CLINICAL MEDICAL POLICY	
Policy Name:	Labiaplasty
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

DISCLAIMER

Highmark Health Options 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 Health Options does not provide coverage for labiaplasty under the medical-surgical benefits of Highmark Health Options.

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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Labia Minora Hypertrophy – A condition described as protuberant labial tissue that extends beyond the labia majora.

Labial Hypertrophy – A condition with enlargement/protuberance of labia minora or labia majora that may be congenital or caused by excessive androgenic hormones. The condition may be unilateral or bilateral. There are no standard diagnostic criteria for labial hypertrophy.

Labiaplasty – A surgical procedure performed to reduce the size and/or shape of the labia minora. The procedure can also include the labia majora or both the majora and minora. Labial tissue can be removed using a 'wedge' or 'trim,' so that the labia minora no longer protrudes beyond the labia majora. Labia majora surgery includes the removal of excess skin or fat injections to plump up the labia majora in order to restore volume. The goal of this procedure is the creation of symmetrically reduced labia. This procedure is sometimes referred to as vulvoplasty.

Female Genital Cosmetic Surgery (FGCS) – Refers to non-medically indicated cosmetic surgical procedures which change the structure and appearance of healthy external genitalia of women, or internally in the case of vaginal tightening. The most common procedures in FGCS include Labiaplasty, hymenoplasty, and Vaginoplasty also known as vaginal reconstruction or vaginal rejuvenation.

PROCEDURES

1. Elective labiaplasty for labial hypertrophy is not covered when the procedure is performed to improve the appearance of the labia, and is therefore considered cosmetic and not medically necessary.

   NOTE: Refer to the Highmark Health Options medical policy for Gender Transition Services for information regarding labiaplasty procedure as part of initial gender reassignment surgery.

   Labiaplasty is not to be confused with simple vulvectomy. A vulvectomy is a gynecological procedure that includes partial or complete removal of tissue of the vulva, and sometimes will include the removal of lymph nodes and tissue in the groin area. The vulva include the labia minora, labia majora, clitoris, and vaginal opening. This procedure is performed typically for oncologic indications.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The place of service for labiaplasty is outpatient.

GOVERNING BODIES APPROVAL

There is no Medicare coverage determination addressing labiaplasty.

CODING REQUIREMENTS

*Non-covered Procedure Codes

CPT Codes	Description
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
58899	Unlisted procedure, female genital system (non-obstetrical)

There is no specific CPT code for labiaplasty.
*These procedure codes will not be reimbursed without Medical Director Approval.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

In most women, the labia are not symmetrical, and it is not unusual for one side to be larger, thicker, or longer than the other. There is no clear cause for labial hypertrophy. There are some claims that causes may include:

- genetics
- estrogen and other female hormone increase during puberty
- exposure to exogenous androgens in infant life
- chronic dermatitis
- vulvar edema
- stretching by manual means or by attaching weights which is done in some aboriginal tribes for the sake of cultural beauty norms
- bone marrow infiltration
- pregnancy (etiology doubtful)
- due to infection or trauma to the area

Most women do not experience any symptoms or discomfort related to labial hypertrophy. Less commonly, some women may experience irritation, discomfort, chronic infections, and pain during exercise or sexual intercourse. There is no specific test or imaging used to diagnose labial hypertrophy. Additionally, there is no anatomic standard for labia minora length and relative laxity and redundancy of labial skin. A physician will typically diagnose this condition based on physical examination and any vaginal or labial symptoms. The initial management of labial hypertrophy is patient counseling and self-care instruction.

During puberty, the labia minora changes as part of normal development, however, the developmental changes of the vulva have not been included in the standard categorization of stages. Because of continued anatomy changes throughout life, younger females should be advised not to seek surgical intervention until after age 18, once development has been completed (RCOG 2013).

Both women and adolescent girls are increasingly seeking medical and surgical attention due to concerns with the size and shape of the labia minora. A few reasons for this trend is based on a change in grooming practices, such as depilation (shaving, waxing, or laser hair removal) of the genital area, exposure to idealized images of genital anatomy through digitally enhanced applications or websites, a growing focus on athleticism, and a distorted view of 'normal genitalia.' As a result, procedures such a labiaplasty are

increasingly being performed. There are other female genital cosmetic surgeries that may be performed with the labiaplasty, including hymenoplasty and vaginoplasty. Of the three procedures, labiaplasty is the most common.

The American Society for Aesthetic Plastic Surgery (2017) reported that the number of labiaplasty procedures increased by 217.3% over the past 5 years. It is noted that there was an overall decrease in the number of procedures performed in 2017 of 10.7% or 10,787 procedures.

There have been advances in techniques in labiaplasty and vaginoplasty resulting in less scarring, less pain, shorter recovery time, and excellent results in the areas often referred to as 'Vaginal Cosmetic Surgery.' Labiaplasty results in a reduction of the labia minora and labia majora to reduce their outward appearance and correct misshapenness or irregularities. There are women seeking treatment for labial hypertrophy who are looking to achieve a better physical appearance for themselves and their sexual partners. There are several labiaplasty procedures identified that include:

- Sculpted linear (or curvilinear) resection
- V-wedge resection/modified V-wedge resection
- Z-plasty technique (variation of the modified V-wedge resection
- Superior-inferior pedicle flap technique
- Stem-iris scissors technique
- De-epithelialization technique

Complications related to labiaplasty are similar to all surgical procedures and can include wound dehiscence and necrosis, localized infection, prolonged swelling, excessive bleeding, hematoma, postoperative discomfort, nerve injury, and entry dyspareunia.

For adolescents seeking medical treatment for labial hypertrophy, the first step is often education and reassurance regarding normal variation in anatomy, growth, and development. Nonsurgical comfort and cosmetic measures may be offered, including supportive garments, personal hygiene measures (such as the use of emollients), and arrangement of the labia minora during exercise, or the use of formfitting clothing. Surgical correction (labiaplasty) in girls younger than 18 years of age should be considered only in those with significant congenital malformation, or persistent symptoms that the physician believes are caused directly by labial anatomy, or both. Physicians should be aware that surgical alteration of the labia that is not necessary to the health of the adolescent, who is younger than 18 years, is a violation of federal criminal law. At least half of the states also have laws criminalizing labiaplasty under certain circumstances, and some of these laws apply to minors and adults. Obstetrician-gynecologists should be aware of federal and state laws that affect this procedure and similar procedures (ACOG, 2017).

The American College of Obstetricians and Gynecologists and the North American Society for Pediatric and Adolescent Gynecology (2016) have advised physicians that adolescents who are seeking labial surgery should be screened for body dysmorphic disorder and referred to mental health professional, if appropriate. A 2014 matched-comparison study (Veale et al.) reported that out of 49 women there were 9 women who met the diagnostic criteria for body dysmorphic disorder.

According to the Royal College of Obstetricians and Gynaecologists (2013), there is a lack of high quality literature on female genital cosmetic surgery (FGCS). There are no controlled trials or prospective studies that are investigating the clinical effectiveness or risks of labiaplasty procedures. Several small case reports and few larger retrospective studies have been published. However, the majority of these studies are authored by the performing surgeons without independent evaluation. In addition, the authors

concluded that labiaplasty should be avoided whenever possible, especially in pre-pubertal females; unless there are strong medical indications that would support benefit from timely surgery.

A technology evaluation performed by Hayes, Inc. (2013) assessed the purpose of labiaplasty for patients with hypertrophy and/or cosmetic reasons. Hayes (2013) determined that the quality of the body of evidence regarding labiaplasty is very low and cannot support a conclusion of efficacy or safety for patients with enlarged or hypertrophied labia minora. There are no randomized controlled studies, and the available observational studies were of poor quality. The primary outcome measures were subjective and did not provide any objective measure of clinical efficacy or safety. In addition, there was no documented consensus regarding the criteria for hypertrophy of the labia minora. The evaluation resulted in a Hayes rating of D2 due to insufficient evidence to assess the safety and/or impact on health outcomes or patient management. This position was reviewed in April 2017 without any change in position, and the report was archived on June 7, 2018.
The UpToDate (2018) review on labia minora hypertrophy states that labia minora hypertrophy is largely subjective and the diagnosis of the condition is based upon presence of symptoms and/or distress associated with labia minora hypertrophy. There is no consensus among gynecologists, pediatricians, or plastic surgeons regarding criteria for surgical intervention or the use of objective clinical measurements to confirm the diagnosis. In the review, several labial measurement references are noted with measurements ranging from 3 to 6 cm. In Australia Medicare guidelines (2018) for labiaplasty, one of the medical necessity criteria is that the length of the labia minora must extend more than 8cm below the vaginal introitus while the patient is in a standing position.

A review of literature failed to provide a standard definition of labial hypertrophy. There are classification systems that use labial length, labial protrusion, and labial shape with clinical symptomatology. The following examples provide various definitions:

Franco's classification categorizes it into four types:

- Type 1: less than 2 cm
- Type 2: 2-4 cm
- Type 3: 4-6 cm
- Type 4: over 6 cm

Motakef (2015) proposed a simplified classification for labial protrusion based on the distance of the lateral edge of the labia minora from that of the labia majora, rather than from the introitus. Three stages described are:

- Stage I: 0-2 cm
- Stage II: 2-4 cm
- Stage III: more than 4 cm

Another classification proposed by Smarrito (2017) includes three types:

- Type I: anterior one third labial hypertrophy, 'in the shape of a flag' which leaves the vaginal orifice unimpeded.
- Type II: middle third labial hypertrophy, 'oblique'
- Type III: posterior third labial hypertrophy , 'complete,' i.e., rounded and voluminous

The author of this proposal concludes that the classification would make the case of dyspareunia more logical because it is linked to the shape of hypertrophy.

According to Miklos and Moore (2008), patients seeking corrective surgery for hypertrophic labia can be divided into three broad groups: those seeking procedures strictly for aesthetic reason; those seeking surgery with functional impairment (pain and or physical discomfort); and those with both problems.

According to several plastic surgery reference sites, female genital cosmetic surgery is a demanding surgical field and there are few surgeons who are skilled enough to perform the delicate procedures with good results. Females seeking these services are cautioned to locate providers that have specialized in performing female genital cosmetic surgeries.

POLICY SOURCE(S)

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Policy History

Date	Activity
01/11/2019	Initial policy developed
07/16/2019	QI/UM Committee approval
09/16/2019	Provider effective date