East Kent Hospitals University NHS

Foundation Trust

ALBUMINURIA – GUIDELINES FOR ALBUMINURIA TESTING IN PEOPLE WITH DIABETES MELLITUS OR AT RISK OF CHRONIC KIDNEY DISEASE

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| Ratified by: | Clinical Biochemistry Senior Staff Group |
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| Name of originator/author: | Dr Edmund Lamb |
| Director responsible for implementation: | Prof F Muhlschlegel |
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Version Control

| Version | Date | Author | Status | Comment |
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| 1.0 | 1 st October 2014 | Dr Edmund Lamb | Final | Earlier guidance put in Q-Pulse format |
| 2.0 | 1 st June 2016 | Dr Edmund Lamb | Final | Guidance updated to include non-diabetic kidney disease and a single cut-off of 3.0 mg/mmol as per NICE CG182. Also changed into Sharepoint format |

| 3.0 | 20 th October 2021 | Dr Edmund Lamb | Final | Updated to reflect minor changes in NICE CKD guidance 20201 |
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Consultation Schedule

| Name & Job Title of Individual / Meeting name | Date consulted |
|---|--------------------------------|
| Dr I John, Consultant Nephrologist and CKD lead, EKHUFT. | 9 th February 2016 |
| Dr M Flynn, Trust Consultant and lead for diabetes and endocrinology, EKHUFT. | 11 th February 2016 |
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Ratification Schedule

| Name of Meeting / Committee | Date approved / authorised |
|--|----------------------------|
| Clinical Biochemistry Senior Staff Meeting | 18 th May 2016 |
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Contents

| | | Page |
|-----|--|------|
| 1. | Introduction, background and purpose | 4 |
| 2. | Definitions | 4 |
| 3 | Scope | 5 |
| 4. | Guidance | 5 |
| | When and how to assess albuminuria | 5 |
| | b. How to assess albuminuria | 5 |
| | c. Further investigation | 6 |
| 6. | Consultation and approval | 7 |
| 7. | Review and revision arrangements | 7 |
| 8. | Training | 7 |
| 9. | Document control including archiving arrangements | 7 |
| 10. | Monitoring | 7 |
| 11. | References | 8 |
| 12. | Appendix. Flow chart: screening for albuminuria | 9 |

1. Introduction, Background and Purpose

This guideline advises on when and how to screen for albuminuria in patients with diabetes or with other conditions that increase risk of chronic kidney disease. Albuminuria is an increase in the urinary loss of albumin. Establishing the diagnosis has both prognostic and management implications in the care of patients with diabetes mellitus and chronic kidney disease. The following local guidelines are based on guidance from the National Institute for Health and Care Excellence (NICE).

2. Definitions

Albuminuria (previously called 'microalbuminuria') is an increase in the urinary loss of albumin. Urinary albumin concentration will be affected by the amount of albumin leaking through the kidney and also by the concentration of the urine itself. To allow for variation in urinary concentration, albuminuria is reported as a ratio of urine albumin to urine creatinine concentrations as mg of albumin/mmol of creatinine. A ratio above or equal to the clinically significant threshold of 3.0 mg/mmo is considered to denote the presence of albuminurial. Note that 3.0 mg/mmol is not a reference range, which would be a much lower value, but a risk threshold.

Higher levels of albuminuria, for example that detectable by crude clinical tests such as protein 'dipsticks', is often referred to as proteinuria (or 'macroalbuminuria') and relates to concentrations >30 mg/mmol.

The diagnosis of albuminuria requires the demonstration of increased albumin loss in at least two out of three urine samples collected in the absence of infection or an acute metabolic crisis. In the international classification of kidney disease, ACR <3.0 mg/mmol is regarded as normal or slightly increased (category A1), 3-30 mg/mmol as moderately increased (category A2), and >30 mg/mmol as severely increased (category A3).

Increased albumin loss in an overnight collection is defined as an overnight albumin rate of loss >20 μ g/min.

3. Scope

This guidance is consistent with that developed by NICE and is intended for use by primary and secondary care in East Kent for the detection of albuminuria in individuals at risk of this complication. Establishing whether a patient has albuminuria has both prognostic and management implications in the care of patients with diabetes mellitus and chronic kidney disease.

4. Guidance

a. When and who to screen for albuminuria

Testing for albuminuria should be offered to people with chronic kidney disease or with conditions which place them at increased risk of chronic kidney disease (NICE NG203):

- Diabetes (NICE NG17, NG18, 28). In people with diabetes, the best possible metabolic control should be achieved before investigating for albuminuria. Patients should not be screened during intercurrent illness. Screening is not indicated in patients with established proteinuria. In the case of type 1 diabetes, screening should be offered annually from age 12 years.
- Hypertension (NICE CG127)
- Previous episode of acute kidney injury
- Cardiovascular disease (ischaemic heart disease, chronic heart failure, peripheral vascular disease or cerebral vascular disease)
- Structural renal tract disease, recurrent renal calculi or prostatic hypertrophy
- Multisystem diseases with potential kidney involvement for example, systemic lupus erythematosus
- gout
- Family history of end-stage kidney disease (glomerular filtration rate <15 mL/min/1.73 m²) or hereditary kidney disease
- Incidental detection of haematuria or proteinuria
- Children and young people with a solitary functioning kidney

b. How to assess albuminuria

An early morning (first sample of the day) mid-stream urine sample should be collected into a plain sterilin pot and sent to the laboratory. If the first urine sample of the day is not available, use a random sample, but be aware that this is associated with an increased risk of false positive results.

The sample container **must** be labelled with the full name, NHS number and sample date. Very occasionally, it may be desirable to confirm the diagnosis by measuring albumin loss in a timed overnight collection. The laboratory can supply urine collection containers.

See Appendix for flowchart.

Do not assess albuminuria/proteinuria using:

- reagent strips unless they are capable of specifically measuring albumin at low concentrations and expressing the result as an ACR.
- the protein:creatinine ratio (PCR). ACR has greater sensitivity than PCR for low levels of proteinuria. For quantification and monitoring of levels of proteinuria of ACR 70 mg/mmol or more, PCR can be used as an alternative. ACR is the recommended method for people with diabetes.

c. Further investigation

An albumin-to-creatinine ratio (ACR) <3.0 mg/mmol requires no further investigation until the patient's next annual review. Patients demonstrating ACRs \geq 3.0 mg/mmol should have urine samples sent to the laboratory on two further occasions (ideally within one month) for ACR measurement. Patients demonstrating increased ACRs in one or both of these further samples have 'higher risk' urine albumin loss and should be managed accordingly (e.g. see relevant NICE guideline). If the initial ACR is \geq 70 mg/mmol (approximately equivalent to 1 g/day proteinuria) then proteinuria is confirmed and a subsequent sample is not required. You may wish to discuss the management of such patients with the secondary care diabetes or nephrology teams.

It is important to always consider causes of increased albumin loss not attributable to intrinsic renal disease. These can include menstrual contamination, vaginal discharge,

| Document Number: BIO NO 321 | WARNING: This is a controlled document | Page 6 of 9 |
|-----------------------------|--|-------------------------|
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uncontrolled hypertension, symptomatic urinary tract infection, uncontrolled diabetes, heart failure, intercurrent illness and strenuous exercise. In patients with type 1 diabetes and albuminuria, suspect other causes of renal disease:

- in the absence of progressive retinopathy
- if blood pressure is particularly high
- if proteinuria develops suddenly
- if significant haematuria is present
- in the presence of systemic ill health

5. Consultation and Approval

East Kent Hospitals University NHS Foundation Trust is the key stakeholder for this policy. This document was prepared in consultation with Dr I John, Consultant Nephrologist and CKD lead, and Dr M Flynn, Trust Consultant and lead for diabetes and endocrinology, EKHUFT.

Copies of correspondence relating to this guidance may be found on the shared drive.

6. Review and Revision Arrangements

Two years from implementation date, by author.

7. Training

All staff involved in requesting, measuring or interpreting urinary albumin loss must adhere to this policy.

8. Document Control including Archiving Arrangements

Archive of this document will be via Q-Pulse, and is responsibility of the owner defined on Q pulse.

9. Monitoring

Within the Trust, compliance with this policy must rest with the requesting Care Groups. Compliance may be assessed by occasional pre-analytical request vetting within the laboratory and by retrospective clinical audit.

10. References and Associated Documents

National Institute for Health and Care Excellence. Chronic kidney disease in adults: assessment and management. NG203, August 2021. https://www.nice.org.uk/guidance/ng203

National Institute for Health and Care Excellence. Diabetes (type 1 and type 2) in children and young people: diagnosis and management.NG18, August 2015. https://www.nice.org.uk/guidance/ng18

National Institute for Health and Care Excellence. Hypertension in adults: diagnosis and management. NG136, August 2019. <u>https://www.nice.org.uk/guidance/ng136</u>

National Institute for Health and Care Excellence. Type 1 diabetes in adults: diagnosis and management NG17, August 2015. <u>https://www.nice.org.uk/guidance/ng17</u>

National Institute for Health and Care Excellence. Type 2 diabetes in adults: management NG28, December 2015. <u>https://www.nice.org.uk/guidance/ng28</u>

Appendix: Flow chart: screening for albuminuria



Document Number: BIO NO 321 Author: Dr E. Lamb Approved by : Dr S Stock WARNING: This is a controlled document

Page 9 of 9 Date of Issue: Nov 2021 Revision: 3.0