were used to summarize protocol distribution overall and by calendar year. Cycle-level outcomes included mean vials per cycle, total FSH IU and LH IU per cycle for mixed protocols, and corresponding FSH-to-LH bioactivity ratios.

RESULTS

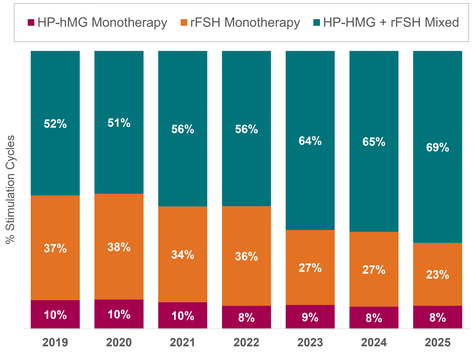
- A total of 792,529 women contributing to total 1,352,773 ovarian stimulation cycles between 2019 and 2025 were included in the analysis. The mean age at cycle initiation was 36.0 years.

Table 1 Participant characteristics at baseline

	rFSH + HP-hMG Mixed N*= 541,888	rFSH Monotherapy N*= 285,738	HP-hMG Monotherapy N*= 96,943
Age Mean (SD), years	35.6 (5.0)	35.7 (4.8)	35.9 (5.3)
Age categories by year, n (%)			
18 - 25	11,983 (2.2)	9,292 (3.3)	3,229 (3.3)
26 – 30	60,863 (11.2)	37,698 (13.2)	11,452 (11.8)
31 – 35	186,076 (34.3)	89,561 (31.3)	28,742 (29.6)
36 – 40	195,847 (36.1)	97,548 (34.1)	34,071 (35.1)
≥ 40	87,119 (16.1)	51,638 (18.1)	19,449 (20.1)
Geographic Region, n (%)			
Northeast	153,325 (28.3)	81,599 (28.6)	21,926 (22.6)
Midwest	81,995 (15.1)	44,877 (15.7)	17,338 (17.9)
South	155,611 (28.7)	95,280 (33.3)	30,446 (31.4)
West	150,855 (27.8)	63,969 (22.4)	27,217 (28.1)

* Some patients may be included in more than one stimulation cycle protocol.

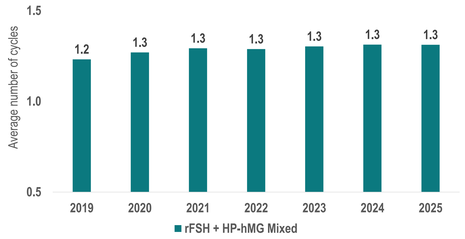
FIGURE 1 Stimulation cycle share by protocol type



- Mixed HP-hMG + rFSH protocols represented the predominant gonadotropin stimulation strategy (N=541,888) throughout the study period.
- Across calendar years, mixed protocols ranged from 52% to 69% of all stimulation cycles, consistently exceeding monotherapy approaches.

- On average, patients underwent 1.29 stimulation cycles per year within rFSH + HP-hMG mixed protocol therapy.

FIGURE 2 Distribution of the average cycles per patient in rFSH + HP-hMG mixed protocol

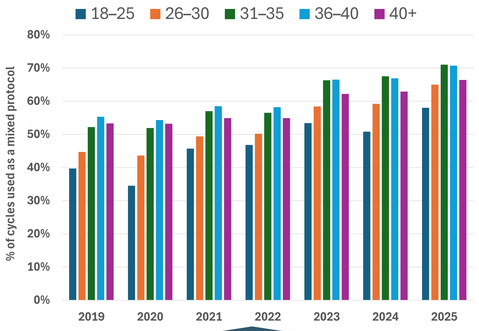


- Among mixed protocol cycles, mean gonadotropin exposure per cycle included approximately 21 HP-hMG-equivalent vials and 40 rFSH-equivalent vials.
- Using labelled bioactivity assumptions (75 IU FSH and 75 IU LH per vial of HP-hMG),[2] mixed protocol stimulation cycles demonstrated an approximate 3:1 FSH-to-LH bioactivity ratio across the stimulation course. This ratio reflects cumulative prescribing behaviour within mixed protocol cycles rather than intrinsic production composition.

TABLE 2 Average vials per cycles in rFSH + HP-hMG mixed protocol

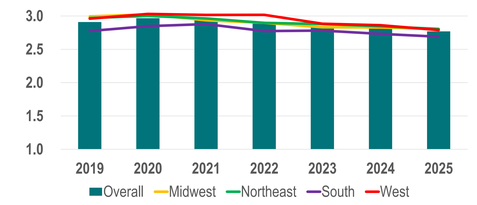
Channel	2019	2020	2021	2022	2023	2024	2025
HP-hMG Vials in Mixed Protocol	20.9	20.7	21.4	21.8	21.6	21.6	22.5
rFSH Vials in Mixed Protocol	40.0	40.8	41.6	41.2	39.8	39.3	39.8

FIGURE 3 rFSH + HP-hMG mixed protocol cycle utilization by age group



- The use of mixed protocols showed a consistent increase over time across all age groups. The highest uptake was consistently observed among women aged 31–35 years and 36–40 years, with mixed-protocol use reaching approximately 71.0% and 70.7%, respectively, by 2025.

FIGURE 4 FSH to LH ratio trend in rFSH + HP-hMG mixed protocol



- Across U.S. census regions, the estimated FSH:LH labeled bioactivity ratio in mixed rFSH + HP-hMG cycles remained tightly clustered around 3:1 from 2019–2025, with minimal regional dispersion. These findings suggest a broadly consistent 'FSH-dominant with LH support' prescribing pattern in mixed stimulation protocols across geographies.

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