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Clinical Policy Bulletin:
Organ Prolapse: Selected Procedures

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Policy

Aetna considers laparoscopic suture rectopexy medically necessary in persons with rectal prolapse.

Aetna considers Lefort colpopleisis medically necessary for severe utero-vaginal prolapse in elderly patients and chronically ill persons who no longer desire coital function.

Aetna considers dynamic magnetic resonance imaging (MRI) medically necessary in persons with complex organ prolapse to supplement the physical examination.

Aetna considers genetic testing for pelvic organ prolapse experimental and investigational because its effectiveness for this indication has not been established.

Background

Pelvic organ prolapse is a relatively common condition in women that can have a significant impact on quality of life. Pelvic organ prolapse typically demonstrates multiple abnormalities and may involve the urethra (urethrocele), bladder (cystocele), vaginal vault, rectum (rectocele), and small bowel (enterocele). Symptoms may include pain, pressure, urinary and fecal incontinence, constipation, urinary retention, and defecatory dysfunction. Total vaginal collapse occurs when the upper portion of the vagina loses its normal shape and sags or bulges down into the vaginal canal or outside of the vagina. It is usually caused by weakness of the pelvic and vaginal tissues and muscles and may occur alone or along with prolapse of other pelvic organs. The bladder (cystocele), urethra (urethrocele), rectum (rectocele), or small bowel (enterocele).

Magnetic resonance imaging (MRI) uses a strong magnetic field, radio waves, and computers to produce 2- or 3-dimensional images of the inside of a patient's body. It is non-invasive and there is no ionizing radiation exposure to the patient.
Dynamic MRI differs from standard MRI in that a large number of images are formed successively and rapidly, by continually updating or reacquiring image data. Based on the clinical evidence, dynamic MRI is an acceptable alternative modality in patients with complex organ prolapse to supplement the physical examination.

Rectal prolapse, or procidentia, is the abnormal protrusion of the rectal mucosa down to or through the anal opening. The main symptom is a protrusion of a reddish mass from the anal opening, especially following a bowel movement. The rectal mucosa is visible and may bleed slightly.

In a laparoscopic suture rectopexy the rectum is fixed to the presacral fascia with suture as opposed to mesh or an Ivalon sponge. Based on the long-term clinical outcomes, laparoscopic suture rectopexy can be considered a treatment option for patients with rectal prolapse.

Vaginal prolapse or pelvic organ prolapse, occurs when the structures of the pelvis protrude into or outside of the vaginal canal. The pelvic organs are the bladder, rectum, or uterus. The term prolapse means slipping from the normal position. Pelvic organ prolapse is caused most commonly by pregnancy, labor, and childbirth. It also can be related to diseases that cause increased pressure in the abdomen, such as obesity, respiratory problems with a long-lasting (chronic) cough, constipation, and pelvic organ cancers. Pelvic organ prolapse can occur after hysterectomy for another gynecological health problem, such as endometriosis, dysfunctional uterine bleeding, or uterine fibroids.

In the LeFort colpocleisis, anterior and posterior rectangular flaps of vaginal mucosa are removed, and the denuded areas are reapproximated with horizontal layers of interrupted absorbable sutures, leaving 2 small tunnels laterally for drainage. Based on the clinical evidence, Lefort colpocleisis should be used only when there is a very good reason not to perform one of the usual operations for prolapse. It is indicated for severe utero-vaginal prolapse in elderly patients and chronically ill patients who no longer desire coital function.

Levin et al (2012) noted that genetic studies require a clearly defined phenotype to reach valid conclusions. These researchers characterized the phenotype of advanced prolapse by comparing women with stage III to IV prolapse with controls without prolapse. Based on the pelvic organ prolapse quantification examination, women with stage 0 to stage I prolapse (controls) and those with stage III to stage IV prolapse (cases) were prospectively recruited as part of a genetic epidemiologic study. Data regarding socio-demographics; medical, obstetric, and surgical history; family history; and body mass index (BMI) were obtained by a questionnaire administered by a trained coordinator and abstracted from electronic medical records. There were 275 case patients with advanced prolapse and 206 controls with stage 0 to stage I prolapse. Based on the recruitment strategy, the women were younger than the controls (64.7 ± 10.1 versus 68.6 ± 10.4 years; p < 0.001); cases were also more likely to have had 1 or more vaginal deliveries (96.0 % versus 82.0 %; p < 0.001). There were no differences in race, BMI, and constipation. Regarding family history, cases were more likely to report that either their mother and/or sister(s) had prolapse (44.8 % versus 16.9 %, p < 0.001). In a logistic regression model, vaginal parity (odds ratio [OR], 4.05; 95% confidence interval [CI]: 1.67 to 9.85) and family history of prolapse (OR, 3.74; 95% CI: 2.16
to 6.46) remained significantly associated with advanced prolapse. The authors concluded that vaginal parity and a family history of prolapse are more common in women with advanced prolapse compared to those without prolapse. These characteristics are important in phenotyping advanced prolapse, suggesting that these data should be collected in future genetic epidemiologic studies.

Wu et al (2012) evaluated the association of laminin gamma-1 (LAMC1) and advance pelvic organ prolapse. These researchers conducted a candidate gene association of patients (n = 239) with stages III to IV prolapse and controls (n = 197) with stages 0 to I prolapse. They used a “linkage disequilibrium (LD)-tagged” approach to identify single-nucleotide polymorphisms (SNPs) in LAMC1 and focused on non-Hispanic white women to minimize population stratification. Additive and dominant multi-variable logistic regression models were used to test for association between individual SNPs and advanced prolapse. A total of 14 SNPs representing 99 % coverage of LAMC1 were genotyped. There was no association between SNP rs10911193 and advanced prolapse (p = 0.34). However, there was a trend toward significance for SNPs rs1413390 (p = 0.11), rs20563 (p = 0.11), and rs20558 (p = 0.12). The authors concluded that although they found that the previously reported LAMC1 SNP rs10911193 was not associated with non-familial prolapse, these results supported further investigation of this candidate gene in the pathophysiology of prolapse.

Ward et al (2014) stated that given current evidence supporting a genetic predisposition for pelvic organ prolapse, they conducted a systematic review of published literature on the genetic epidemiology of pelvic organ prolapse. Inclusion criteria were linkage studies, candidate gene association and genome-wide association studies in adult women published in English and indexed in PubMed through December 2012, with no limit on date of publication. Methodology adhered to the PRISMA guidelines. Data were systematically extracted by 2 reviewers and graded by the Venice criteria for studies of genetic associations. A meta-analysis was performed on all SNPs evaluated by 2 or more studies with similar methodology. The meta-analysis suggested that collagen type 3 alpha 1 (COL3A1) rs1800255 genotype AA is associated with pelvic organ prolapse (OR, 4.79; 95 % CI: 1.91 to 11.98; p = 0.001) compared with the reference genotype GG in populations of Asian and Dutch women. There was little evidence of heterogeneity for rs1800255 (p value for heterogeneity = 0.94; proportion of variance because of heterogeneity, I(2) = 0.00 %). There was insufficient evidence to determine whether other SNPs evaluated by 2 or more papers were associated with pelvic organ prolapse. An association with pelvic organ prolapse was seen in individual studies for estrogen receptor alpha (ER-α) rs2228480 GA, COL3A1 exon 31, chromosome 9q21 (heterogeneity logarithm of the odds score 3.41) as well as 6 SNPs identified by a genome-wide association study. The authors concluded that overall, individual studies were of small sample size and often of poor quality. They stated that future studies would benefit from more rigorous study design as outlined in the Venice recommendations.

Cartwright et al (2014) noted that family studies and twin studies demonstrated that lower urinary tract symptoms (LUTS) and pelvic organ prolapse are heritable. In this review, these investigators aimed to identify genetic polymorphisms tested for an association with LUTS or prolapse, and to assess the strength, consistency, and risk of bias among reported associations. PubMed and HuGE Navigator were
searched up to May 1, 2014, using a combination of genetic and phenotype key words, including "nocturia", "incontinence", "overactive bladder", "prolapse", and "enuresis". Major genetics, urology, and gynecology conference abstracts were searched from 2005 through 2013. These researchers screened 889 abstracts, and retrieved 78 full texts. In all, 27 published and 7 unpublished studies provided data on polymorphisms in or near 32 different genes. Fixed and random effects meta-analyses were conducted using co-dominant models of inheritance. They assessed the credibility of pooled associations using the interim Venice criteria. In pooled analysis, the rs4994 polymorphism of the ADRB3 gene was associated with overactive bladder (OR, 2.5; 95 % CI: 1.7 to 3.6; n = 419). The rs1800012 polymorphism of the COL1A1 gene was associated with prolapse (OR, 1.3; 95 % CI: 1.0 to 1.7; n = 838) and stress urinary incontinence (OR, 2.1; 95 % CI: 1.4 to 3.2; n = 190). Other meta-analyses, including those for polymorphisms of COL3A1, LAMC1, MMP1, MMP3, and MMP9 did not show significant effects.

Many studies were at high-risk of bias from genotyping error or population stratification. The authors concluded that these meta-analyses provided moderate epidemiological credibility for associations of variation in ADRB3 with overactive bladder, and variation of COL1A1 with prolapse. Moreover, they stated that clinical testing for any of these polymorphisms cannot be recommended based on current evidence.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

**Laparoscopic suture rectopexy** - no specific code:

**Dynamic magnetic resonance imaging (MRI)** - no specific code:

57120

ICD-9 codes covered if selection criteria are met:

569.1 Rectal prolapse

618.00 - Genital prolapse

618.9

The above policy is based on the following references:

Dynamic Magnetic Resonance Imaging


Laparoscopic Suture Retropexy


LeFort Colpocleisis


Genetic Testing for Pelvic Organ Prolapse


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