

<b>Reference Number:</b> <b>Version Number: 1</b>	<b>Date of Next Review: December 2022</b> <b>Previous Trust/LHB Reference Number:</b>
<b>Title: Guideline for the management of raised serum CA 125 levels with normal pelvic ultrasound findings in Primary and Secondary care</b>	
<b>Introduction and Aim</b> <p>This guideline will aid clinicians to manage patients with raised CA 125 levels with normal pelvic ultrasound scan findings as there is a great deal of anxiety that cancer is being missed due to the raised tumour marker level.</p> <p><i>Is the document supporting a policy? No</i></p> <p><i>What will it achieve? Improve management of patients with raised CA125 levels with normal pelvic ultrasound findings</i></p>	
<b>Objectives</b> <ul style="list-style-type: none"> <li>To streamline management of patients with raised CA 125 with normal Pelvic ultrasound findings</li> </ul>	
<b>Scope</b> <p>This policy applies to all healthcare professionals in all locations including those with honorary contracts</p>	
<b>Equality Health Impact Assessment</b>	<i>An Equality Health Impact Assessment (EHIA) has not been completed.</i>
<b>Documents to read alongside this Procedure</b>	

<b>Approved by</b>	<i>Gynaecology Professional Forum</i>
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Summary of reviews/amendments			
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AS V 11/21			

## Guideline for the management of raised serum CA 125 levels with normal pelvic ultrasound findings in Primary Care

### Introduction:

Serum CA 125 levels are being increasingly checked in women of all ages in the primary care as per NICE guidelines (CG122). If the CA 125 level is raised (> 35U/L), an ultrasound scan (USS) is arranged by the GP in the primary care which confirms presence or absence of pathology which would explain the raised CA 125 levels. There is a fair number of patients being referred to the gynaecology department with raised CA 125 levels with a normal ultrasound scan of the pelvis with normal ovaries.

### **Indication to carry out CA 125 in primary care (CG 122):**

Women (especially if 50 or over) presenting with one or more of the following symptoms on a persistent (at least 1 month) or frequent (12 times per month) basis:

- ☐ persistent abdominal distension (women often refer to this as 'bloating')
- ☐ feeling full (early satiety) and/or loss of appetite
- ☐ pelvic or abdominal pain
- ☐ increased urinary urgency and/or frequency
- ☐ unexplained weight loss
- ☐ unexplained fatigue
- ☐ unexplained changes in bowel habit (for example, constipation or diarrhoea)
- ☐ symptoms that suggest irritable bowel syndrome - if the woman is 50 years or over

**If serum CA-125 is 35 U/ml or greater, an ultrasound scan of the abdomen and pelvis should be arranged.**

### **Causes for Raised CA 125 levels: Table 1**

<b>Benign conditions causing raised CA125</b>	<b>Malignant conditions causing raised CA125</b>
<ul style="list-style-type: none"> <li>• <b>Physiological conditions:</b> ovulation, pregnancy, menstruation</li> <li>• <b>Benign gynaecological conditions:</b> PID, endometriosis, benign ovarian cysts, fibroids</li> <li>• <b>Autoimmune disease:</b> Sjogrens syndrome, polyarteritis nodosa, SLE sarcoidosis</li> <li>• <b>GI conditions:</b> colitis, diverticulitis</li> <li>• <b>Liver conditions:</b> chronic active hepatitis, cirrhosis</li> <li>• <b>Other:</b> heart failure, pericarditis, pancreatitis, renal disease, recent surgery, ascites, pleural effusion</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Gynaecological malignancy:</b> ovarian, cervical, endometrial cancers</li> <li>• <b>Other malignant conditions:</b> breast, lung, bowel, pancreatic cancer (any site involving pleural, pericardial and peritoneal surfaces), sometimes in non-Hodgkin's lymphoma,</li> </ul>

### **Management: (Algorithm 1)**

CA 125 has poor sensitivity and specificity for detection of ovarian cancer. This is more so in premenopausal women. There is evidence that even CA 125 levels of 200 are likely to be because of benign conditions in premenopausal women. The only role where the CA 125 test has proven utility is for monitoring ovarian cancer and for a preoperative test in patients with an ovarian mass.

In the presence of a normal pelvic ultrasound, if a serum CA-125 assay is raised more than 35 units/ml, further appropriate investigations need to be considered to exclude/treat the common differential diagnoses (see Table 1). When serum CA-125 levels are raised, serial monitoring of CA-125 may be helpful as rapidly rising levels are more likely to be associated with malignancy than high levels which remain static.

99% of healthy women have values less than 35. Levels above 35 units are certainly seen in healthy women, but beyond the cutoff point of 35, the higher the value, the more likely there is trouble somewhere in the body.

## **References:**

American College of Obstetricians and Gynecologists. Management of adnexal masses. ACOG Practice Bulletin No. 83. Washington DC: ACOG; 2007.

RCOG, Royal College of Obstetricians and Gynaecologists. Management of Suspected Ovarian Masses in Premenopausal Women. Guideline no. 62. 2011.

RCOG, Royal College of Obstetricians and Gynaecologists. Ovarian cysts in postmenopausal women. Guideline no. 34. 2016.

National Institute for Health and Clinical Excellence. *Ovarian cancer: The recognition and initial management of ovarian cancer*. NICE clinical guideline 122. London: NICE; 2011.

## Algorithm 1: Management of raised CA 125 levels and normal pelvic ultrasound

