Service Specification No.	EPCS 10
Service	Ring Pessary Service
Commissioner Lead	Colin Webb, Commissioning Manager
Provider Lead	Hull Primary Care
Period	1 November 2020 – 31 March 2025
Date of Review	April - Annually

1. Population Needs

1.1 National/local context and evidence base

1.1.1 Pelvic organ prolapse is a very common condition, with half of women over the age of 50 experiencing symptoms and 1 in 10 women by the age of 80 having surgery for prolapse.

1.1.2 Normally caused by pregnancy and childbirth, prolapse occurs when the pelvic floor muscles holding the organs within a woman's pelvis (uterus, bladder and rectum) are weakened or overstretched and the organs bulge from their natural position into the vagina.

1.1.3 Complications can start due to large birth weight babies, multiple childbirths, forceps or suction deliveries, episiotomies that are not repaired well. Women who have delivered via caesarean section are also susceptible to pelvic organ prolapse. Pelvic organ prolapse is not just restricted to women who have delivered. Those who have never delivered or who have never been pregnant also have been known to suffer with some kind of prolapse.

1.1.4 Other reasons for uterine prolapse may include:

- Ageing: uterine prolapse is more common in older women.
- Menopause: low levels of oestrogen can weaken tissues
- Being overweight: being heavy or obese can put a strain on the uterus
- Persistent cough: smoking or a lung condition can weaken muscles
- Long term constipation: straining to open the bowels can trigger prolapse
- Lifting or manual labour: repeated strain can weaken the pelvic tissues
- Genetic disorders: these can affect body tissues as in Marfan Syndrome
- Previous pelvic surgery: a hysterectomy or bladder repair may weaken the pelvic floor.

1.1.5 Plain ring pessaries (not containing any hormonal or other substance) can be an effective symptomatic treatment for pelvic organ prolapse and are more acceptable to some patients than surgery.

1.1.6 Several studies have evaluated the success of pessary fitting, with success rates ranging from 41% to 92%. Success rates of up to 62% have been associated with patients with prolapse stages III and IV, indicating pessaries are an excellent option even in a population with advanced pelvic organ prolapse (POP). In one study, up to 53% of women continued pessary use 3 years after successful pessary fitting.

1.1.7 The 2013 Cochrane review found that pessaries were effective for the approximately 60% of women who completed the study with no significant differences identified between the two types of pessary. However, methodological flaws were noted in the trial, as elaborated under risk of bias assessment. There is no consensus on the use of different types of device, the indications nor the pattern of replacement and follow-up care. There is an urgent need for randomised studies to address the use of pessaries in comparison with no treatment, surgery and conservative measures.

References:

1. G, Amundsen C, Bent A, et al. The e PESSRI study: symptom relief outcomes of a randomized crossover trial of the ring and Gellhorn pessaries. Am J Obstet Gynecol. 2007;196(4):405.e1-e8.
2. Mutone MF, Terry C, Hale DS, Benson JT. Factors which influence the short-term success of pessary management of pelvic organ prolapse. Am J Obstet Gynecol. 2005;193(1):89-94.
3. Clemons JL, Aguilar VC, Sokol ER, Jackson ND, Myers DL. Patient characteristics that are associated with continued pessary use versus surgery after 1 year. Am J Obstet Gynecol. 2004;191(1):159-164.
4. Jones K, Yang L, Lowder JL, et al. Effect of pessary use on genital hiatus measurements in women with pelvic organ prolapse. Obstet Gynecol. 2008;112(3): 630-636.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	✓
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	✓
Domain 4	**Ensuring people have a positive experience of care**	✓
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	✓

3. Scope

3.1 Aims and objectives of service

The aim of this service is provide a ring pessary fitting service within a primary care setting which will:

- Help reduce inequality of care across Hull through provision of an accessible and convenient service in an out of hospital environment;
- Increase choice for all patients;
- Provide an integrated and collaborative approach to ensure a seamless service;
- Provide faster access to management of gynaecology conditions in a primary care setting;

3.2 Service description/care pathway

3.2.1 This service is broken into two parts for which the Provider may offer those patients who satisfy the relevant treatment thresholds one or both of;

- Ring pessary initial consultation, sizing and fitting
- Review and replacement of pessary every 4 to 6 months

3.2.2 Patients must be clinically assessed by their own practice prior to the commencement of the service and the fitting of the pessary should only be carried out when it is safe and appropriate to do so.

3.2.3 Patients will be expected to book a follow up appointment by instruction of the providing clinician; this will be booked through their own practice with referral made to the service if provided by another practice within the PCN.

3.2.4 The provider may wish to offer this service to their own registered patients only or open up this service to patients registered within their Primary Care Network.

3.2.5 In addition the Provider will ensure:
Procedures are carried out by a medically qualified person or a nurse who is trained to fit the pessary;

- procedures are carried out in suitable clinic room facilities;
- the national policy for obtaining the patient's informed consent to examination and treatment is adhered to;
- adequate records are maintained (a copy of which should be included in the patient's medical record) of the service provided, incorporating all known information relating to any significant events, e.g. treatment given, any additional related referral, infections, etc. A copy of this information should be sent to the referring clinician where this involves another GP practice within 5 working days of the procedure taking place.

3.2.6 If a practice within a Primary Care Network registered with the Hull CCG but not contracted to deliver this service will be expected to refer their patients requiring this treatment using a secure electronic referral and booking system.

3.2.7 In the instance of 3.2.5 both practices have a responsibility in monitoring the information flow in terms of referral, acceptance and information to be included within the patient's clinical record.

3.3 Population covered

3.3.1 Women registered with a GP practice that is a member of NHS Hull CCG.

3.3.2 The Provider must ensure that all women registered with a practice that is a member of the Primary Care Network can access the service.

3.4 Acceptance and exclusion criteria

3.4.1 The service is available to any females over the age of 16 years diagnosed clinically as having a form of uterine prolapse, cystocele or rectocele following clinical examination who complains of:

- Bulge or lump in the vagina
- The vagina protruding from the body
- A pulling or stretching feeling in the groin area
- Difficult or painful sexual intercourse
- Vaginal pain, pressure, irritation, bleeding, or spotting
- Urinary and faecal incontinence
- Difficulty with bowel movements
- Delayed or slow urinary stream

3.4.2 The service is not intended for women who are clinically assessed by their own GP as unsuitable for treatment for pelvic organ prolapse with a ring pessary with:

- Evidence of an active pelvic infection or severe ulceration
- Allergy to either silicone or latex

3.5 Interdependence with other services/providers/bodies

3.5.1 The Provider will be required to ensure they communicate as appropriate with other providers of gynaecology services including:

- Hull University Teaching Hospital Trust
- City Health Care Partnership CIC

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

4.1.1 As stated in paragraphs SC2 (Regulatory Requirements) and SC3 (Service Standards) the Provider is required to adhere to all national standards as issued from time to time by any relevant Regulatory and Statutory bodies including guidance issued by appropriate competent bodies (e.g. Royal Colleges).

4.2 Applicable local standards

4.2.1 Practitioners must have had relevant training to ensure appropriate patient selection, pessary fitting and long term follow-up to minimise the potential for uncommon but sometimes serious side-effects of long term pessary use such as erosion and infection. 'Guidelines for the Use and Support of Pessaries in the Management of Pelvic Organ Prolapse' (ANMF).

4.2.2 It is a requirement that assessment and fitting of ring pessaries is performed by a suitably trained GP or Practice Nurse.

4.2.3 The Provider must be able to provide evidence of staff training and competency which may be requested by the Commissioner at any time.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements

5.1.1 The Provider will develop and follow a standard operating policy for provision of this service.

5.1.2 It is a condition of participation in this service that practitioners will give notification, within 48 hours (two working days), of the information becoming known to him/her, to the CCG clinical governance lead, of all relevant significant adverse events, emergency admissions or deaths of any patient treated under this service. This is in addition to any statutory obligations.

6. Location of Provider Premises

6.1 Premises

6.1.1 The service will be provided from the Provider's Premises located at: Hull GP Practices.

7. Individual Service User Placement

Not applicable