

NHS Basildon and Brentwood CCG Proposed SRP changes

Current SRP	
Policy statement:	Female Genital Prolapse (Surgical and Non-Surgical)
Status:	Threshold
South Essex CCGs will only fund surgical interventions for Uterovaginal Prolapse in the following circumstances:	
<ul style="list-style-type: none">• In cases of mild to moderate symptomatic cystoceles where trial of a pessary has failed.• In cases of mild to moderate symptomatic rectoceles.• In severe cases of prolapse or procedentia	
Initially, patients should be assessed and managed conservatively in primary care. Also refer to sections below on vaginal pessaries and surgery.	
1. Watchful waiting , with observation for the development of new symptoms or complications is appropriate if the prolapse is minimal (Stage I), or asymptomatic	
2. Conservative treatment options	
2.1 Lifestyle modification	
<ul style="list-style-type: none">• Treatment of conditions that increase intra-abdominal pressure: constipation, chronic cough, overweight/obesity; reduction of heavy lifting (while POP has been associated with these factors, the role of lifestyle modification in prevention/treatment has not been investigated)	
2.2. Pelvic floor muscle exercises	
<ul style="list-style-type: none">• Role in managing prolapse unclear; probably not useful if the prolapse extends to or beyond the vaginal introitus.• Cochrane review 2006: concluded evidence was insufficient (from 3 randomised trials) to judge the value of conservative management of POP, & that further trials were needed• The pilot study for the Pelvic Organ Prolapse Physiotherapy (POPPY) multi-centre trial suggested that pelvic floor muscle training delivered by a physiotherapist to symptomatic Stage I or II POP women in an outpatient setting may reduce the severity of prolapse	
2.3. Local (vaginal) oestrogen creams and oral treatments see CCG formulary See Medicines Management and further information on criteria for funding, please see the Medicines Management section of each CCG website at:	
<ul style="list-style-type: none">• Brentwood and Basildon CCG: http://www.basildonandbrentwoodccg.nhs.uk/• Castle Point and Rochford CCG : https://www.castlepointandrochfordccg.nhs.uk/• Southend CCG: http://www.southendccg.nhs.uk/• Thurrock CCG: http://www.thurrockccg.nhs.uk/	
3. Vaginal pessary insertion – those participating in active vaginal intercourse should be offered surgery once occult urodynamic stress incontinence has been explored.	
<ul style="list-style-type: none">• Cochrane review 2004: no RCTs of pessary use in women with prolapse; there is no consensus on the use of different types of device, the indications, nor the patterns of replacement & follow-up care; evidence on pessary selection and management is incomplete so trial and error, expert opinion, and experience remain the best guides for use and management of the pessary• Although not supported by definitive evidence, current opinion is that pessaries are effective¹ & should be considered before surgery in women who have symptomatic prolapse; they can be attempted in all POP cases	

irrespective of stage

- For short-term relief before surgery, or in the long-term if surgery is not wanted or recommended
- To predict surgical outcomes or unmask occult urodynamic stress incontinence before surgery, as part of the investigation of continent women with POP (so that the decision to perform a concomitant continence procedure along with pelvic reconstruction can then be individually tailored)
- Risk factors for unsuccessful fitting include: short vaginal length <6 cm and wide introitus fingerbreadths; local oestrogens may play a role in successful fitting
- Failure to retain the pessary has been associated with increasing parity and previous hysterectomy; and discontinuation with history of hysterectomy or prolapse surgery, and stress incontinence;
- Follow-up: no clear consensus on how often to follow up¹ ; after 3 months & then every 6 months, if there are no complications, has been suggested;
- Complications tend to occur in women who are not regularly followed up¹; self-care of pessary is also important to minimise adverse events¹⁶; however, many patients find insertion & removal of most pessary types challenging

4. Surgery - those participating in active vaginal intercourse should be offered use of pessaries prior to surgical intervention for those women who have symptomatic prolapse. Or to unmask occult urodynamic stress incontinence before surgery **Refer to section on use of vaginal pessaries above**

- Assessed as effective, but with a close risk/benefit in mild cases; a combination of procedures may be required and reoperation is required in 29% of cases
- Types of repair surgery vary depending on type of POP & associated symptoms, whether the woman is sexually active & her fitness for surgery

Reconstructive surgery (abdominal or vaginal approach)

- 2010 Cochrane review of surgical management of POP: found 40 RCTs with a variety of types of POP⁵
 - There was not enough evidence on most types of common prolapse surgery nor about the use of mesh or grafts in vaginal prolapse surgery
 - Impact of POP surgery on bowel, bladder and sexual function can be unpredictable and may make symptoms worse or result in new symptoms such as leakage of urine (unmask occult SI) or problems with intercourse
 - Uterine/vaginal vault prolapse: abdominal sacral colpopexy may be better than vaginal sacrospinous colpopexy – it was associated with a lower rate of recurrent vault prolapse and dyspareunia; these benefits must be balanced against a longer operating time, longer time to return to activities of daily living and increased cost of the abdominal approach
 - Posterior vaginal wall prolapse/rectocele: posterior vaginal wall repair may be better than transanal repair in terms of recurrence of prolapse (limited evidence)
 - Value of the addition of a continence procedure to a prolapse repair operation in women who are dry before operation remains to be assessed

Use of mesh/graft inlays (biological or synthetic):

- 2010 Cochrane review: use of mesh or grafts at the time of anterior vaginal wall repair reduces the risk of recurrent anterior wall prolapse on examination; however, evidence of benefit to the woman, including

- symptoms and quality of life improvement, is lacking for the use of grafts over native tissue repairs
- 2008 NICE guidance: surgical repair of vaginal wall prolapse using mesh

See Synthetic Mesh and Biological Mesh (see SRP)

Obliterative Surgery

- Corrects POP by moving the pelvic viscera back into the pelvis & closing of the vaginal canal; vaginal intercourse is no longer possible

Clinical scenarios where surgery will not be routinely funded	Clinical scenarios where referral for specialist assessment is necessary to determine suitability for surgery
Asymptomatic pelvic organ prolapse	Failure of pessary
Mild pelvic organ prolapse (unless combined with urinary/faecal incontinence)	Women with symptomatic prolapse (including those combined with urethral sphincter incompetence or faecal incontinence)
	Prolapse combined with urethral sphincter incompetence/ urinary incontinence or faecal incontinence
	Women with moderate to severe prolapse who want definitive treatment

Recommendations

- Initially, patients should be assessed and managed conservatively in primary care
- All patients should have a trial of ring pessary, including suitable candidates for surgery, as part of the investigation of continent women with prolapse; the decision to perform a concomitant continence procedure along with pelvic reconstruction can then be individually tailored

Patient information:

<http://www.nhs.uk/conditions/Prolapse-of-the-uterus/Pages/Introduction.aspx>

Proposed Change to SRP

Policy statement:

Female Genital Prolapse (Surgical and Non-Surgical)

Status:

Individual Prior Approval

Definition:

Pelvic organ prolapse is bulging of one or more of the pelvic organs into the vagina. These organs are the uterus, vagina, bowel and bladder.¹

Non- Surgical Interventions:

The CCG will only fund (Vaginal Prolapse/ Asymptomatic pelvic organ prolapse/Mild pelvic organ prolapse) the following non-surgical interventions and will not fund surgical intervention unless these options have been tried and there is evidence that they have been unsuccessful in managing the Female Genital Prolapse.

¹ <http://www.nhs.uk/conditions/Prolapse-of-the-uterus/Pages/Introduction.aspx>

Patients should be assessed and managed conservatively in primary care with the following interventions:

Watchful waiting, with observation for the development of new symptoms or complications is appropriate if the prolapse is asymptomatic

Conservative treatment options

Lifestyle modification

- Treatment of conditions that increase intra-abdominal pressure: constipation, chronic cough, overweight/obesity; reduction of heavy lifting (while Pelvic Organ Prolapse (POP)) has been associated with these factors, the role of lifestyle modification in prevention/treatment has not been investigated)

Pelvic floor muscle exercises

- Role in managing prolapse unclear; probably not useful if the prolapse extends to or beyond the vaginal introitus.
- Cochrane review 2006: concluded evidence was insufficient (from 3 randomised trials) to judge the value of conservative management of POP, & that further trials were needed
- The pilot study for the Pelvic Organ Prolapse Physiotherapy (POPPY) multi-centre trial suggested that pelvic floor muscle training delivered by a physiotherapist to symptomatic Stage I or II POP women in an outpatient setting may reduce the severity of prolapse

Local (vaginal) oestrogen creams and oral treatments (see CCG formulary)

- Brentwood and Basildon CCG: <http://www.basildonandbrentwoodccg.nhs.uk/>

Vaginal pessary insertion:

- Although not supported by definitive evidence, current opinion is that pessaries are effective & should be considered before surgery in women who have symptomatic prolapse; they can be attempted in all POP cases irrespective of stage
- Those participating in active vaginal intercourse should be offered use of pessaries for those women who have symptomatic prolapse. Or to unmask occult urodynamic stress incontinence before surgery
- To predict surgical outcomes or unmask occult urodynamic stress incontinence before surgery, as part of the investigation of continent women with POP (so that the decision to perform a concomitant continence procedure along with pelvic reconstruction can then be individually tailored)
- Risk factors for unsuccessful fitting include: short vaginal length <6 cm and wide introitus fingerbreadths; local oestrogens may play a role in successful fitting
- Failure to retain the pessary has been associated with increasing parity and previous hysterectomy; and discontinuation with history of hysterectomy or prolapse surgery, and stress incontinence;
- Follow-up: no clear consensus on how often to follow up; after 3 months & then every 6 months, if there are no complications.
- Complications tend to occur in women who are not regularly followed up; self-care of pessary is also important to minimise adverse events; however, many patients find insertion & removal of most pessary types challenging

Evidence:

Cochrane review 2004: Pessary use in women with prolapse; there is no consensus on the use of different types of device, the indications, nor the patterns of replacement & follow-up care; evidence on pessary selection and management is incomplete so trial and error, expert opinion, and experience remain the best guides for use and management of the pessary

Surgical Intervention:

The CCG will only fund surgery for Female Genital Prolapse (Vaginal Prolapse/ Asymptomatic pelvic organ prolapse/Mild pelvic organ prolapse) where there is evidence of the failure of the non-surgical interventions shown above.

The CCG will fund surgery for Female Genital Prolapse for those who meet the following criteria:

- Women with symptomatic prolapse (including those combined with urethral sphincter incompetence or faecal incontinence)
- Prolapse combined with urethral sphincter incompetence/ urinary incontinence or faecal incontinence

Use of slings for management of vaginal prolapse – is not funded by the CCG:

Evidence:

NICE Interventional Procedure Guidance (IPG282)

Current evidence on the safety and efficacy of insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair is inadequate.

Obliterative Surgery

Corrects POP by moving the pelvic viscera back into the pelvis & closing of the vaginal canal; vaginal intercourse is no longer possible