Exploratory Laparoscopic Gynecologic Surgery

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: December 8, 2023

Important Notices

Notices & Disclaimers:

GUIDELINES SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice.

Other Notices:

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Guideline Information:

Specialty Area: Obstetrics and Gynecology
Guideline Name: Exploratory Laparoscopic Gynecologic Surgery (Single Service)

Literature review current through: 12/8/2023
Document last updated: 12/8/2023
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Exploratory Laparoscopic Gynecologic Surgery

General Guidelines

- **Units, Frequency, & Duration:** Single procedures are performed as needed for defined criteria.
- **Criteria for Subsequent Requests:** Approval when medical necessity criteria below are met.
- **Recommended Clinical Approach:** None.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Exploratory Laparoscopic Gynecologic Surgery (e.g., Myomectomy, Oophorectomy, and Salpingectomy)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ **Cancer-related** indications that are **ANY** of the following:
  - Cervical cancer and **ANY** of the following:
    - Trachelectomy for stage IA1, IA2, IB1, 1B2; **OR** [1-2]
    - Evaluation via laparoscopy is necessary to examine the sentinel or para-aortic lymph nodes when **ANY** of the following is TRUE:
      - ◆ Stage IA1 with lymphovascular space invasion or stage IA2 cervical cancer treated with conization; **OR**
      - ◆ Stage IA2, IB1, and select 1B2 cervical cancer treated with radical vaginal or abdominal trachelectomy; **OR**
      - ◆ In conjunction with pelvic node dissection; **OR**
  - Endometrial cancer[3-4]; **OR**
  - Cytoreduction (e.g., debulking) is indicated for **ANY** of the following known or suspected cancers[5-7]:
    - Primary peritoneal cancer; **OR**
    - Fallopian tube; **OR**
  - Ovarian cancer and **ANY** of the following:
    - Laparoscopic evaluation is required to decide the appropriateness of debulking surgery[5-6]; **OR**
    - Cytoreduction (e.g., debulking); **OR**

        - Relapsed malignant sex cord-stromal tumor[5]; **OR**
        - Ovarian carcinoma and cytoreductive surgery when **ALL** of the following is TRUE:[5]
            - Absence of ascites; **AND**
            - Limited foci of disease amenable to complete resection; **AND**
            - Good/acceptable functional status; **AND**
            - Recurrence of at least six months following chemotherapy treatment with a complete response; **OR**
    - Uterine sarcoma with **ANY** of the following:
        - Isolated pelvic residual disease or recurrence[3]; **OR**
        - Isolated vaginal residual disease or recurrence[3]; **OR**
- **Infertility-related** indications as evidenced by **ANY** of the following:[8-9]
    - For infertility evaluation or treatment and **ALL** of the following:
        - Evidence of infertility as indicated by **ANY** of the following:
            - For a female 34 years of age or younger, failure to achieve conception after at least 12 months of unprotected heterosexual intercourse; **OR**
            - For a female 35 years of age or older, failure to achieve conception after at least 6 months of unprotected heterosexual intercourse; **OR**
        - Hormone laboratory results are an acceptable level (e.g., prolactin, follicle-stimulating hormone, mid-luteal progesterone); **AND**
        - Imaging (e.g., transvaginal ultrasound, hysterosalpingogram, sonohysterography) is **ANY** of the following:
            - Non-diagnostic; **OR**
            - Exhibits pathology that can be managed surgically (e.g., endometriosis); **OR**
    - Patient has a diagnosis of polycystic ovary syndrome that has not responded to pharmacological treatment (e.g., letrozole, clomiphene citrate, metformin)[10-11]; **OR**
- **Myomectomy** needed, as indicated by **ANY** of the following:[12]
    - Acute torsion of pedunculated leiomyoma; **OR**
    - Leiomyoma and **ALL** of the following:
        - Symptoms include **ANY** of the following:
            - Abnormal uterine bleeding that is unsuccessful in non-surgical management (e.g., hormonal therapy); **OR**
            - Infertility due to leiomyoma; **OR**

        - Iron-deficiency anemia; **OR**
        - Dyspareunia; **OR**
        - Pelvic pain or pressure; **OR**
        - Urinary or bowel dysfunction; **AND**
    - Symptoms have been ruled out by other procedures (e.g., endometrial sampling, hysteroscopy, urinalysis, urine culture); **OR**
- **Oophorectomy** (or removal of ovary) when **ANY** of the following are TRUE:
    - Bilateral oophorectomy for premenopausal female with estrogen or progesterone receptor-positive breast cancer[13]; **OR**
    - Prophylactic bilateral salpingo-oophorectomy due to gene mutation associated with elevated risk of ovarian cancer (e.g., BRCA1, BRCA2, BRIP1, RAD51C, RAD51D)[14-15]; **OR**
    - Adnexal mass or ovarian disease; **OR**
    - Adnexal torsion[16]; **OR**
    - Androgen-producing ovary unresponsive to medical therapy; **OR**
- **Oophoropexy** (or ovarian transposition) to preserve fertility when **ALL** of the following are TRUE:[17]
    - Patient is premenopausal; **AND**
    - Pelvic irradiation for cancer; **OR**
- **Salpingectomy** (removal of tube) when **ANY** of the following are TRUE:
    - Adnexal cyst with tubal involvement; **OR**
    - Adnexal torsion[16]; **OR**
    - Hydrosalpinx[18]; **OR**
    - Tubal sterilization indicated for contraception[18]; **OR**
    - Tubo-ovarian abscess and **ANY** of the following are TRUE:[19-20]
        - Unsuccessful treatment with percutaneous drainage or IV antibiotics ; **OR**
        - Ruptured abscess; **OR**
- **Pelvic pain** as evidenced by **ANY** of the following:
    - Chronic pelvic pain evaluation needed and **ALL** of the following are TRUE:[21]
        - Pain lasting six months or more; **AND**
        - Testing (e.g., pelvic exam, STD testing, urinalysis, transvaginal ultrasound) does not reveal specific etiology; **AND**
        - **ANY** of the following:
            - Pain interferes with the patient's function and mobility; **OR**

        - Concern about other causes that may interfere with other treatments for chronic pain; **OR**
    - Endometrioma[22-23]; **OR**
    - Endometriosis is suspected and **ALL** of the following:[22-23]
        - Moderate to severe pain that is not treatable with NSAIDs; **AND**
        - Other etiology of pain is not identified by history, physical examination, and testing (e.g., transvaginal ultrasound); **AND**
        - Prescribed hormone therapy is unsuccessful or not appropriate for the patient and **ANY** of the following:
            - Failure of an observed trial of hormone therapy for three months or more (e.g., oral contraceptive pills, levonorgestrel intrauterine system, estrogen/progestin, gonadotropin-releasing hormone analogs); **OR**
            - Patient wishes to preserve fertility and medical treatments are not appropriate; **OR**
            - Side effects of treatment are intolerable; **OR**
- **Ectopic pregnancy**[24-25]**; OR**
- Any process within the pelvic region such as adhesions, neoplasms, or endometriosis that interferes with normal function of pelvic organs (eg. ureter, bowel); **OR**
- **Transabdominal cerclage** when **ANY** of the following is TRUE:
    - Absence of cervical tissue due to previous cervical surgery[26]; **OR**
    - Diagnosis of cervical insufficiency but cannot be placed because of anatomical limitations (e.g., post-trachelectomy)[27]; **OR**
    - Exocervix; **OR**
    - Previously failed vaginal cerclage[26,28]; **OR**
    - Severe cervical hypoplasia; **OR**
    - Unsuccessful cerclage procedure that resulted in a second-trimester pregnancy loss[27]

Non-Indications

- **Exploratory Laparoscopic Gynecologic Surgery (e.g., Myomectomy, Oophorectomy, and Salpingectomy)** is not considered appropriate if **ANY** of the following is **TRUE**:
    - There is no absolute contraindication to laparoscopic surgery but patients with significant medical comorbidities should be treated with caution just like any other surgery.[29]

Level of Care Criteria

Inpatient or Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58662	Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method
58670	Laparoscopy, surgical; with fulguration of oviducts (with or without transection)

Medical Evidence

Laughlin-Tommaso et al. conducted a comparative study on short-term health-related quality of life (QoL) outcomes following myomectomy. A national registry was utilized to identify pre-menopausal women scheduled for a hysteroscopic, abdominal, or laparoscopic myomectomy. Of the 1206 women included, improved QoL was reported by all women. The authors note that laparoscopic and abdominal techniques have a faster recovery time.[30]

Eleje et al. (2018) analyzed ten cohort studies that included 8087 participants to determine the benefits of risk-reducing salpingo-oophorectomy (RRSO) in women with BRCA1 or BRCA2 mutations. Overall survival was longer than among patients who did not have RRSO. The authors note that future research should focus on bone fracture incidence, quality of life, or severe adverse events for RRSO.[31]

References

1. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines: Cervical cancer (ver. 1.2024). Published September 20, 2023. Accessed October 18, 2023. https://www.nccn.org/.
2. Nitecki R, Woodard T, Rauh-Hain JA. Fertility-sparing treatment for early-stage cervical, ovarian, and endometrial malignancies. Obstet Gynecol. 2020 Dec;136(6):1157-1169. doi: 10.1097/AOG.0000000000004163. PMID: 33156194; PMCID: PMC7680432.
3. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines: Uterine neoplasms (ver. 1.2024). Published September 20, 2023. Accessed October 18, 2023. https://www.nccn.org/.
4. Albright BB, Monuszko KA, Kaplan SJ, et al. Primary cytoreductive surgery for advanced stage endometrial cancer: A systematic review and meta-analysis. Am J Obstet Gynecol. 2021 Sep;225(3):237.e1-237.e24. doi: 10.1016/j.ajog.2021.04.254. PMID: 33957111; PMCID: PMC8717361.
5. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines: Ovarian cancer including fallopian tube cancer and primary peritoneal cancer (ver. 2.2023). Published June 2, 2023. Accessed October 18, 2023. https://www.nccn.org/.
6. Zeng S, Yu Y, Cui Y, et al. Efficacy and safety of minimally invasive surgery versus open laparotomy for interval debulking surgery of advanced ovarian cancer after neoadjuvant chemotherapy: A systematic review and a meta-analysis. Front Oncol. 2022 Jul 18:12:900256. doi: 10.3389/fonc.2022.900256. PMID: 35924170; PMCID: PMC9341245.
7. Coleridge SL, Bryant A, Kehoe S, et al. Neoadjuvant chemotherapy before surgery versus surgery followed by chemotherapy for initial treatment in advanced ovarian epithelial cancer. Cochrane Database Syst Rev. 2021 Jul 30;7(7):CD005343. doi: 10.1002/14651858.CD005343.pub6. PMID: 34328210; PMCID: PMC8406953.
8. Practice Committee of the American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: A committee opinion. Fertil Steril. 2020 Mar;113(3):533-535. doi: 10.1016/j.fertnstert.2019.11.025. PMID: 32115183.
9. Carson SA, Kallen AN. Diagnosis and management of Infertility: A review. JAMA. 2021 Jul 6;326(1):65-76. doi: 10.1001/jama.2021.4788. PMID: 34228062; PMCID: PMC9302705.
10. Mejia RB, Summers KM, Kresowik JD, et al. A randomized controlled trial of combination letrozole and clomiphene citrate or letrozole alone for ovulation induction in women with polycystic ovary syndrome. Fertil Steril. 2019 Mar;111(3):571-578.e1. doi: 10.1016/j.fertnstert.2018.11.030. PMID: 30683591.

11. Teede HJ, Tay CT, Laven J, et al. Recommendations from the 2023 international evidence-based guideline for the assessment and management of polycystic ovary syndrome. J Clin Endocrinol Metab. 2023 Sep 18;108(10):2447-2469. doi: 10.1210/clinem/dgad463. PMID: 37580314; PMCID: PMC10505534.
12. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins-Gynecology. Management of symptomatic uterine leiomyomas: ACOG practice bulletin, number 228. Obstetrics & Gynecology 2021;137(6):e100-e115. DOI: 10.1097/AOG.0000000000004401.
13. Kotsopoulos J, Huzarski T, Gronwald J, et al. Bilateral oophorectomy and breast cancer risk in BRCA1 and BRCA2 mutation carriers. J Natl Cancer Inst. 2016 Sep 6;109(1):djw177. doi: 10.1093/jnci/djw177. PMID: 27601060; PMCID: PMC6284253.
14. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines: Genetic/familial high-risk assessment - breast, ovarian, and pancreatic (ver. 2.2024). Published September 27, 2023. Accessed October 18, 2023. https://www.nccn.org/.
15. American College of Obstetricians and Gynecologists (ACOG). Hereditary cancer syndromes and risk assessment: ACOG committee opinion, number 793. Obstet Gynecol. 2019 Dec;134(6):e143-e149. doi: 10.1097/AOG.0000000000003562. PMID: 31764758.
16. Bridwell RE, Koyfman A, Long B. High risk and low prevalence diseases: Ovarian torsion. Am J Emerg Med. 2022 Jun:56:145-150. doi: 10.1016/j.ajem.2022.03.046. PMID: 35397355.
17. Hoppe RT, Advani RH, Ai WZ, et al. NCCN guidelines® insights: Hodgkin lymphoma, version 2.2022. J Natl Compr Canc Netw. 2022 Apr;20(4):322-334. doi: 10.6004/jnccn.2022.0021. PMID: 35390768.
18. American Society for Reproductive Medicine (ASRM). Role of tubal surgery in the era of assisted reproductive technology: A committee opinion. Fertil Steril. 2021 May;115(5):1143-1150. doi: 10.1016/j.fertnstert.2021.01.051. PMID: 33642065.
19. Zhu S, Ballard E, Khalil A, et al. Impact of early surgical management on tubo-ovarian abscesses. J Obstet Gynaecol. 2021 Oct;41(7):1097-1101. doi: 10.1080/01443615.2020.1821620. PMID: 33249968.
20. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.
21. Lamvu G, Carrillo J, Ouyang C, et al. Chronic pelvic pain in women: A review. JAMA. 2021 Jun 15;325(23):2381-2391. doi: 10.1001/jama.2021.2631. PMID: 34128995.
22. Zondervan KT, Becker CM, Missmer SA. Endometriosis. N Engl J Med. 2020 Mar 26;382(13):1244-1256. doi: 10.1056/NEJMra1810764. PMID: 32212520.

23. Nezhat C, Vang N, Tanaka PP, et al. Optimal management of endometriosis and pain. Obstet Gynecol. 2019 Oct;134(4):834-839. doi: 10.1097/AOG.0000000000003461. PMID: 31503153.
24. Hendriks E, Rosenberg R, Prine L. Ectopic pregnancy: Diagnosis and management. Am Fam Physician. 2020 May 15;101(10):599-606. PMID: 32412215.
25. Hao HJ, Feng L, Dong LF, et al. Reproductive outcomes of ectopic pregnancy with conservative and surgical treatment: A systematic review and meta-analysis. Medicine (Baltimore). 2023 Apr 25;102(17):e33621. doi: 10.1097/MD.0000000000033621. PMID: 37115078; PMCID: PMC10145868.
26. Simcox R, Shennan A. Cervical cerclage: A review. Int J Surg. 2007 Jun;5(3):205-9. doi: 10.1016/j.ijsu.2006.02.006. PMID: 17509504.
27. American College of Obstetricians and Gynecologists (ACOG). ACOG practice bulletin no. 142: Cerclage for the management of cervical insufficiency. Obstet Gynecol. 2014 Feb;123(2 Pt 1):372-379. doi: 10.1097/01.AOG.0000443276.68274.cc. PMID: 24451674.
28. Clark NV, Einarsson JI. Laparoscopic abdominal cerclage: A highly effective option for refractory cervical insufficiency. Fertil Steril. 2020 Apr;113(4):717-722. doi: 10.1016/j.fertnstert.2020.02.007. PMID: 32147177.
29. Madhok B, Nanayakkara K, Mahawar K. Safety considerations in laparoscopic surgery: A narrative review. World J Gastrointest Endosc. 2022 Jan 16;14(1):1-16. doi: 10.4253/wjge.v14.i1.1. PMID: 35116095 PMCID: PMC8788169.
30. Laughlin-Tommaso SK, Lu D, Thomas L, et al. Short-term quality of life after myomectomy for uterine fibroids from the COMPARE-UF Fibroid Registry. Am J Obstet Gynecol. 2020 Apr;222(4):345.e1-345.e22. doi: 10.1016/j.ajog.2019.09.052. PMID: 31678093.
31. Eleje GU, Eke AC, Ezebialu IU, et al. Risk-reducing bilateral salpingo-oophorectomy in women with BRCA1 or BRCA2 mutations. Cochrane Database Syst Rev. 2018 Aug 24;8(8):CD012464. doi: 10.1002/14651858.CD012464.pub2. PMID: 30141832; PMCID: PMC6513554.

Clinical Guideline Revision History/Information

Original Date: December 8, 2023	
Review History	