



## World Trade Center (WTC) Health Program Medical Coverage Determination Endometrial Cancer and Endometrial Intraepithelial Neoplasia (Uterine Cancer)

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### I. Coverage Overview

This Medical Coverage Determination (MCD) outlines the certification and coverage of endometrial cancer and endometrial intraepithelial neoplasia (EIN) for the Clinical Centers of Excellence (CCE) and Nationwide Provider Network (NPN) members.

Malignant neoplasms of corpus uteri and uterus, part unspecified were added to the List of WTC-Related Health Conditions on January 18<sup>th</sup>, 2023.<sup>1</sup> Endometrial cancer, colloquially known as uterine cancer, is a common malignancy of the female reproductive tract.<sup>2</sup> The endometrium is the inner lining of the uterine body, containing a functional, hormonally sensitive layer shed in a cyclical pattern during menstruation in reproductive-age women.<sup>3</sup>

EIN (also referred to as atypical endometrial hyperplasia) is the precursor lesion to endometrioid adenocarcinoma<sup>4</sup> and is identified by the focal or multifocal presence of altered cellularity and crowded endometrial glands significantly different from background endometrium.<sup>5,6</sup> Because characteristics of currently available endometrial sampling technologies limit the exclusion of endometrial carcinoma in a patient with EIN, definitive

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<sup>1</sup> See 42 C.F.R. § 88.15(d)(15), available at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-G/part-88>.

<sup>2</sup> The WTC Health Program defines the term “uterine cancer” as ICD-10 code C54, including the following specific malignant neoplasms: Isthmus uteri (C54.0), endometrium (C54.1), myometrium (C54.2), fundus uteri (C54.3), overlapping sites of corpus uteri (C54.8), and corpus uteri, unspecified (C54.9); and ICD-10 code C55, including only a single sub-category, malignant neoplasm of uterus, part unspecified. See Federal Register Doc. 2023-00645: World Trade Center Health Program; Addition of Uterine Cancer to the List of WTC-Related Health Conditions, at <https://www.federalregister.gov/d/2023-00645>.

<sup>3</sup> See National Cancer Institute (NCI), Endometrial Cancer Treatment (PDQ®)—Health Professional Version, at <https://www.cancer.gov/types/uterine/hp/endometrial-treatment-pdq>.

<sup>4</sup> See ACOG, Endometrial Intraepithelial Neoplasia (ACOG Committee Opinion Number 631), at <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/05/endometrial-intraepithelial-neoplasia>.

<sup>5</sup> See Trimble, C. L., Method, M., Leitao, M., Lu, K., Ioffe, O., Hampton, M., Higgins, R., Zaino, R., Mutter, G. L., & Society of Gynecologic Oncology Clinical Practice Committee (2012). Management of endometrial precancers. *Obstetrics and gynecology*, 120(5), 1160–1175, at <https://doi.org/10.1097/aog.0b013e31826bb121>.

<sup>6</sup> The WTC Health Program will recognize the International Endometrial Collaborative Group nomenclature for purposes of this MCD. Historical pathology labeled atypical simple hyperplasia or atypical complex hyperplasia will be considered akin to EIN, and simple hyperplasia and complex hyperplasia without atypia will be interpreted as benign conditions and, therefore, not eligible for certification by the Administrator of the WTC Health Program. See ACOG, Endometrial Intraepithelial Neoplasia (ACOG Committee Opinion Number 631), at <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/05/endometrial-intraepithelial-neoplasia>.

surgical management is the gold standard to rule out concurrent adenocarcinoma or prevent progression to carcinoma.<sup>7,8</sup>

NOTE: Uterine sarcomas<sup>9</sup> (carcinosarcomas, leiomyosarcomas, and endometrial stroma sarcomas) are uncommon stromal or mesenchymal malignancies of the uterine corpus,<sup>10</sup> and have been covered under the WTC Health Program Rare Cancer policy since 05/05/2014.<sup>11</sup> Invasive cervical cancer (cancer of the lower uterine segment) is also covered by the WTC Health Program as a "Rare Cancer."<sup>12</sup> Historically, endometrial cancer has been covered as a health condition medically associated with a certified WTC-related health condition (Medically Associated Condition or MAC)<sup>13</sup> by the WTC Health Program in certain cases when clinically appropriate and all program requirements are met.<sup>14</sup> This document refers specifically to certification requirements and medical coverage for WTC-related endometrial cancer and EIN only.

## II. Certification and Eligibility Requirements for WTC-Related Endometrial Cancer and EIN

To qualify as a WTC-related health condition, endometrial cancer or EIN must be diagnosed with a minimum latency of four or more years since the date of the member's first 9/11-related exposures;<sup>15</sup> a definitive pathology report must also be provided. The CCE/NPN will follow standard procedures for requesting certification using the WTC-3 Certification Request process. All documentation for endometrial cancer or EIN certification requests is subject to audit by the WTC Health Program. For detailed certification request procedures, see instructions found in the WTC Health Program's Administrative Manual.<sup>16</sup>

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<sup>7</sup> "Atypical hyperplasia has a 36% progression rate, and even with progestins, 27% have been reported to progress, but it is uncertain if this is coexistent cancer that is eventually identified." From DiSaia, P. J., Creasman, W. T., Mannell, R. S., McMeekin, S., Mutch, D. G., (2018). Endometrial Hyperplasia, Estrogen Therapy, and the Prevention of Endometrial Cancer. In L.M. Landrum, R.E. Zuna, , & J.L. Walker. In *Clinical gynecologic oncology* (pp. 105–120). Elsevier. <https://doi.org/10.1016/B978-0-323-40067-1.00004-8>.

<sup>8</sup> "Endometrial intraepithelial neoplasia (EIN), formally known as complex atypical hyperplasia (CAH), is a premalignant lesion of the endometrium that is of clinical significance because of an approximately 40% risk of progression to endometrial adenocarcinoma (EC). Furthermore, the prevalence of concurrent EC in patients diagnosed with EIN undergoing hysterectomy approaches 43%." From Vetter, M. H., Smith, B., Benedict, J., Hade, E. M., Bixel, K., Copeland, L. J., Cohn, D. E., Fowler, J. M., O'Malley, D., Salani, R., & Backes, F. J. (2020). Preoperative predictors of endometrial cancer at time of hysterectomy for endometrial intraepithelial neoplasia or complex atypical hyperplasia. *American Journal of Obstetrics and Gynecology*, 222(1). <https://doi.org/10.1016/j.ajog.2019.08.002>.

<sup>9</sup> See NCI, Uterine Sarcoma Treatment (PDQ®)—Health Professional Version, at <https://www.cancer.gov/types/uterine/hp/uterine-sarcoma-treatment-pdq>.

<sup>10</sup> See National Comprehensive Cancer Network (NCCN), NCCN Guidelines: Uterine Neoplasms, at <https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1473>.

<sup>11</sup> See WTC Health Program Policy and Procedure (P&P), Rare Cancer, at [https://www.cdc.gov/wtc/pdfs/policies/WTCHP\\_PP\\_RareCancers05052014-508.pdf](https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_RareCancers05052014-508.pdf).

<sup>12</sup> A rare cancer is defined as any type of cancer that occurs in less than 15 cases per 100,000 persons per year in the United States. See 42 C.F.R. § 88.15(d)(25), available at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-G/part-88>.

<sup>13</sup> A health condition medically associated with a WTC-related health condition (MAC) is a condition that results from treatment or progression of a WTC-related condition. See 42 C.F.R. § 88.1 at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-G/part-88>. See also [Health Conditions Medically Associated with World Trade Center-Related Health Conditions \(cdc.gov\)](https://www.cdc.gov/health-conditions/medically-associated-with-wtc-related-health-conditions).

<sup>14</sup> For example, members who were certified for WTC-related breast cancer and were treated with Tamoxifen as adjunctive therapy and were diagnosed with endometrial cancer may have their endometrial cancer certified as a MAC. For additional information, see ACOG, Tamoxifen and Uterine Cancer, at <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/06/tamoxifen-and-uterine-cancer>.

<sup>15</sup> See WTC Health Program Policy and Procedure (P&P), Minimum Latency and Type or Categories of Cancer, at <https://www.cdc.gov/wtc/pdfs/policies/WTCHP-Minimum-Cancer-Latency-PP-01062015-508.pdf>.

<sup>16</sup> See WTC Health Program Administrative Manual [Chapter 3] at <https://www.cdc.gov/wtc/ppm.html#certification>.

## A. Early or Premature Menopause

If interventions to treat certified endometrial cancer or EIN result in early or premature menopause, then certification may be requested for menopause as a medically associated condition to the certified WTC-related endometrial cancer or EIN.<sup>17</sup>

## B. Synchronous Primaries

Synchronous primary cancers of the endometrium and ovary are rare and found in under 10% of hysterectomy/oophorectomy surgical specimens. Histology is often the same in both the endometrium and ovary, making it unclear whether there are two separate primary tumors or a metastasis from the endometrium to the ovary, or vice versa.<sup>18</sup> To be considered two separate primaries translating to two separate certifications, endometrial cancer and ovarian cancer, the medical and pathology records must substantiate histopathologically separate tumors.<sup>19</sup>

## III. Covered Services

The WTC Health Program covers cancer treatment following the clinical practice guidelines set forth by the National Comprehensive Cancer Network (NCCN). Covered services under the WTC Health Program include diagnostic endometrial sampling, as well as medically necessary treatment for certified endometrial carcinoma and EIN.<sup>20,21</sup> Members may also be enrolled in Case Management or Intensive Case Management (ICM) for coordination of care.

Coverage is permitted only when in accordance with the Program formulary and other Program guidelines.<sup>22</sup> Refer to the WTC Health Program Codebook for a full list of covered medical services, procedures, and diagnosis codes.

## A. Fertility-Sparing Treatment<sup>23</sup>

The WTC Health Program will cover fertility-sparing via hormone-based therapy only for eligible members certified for low-grade endometrial cancer or EIN.<sup>24</sup> Members must be adequately counseled that medical management is not standard of care and have documentation maintained in the member's record.

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<sup>17</sup> Premature menopause is defined as menopause onset occurring before age 40, while early menopause is onset occurring before age 45. See the 2022 Hormone Therapy Position Statement of the North American Menopause Society, at [https://journals.lww.com/menopausejournal/Abstract/2022/07000/The\\_2022\\_hormone\\_therapy\\_position\\_statement\\_of\\_The.4.aspx](https://journals.lww.com/menopausejournal/Abstract/2022/07000/The_2022_hormone_therapy_position_statement_of_The.4.aspx).

<sup>18</sup> Blake Gilks, C., & Singh, N. (2018). Synchronous carcinomas of endometrium and ovary: A pragmatic approach. *Gynecologic oncology reports*, 27, 72–73. <https://doi.org/10.1016/j.gore.2018.12.009>.

<sup>19</sup> Dębska-Szmich, S., Czernek, U., Krakowska, M., Frąckowiak, M., Zięba, A., Czyżykowski, R., Kulejewska, D., & Potemski, P. (2014). Synchronous primary ovarian and endometrial cancers: a series of cases and a review of literature. *Menopause review*, 13(1), 64–69. <https://doi.org/10.5114/pm.2014.41084>.

<sup>20</sup> See NCCN Systemic Therapy for Endometrial Carcinoma at [https://www.nccn.org/professionals/physician\\_gls/pdf/uterine.pdf](https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf).

<sup>21</sup> See ACOG, Conclusions and Recommendations and Nonsurgical Management Options, at <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/05/endometrial-intraepithelial-neoplasia>

<sup>22</sup> See generally WTC Health Program Administrative Manual for a full description of Program guidelines, policies, and procedures, at <https://www.cdc.gov/wtc/ppm.html>.

<sup>23</sup> For the purposes of this MCD, fertility-sparing treatment refers only to uterine preservation.

<sup>24</sup> See NCCN Clinical Practice Guidelines in Oncology for Uterine Neoplasms, at [https://www.nccn.org/professionals/physician\\_gls/pdf/uterine.pdf](https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf).

Coverage of fertility-sparing treatment is limited to those services related to endometrial disease only. This includes appropriate clinical counseling, additional diagnostics as needed, medically necessary hormonal therapy, and follow-up disease surveillance per NCCN guidelines. The WTC Health Program is not responsible for any subsequent evaluation/management of fertility status, such as genetic counseling or reproductive endocrinology consultation. coverage does not include infertility and oncofertility services or any subsequent pregnancy-related, post-partum, or neonatal services, including global obstetric fees.

Fertility-sparing treatment requires a Prior Authorization Level 3 (PA3). The WTC Health Program will review the medical justification provided by the CCE/NPN Clinical Director and determine whether the fertility-sparing treatment is appropriate to treat the member's certified endometrial cancer or EIN on a case-by-case basis. The WTC Health Program will also ensure that the member meets the PA3 criteria listed below in Section III.B.

## **B. PA3 Criteria for Fertility-Sparing Treatment**

The PA3 for fertility-sparing treatment will cover a 12-month authorization period. The CCE/NPN Clinical Director may request prior authorization for fertility-sparing treatment if ALL the criteria<sup>25</sup> below (a. through f.) are met and clearly documented in the member's medical record:

- a. EIN or Grade 1 endometrioid adenocarcinoma on surgical pathology (D&C);
- b. Disease limited to endometrium on imaging (MRI/TVUS);
- c. Absence of metastatic disease on imaging;
- d. No contraindications to pregnancy;
- e. No contraindications to medical management of EIN or Grade 1 endometrioid adenocarcinoma; and
- f. Documentation patients have been counseled that medical management is not standard of care.

## **C. Subsequent Authorizations for Fertility-Sparing Treatment**

The PA3 request for fertility-sparing treatment will only cover a 12 calendar-month authorization period. Once the PA3 is approved, the authorization period starts the day the member begins receiving fertility-sparing treatment and ends when the 12 calendar-month period is over, unless a new PA3 is submitted to the WTC Health Program. The WTC Health Program-affiliated provider must furnish a plan of care to the CCE/NPN Clinical Director prior to the end of the current authorization period, and before the start of each new authorization period. The CCE/NPN Clinical Director must submit a new PA3 request and the WTC Health Program must approve the request, reconfirming that the member's fertility-sparing treatment is appropriate and all criteria in the MCD are met.

## **D. Prior Authorization Request Submission Requirements**

The PA3 request for fertility-sparing treatment must be signed by the requesting CCE/NPN Clinical Director and submitted to the Third-Party Administrator (TPA)

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<sup>25</sup> See NCCN Clinical Practice Guidelines in Oncology for Uterine Neoplasms, at [https://www.nccn.org/professionals/physician\\_gls/pdf/uterine.pdf](https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf).

contractor securely following the Program's standard procedures. The WTC Health Program will decide whether to authorize the service and will inform the TPA contractor, who will subsequently inform the CCE/NPN of the decision.

The CCE/NPN will maintain documentation in the member's medical record, as well as documentation related to the PA3 Request. Incomplete or inaccurate requests will be returned to the requesting CCE/NPN for additional information.

All documentation used to complete authorization of uterine preservation is subject to audit by the WTC Health Program. For detailed Prior Authorization procedures, see instructions found in the WTC Health Program's Administrative Manual.<sup>26</sup>

#### **IV. Certification and Coverage Exclusions**

##### **A. Benign Lesions of the Endometrium**

The WTC Health Program will **NOT COVER** benign lesions of the endometrium. Benign endometrial hyperplasia (also referred to as nonatypical endometrial hyperplasia) differs from EIN in that glandular crowding is the resultant field effect of excess estrogen and is not in itself prone to malignant transformation.<sup>27</sup> Benign endometrial hyperplasia is not eligible for certification nor covered in the WTC Health Program.

Additional benign endometrial lesions not eligible for coverage beyond diagnostic intervention include, but are not limited to:

- Endometrial polyps
- Endometrial glandular hyperplasia
- Endometrial metaplasia
- Leiomyoma
- Adenofibroma
- Adenoma
- Endometrial stromal nodules

##### **B. Infertility and Oncofertility Services**

The WTC Health Program will **NOT COVER** infertility and oncofertility services including:

- Artificial Reproductive Technologies necessary to mitigate pre-existing disease or as a result of definitive treatment of endometrial cancer or EIN, including, but not limited to, ovulation induction, cryopreservation, intrauterine insemination, in vitro fertilization, and gestational carriers.
- Fertility therapies necessary to hasten pregnancy prior to definitive treatment of endometrial cancer or EIN, as outlined above.
- Fertility evaluation services including reproductive endocrinology consultation, preconception counseling, and/or genetic counseling for eligible members receiving for management of their EIN or low-grade endometrial carcinoma.

##### **C. Obstetrical and Neonatal Services**

The WTC Health Program will **NOT COVER** subsequent pregnancy-related,

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<sup>26</sup> WTC Health Program Administrative Manual, [Chapter 4, Section 3.4], at [https://www.cdc.gov/wtc/ppm.html#medical\\_prior](https://www.cdc.gov/wtc/ppm.html#medical_prior).

<sup>27</sup> See Footnote 6.

post-partum, or neonatal services in members who elect fertility-sparing treatments. Only ongoing surveillance and other procedures specific to the member's certified EIN or low-grade endometrial carcinoma will be covered during pregnancy and delivery.<sup>28</sup>

## **V. Billing/Coding Guidelines**

All applicable codes are listed in the WTC Health Program Codebook, located on the Centralized Accessible Realtime Enterprise (CARE) portal.

For consideration of codes that are not currently included in the WTC Health Program Codebook, please submit a WTC-5 Medical Code Request form to the Third-Party Administrator (TPA) contractor via the standard [WTCMedCode@csra.com](mailto:WTCMedCode@csra.com) mailbox process.

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<sup>28</sup> In rare situations, portions of obstetrical procedures (e.g. cesarean section, hysterectomy, etc.) may be covered due to endometrial disease. Please contact the WTC Health Program in these circumstances.