



# Pharmacological Treatment of Gynecological Pathologies: A Comprehensive Review of Current Agents, Emerging Therapies, and Clinical Evidence

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## ABSTRACT

Gynecological pathologies—including endometriosis, uterine fibroids, polycystic ovary syndrome (PCOS), and gynecological malignancies—collectively impose an enormous burden on women's health worldwide. Pharmacological management has advanced considerably over the past decade, driven by the introduction of oral gonadotropin-releasing hormone (GnRH) antagonists, selective progesterone receptor modulators, targeted biologics, immune checkpoint inhibitors, and poly(ADP-ribose) polymerase (PARP) inhibitors. This comprehensive review synthesizes current evidence on pharmacological treatment across the spectrum of gynecological conditions, evaluating mechanisms of action, clinical efficacy, safety profiles, and regulatory status. Landmark trials such as SPIRIT 1&2, RUBY, NRG-GY018, PRIMA, and KEYNOTE-A18 have redefined first-line treatment standards in recent years. Individualization of therapy, biomarker-guided drug selection, and combination strategies represent the evolving frontiers. This review provides clinicians with an integrated, evidence-based framework for selecting optimal pharmacological agents in gynecological practice.

**Keywords:** *gynecological pathologies; pharmacotherapy; GnRH antagonists; PARP inhibitors; immune checkpoint inhibitors; endometriosis; uterine fibroids; PCOS*

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## INTRODUCTION

Gynecological pathologies constitute a substantial proportion of the global disease burden in women of reproductive and post-reproductive age. Endometriosis affects an estimated 10% of women of reproductive age worldwide, contributing significantly to chronic pelvic pain, dysmenorrhea, and infertility [1, 2]. Uterine fibroids (leiomyomas) are the most prevalent pelvic tumors in women, with prevalence estimates ranging from 20% to 80% depending on age, ethnicity, and diagnostic modality [3, 25]. Polycystic

ovary syndrome (PCOS) affects approximately 8–13% of women of reproductive age and represents the leading endocrine cause of anovulatory infertility [28, 33]. Gynecological malignancies—including cancers of the ovary, endometrium, and cervix—account for a large fraction of female cancer-related mortality globally, with ovarian cancer remaining the most lethal gynecological cancer due to late-stage diagnosis [1, 2, 3].

Historically, pharmacological management of gynecological conditions relied heavily on hormonal therapies, nonsteroidal anti-inflammatory drugs (NSAIDs), and cytotoxic chemotherapy regimens with limited specificity. However, a paradigm shift has occurred in the last decade. The development and regulatory approval of oral GnRH antagonists with hormonal add-back therapy (relugolix, elagolix, linzagolix) has transformed the management of both endometriosis and uterine fibroids by providing rapid, reversible, and well-tolerated hormone suppression [16, 21, 22]. Simultaneously, the oncological landscape has been revolutionized by PARP inhibitors (olaparib, niraparib) and anti-angiogenic agents (bevacizumab) in ovarian cancer, and by immune checkpoint inhibitors targeting the PD-1/PD-L1 axis (pembrolizumab, dostarlimab) in endometrial and cervical cancers [4, 5, 8, 13, 14].

Given the rapid pace of innovation in gynecological pharmacotherapy, a comprehensive, updated synthesis is warranted. This review applies the IMRAD structure to describe the methods of evidence retrieval, consolidate results across therapeutic categories, and discuss clinical implications and future directions for the pharmacological management of principal gynecological pathologies.

## METHODS

This comprehensive narrative review was conducted by systematically searching electronic databases including PubMed/MEDLINE, Cochrane Library, Embase, and ClinicalTrials.gov. Searches covered the period from January 2018 to May 2026, with priority given to publications from 2020 onward to capture the most current evidence. Search terms were combined using Boolean operators and included: 'gynecological pathologies,' 'pharmacotherapy,' 'endometriosis treatment,' 'uterine fibroids drug therapy,' 'PCOS pharmacological management,' 'GnRH antagonists,' 'PARP inhibitors gynecology,' 'immune checkpoint inhibitors gynecologic oncology,' and related terms. Eligible publications included randomized controlled trials (RCTs), systematic reviews, meta-analyses, phase II/III clinical trials, and authoritative clinical practice guidelines. Grey literature, conference abstracts without peer-reviewed follow-up, and publications in languages other than English were excluded. A total of 60 publications were included. Evidence was organized thematically by gynecological condition: endometriosis, uterine fibroids, PCOS, ovarian cancer, endometrial cancer, and cervical cancer. Drug comparisons are presented in tabular form.

**Table 1. Comprehensive Comparison of Pharmacological Agents Used in Gynecological Pathologies**

Drug	Class	Indication	Mechanism of Action	Dose / Route	Main Adverse Effects
Elagolix	GnRH antagonist	Endometriosis pain	Blocks pituitary GnRH receptors → ↓ LH/FSH/estradiol	150 mg/d or 200 mg bid; oral	Hot flushes, BMD loss, ↑ lipids
Relugolix combo (E2/NETA)	GnRH antagonist + add-back	Endometriosis pain; uterine fibroids	GnRH receptor blockade with estrogen/progestin add-back to mitigate hypoestrogenic effects	40 mg/d oral (combo tablet)	Hot flushes, headache, minimal BMD loss with add-back
Linzagolix	GnRH antagonist	Endometriosis; uterine fibroids	Competitive GnRH receptor antagonist; dose-dependent estrogen suppression	75 mg or 200 mg/d; oral	Vasomotor symptoms, BMD changes at high dose
Dienogest 2 mg/d	Progestin	Endometriosis pain	Progesterone receptor agonist → decidualization & atrophy of endometriotic lesions	2 mg/d oral; long-term use	Irregular bleeding, weight gain, mood changes
LNG-IUD (Mirena)	Progestin (IUD)	Endometriosis; heavy menstrual bleeding; fibroids (symptomatic)	Local levonorgestrel → endometrial atrophy; suppresses endometriotic foci	52 mg IUD; 5-yr duration	Irregular spotting (first 3-6 mo), ovarian cysts
Ulipristal acetate (UPA)	SPRM	Uterine fibroids (pre-op/intermittent)	Selective progesterone receptor modulator → fibroid apoptosis, ↓ VEGF	5 mg/d oral for up to 8 weeks × intermittent courses	Rare serious hepatotoxicity (EMA suspension), endometrial thickening
Elagolix + E2/NETA (Oriahnn)	GnRH antagonist + add-back	Heavy menstrual bleeding due to fibroids	Hypothalamic-pituitary suppression → ↓ estrogen; add-back prevents bone loss	300 mg bid + 1 mg E2/0.5 mg NETA oral	Hot flushes, BMD loss (limited to 24 months)
Tranexamic acid	Antifibrinolytic	Heavy menstrual bleeding (fibroids)	Inhibits plasminogen activation → ↓ fibrinolysis → hemostasis	1-1.3 g TID oral (menstruation days)	Nausea, thromboembolic risk (rare)
Olaparib	PARP inhibitor	Ovarian cancer maintenance (BRCA+/HRD)	Blocks PARP1/2 → synthetic lethality in BRCA-mutated/HRD tumors	300 mg bid oral	Nausea, fatigue, anemia, MDS (rare)
Niraparib	PARP inhibitor	Ovarian cancer 1st-line maintenance (all-comers)	Pan-PARP inhibition without requiring BRCA mutation	200-300 mg/d oral (individualized start dose)	Thrombocytopenia, anemia, hypertension, nausea
Bevacizumab	Anti-VEGF (mAb)	Advanced ovarian cancer (1st line + recurrence)	Binds VEGF-A → inhibits tumor angiogenesis	15 mg/kg IV q3w with chemo then maintenance	Hypertension, proteinuria, thrombosis, bowel perforation

Drug	Class	Indication	Mechanism of Action	Dose / Route	Main Adverse Effects
Pembrolizumab	Anti-PD-1 checkpoint inhibitor	Advanced/recurrent endometrial cancer (1st line)	Blocks PD-1/PD-L1 interaction → restores T-cell anti-tumor immunity	200 mg IV q3w with carboplatin/paclitaxel	Immune-related AEs: colitis, pneumonitis, thyroiditis
Dostarlimab	Anti-PD-1 checkpoint inhibitor	Advanced/recurrent endometrial cancer (dMMR)	Anti-PD-1 monoclonal antibody → T-cell activation against tumor cells	500 mg IV q3w (4 doses) then 1000 mg q6w	Immune-related AEs, fatigue, rash
Pembrolizumab (cervical)	Anti-PD-1 checkpoint inhibitor	Persistent/recurrent/metastatic cervical cancer (PD-L1+)	PD-1 blockade → immune reactivation; synergistic with HPV-driven antigenicity	200 mg IV q3w + chemo ± bevacizumab	Immune-related AEs, infusion reactions
Letrozole	Aromatase inhibitor	PCOS-related anovulatory infertility	Inhibits aromatase → ↓ estrogen → ↑ FSH → follicular recruitment	2.5-7.5 mg/d oral (days 3-7 of cycle)	Hot flushes, fatigue; lower multiple pregnancy rate than clomiphene
Metformin	Biguanide (insulin sensitizer)	PCOS metabolic features ± ovulation induction	Activates AMPK → ↓ hepatic glucose output → ↓ insulin resistance → ↓ androgen	1500-2000 mg/d oral (titrated)	GI upset (nausea, diarrhea), rarely lactic acidosis
COC (ethinyl estradiol + progestin)	Combined oral contraceptive	PCOS: menstrual regulation, hyperandrogenism	Suppresses LH → ↓ ovarian androgen; ↑ SHBG → ↓ free testosterone	Low-dose EE (20-30 µg) + progestin; daily oral	VTE risk, headache, mood changes, hypertension

Note: COC = combined oral contraceptive; dMMR = mismatch repair deficient; E2 = estradiol; EMA = European Medicines Agency; FDA = Food and Drug Administration; GnRH = gonadotropin-releasing hormone; HMB = heavy menstrual bleeding; HRD = homologous recombination deficiency; LH = luteinizing hormone; mAb = monoclonal antibody; NETA = norethisterone acetate; NMPP = non-menstrual pelvic pain; PARP = poly(ADP-ribose) polymerase; pMMR = proficient mismatch repair; PFS = progression-free survival; SHBG = sex hormone-binding globulin; SPRM = selective progesterone receptor modulator; VTE = venous thromboembolism.

## RESULTS

### Pharmacotherapy of Endometriosis

Among the most significant pharmacological advances in endometriosis management are the second-generation oral GnRH antagonists. Elagolix, at a dose of 150 mg/day for up to 24 months or 200 mg twice daily for up to 6 months, demonstrated statistically significant reductions in dysmenorrhea scores and non-menstrual pelvic pain (NMPP) compared with placebo in two pivotal Phase III trials involving over 870 patients. The 150 mg dose demonstrated a favorable bone mineral density (BMD) profile suitable for longer-term use, while the higher dose requires monitoring due to hypoestrogenic effects. Relugolix combination therapy (40 mg/day relugolix with add-back estradiol 1 mg and norethisterone acetate 0.5 mg) achieved pain response rates of approximately

75% for dysmenorrhea at 24 weeks in the SPIRIT 1 and 2 trials, with a 2-year open-label extension demonstrating sustained efficacy and BMD protection attributable to hormonal add-back. Linzagolix at 75 mg/day or 200 mg/day provides dose-dependent hormonal suppression with the option for titration based on clinical response and tolerability.

Progestins remain a cornerstone of endometriosis pharmacotherapy. Dienogest 2 mg/day demonstrated non-inferiority to GnRH agonist leuprolide acetate for pain reduction, with superior BMD preservation and an acceptable bleeding profile. The levonorgestrel-releasing intrauterine system (LNG-IUD, 52 mg) reduces endometriosis-associated pain through local endometrial suppression and is particularly useful in women seeking concurrent contraception. NSAIDs, while widely prescribed, have limited evidence specifically for endometriosis and are generally used as adjuncts to hormonal therapies.

### **Pharmacotherapy of Uterine Fibroids**

Pharmacological management of symptomatic uterine fibroids has been transformed by the approval of oral GnRH antagonist combination preparations. Elagolix 300 mg twice daily with add-back estradiol/norethisterone acetate (OriaHnn) was approved by the FDA in 2020 for heavy menstrual bleeding (HMB) associated with uterine leiomyomas, based on the ELARIS UF-1 and UF-2 trials where 68–69% of women achieved the bleeding response criterion at 6 months versus 9% with placebo. Relugolix combination therapy (Myfembree) received FDA approval in 2021 for this indication, with the LIBERTY 1 and 2 trials demonstrating response rates of 71–73%. A 2024 meta-analysis of 11 RCTs including 4,164 patients confirmed that GnRH antagonists significantly control uterine bleeding (RR = 5.09; 95% CI 3.19–8.14) and reduce fibroid volume by approximately 27% versus placebo.

Ulipristal acetate (UPA), a selective progesterone receptor modulator, demonstrated fibroid volume reduction of up to 40% and bleeding control rates of approximately 90% in the PEARL I–IV trials. However, following rare cases of serious hepatotoxicity, the European Medicines Agency suspended its marketing authorization in 2020, and UPA is currently unavailable in most markets. Tranexamic acid, an antifibrinolytic agent, reduces menstrual blood loss by approximately 40–50% and remains a useful option for acute HMB management without hormonal side effects. The LNG-IUD reduces menstrual blood loss by over 90% in women with non-cavity-distorting fibroids and provides a long-term alternative to surgical intervention.

### **Pharmacotherapy of Polycystic Ovary Syndrome**

The 2023 International Evidence-Based Guideline for PCOS, representing the most authoritative synthesis of evidence to date, recommends combined oral contraceptive pills (COCs) as first-line pharmacological therapy for menstrual irregularity and

hyperandrogenism. Low-dose preparations containing 20–30 µg ethinyl estradiol with progestins demonstrating anti-androgenic properties are preferred. COCs reliably restore menstrual cycle regularity in over 80% of treated women and significantly reduce hirsutism and acne through suppression of luteinizing hormone and elevation of sex hormone-binding globulin.

For anovulatory infertility, letrozole (2.5–7.5 mg/day on days 3–7 of the menstrual cycle) is the first-line pharmacological therapy per the 2023 guideline, having demonstrated superior live birth rates (27.5% vs. 19.1%) compared to clomiphene citrate in the landmark Legro et al. RCT with a lower multiple pregnancy rate. Clomiphene citrate retains a role as second-line therapy or in combination with metformin in clomiphene-resistant patients. Metformin (1500–2000 mg/day) is recommended primarily for metabolic features of PCOS, including insulin resistance and dyslipidemia, and as an adjunct to letrozole in overweight patients. GLP-1 receptor agonists represent an emerging pharmacological option in obese women with PCOS, endorsed by the 2023 guideline for weight management.

### **Pharmacotherapy of Gynecological Malignancies**

In ovarian cancer, first-line treatment consists of platinum-taxane chemotherapy (carboplatin/paclitaxel) with bevacizumab and/or PARP inhibitor maintenance based on tumor biomarker profile. Bevacizumab, approved based on the GOG-0218 and ICON7 trials, reduces progression risk (HR 0.75) with benefit most pronounced in high-risk subgroups. Olaparib as maintenance therapy (SOLO-1) reduced disease progression risk by 56% in BRCA-mutated advanced ovarian cancer. The PAOLA-1 trial demonstrated that olaparib combined with bevacizumab significantly prolonged progression-free survival vs. bevacizumab alone (HR 0.63), particularly in HRD-positive patients (HR 0.33). Niraparib demonstrated efficacy across all HRD subgroups in the PRIMA trial (PFS 13.8 vs. 8.2 months, placebo), making it suitable as universal first-line maintenance.

Endometrial cancer pharmacotherapy was dramatically transformed in 2023 by the addition of immune checkpoint inhibitors to standard carboplatin/paclitaxel chemotherapy. Pembrolizumab (NRG-GY018 trial) reduced progression risk by 70% in dMMR tumors (HR 0.30) and 46% in pMMR tumors (HR 0.54). Dostarlimab (RUBY trial) demonstrated a hazard ratio of 0.36 for progression in dMMR patients, with updated 2024 overall survival data confirming durable benefit. Antibody-drug conjugates (ADCs) such as mirvetuximab soravtansine (FR $\alpha$ -targeted) and trastuzumab deruxtecan represent emerging therapies under active investigation. For cervical cancer, pembrolizumab added to chemoradiotherapy (KEYNOTE-A18) significantly improved overall survival (HR 0.67) in locally advanced disease.

### **DISCUSSION**



The past five years have witnessed unprecedented progress in gynecological pharmacotherapy, with each major disease area experiencing practice-changing advances. The development of oral GnRH antagonists with hormonal add-back represents perhaps the most transformative advance in benign gynecological disease management. Unlike GnRH agonists, which cause an initial flare of gonadotropins and require subcutaneous administration, oral GnRH antagonists competitively block GnRH receptors from the first dose, producing immediate and titratable estrogen suppression without an initial flare [17, 21]. The integration of low-dose estrogen/progestin add-back mitigates hypoestrogenic sequelae—particularly BMD loss and vasomotor symptoms—enabling long-term use without the historical constraints of GnRH agonists, which were limited to 3–6 months of use in many guidelines [22, 36]. Nonetheless, head-to-head comparisons between different GnRH antagonist preparations are lacking, as are long-term data (beyond 2 years) regarding post-treatment fibroid regrowth and endometriosis recurrence, representing significant gaps in current evidence [21, 26].

In oncology, the immune checkpoint inhibitor era has fundamentally altered the outlook for endometrial and cervical cancer. The stratification of endometrial cancer patients by mismatch repair status (dMMR vs. pMMR) has become a clinical imperative, given the markedly greater benefit observed in dMMR patients with pembrolizumab and dostarlimab [4, 5, 7]. However, the observation that pMMR patients also derive meaningful benefit from checkpoint inhibition—particularly when combined with chemotherapy—has broadened the eligible population substantially, challenging earlier assumptions about the necessity of predictive biomarkers for treatment selection [4, 52]. The synergy between PARP inhibitors and immune checkpoint blockade, mediated by PARP-induced DNA damage repair stress activating the cGAS-STING pathway and enhancing tumor immunogenicity, is actively being explored across gynecological malignancies and may define next-generation combination strategies [23, 46].

The management of PCOS illustrates the importance of individualized pharmacotherapy. The 2023 International Guideline's endorsement of letrozole as first-line for ovulation induction reflects the robust evidence base accumulated since the pivotal Legro trial [27, 28]. Notably, the guideline also endorses GLP-1 receptor agonists—validated in metabolic medicine—for weight management in PCOS, representing the integration of broader endocrinological pharmacotherapy into gynecological practice [28, 35]. Metformin continues to provide metabolic benefit but should be recognized as complementary to, rather than a substitute for, letrozole in the infertility setting [30, 32].

Several unmet needs and future directions warrant attention. The suspension of ulipristal acetate due to hepatotoxicity has left a gap in the selective progesterone

receptor modulator space, with no approved SPRM currently available in major markets [40, 41]. Novel SPRMs are under investigation. The expansion of antibody-drug conjugate technology, already demonstrated with mirvetuximab soravtansine and trastuzumab deruxtecan in ovarian and other gynecological cancers [55, 56], promises highly targeted cytotoxicity with reduced off-target effects. The role of prophylactic pharmacotherapy—including low-molecular-weight heparin for venous thromboembolism prevention in gynecological oncology patients undergoing chemotherapy—is increasingly recognized and codified in major guidelines [48, 49]. Integration of these supportive pharmacological measures with active oncological treatment is essential for optimizing patient outcomes.

## CONCLUSION

Pharmacological management of gynecological pathologies has entered a new era characterized by precision, diversity, and unprecedented clinical efficacy. Oral GnRH antagonists with hormonal add-back have redefined standards for endometriosis and uterine fibroid management, offering patients and clinicians a long-awaited oral, well-tolerated alternative that does not compromise bone health over extended treatment courses. In gynecological oncology, the integration of immune checkpoint inhibitors into first-line regimens for endometrial and cervical cancer, alongside the mature evidence supporting PARP inhibitor and anti-VEGF maintenance therapy in ovarian cancer, has produced measurable improvements in progression-free and overall survival across biomarker-defined and unselected patient populations. For PCOS, the consolidation of letrozole as the preferred ovulation-induction agent alongside the emerging role of GLP-1 receptor agonists reflects the growing recognition that this complex syndrome demands treatment strategies that extend beyond reproductive endpoints to encompass metabolic and long-term wellbeing. The trajectory of gynecological pharmacotherapy points toward increasingly biomarker-guided, patient-centered, and combination-based strategies. Clinicians must remain engaged with rapidly evolving evidence to ensure that the remarkable advances of the past decade translate into real-world improvements in the health and quality of life of women living with these conditions.

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