

Gynecology

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Hysterectomy, Vaginal (MCG ORG: S-660 ISC, 30th Edition)
- Pelvic Ultrasound, Transvaginal (MCG ORG: A-0109 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
58260-58263, 58267, 58270	Vaginal hysterectomy for uterus 250 g or less, with or without removal of tube(s)/ovary(s), with repair of enterocele or colpo-urethrocystopexy
58275, 58280	Vaginal hysterectomy with total or partial vaginectomy, with or without repair of enterocele
58290-58294	Vaginal hysterectomy for uterus greater than 250 g, with or without removal of tube(s)/ovary(s) and repair of enterocele
00T97ZZ, 00T98ZZ, 00T99ZZ	Resection of uterus, vaginal or endoscopic approach (ICD-10-PCS procedure)
76830	Ultrasound, transvaginal (diagnostic pelvic imaging)
0690T	Transvaginal pelvic ultrasound, including image documentation and interpretation (emerging technology code)
S4024	Ancillary transvaginal ultrasound service (HCPCS)

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding gynecology services, including vaginal hysterectomy for malignant, premalignant, and benign gynecologic disease and transvaginal pelvic ultrasound for evaluation of abnormal bleeding, adnexal masses, and other pelvic conditions, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of gynecology services and to determine when such services are medically necessary.

These services span surgical treatment and diagnostic imaging for gynecologic disease, which in the Medicare Advantage population frequently involves postmenopausal bleeding requiring prompt evaluation for malignancy, alongside benign conditions amenable to definitive surgical management. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary surgical and diagnostic services and inappropriate approval of procedures that are not indicated or could be addressed by a less invasive approach.

Potential Clinical Harms:

Vaginal hysterectomy: Inappropriate denial of hysterectomy for malignant or premalignant gynecologic disease (e.g., endometrial cancer, cervical adenocarcinoma in situ, endometrial intraepithelial neoplasia) could allow progression of cancer with worsening stage, nodal spread,

and increased mortality. For benign disease such as symptomatic leiomyoma, adenomyosis, endometriosis, or pelvic organ prolapse refractory to conservative measures, denial could prolong disabling bleeding, anemia, pain, and loss of function. Forcing reliance on repeated lesser interventions exposes patients to cumulative procedural risk and delayed definitive treatment.

Transvaginal pelvic ultrasound: Inappropriate denial of transvaginal ultrasound for postmenopausal or abnormal uterine bleeding, a suspected adnexal mass, or suspected ectopic pregnancy could delay detection of endometrial or ovarian carcinoma or allow a tubal ectopic pregnancy to progress to rupture and hemorrhage. Because transvaginal ultrasound is more accurate than the transabdominal approach for measuring endometrial thickness and characterizing adnexal lesions, denial undermines the first-line evaluation pathway for these potentially life-threatening conditions.

Clinical Benefits:

Vaginal hysterectomy: MCG criteria provide validated indications drawn from specialty society guidelines and an obstetrics and gynecology textbook, reserving hysterectomy for malignant and premalignant disease where it decreases cancer-related morbidity and mortality, and for benign disease where it offers definitive management of abnormal uterine bleeding, leiomyoma, adenomyosis, endometriosis, and pelvic organ prolapse. By tying the procedure to these specific indications, the criteria directly counter the harms of cancer progression and prolonged disabling benign disease identified above, while supporting appropriate ambulatory-level care: analysis of Medicare procedure data shows 96% of patients undergoing vaginal hysterectomy were discharged the day of or the day after surgery.

Transvaginal pelvic ultrasound: MCG criteria apply diagnostic accuracy evidence demonstrating at least moderate certainty of at least moderate net benefit for the major indications, citing that transvaginal ultrasound is more accurate than the transabdominal approach for endometrial thickness measurement used in the initial detection of endometrial carcinoma in patients with abnormal uterine bleeding. This directly addresses the harm of delayed cancer and ectopic-pregnancy diagnosis identified above by establishing transvaginal ultrasound as the appropriate first-line imaging study for these presentations.

Reduction of unwarranted variation and overutilization: MCG criteria also identify circumstances where a less invasive alternative is appropriate (e.g., medical or hormonal management of benign hyperplasia when not contraindicated, conservative management of asymptomatic findings), reducing unnecessary surgical exposure in this population. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current gynecologic specialty society guidelines and high-quality diagnostic evidence. Use of these criteria ensures patients receive the most clinically appropriate level of care, and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use:

Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for specific gynecology services, including vaginal hysterectomy and transvaginal pelvic ultrasound. While Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical indications and thresholds (e.g., the malignant, premalignant, and benign disease states warranting hysterectomy, or the bleeding, mass, and pregnancy findings warranting transvaginal imaging) required to distinguish

indicated from nonindicated procedures and inpatient-appropriate from ambulatory-appropriate care.

Applicable Medicare References:

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard
- Medicare Benefit Policy Manual, Chapter 1: Inpatient Hospital Services Covered Under Part A (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 14: Medical Devices (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (CMS IOM Publication 100-02)
- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: For vaginal hysterectomy and transvaginal pelvic ultrasound, no specific NCD or LCD fully establishes clinical procedural thresholds; Original Medicare criteria are not fully established for these services, requiring supplementation.
- Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

Within the above statutes and regulations, coverage criteria for these specific gynecology services are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of vaginal hysterectomy for malignant, premalignant, and benign gynecologic disease versus medical or less invasive management;
- Medical necessity and appropriateness of transvaginal pelvic ultrasound for abnormal bleeding, adnexal mass evaluation, suspected ectopic pregnancy, and related indications;
- Appropriate level of care (ambulatory versus inpatient), expected clinical course, and identification of complications that warrant inpatient admission or stay extension following hysterectomy.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of gynecology services. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure surgical and diagnostic services are not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Background

Hysterectomy, Vaginal (MCG ORG: S-660 ISC)

Vaginal hysterectomy is surgical removal of the uterus through a vaginal approach and is indicated for a range of malignant, premalignant, and benign gynecologic conditions, including endometrial and cervical cancer, endometrial intraepithelial neoplasia, abnormal uterine bleeding, leiomyoma, adenomyosis, endometriosis, and pelvic organ prolapse. The procedure is treated as ambulatory, recognizing that an ambulatory procedure may include one postoperative overnight stay depending on payer and regulatory definitions, including the CMS Two-Midnight Rule.

Pelvic Ultrasound, Transvaginal (MCG ORG: A-0109 AC)

Transvaginal pelvic ultrasound is an ambulatory diagnostic imaging study indicated for abnormal gynecologic bleeding, adnexal mass or suspected ovarian cancer evaluation, suspected ectopic pregnancy, infertility evaluation, suspected congenital uterine anomaly, and numerous other pelvic indications. It provides higher-resolution assessment of the endometrium and adnexa than the transabdominal approach. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

Evidence Summary

Hysterectomy, Vaginal (MCG ORG: S-660 ISC)

The evidence for the clinical indications in this guideline includes 19 published peer-reviewed articles, 13 specialty society or other evidence-based guidelines, 3 Cochrane systematic reviews, and 5 book sections. Key evidence includes:

- For malignant or premalignant gynecologic disease (e.g., persistent cervical high-grade intraepithelial lesion, cervical adenocarcinoma in situ, endometrial cancer), specialty society guidelines state that hysterectomy is appropriate to decrease cancer-related morbidity and mortality.
- For benign gynecologic disease, an obstetrics and gynecology textbook, specialty society guidelines, and a review article state that hysterectomy may be appropriate for definitive management of conditions such as abnormal uterine bleeding, leiomyoma, adenomyosis, endometriosis, pelvic organ prolapse, and vesicouterine fistula.
- For cancer risk reduction in an individual at increased risk for endometrial cancer, a consensus guideline states that patients should be offered hysterectomy after counseling about benefits and risks.
- Analysis of procedure data for a Medicare-insured population shows 96% of patients undergoing vaginal hysterectomy were discharged the day of or the day after surgery, supporting ambulatory-level care.

Pelvic Ultrasound, Transvaginal (MCG ORG: A-0109 AC)

The evidence for the clinical indications in this guideline includes 127 published peer-reviewed articles, 24 specialty society or other evidence-based guidelines, 2 Cochrane systematic reviews, and 2 book sections. Key evidence includes:

- For abnormal gynecologic bleeding, evidence demonstrates at least moderate certainty of at least moderate net benefit. Transabdominal ultrasound is less accurate than transvaginal ultrasound in measuring endometrial thickness, which is used for the initial detection of endometrial carcinoma in patients presenting with abnormal uterine bleeding.
- For adnexal mass or suspected ovarian cancer, specialty society guidelines support transvaginal ultrasound as the initial imaging modality for characterizing adnexal lesions and guiding further evaluation.
- For suspected ectopic pregnancy, including after failed medical treatment, transvaginal ultrasound is supported as the appropriate imaging study to localize the pregnancy and detect complications.

- Additional indications supported by specialty society guidance include infertility evaluation, suspected congenital uterine anomaly, lost intrauterine device localization, and cancer surveillance in patients with high-risk hereditary syndromes.

Rationale (from MCG)

Use of these MCG care guidelines helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate setting for gynecologic surgical and diagnostic services. For the hysterectomy guideline, the evidence-based clinical criteria assist the clinician in the decision to appropriately perform the procedure and to determine the appropriate level of care, including identification of complex factors that make it reasonable to expect a necessity for hospital care across 2 or more midnights and CMS Two-Midnight Rule exceptions for Medicare enrollees. For the transvaginal ultrasound guideline, the criteria help the clinician decide when transvaginal imaging is the appropriate diagnostic study. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition):

- Code of Federal Regulations (CFR): 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101 (vaginal hysterectomy); 42 CFR 419.22; 42 CFR 422.101 (transvaginal pelvic ultrasound)
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 1 (Inpatient Hospital Services); Chapter 6 (Hospital Services Under Part B); Chapter 14 (Medical Devices); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5
- Medicare Coverage Determinations: Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx>

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