

| CLINICAL MEDICAL POLICY | | |
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| Policy Name: | Hysterectomy for Benign Conditions | |
| Policy Number: | MP-020-MD-PA | |
| Responsible Department(s): | Medical Management | |
| Provider Notice/Issue Date: | 06/01/2024; 07/01/2023; 06/01/2022; 09/17/2021; 9/21/2020; 01/20/2020; 11/15/2018; 10/01/2017 | |
| Effective Date: | 07/01/2024; 08/01/2023; 07/01/2022; 10/18/2021; 10/19/2020; 01/20/2020; 11/15/2018; 10/01/2017 | |
| Next Annual Review: | 04/2025 | |
| Revision Date: | 04/17/2024; 04/19/2023; 04/20/2022; 08/18/2021; 08/19/2020; 08/21/2019; 08/01/2018; 03/01/2017 | |
| Products: | Highmark Wholecare™ Medicaid | |
| Application: | All participating hospitals and providers | |
| Page Number(s): | 1 of 8 | |

Policy History

| Date | Activity |
|------------|---------------------------------------------------------------------------------------|
| 07/01/2024 | Provider Effective date |
| 05/14/2024 | PARP Approval |
| 04/17/2024 | QI/UM Committee review |
| 04/17/2024 | Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and |
| | 'Reference Sources.' |
| 08/01/2023 | Provider Effective date |
| 05/31/2023 | PARP Approval |
| 04/19/2023 | QI/UM Committee review |
| 04/19/2023 | Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and |
| | 'Reference Sources' sections. |
| 07/01/2022 | Provider Effective date |
| 05/17/2022 | PARP Approval |
| 04/20/2022 | QI/UM Committee review |
| 04/20/2022 | Annual Review: Renamed policy from 'Place of Service' to 'Hysterectomy for Benign |
| | Conditions.' Restructured policy to focus solely on medical necessity for vaginal and |
| | laparoscopic hysterectomy. Added medical necessity guidelines and |
| | contraindications. Removed cholecystectomy information. Updated Summary of |
| | Literature and Reference Sources sections. |
| 10/18/2021 | Provider effective date |

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| 08/18/2021 | QI/UM Committee Review |
|------------|----------------------------------------------------------------------------------------|
| 08/18/2021 | Annual Review: No changes to clinical criteria. Updated Reference Sources section. |
| 10/19/2020 | Provider Effective Date |
| 08/19/2020 | QI/UM Committee Review |
| 08/19/2020 | Annual Review: No change in coverage position; corrected coding description for |
| | procedure code 58270; updated Reference section |
| 01/20/2020 | Provider effective date |
| 08/21/2019 | Annual Review: Added sentence under Procedures to identify the specific procedures |
| | this policy addresses. No other changes were made to the policy. |
| 08/21/2019 | QI/UM Committee Review Approval |
| 11/15/2018 | Provider effective date |
| 09/17/2018 | PARP approval |
| 08/15/2018 | QI/UM Committee Review |
| 08/15/2018 | Annual Review: Removed the word 'Covered' from the procedure code table in |
| | Attachment B; Removed hyperlinks; No other changes made to the policy |
| 10/01/2017 | Provider Effective Date |
| 08/02/2017 | PARP approval annual review: Revision of language in #2 criteria of Procedures stating |
| | inpatient requests must be approved by medical director. |
| 01/01/2017 | Annual Review. Policy revised: Added Policy History box; Changed Operational |
| | Guidelines from post-service to preservice |
| 09/01/2016 | Provider effective date |
| 06/20/2016 | PARP approval of UM InterQual Changes on Place of Service |
| 06/15/2016 | QI/UM Committee review |
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Disclaimer

Highmark Wholecare[™] medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare[™] provides coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary services performed as an outpatient.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Outpatient Surgery Setting – Outpatient surgery is performed in a variety of settings including but not limited to: Ambulatory surgical centers freestanding, ambulatory surgical settings within a hospital setting, or physician office.

Hysterectomy - surgery to remove the uterus and the cervix. The ovaries and fallopian tubes may also be removed. A total hysterectomy may be done through the vagina (with no incisions in the abdomen) or through an incision (cut) in the abdomen. Also called complete hysterectomy and simple hysterectomy.

Procedures

- 1. Highmark Wholecare may consider hysterectomy surgery, with or without salpingo-oophorectomy (removal of fallopian tubes and ovaries), for a gynecologic non-malignant or non-emergent condition, to be medically necessary when ALL of the following conditions are met:
 - A. The performed procedure is for ANY ONE of the following conditions:
 - 1) Abnormal uterine bleeding (i.e., menorrhagia, hypermenorrhea), when ALL of the following are met:
 - a) Other conservative treatments have failed to control the bleeding; AND
 - b) Endometrial biopsy sampling has been performed and is negative for cancer; AND
 - c) Significant bleeding is recurrent and is interfering with Activities of Daily Living (ADL); OR
 - 2) Adenomyosis:
 - a) Individual has an enlarged uterus, based on clinical examination and it is present in ultrasound or MRI; OR
 - 3) Endometriosis, when ALL of the following are met:
 - a) A diagnosis has been surgically confirmed; AND
 - b) Conservative treatments have failed to control symptoms, including failure, intolerance, or contraindication to hormone therapy (ie, oral contraceptive pills); AND
 - c) Pain significantly interferes with ADLs; OR
 - 4) Genetic predisposition to cancer:
 - a) A BRCA 1 or BRCA 2 mutation has been confirmed by genetic testing
 - b) Hereditary nonpolyposis colorectal cancer (HNPCC) Lynch syndrome diagnosis is documented; OR
 - 5) Symptomatic pelvic prolapse, stage II or greater, with urinary and/or bowel dysfunction.
 - B. Vaginal hysterectomy is considered the approach of choice whenever feasible.
 - Laparoscopic hysterectomy is a preferable alternative to open abdominal hysterectomy for those individuals in whom a vaginal hysterectomy is not indicated or feasible.
 - The provider should account for clinical factors and determine which route of hysterectomy will most safely facilitate removal of the uterus and optimize

patient outcomes, given the clinical situation and provider training and experience.

- 2. When hysterectomy surgery is considered not medically necessary
 - Services identified as appropriate in the outpatient setting will not be reimbursed in the inpatient setting without a Highmark Wholecare Medical Director approval.
 - Hysterectomy performed for any condition not listed in this medical policy will be considered not medically necessary.
- 3. A procedure is considered appropriate in the outpatient setting when:
 - The procedure requires the services of the recovery room
 - Post-operative care can be managed at home

Note: If services require a higher-level setting, supporting medical documentation must be provided at the time of the request.

4. Contraindications

There are no absolute contraindications, but some of the relative contraindications to vaginal hysterectomy are:

- Pelvic radiation
- Large uterus
- Prior pelvic surgeries
- Suspected severe pelvic adhesion and anatomical distortion from PID (pelvic inflammatory disease) or endometriosis.
- Morbid obesity
- Nulliparity
- Lack of uterine descent

Note: This policy does not apply to hysterectomy for gender affirmation services. (Please refer to the Highmark Wholecare [™] 'Gender Affirmation Services' medical policy, MP-033-MD-PA.)

5. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare[™] at any time pursuant to the terms of your provider agreement.

6. Place of Service

The proper place of service for an uncomplicated vaginal or laparoscopic hysterectomy is the outpatient setting.

Governing Bodies Approval

CMS

The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

• National Coverage Determination (NCD) Sterilization (230.3)

Summary of Literature

Hysterectomy

The American Congress of Obstetricians and Gynecologists (ACOG) has identified hysterectomy as one of the most frequently performed surgeries in the United States. Selection of the route of hysterectomy for benign causes can be influenced by the size and shape of the vagina and uterus; accessibility to the uterus; extent of extra-uterine disease; the need for concurrent procedures; surgeon training and experience; average case volume; available hospital technology, devices, and support; whether the case is emergent or scheduled; and preference of the informed patient.

Minimally invasive approaches to hysterectomy should be performed, whenever feasible, based on their well-documented advantages over abdominal hysterectomy. The obstetrician–gynecologist should discuss the options with the patient and make clear recommendations on which route of hysterectomy will maximize benefits and minimize risks given the specific clinical situation. The surgeon should account for clinical factors and determine which route of hysterectomy will most safely facilitate removal of the uterus and optimize patient outcomes, given the clinical situation and surgeon training and experience. (ACOG, 2021).

According to the Society of Obstetricians and Gynecologists of Canada (SOGC) clinical practice guidelines, vaginal hysterectomy should be considered the first choice for all benign indications, while laparoscopicassisted approaches should be considered when using such an approach reduces the need for a laparotomy. There are several types of hysterectomy, all of which include the removal of the uterus. In a subtotal hysterectomy (also referred to as a supracervical or partial hysterectomy), the upper two thirds of the uterus is removed, while the cervix is left in place. A total hysterectomy (or complete hysterectomy) involves the removal of the entire uterus as well as the cervix. If both the ovaries and the fallopian tubes are removed during a total hysterectomy, a radical hysterectomy, involves removal of the uterus, cervix, ovaries, fallopian tubes and, possibly, upper portions of the vagina and affected lymph glands. This procedure is strongly recommended for serious complications and diseases such as cancer (Rice, Howard, 2006).

Hysterectomy can majorly impact a patient's quality of life and have long-term physical, psychological, and mental health effects. Healthcare practitioners should thoroughly counsel patients before hysterectomy so that they can make informed decisions about their treatment (Pillarisetty, Mahdy, 2021).

Hysterectomy is considered a safe procedure, but as with any operation, there are risks:

- Slow return of normal bladder emptying requiring use of catheter
- Slow return of normal bowel function
- Changes in bowel or bladder function
- Bladder or urinary infections
- Pelvic pain, including pain with sexual activity
- Infection of vaginal incisions and possibly the skin near the vaginal opening
- Deep vein thrombosis or pulmonary embolism
- Bleeding requiring transfusion or damage to nearby organ
- Bowel obstruction (AUGS, 2016)

Vaginal Approach

According to ACOG, the vaginal approach is preferred among the minimally invasive approaches. Evidence demonstrates that it is associated with better outcomes when compared with other approaches to

hysterectomy. Advantages include less pain, rapid recovery, faster return to work, lower costs, and lower morbidity. It is usually performed for benign reasons. Opportunistic salpingectomy usually can be safely accomplished at the time of vaginal hysterectomy (ACOG, 2021).

Laparoscopic Approach

ACOG considers laparoscopic hysterectomy as a preferable alternative to open abdominal hysterectomy for those patients in whom a vaginal hysterectomy is not indicated or feasible.

Patients who have laparoscopic hysterectomy without perioperative complication or comorbidities can be discharged home on the same day, or stay in the hospital overnight, typically one night. Observational studies have consistently found the same day discharge is safe and less costly and experience fewer postoperative complications. When compared with abdominal hysterectomy, laparoscopic surgery results in less pain, has a lower risk of infection (ACOG, 2021).

The role of robotic assistance for execution of laparoscopic hysterectomy has not been clearly determined and more data are necessary to determine the most appropriate evidence-based applications for this technology (ACOG, 2021).

Rationale

A 2018 prospective, randomized, double-blind study was designed to investigate as primary outcome the postoperative pain after vaginal hysterectomy and laparoscopic-assisted vaginal hysterectomy with and without peritoneal closure. The postoperative pain was measured using visual analogue scale (VAS). A total of 192 patients with benign uterine diseases were eligible for analysis and were divided in four groups: LAVH and VH with and without peritoneal closure (PC), respectively. The patients' characteristics including parity, BMI, previous abdominal operations, and uterus weight were well balanced between the groups. The study found that vaginal hysterectomy is associated with shorter operating time and reduced postoperative pain compared to laparoscopic-assisted vaginal hysterectomy (Eggemann, Ignatov, Frauchiger-Heuer, et al., 2018).

Uterine size has previously been cited as a barrier to performing a minimally invasive hysterectomy, however, gynecologic surgeons have been able to demonstrate that laparoscopic and vaginal hysterectomy is feasible with increasingly large uteri. A study published by the American Journal of Obstetrics and Gynecology sought to determine if there is an association between uterine weight and post-hysterectomy complications and if differences in that association exist across vaginal, laparoscopic, and abdominal approaches. The study collected quality improvement data from the American College of Surgeons National Surgical Quality Improvement Program database, composed of patient information and 30-day postoperative outcomes from >500 hospitals across the United States and targeted data files, which includes additional data on procedure-specific risk factors and outcomes in >100 of those participating hospitals. It was found that while uterine weight was an independent risk factor for posthysterectomy complications, abdominal hysterectomy had higher odds of any complication, when compared to laparoscopic hysterectomy, even for enlarged uteri. The study suggests that uterine weight alone is not an appropriate indication for abdominal hysterectomy. It was also found that it is safe to perform larger hysterectomies laparoscopically, and patients with enlarged uteri should be referred to experienced surgeons who are able to offer laparoscopic hysterectomies in this case (Louie, Strassle, Moulder, Dizon, et al., 2018).

In a study reported by Guta (2011), 19 laparoscopically assisted vaginal hysterectomies and 17 total laparoscopic hysterectomies were performed. The 2 groups were similar in age, BMI, uterine weight, and surgical time. Comparing the two groups, there were no statistically significant differences in pain

throughout any time points of the study. The author concluded there were no statistically significant differences in pain during the postoperative period between the two groups. The study concluded that outpatient hysterectomy is a safe procedure which may improve patient satisfaction surgically and financially, and either approach is well tolerated by patients.

An observational study on a comparison of postoperative outcomes in outpatient and inpatient laparoscopic hysterectomy procedures reported that overall morbidity was low in both the inpatient and outpatient populations. It was noted that there were significantly fewer 30-day complications observed in the outpatient group compared to the inpatient surgery group. The outpatient group experienced fewer wound complications, lower medical complications and deep vein thrombosis (Khavanin, 2013).

Coding Requirements

| CPT Code | Description |
|----------|-----------------------------------------------------------------------------------------------------------------------------------|
| 58260 | Vaginal hysterectomy, for uterus 250 g or less |
| 58262 | Vaginal hysterectomy, for uterus 250 g or less; with removal tube(s), and or ovary(s) |
| 58263 | Vaginal hysterectomy, for uterus 250 g or less with removal of tubes and/or ovary(s) with repair of enterocele |
| 58270 | Vaginal hysterectomy, for uterus 250g or less with repair of enterocele |
| 58290 | Vaginal hysterectomy with uterus greater than 250 g |
| 58291 | Vaginal hysterectomy with uterus greater than 250g; with removal of tube(s) or ovary(s) |
| 58292 | Vaginal hysterectomy with uterus greater than 250 g; with removal of tube(s) or ovary(s), with repair of enterocele |
| 58294 | Vaginal hysterectomy for uterus greater than 250 g with repair of enterocele |
| 58541 | Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less |
| 58542 | Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less, with removal of tube(s) and/or ovary(s) |
| 58543 | Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g |
| 58544 | Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s) |
| 58550 | Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less |
| 58552 | Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s) |
| 58553 | Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g |
| 58554 | Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s) |
| 58570 | Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g or less |
| 58571 | Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g or less; with removal of tube(s) and/or ovary(s) |
| 58572 | Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g |
| 58573 | Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s) |

Procedure Codes

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare[™] contract.

Reference Sources

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