Organ Prolapse: Selected Procedures

Number: 0858

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers the following procedures medically necessary:

- Dynamic magnetic resonance imaging (MRI) in persons with complex organ prolapse to supplement the physical examination
- Laparoscopic suture rectopexy in persons with rectal prolapse
- Lefort colpocleisis medically necessary for severe utero-vaginal prolapse in elderly persons and chronically ill persons who no longer desire coital function
- Sacrocolpopexy for the treatment of vaginal apical prolapse repair

Policy History

Last Review: 10/13/2016
Effective: 08/09/2013
Next Review: 10/12/2017

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Aetna considers the following procedures experimental and investigational because their effectiveness has not been established:

- Biologic graft for the treatment of vaginal apical prolapse
- Genetic testing for pelvic organ prolapse

See also CPB 0223 – Urinary Incontinence (../200_299/0223.html) (Pessary for the treatment of pelvic organ (uterine) prolapse)

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-\(\alpha\)) 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. (2015) 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
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.

**Bilateral Abdominal Sacrocolpopexy with Polyvinylidene Fluoride Mesh:**

Rajshekhar and colleagues (2016) evaluated the safety and effectiveness of a modified technique of bilateral abdominal sacrocolpopexy in which both utero-sacral ligaments are replaced with polyvinylidene fluoride mesh to provide support to the cervix (cervico-sacropexy [CESA]) or vaginal vault (vagino-sacropexy [VASA]). In a retrospective, observational study, a total of 50 women with post-hysterectomy vault prolapse or recurrent apical prolapse following previous vaginal repair underwent bilateral sacrocolpopexy between July 1, 2013, and December 31, 2014. Before surgery and 3 months afterwards, prolapse was assessed using the Pelvic Organ Prolapse Quantification scale and functional outcomes were recorded using the International Consultation on Incontinence Questionnaire for vaginal symptoms and urinary incontinence. At 3 months, 47 (94 %) patients reported no bulge symptoms and the mean point C was -7.6. Complications comprised bladder injury in 1 (2 %) and minor wound problems in 3 (6 %) patients. No mesh erosion was reported. The authors
concluded that bilateral abdominal sacrocolpopexy appeared to be a safe and effective option for apical prolapse. However, they stated that longer-term follow-up is needed to detect prolapse recurrence and mesh-related complications.

**Biologic Graft:**

On behalf of the Society of Gynecologic Surgeons Systematic Review Group, Shimpf and associates (2016) updated clinical practice guidelines on graft and mesh use in transvaginal pelvic organ prolapse repair based on systematic review. Eligible studies, published through April 2015, were retrieved through ClinicalTrials.gov, Medline, and Cochrane databases and bibliography searches. These investigators included studies of transvaginal prolapse repair that compared graft or mesh use with either native tissue repair or use of a different graft or mesh with anatomic and symptomatic outcomes with a minimum of 12 months of follow-up. Study data were extracted by 1 reviewer and confirmed by a 2nd reviewer. Studies were classified by vaginal compartment (anterior, posterior, apical, or multiple), graft type (biologic, synthetic absorbable, synthetic non-absorbable), and outcome (anatomic, symptomatic, sexual function, mesh complications, and return to the operating room). They found 66 comparative studies reported in 70 articles, including 38 randomized trials; quality of the literature has improved over time, but some outcomes still show heterogeneity and limited power. In the anterior vaginal compartment, synthetic non-absorbable mesh consistently showed improved anatomic and bulge symptom outcomes compared with native tissue repairs based on meta-analyses. Other subjective outcomes, including urinary incontinence or dyspareunia, generally did not differ. Biologic graft or synthetic absorbable mesh use did not provide an advantage in any compartment. Synthetic mesh use in the posterior or apical compartments did not improve success. Mesh erosion rates ranged from 1.4 to 19 % at the anterior vaginal wall, but 3 to 36 % when mesh was placed in multiple compartments. Operative mesh revision rates ranged from 3 to 8 %. The authors concluded that synthetic mesh augmentation of anterior wall prolapse repair improved anatomic outcomes and bulge symptoms compared with native tissue repair. On the other hand, biologic grafts did not improve prolapse repair outcomes in any compartment; mesh erosion occurred in up to
36 % of patients, but re-operation rates were low.

Sacrocolpopexy:

Alas and Anger (2015) stated that pelvic organ prolapse is a prevalent condition, with up to 12 % of women requiring surgery in their lifetime. These investigators reviewed the therapeutic options for apical prolapse, specifically. Both conservative and surgical management options are acceptable and should be based on patient preferences. Pessaries are the most commonly used conservative management options. Guided pelvic floor muscle training is more beneficial than self-taught Kegel exercises, though may not be effective for high stage or apical prolapse. Surgical options include abdominal and vaginal approaches, the latter of which can be performed open, laparoscopically, and robotically. A systematic review has demonstrated that sacrocolpopexy has better long-term success for treatment of apical prolapse than vaginal techniques, but vaginal surgery can be considered an acceptable alternative. Recent data has demonstrated equal effectiveness between uterosacral ligament suspension and sacrospinous ligament suspension at 1 year. To-date, 2 randomized controlled trials (RCTs) have demonstrated equal effectiveness between robotic and laparoscopic sacrocolpopexy. Though abdominal approaches may have increased long-term durability, when counseling their patients, surgeons should consider longer operating times and increased pain and cost with these procedures compared to vaginal surgery.

The authors concluded the following:

- Pelvic floor physical therapy (PFPT) with a physical therapist is the best approach to conservative management of apical prolapse
- Pessaries should be managed with regular follow-up care to minimize complications
- Minimally invasive sacrocolpopexy appears as effective as the gold standard abdominal sacrocolpopexy (ASC)
- Robotic assisted sacrocolpopexy (RASC) and laparoscopic assisted sacrocolpopexy (LASC) are equally effective and should be utilized by pelvic floor surgeons based on their skill level and expertise in laparoscopy
Uterosacral ligament suspension (USLS) and sacrospinous ligament suspension (SSLS) are considered equally effective procedures and can be combined with a vaginal hysterectomy.

Obliterative procedures are effective but are considered definitive surgery.

The use of transvaginal mesh has been shown in some studies to be superior to native tissue repairs with regard to anatomic outcomes, but complication rates are higher. Transvaginal mesh should be reserved for surgeons with adequate training so that complications are minimized.

Costantini and colleagues (2016) noted that sacrocolpopexy is considered a reference operation for pelvic organ prolapse repair but its indications and technical aspects are not standardized. A faculty of urogynecology surgeons critically evaluated the peer-reviewed literature published until September 2015 aiming to produce evidence-based recommendations. PubMed, Medline, and the Cochrane Library were searched for RCTs published in English language. The modified Oxford data grading system was used to access quality of evidence and grade recommendations. The Delphi process was implemented when no data was available. A total of 13 RCTs were identified, that provided levels I to III of evidence on various aspects of sacrocolpopexy. Sacrocolpopexy is the preferred procedure for vaginal apical prolapse (Grade A), monofilament polypropylene mesh is the graft of choice and the laparoscopic approach is the preferred technique (Grade B). Grade B recommendation supports the performance of concomitant procedures at the time of sacrocolpopexy. Grade C recommendation suggests either permanent or delayed sutures for securing the mesh to the vagina, permanent tackers or sutures for securing the mesh to the sacral promontory and closing the peritoneum over the mesh. A Delphi process Grade C recommendation supports proceeding with sacrocolpopexy after uncomplicated, intra-operative bladder or small bowel injuries. The authors concluded that there is insufficient or conflicting data on hysterectomy (subtotal or total) or uterus preservation during sacrocolpopexy (Grade D). They stated that sacrocolpopexy remains an excellent option for vaginal apical prolapse repair. The issue of uterine preservation or excision during the procedure requires further clarification. Variations
exist in the performance of most technical aspects of the procedure.

Also, an UpToDate review on “Pelvic organ prolapse in women: Surgical repair of apical prolapse (uterine or vaginal vault prolapse)” (Kenton, 2016) states that “No high quality evidence is available to guide surgeons regarding uterine preservation at the time of vaginal apical suspension procedures … Apical prolapse repair via open abdominal sacral colpopexy is more effective at restoring vaginal topography than traditional vaginal repairs, although subjective outcomes are similar after the two types of procedures. We suggest abdominal sacral colpopexy rather than transvaginal repair for most women undergoing apical prolapse repair. Laparoscopic sacrocolpopexy is as effective as open sacrocolpopexy, but results in decreased blood loss and shorter hospital stays. For women with apical prolapse undergoing abdominal sacral colpopexy, we recommend synthetic mesh over biografts. Synthetic mesh use in sacral colpopexy reduces the risk of recurrent apical prolapse … For women undergoing repair of apical prolapse, a concomitant continence procedure is often performed to treat or prevent stress urinary incontinence. Mid-urethral slings are the preferred concomitant procedure if a vaginal route is used for prolapse repair; some surgeons also place a mid-urethral sling at the time of abdominal sacral colpopexy”.

Furthermore, and UpToDate review on “Pelvic organ prolapse in women: Choosing a primary surgical procedure” (Jelovsek, 2016) states that “The common wisdom has been that retaining the uterus increases the risk of recurrent prolapse, although there are no data to support this. The role of hysterectomy at the time of surgery for POP is currently debatable and there are no data supporting hysterectomy at the time of surgery for POP. There are 3 under-powered studies that describe uterine preservation at the time of surgery for POP and uterine preservation did not affect the risk of POP recurrence”. 

CPT Codes / HCPCS Codes / ICD-10 Codes
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

ICD-10 codes will become effective as of October 1, 2015:

CPT codes covered if selection criteria are met:

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

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

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**Genetic testing [not all-inclusive]:**

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ICD-10 codes covered if selection criteria are met:

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<td>K62.2 - K62.3</td>
<td>Anal and rectal prolapse</td>
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<tr>
<td>N81.0 - N81.9</td>
<td>Female genital prolapse</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

**Dynamic Magnetic Resonance Imaging**


Laparoscopic Suture Retropexy


11. Senagore AJ. Management of rectal prolapse: The role of


LeFort Colpocleisis


Genetic Testing for Pelvic Organ Prolapse


Bilateral Abdominal Sacrocolpopexy with Polyvinylidene Fluoride Mesh

Biologic Graft


Sacrocolpopexy

AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0858
Organ Prolapse: Selected Procedures

There are no amendments for Medicaid.