MANAGEMENT IN CONFIDENCE

CLINICAL PRIORITIES ADVISORY GROUP
02 April 2019

Agenda Item No	
National Programme	Women & Children
Clinical Reference Group	Specialised Women's
URN	1758

Title
Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse (16 years and above)

Actions Requested	1. Agree the service specification proposition
	2. Recommend its approval as an in-year service development

Proposition
NHS England proposes that complex and repeat surgery for these conditions as well as vaginal mesh removal services should be commissioned against the following services specifications: - • Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse (see CPAG URN report 1649). • Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse. The specification for Women With Complications Of Mesh Inserted For Urinary Incontinence and Vaginal Prolapse is a new service specification although the treatment and management of these cases is referenced in the current service specification Complex Gynaecology: Recurrent Prolapse and Urinary Incontinence (E10/S/d). Devices have been used for many years in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). These devices are commonly known as meshes. This is a broad term that covers a number of different types of manufactured biological and synthetic devices. There are also used in other surgical procedures such as common hernia repair. Surgical mesh is used in the treatment of SUI and POP to provide extra artificial support when repairing weakened of damaged tissues.

For many women suffering the distressing effects of SUI and POP, surgical procedures using mesh devices have proved an effective form of treatment which can be far less invasive than alternative surgical procedures. There is published evidence to suggest improved outcomes for procedures using mesh however, complications can include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel.

A number of patient groups have been reporting complications following mesh procedures and a Mesh Oversight Group was convened and chaired by Professor Keith Willett (Medical Director for Acute Care in NHS England). The Mesh Oversight Group Report was published in July 2017 with a series of recommendations. These recommendations also included the following:

"The national specialised commissioning team will develop, consult on and publish a service specification for the centres providing an experienced team for mesh removal. This will include advice on referral, multidisciplinary assessment to consider mesh removal, and surgery by expert teams. There will be a procurement of a limited number of centres providing the balance between geographical access and maximising centre activity to rapidly build expertise. These centres will be linked by a national network to report their treatment outcomes".

The review of the service specifications has also been referenced in the July 2018 Vaginal Mesh: High Vigilance Restriction Period that announced a national pause in the use by the NHS of surgical mesh/tape to treat stress urinary incontinence for urogynaecological prolapse.

The high vigilance restriction will remain in place until the following conditions are met:

a. Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly.
b. Surgeons report every procedure to a national database.
c. A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery.
d. Reporting of complications via MHRA is linked to the register.
e. Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh.
f. NICE guidelines on the use of mesh for SUI are published.

This new service specification will ensure that those patients who need treatment for complications of mesh inserted for urinary incontinence and vaginal prolapse are treated in a small number of designated hospitals by clinicians with the right skills and experience.

Clinical Panel Recommendation
Not applicable.

The committee is asked to receive the following assurance:	
1.	The Head of Clinical Effectiveness confirms that the proposal has completed the appropriate sequence of governance steps and does not require an Evidence Review or Clinical Panel Report.
2.	The Head of the Cancer Programme confirms the proposal is supported by an: Impact Assessment; Stakeholder Engagement Report; Consultation Report; Equality Impact and Assessment Report; Service Specification Proposition. The relevant National Programme of Care Board has approved these reports.
3.	The Director of Finance (Specialised Commissioning) confirms that proposal is cost neutral
4.	The Operational Delivery Director (Specialised Commissioning) confirms that the service and operational impacts have been completed
5.	The Director of Nursing (Specialised Commissioning) confirms that the proposed quality indicators have been adequately defined.

The following documents are included (others available on request):	
1.	Service specification
2.	A Stakeholder Engagement report and a Consultation Report
3.	Evidence Summary – not applicable
4.	Clinical Panel Report – not applicable
5.	Equality Impact and Assessment Report
6	An Integrated Impact Assessment

Considerations from review by Rare Disease Advisory Group
Not applicable.

Pharmaceutical considerations
None.

Considerations from review by National Programme of Care
Benefit of Service Specification: This is a new service specification specifically for vaginal mesh removal. The development of this service specification was a requirement of the recommendations set out in the Mesh Oversight Group Report. The service specification will result in the commissioning of designated mesh removal service to improve patient safety and confidence. **Implementation timescale:** **Service reconfiguration / procurement required. Expected implementation date April 2020**