Clinical Policy Title: Endometrial ablation

Clinical Policy Number: 12.03.03

Effective Date: April 1, 2015
Initial Review Date: November 15, 2014
Most Recent Review Date: November 18, 2015
Next Review Date: November 2016

Related policies:

CP# 12.03.02  Intrauterine artery embolization for fibroids

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of endometrial ablation (EA) to be clinically proven and, therefore, medically necessary when the following criteria are met:

- A history of menorrhagia (heavy bleeding) as evidenced by:
  - Profuse bleeding or repetitive periods longer than eight days.
  - Anemia due to acute or chronic blood loss.
- Unresponsiveness to at least three months of hormonal therapy (if not contraindicated).
- Review of endometrial histopathological and endometrial sampling results before endometrial ablation (i.e., endometrial ablation is not appropriate in women with endometrial hyperplasia or cancer).
- Diagnostic evaluation of the endometrium within the past 12 months by endometrial biopsy, or dilatation and curettage (D&C) to show no evidence of remediable pathology.
- Endometrial and cervical pre-cancers or cancers have been ruled out.

Policy contains:
- Endometrial ablation (EA).
- Menorrhagia.
Prestige Health Choice considers the following methods for performing EAs to be clinically proven and, therefore, medically necessary (definitions of each method can be found in the glossary):

- Radiofrequency.
- Freezing (cryoablation).
- Heated fluid (hydrothermal).
- Heated balloon (thermal).
- Microwave energy.
- Electrosurgery.
- Laser.

**Limitations:**

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at [http://ahca.myflorida.com/Medicaid/](http://ahca.myflorida.com/Medicaid/).

All other techniques used for EA are not medically necessary.

EA is an ambulatory procedure unless the patient requires hospitalization for other indications.

EA should not be done in women past menopause.

EA is not recommended for women with certain medical conditions, including the following:

- Other disorders of the uterus or endometrium.
- Endometrial hyperplasia.
- Cancer of the uterus.
- Recent pregnancy.
- Current or recent infection of the uterus.

Contraindications for EA include:

- Known or suspected endometrial carcinoma or pre-malignant change of the endometrium (e.g., unresolved adenomatous hyperplasia).
- Presence of enlarged uterus (e.g., greater than 10 cm in length or comparable to 12 weeks gestation or more).
- Any anatomic or pathologic condition in which weakness of the myometrium could exist (e.g., history of previous classical cesarean section(s) or transmural myomectomy).
• Uterine prolapse.
• Submucosal myomas.
• Active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis).
• Pregnancy or desire to become pregnant in the future.
• Intrauterine device (IUD) in place.
• Active pelvic inflammatory disease (PID).

**Alternative covered services:**

• Conservative medical treatment as prescribed by treating specialist.
  - Analgesics, antibiotics, antiprostaglandins, oral contraceptives, and gonadotropin-releasing hormone (Gn-RH) agonists danazol.
  - Non-steroidal anti-inflammatory drugs (NSAIDs.)

• Dilation and curettage (D&C).
• Endometrial biopsy.
• Hysterectomy for members who are candidates, based on the assessment and treatment failures of their treating providers.

**Background**

Heavy menstrual bleeding (HMB), also known as menorrhagia, is defined as excessive menstrual blood loss that interferes with a woman's physical, social, emotional, and/or material quality of life. It can occur alone or in combination with other symptoms. Menorrhagia is a very common problem. Menstrual cycles longer than 35 days, or shorter than 21 days are abnormal.

Medical treatment consists of anti-fibrinolytic tranexamic acid, NSAIDs, the combined contraception pill, progestogen, danazol, or analogues of Gn-RH. In women who refuse or fail medical management, D&C is an appropriate diagnostic step, as the addition of hysteroscopy will aid in the treatment of endometrial polyps or the performance of directed uterine biopsies. As a rule, D&C has not been shown to be very efficacious with dysfunctional uterine bleeding and should not be used as a therapeutic treatment.

Abdominal or vaginal hysterectomy may be necessary in patients who have failed or declined hormonal therapy, have symptomatic anemia, and who experience a disruption in their quality of life from persistent, unscheduled bleeding. Hysterectomy is the only treatment for HMB that guarantees complete cessation of menstrual periods, but is associated with peri- and post-operative complications. This includes incontinence and other urinary problems, fatigue, infection, pelvic pain and sexual problems. Overall, one in 30 women suffer a major adverse event during or soon after the operation, and the procedure has a mortality rate of 0.4 to 1.1 deaths, per 1,000 operations. Hysterectomy is costly and has significant resource implications, because it requires general anaesthesia, long operating
theatre times, and a post-operative hospital stay of up to seven days. Full recovery may take one to three months.

Minimally invasive procedures that destroy the lining of the uterus (the endometrium) are alternatives to hysterectomy. EA may be performed using lasers, radiofrequency waves, cryosurgery, electrocautery, microwaves, heated saline, or a heated balloon. Thermal fluid-filled balloon, cryosurgical EA, instillation of heated saline, and radiofrequency ablation can be performed without general anesthesia in a physician’s office and do not require hysteroscopic guidance. Microwave ablation may also be performed in a physician’s office, but does require use of the hysteroscope.

The most widely used first-generation EA techniques are transcervical resection of the endometrium (TCRE) using a loop diathermy electrode and roller-ball ablation (RB), or using an electrode with a movable ball or cylinder. All first-generation EA techniques require direct visualisation of the endometrium, using a hysteroscope. The success rates of these techniques depend heavily on the skills and experience of the operator. Possible perioperative adverse effects with the first generation EA techniques include electrosurgical burns, uterine perforation, hemorrhage, infection, and fluid overload, (which may cause congestive cardiac failure, hypertension, hemolysis, coma and death). The Minimally Invasive Surgical Techniques-Laser, EndoThermal or Endoresection (MISTLETOE) study (of more than 10,000 women) in England and Wales, and the Scottish Audit of Hysteroscopic Surgery study (SAHS) (of about 1,000 women) reported mortality rates of 0.26 deaths per 1,000 procedures (Overton, 1997; SAHS, 1997).

Second-generation EA techniques provide simpler, quicker and more effective treatment options for HMB compared with first-generation EA techniques and hysterectomy. These techniques are less operator-dependent, but they rely heavily on the devices themselves to ensure safety and efficacy. They do not require direct visualisation of the uterine cavity, and can be carried out under either local or general anaesthesia. Second-generation EA techniques include fluid-filled thermal balloon EA (TBEA), radiofrequency (thermoregulated) balloon EA, hydrothermal EA, 3-D bipolar radiofrequency EA, microwave EA (MEA), diode laser hyperthermy, cryoablation and photodynamic therapy.

In 1997, the U.S. Food and Drug Administration (FDA) approved the ThermaChoice® Uterine Balloon Therapy System (Gynecare, Somerville, NJ), the first non-hysteroscopic ablation device to treat excessive uterine bleeding (menorrhagia) due to benign (non-cancerous) causes. ThermaChoice consists of a balloon that is inserted through the neck of the cervix and into the uterus. Through a catheter connected to a controller console, the balloon is inflated with fluid and heated to 188°F (87°C) for eight minutes to destroy the uterine lining.

In 2001, the FDA approved similar devices to be used only in women who have not yet reached menopause and whose child-bearing is complete. The Hydro ThermAblator® (BEI Medical Systems Inc., Teterboro, NJ) delivers heated saline solution into the uterus. The heated saline solution is delivered using hysteroscopic guidance to destroy the uterine lining in about 10 minutes. The HerOption® Uterine Cryoblation Therapy System (CryoGen Inc., San Diego, CA) uses an ultrasound-guided cryoprobe capable
of producing temperatures down to minus 148°F (minus 100°C) at the tip. This extreme cold is applied to the tissue for 10 minutes to freeze and destroy the uterine lining.

The most frequently used second-generation EA techniques and the focus of this policy are fluid-filled TBEA and MEA.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on October 13, 2014 and November 10, 2015. Search terms were: "Menorrhagia"[MeSH] and "Endometrial Ablation Techniques"[MeSH], and free text terms “menorrhagia,” “endometrial ablation,” and “heavy bleeding.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

EA techniques offer a less invasive surgical alternative to hysterectomy. While the rapid development of a number of new methods of endometrial destruction has made systematic comparisons between individual methods and the gold standard first-generation techniques difficult, the existing evidence suggests success, satisfaction rates, and complication profiles of newer techniques of ablation compare favorably with hysteroscopic techniques (Lethaby, 2013; Daniels, 2012).

Most of the newer techniques are technically easier to perform than traditional hysteroscopy-based methods. Although equipment failures for MEA and TBEA were reported in early usage, the devices have been improved and these failures are now much less common. Adverse events with second-generation EA techniques include uterine infection, perforation, visceral burn, bleeding, hematometra, laceration,
intra-abdominal injury and cyclical pain. Women who do not respond to initial EA may require further ablations or, eventually, hysterectomy.

Evidence-based guidelines agree that for pre-menopausal patients who choose EAs, childbearing is complete, a form of contraception is required, underlying uterine pathology is ruled out (i.e., hyperplasia or malignancy), expectations are clearly outlined (patient satisfaction, not amenorrhea), and risk of requiring a future hysterectomy is discussed (Matteson, 2012; ACOG 2007 and 2013; Singh, 2013). In women with bleeding caused mainly by ovulatory disorders or endometrial hemostatic disorders, any of the following treatments may be chosen: hysterectomy, EA, systemic medical therapies, or levonorgestrel-releasing intrauterine systems. In choosing between EA and hysterectomy, if a woman's preference is for amenorrhea, less pain or avoiding additional therapy, hysterectomy is suggested. If her preference is for lower operative and postoperative procedural risk, and a shorter hospital stay, EA is recommended. Premenopausal patients undergoing endometrial ablation should be counseled to use appropriate contraception.

The most common contraindications to EA include recent pregnancy, the presence of active or recent uterine infection, endometrial malignancy or hyperplasia, or endometrial cavities that exceed device limitations. In cases of suspected uterine displacement, clinicians should verify the correct placement using ultrasound before the device is activated. In addition to ultrasound, the use of hysteroscopy prior to the insertion of the ablation device is recommended, if the device is not a balloon. The concurrent use of diathermy during such procedures should not be undertaken, because of the risk of the ablation device as a source of alternate site burns.

Policy updates:

We identified one new evidence-based guideline produced by the Society of Obstetricians and Gynaecologists in Canada (SOGC) (Laberge, 2015). Their results are in agreement with the original policy. Therefore, no changes to the policy are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laberge (2015)</td>
<td>Key points:</td>
</tr>
<tr>
<td>SOGC</td>
<td>• Systematic review and evidence-based guidelines generally concur with other guidelines.</td>
</tr>
<tr>
<td></td>
<td>• EA is a safe and effective minimally invasive option for the treatment of abnormal uterine bleeding (AUB) of benign etiology.</td>
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<td>• The choice of which device to use depends primarily on surgical judgment and the availability of resources.</td>
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<td></td>
<td>• Low-risk patients with satisfactory pain tolerance are good candidates to undergo endometrial ablation in settings outside the operating room, or in free-standing surgical centers.</td>
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<tr>
<td></td>
<td>• Both resectoscopic and non-resectoscopic endometrial ablation are relatively safe.</td>
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### Citations

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Lethaby (2013) Cochrane review</td>
<td>Endometrial resection and ablation techniques for heavy menstrual bleeding.</td>
</tr>
<tr>
<td></td>
<td>procedures with low complication rates. The complications perforation with potential injury to contiguous structures, hemorrhage, and infection.</td>
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<tr>
<td></td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• For resectoscopic endometrial ablation, a strict protocol should be followed for fluid monitoring and management, to minimize the risk of complications of distension medium overload.</td>
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<tr>
<td>Daniels (2012)</td>
<td>Relative effectiveness of</td>
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<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• Meta-analysis of 19 RCTs involving 3,287 women unresponsive to medical treatment.</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| second generation ablation techniques in the treatment of heavy menstrual bleeding | • Bipolar radiofrequency and microwave ablation resulted in higher rates of amenorrhea than thermal balloon ablation at around 12 months (odds ratio [OR] 2.51, 95% CI 1.53 to 4.12, \( p < 0.001 \); and OR 1.66, 95% CI 1.01 to 2.71, \( p = 0.05 \), respectively), but no significant difference between techniques in the number of women dissatisfied with treatment, or still experiencing heavy bleeding.  
• Compared with bipolar radio frequency and microwave devices, free-fluid ablation had a higher number of women still experiencing heavy bleeding (95% CI 2.19, 1.07 to 4.50, \( p = 0.03 \); and 95% CI 2.91, 1.23 to 6.88, \( p = 0.02 \), respectively).  
• Compared with radiofrequency ablation, free-fluid ablation was associated with reduced rates of amenorrhea (95% CI 0.36, 0.19 to 0.67, \( p = 0.004 \)) and increased rates of dissatisfaction (95% CI 4.79, 1.07 to 21.5, \( p = 0.04 \)).  
• Of the less commonly used devices, endometrial laser intra-uterine thermotherapy was associated with increased rates of amenorrhea, compared with all the other devices. Cryoablation led to a reduced rate compared with bipolar radiofrequency and microwave.  
• Authors concluded bipolar radiofrequency and microwave ablative devices are more effective than thermal balloon and free-fluid ablation in the treatment of HMB, with second generation EA devices. |
| Vitagliano (2014) Thermal balloon ablation vs. transcervical endometrial resection; evaluation of postoperative pelvic pain in women treated for DUB | Key points:  
• A longitudinal observational study of 47 women affected by dysfunctional uterine bleeding (DUB) who underwent EA. The authors collected evaluation of pelvic pain at one hour and four hours after intervention, and the individual necessity of analgesics. After 30 days, all patients underwent a gynecological visit to evaluate postoperative outcome.  
• Pelvic pain was higher one hour and four hours after procedure in thermal balloon ablation group, and patients in the same group required more analgesic rescue dose. There were no complications such as uterine perforation, heavy blood loss or thermal injuries with both the procedures.  
• Thermal balloon ablation appears a more painful procedure than endometrial resection, both in the immediate postsurgical time, and 30 days after surgery. Ad hoc anesthesiologic and analgesic protocol should be adopted to ensure quick recovery and good acceptance of the procedure. |
| Bongers (2004) Current treatment of DUB | Key points:  
• Review of effectiveness studies.  
• Antifibrinolytic tranexamic acid is the most effective medical therapy for DUB.  
• Medical therapy is not as effective as endometrial resection in terms of patient satisfaction and health-related quality of life.  
• The levonorgestrel releasing intrauterine device (IUD) is effective for DUB. IUD vs. hysterectomy showed similar quality of life (QOL) outcomes.  
• Ablation techniques of the first generation are effective and safe when used by trained surgeons, but have a learning curve.  
• Ablation techniques of the second generation are effective, but long-term follow-up data are not available. No large RCTs comparing the levonorgestrel-releasing IUD to first- and second-generation EA techniques were found.  
• Hysterectomy has a relatively high complication rate, but a high satisfaction rate and
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| Kucukozkan (2004) | Chemical EA with trichloroacetic acid (TCA)  
- Prospective trial of 90 volunteers allocated into three treatment groups comprised of 30 patients. In group I, cases underwent D&C before EA. In group II, cases were administered danazol before ablation. Cases in group III received goserelin acetate on the same day and 28 days after ablation. Endometrium was evaluated by biopsy, transvaginal ultrasonography, and hysteroscopy. EA was performed with 95% TCA. All of the patients were evaluated three and six months after TCA application.  
- At six months the success rate was recorded as 83% in the first group, 92.3% in the second group and 96.6% in the third group. The mean length of uterine cavity was reduced in all groups, and only significant in Goserelin group (P<0.5). Endometrial thickness was decreased significantly in all treatment groups (P<0.001).  
- EA by TCA may be an alternative treatment method in the management of DUB. Moreover, suppression of endometrium with danazol, or especially with goserelin acetate before ablation, resulted in significant success rates. |
- Forty patients recruited to assess the efficacy and safety of endometrial laser intrauterine thermo-therapy using the gynelase.  
- At 12 months, the average menstrual score reduction was 88%, the amenorrhea rate was 70%, and the hypomenorrhea rate 16%. Four women (10%) have had a hysterectomy for persistent menorrhagia, and one (3%) for pelvic pain.  
- One patient (3%) has had a further endometrial laser ablation. No major complications, and 34 patients (85%) were satisfied with the treatment. The system is easy to use and has a short learning curve. |

**Glossary**

**Adenomyosis** — Condition in which the tissue that normally lines the uterus begins to grow in the muscle wall of the uterus.

**Dilation and curettage (D&C)** — Procedure in which the cervix is dilated and a curette is used to scrape and remove uterine tissue.

**Electrosurgery** — Procedure using a resectoscope, which is a slender telescopic device that is inserted into the uterus. It has an electrical wire loop, roller-ball, or spiked-ball tip that destroys the uterine lining. This method is usually performed in an operating room with general anesthesia. It is not as frequently used as the other methods.
Endometrial ablation (EA) — Procedure that destroys a thin layer of the lining of the uterus and stops the menstrual flow in many women. In some women, menstrual bleeding does not stop, but is reduced to normal or lighter levels. If ablation does not control heavy bleeding further treatment or surgery may be required.

Endometrial hyperplasia — Condition in which the lining of the uterus grows too thick. If left untreated over time, this condition may lead to cancer.

Fibroids — Benign (noncancerous) growths that form on the inside of the uterus, on its outer surface, or within the uterine wall itself.

Freezing — A thin probe is inserted into the uterus. The tip of the probe freezes the uterine lining. Ultrasound is used to help guide the procedure.

Heated fluid — Fluid is inserted into the uterus through a hysteroscope, a slender, light-transmitting device. The fluid is heated and stays in the uterus for approximately 10 minutes to destroy the endometrium.

Heated balloon — A balloon is placed in the uterus with a hysteroscope. Heated fluid is injected into the balloon. The balloon expands until its edges touch the uterine lining. The heat destroys the endometrium.

Hysterectomy — Removal of the uterus.

Intrauterine device (IUD) — A small device that is inserted and left inside the uterus to prevent pregnancy.

Laser (Nd:YAG laser) — Surgical laser modified with a single channel thermometry unit, a computer, a printer, and a computer-controlled laser exposure shutter.

Menopause — The process in a woman’s life when ovaries stop functioning and menstruation stops.

Microwave energy — A special probe is inserted into the uterus through the cervix. The probe applies microwave energy to the uterine lining, which destroys it.

Polycystic ovary syndrome — Condition characterized by two of the following three features: the presence of growths called cysts on the ovaries, irregular menstrual periods, and an increase in the levels of certain hormones.

Polyps — Growths that develop from membrane tissue, such as the lining of the inside of the uterus.
Radiofrequency — Procedure in which a probe is inserted into the uterus through the cervix. The tip of the probe expands into a mesh-like device that sends radiofrequency energy into the lining. The energy and heat destroy the endometrial tissue, while suction is applied to remove it.

References

Professional society guidelines/other:


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on November 11, 2015 using terms endometrial ablation | Open Studies. Ten studies found, 3 relevant.

Patient Centered Results for Uterine Fibroids. ClinicalTrials.gov Web site. 


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>58353</td>
<td>Endometrial ablation, thermal, without hysteroscopic guidance</td>
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<tr>
<td>58356</td>
<td>Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed</td>
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<tr>
<td>58563</td>
<td>Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>D50.0</td>
<td>Iron deficiency anemia secondary to blood loss (chronic)</td>
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<tr>
<td>D62</td>
<td>Acute posthemorrhagic anemia</td>
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<tr>
<td>N92.0</td>
<td>Excessive and frequent menstruation with regular cycle</td>
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<th>HCPCS Level II</th>
<th>Description</th>
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