

## Protocol for Raised Ca 125 in Postmenopausal Women Referred into / or seen in Secondary Care

|                                   |   |
|-----------------------------------|---|
| <b>Document Type:</b>             | Clinical Guidelines   |
| <b>Ref:</b>                       | (For Non-Clinical References – Contact: <a href="mailto:CTM_Corporate_Governance@wales.nhs.uk">CTM_Corporate_Governance@wales.nhs.uk</a><br>For Clinical References – Contact: <a href="mailto:CTM_ClinicalPolicies@wales.nhs.uk">CTM_ClinicalPolicies@wales.nhs.uk</a> ) |
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| <b>Approved By:</b>               | <b>Health Board</b>   |
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| <b>Review Date:</b>               | September 2027  |
| <b>Version:</b>                   | 2   |

### Target Audience:

|   |   |
|---|---|
| <b>People who need to know about this document in detail</b>          | All staff involved in the care of postmenopausal patients                     |
| <b>People who need to have a broad understanding of this document</b> | Care Group Directors<br>Chief Operating Officer<br>Executive Medical Director |
| <b>People who need to know that this document exists</b>              | All staff involved in the care of postmenopausal patients                     |

### Integrated Impact Assessment:

|   |                                 |
|---|---------------------------------|
| <b>Equality Impact Assessment Date &amp; Outcome</b>                        | <b>Date:</b><br><b>Outcome:</b> |
| <b>Welsh Language Standard</b>  | Choose an item.                 |
| <b>Date of approval by Equality Team:</b>                                   | (00/00/0000)                    |
| <b>Aligns to the following Wellbeing of Future Generation Act Objective</b> | Choose an item.                 |



### Disclaimer:

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 1

If the review date of this document has passed please ensure that the version you are using is the most up to date version either by contacting the author or [CTM\\_Corporate\\_Governance@wales.nhs.uk](mailto:CTM_Corporate_Governance@wales.nhs.uk)

## COMPONENTS:

A policy must contain the following components and must also be written to include the values and behaviours of the organisation wherever relevant:

It is accepted that for Clinical Policies and or other Written Control Documents (Procedures, Guidance etc.) the policy components below may not all be relevant.

For guidance on Clinical Policy Development please contact:

[CTM\\_ClinicalPolicies@wales.nhs.uk](mailto:CTM_ClinicalPolicies@wales.nhs.uk)

For guidance on Non Clinical Policy Development please contact:

[CTM\\_Corporate\\_Governance@wales.nhs.uk](mailto:CTM_Corporate_Governance@wales.nhs.uk)

Or visit the Policy Author Page on SharePoint:

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 2

## CONTENTS PAGE

|   |          |
|---|----------|
| Guideline Definition .....  | 4        |
| Purpose .....   | 4        |
| Scope.....  | 4        |
| Roles and Responsibilities.....   | 4        |
| Training Requirements.....  | 4        |
| Monitoring of Compliance .....  | 4        |
| Complaints .....  | 5        |
| Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care .....                      | 6        |
| Addendum: .....   | 7        |
| Guideline for the management of raised serum CA 125 levels with normal pelvic ultrasound findings in Primary Care ..... | 7        |
| <b>References.....</b>  | <b>8</b> |

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 3

## Guideline Definition

Clinical guidelines are systemically developed statements that assist clinicians and patients in making decisions about appropriate treatments for specific conditions.

They allow deviation from a prescribed pathway according to the individual circumstances and where reasons can be clearly demonstrated and documented.

## Purpose

- to ensure women presenting to CTM UHB with a raised CA125 have access to standardised care for the diagnosis and treatment.
- to ensure clinicians investigate and treat a raised CA125 according to evidence based practice

## Scope

This policy applies to all healthcare professionals in all locations including those with honorary contracts

## Roles and Responsibilities

In seeking further advice on any uncertainties contained in this document, or if you feel that there is new or more updated advice it is your responsibility to contact the guideline author or Approval Group manager so that any amendments can be made.

The guideline Approval Group is responsible for disseminating this guideline to all appropriate staff.

The guideline author or a named alternative is responsible for updating the guideline with any amendments that they become aware of or are highlighted to them.

All health professionals are responsible to ensure that the guideline is utilised effectively, and to ensure that they are competent and compassionate in the implementation of it.

## Training Requirements

There is no mandatory training associated with this guideline.

## Monitoring of Compliance

By audit and review of complaints relating to miscarriage diagnosis and management.

The Governance Department will collate any complaints and distribute to the relevant individuals for comments, and share any learning points.

The Service Lead will oversee any governance issues, make relevant recommendations to the directorate, and advise the Clinical Director or the directorate of any matters that require implementation.

The Health Board reserves the right, without notice, to amend any monitoring requirements in order to meet any statutory obligations or the needs of the organisation

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 4

## Complaints

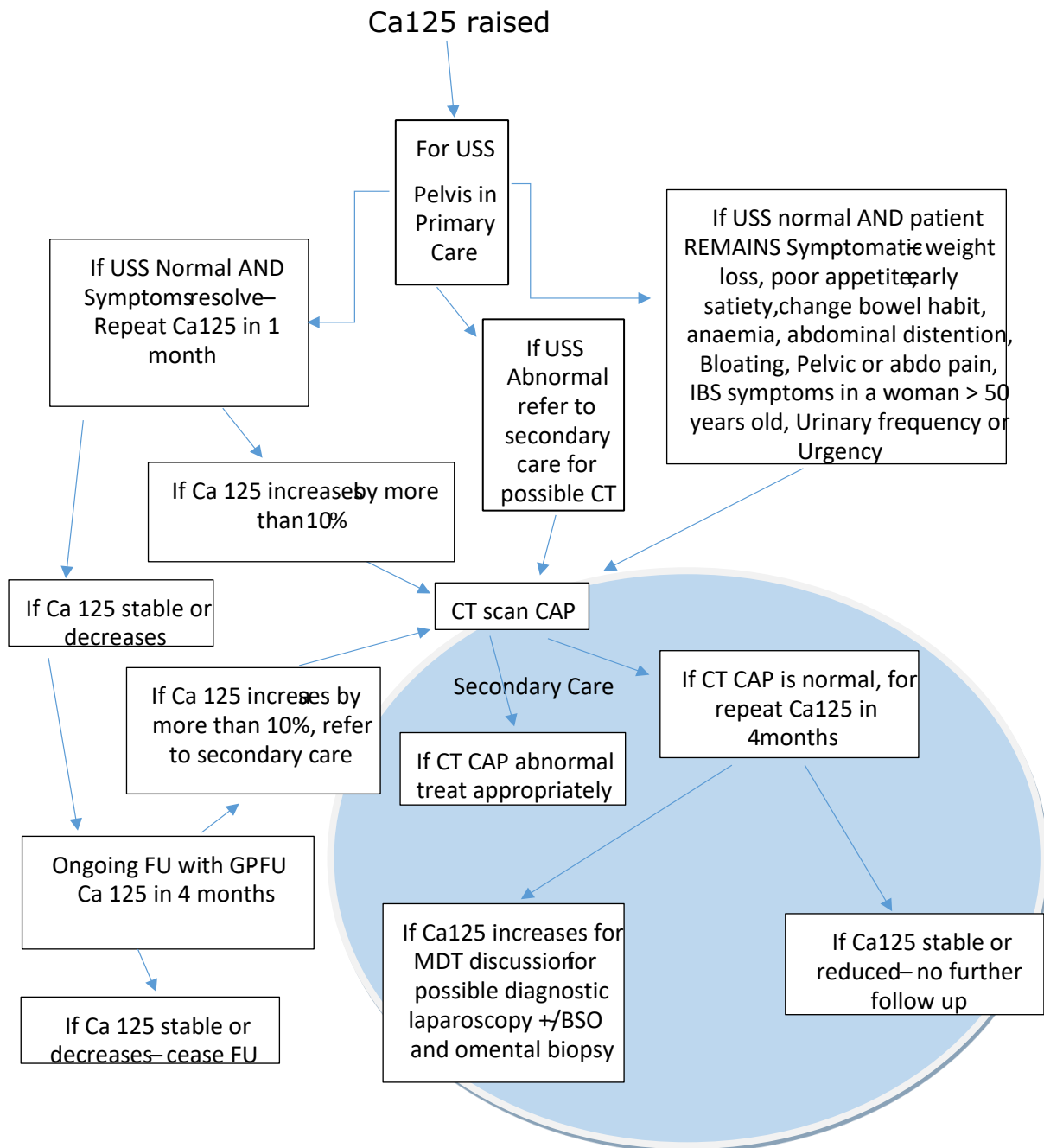
All complaints should try to be resolved with the patient during any contact to avoid escalation. There concerns should be listened to and documented. If it is not possible to address any concerns at the time, or if the complaint is of a serious nature, the patient's complaint should be discussed with the consultant in charge for the day, or the patient should be given details of how to raise a formal complaint via the local governance department.

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 5

## Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care



Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 6

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.

## Addendum:

[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.**

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 7

## Causes for Raised CA 125 levels: Table 1

| Benign conditions causing raised CA125  | Malignant conditions causing raised CA125   |
|---|---|
| <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> |

### Comment:

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 cut-off point of 35, the higher the value, the more likely there is trouble somewhere in the body. If endometriosis suspected clinically, especially if the Ca 125 is markedly raised - please discuss with a Gynae radiologist re suitability for MRI.

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 8

## References

American College of Obstetricians and Gynaecologists. 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.

Ref:

Policy Title: Protocol for Raised Ca 125 in POSTMENOPAUSAL WOMEN Referred into / or seen in Secondary Care

Page Number: 9