PARAPROTEINS – MANAGEMENT OF PATIENTS

Version:	1.0
Ratified by:	Biochemistry Senior Staff group
Date ratified:	15 May 2014
Name of originator/author:	E Kearney, E Hall and J Lindsay
Director responsible for implementation:	Prof Fritz Muhlschlegel
Date issued:	27 May 2014
Review date:	27 May 2017
Target audience:	Clinical staff (medical, nursing and scientific), Trust wide and primary care

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Version Control Schedule

Version	Date	Author	Status	Comment
1.0	18/3/2014	E Kearney, E Hall, J Lindsay		

Contents

1 Policy Summary

This policy gives guidance to clinicians when a new paraprotein band is detected.

2 Introduction

Paraprotein bands may be present in:

Symptomatic myeloma — defined as any amount of paraprotein in serum or urine *and* >10% clonal plasma cells in bone marrow *and* symptoms of myeloma-related organ or tissue involvement.

Asymptomatic myeloma — defined as serum paraprotein > 30 g/L *and/or* >10% clonal plasma cells in bone marrow *and no* symptoms of myeloma-related organ or tissue involvement. Median time to progress to symptomatic myeloma is 12-32 months

MGUS — Monoclonal Gammopathy of Undetermined Significance (MGUS) defined as serum paraprotein < 30 g/L *and* <10% clonal plasma cells in bone marrow *and no* symptoms of myeloma-related organ or tissue involvement.
Percentage risk of progression to myeloma or other B cell malignancy is related to paraprotein concentration; 20% risk of progression within 10 years at 20 g/L.

AL amyloidosis

Solitary plasmacytoma

B cell non-Hodgkin lymphoma (including Waldenström macroglobulinaemia)

Chronic lymphocytic leukaemia

3 Purpose and Scope

This policy outlines the next follow up steps when a new paraprotein band is detected.

4 Definitions

A paraprotein band is an abnormal immunoglobulin or immunoglobulin light chain that is produced in excess by the clonal proliferation of plasma cells.

5 Duties

All staff involved in the caring for patients with a new paraprotein band, whether clinical or laboratory must adhere to this policy.

6 Paraprotein bands management of patients

6.1 Diagnosis

All patients with a new paraprotein band must have full blood count, ESR, electrolytes and eGFR, calcium and albumin, uric acid, urine and serum electrophoresis (immunofixation/immunotyping), immunoglobulins, CRP and LDH to assess risk. X-rays are required if there are bony symptoms.

6.2 Refer to Consultant Haematologist for assessment:

- All IgD, and IgE paraprotein bands
- All serum IgG paraprotein bands > 15 g/L
- All serum IgA and IgM paraprotein bands >10 g/L
- All patients under the age of 50 years
- All patients with symptoms suggesting myeloma-related organ or tissue involvement or other B cell malignancy
  - anaemia (Hb <100 g/L)
  - thrombocytopaenia
  - neutropaenia
  - hypercalcaemia (adjusted calcium > 2.8 mmol/L)
  - renal insufficiency (creatinine > 173 umol/L)
  - Bence Jones proteinuria (>500 mg/L)
  - lytic bone lesions or osteoporosis with compression fractures
  - symptomatic hyperviscosity, eg. visual disturbance, neuropathy, bleeding
  - amyloidosis, eg nephrotic syndrome or heart failure
  - recurrent bacterial infection (more than 2 episodes in 12 months)
  - lymphadenopathy, hepatosplenomegaly

6.3 Management of patients not referred to consultant haematologists:

Any primary or secondary care patients not referred to Haematology must have serum and urine electrophoresis repeated at 6 months (for the first year and annually thereafter if stable) with a clinical review to ensure there is no progression. If there is progression (IgG paraprotein > 15 g/L, IgA or IgM paraprotein >10 g/L, Bence Jones proteinuria > 500 mg/L) referral to Haematology is indicated.

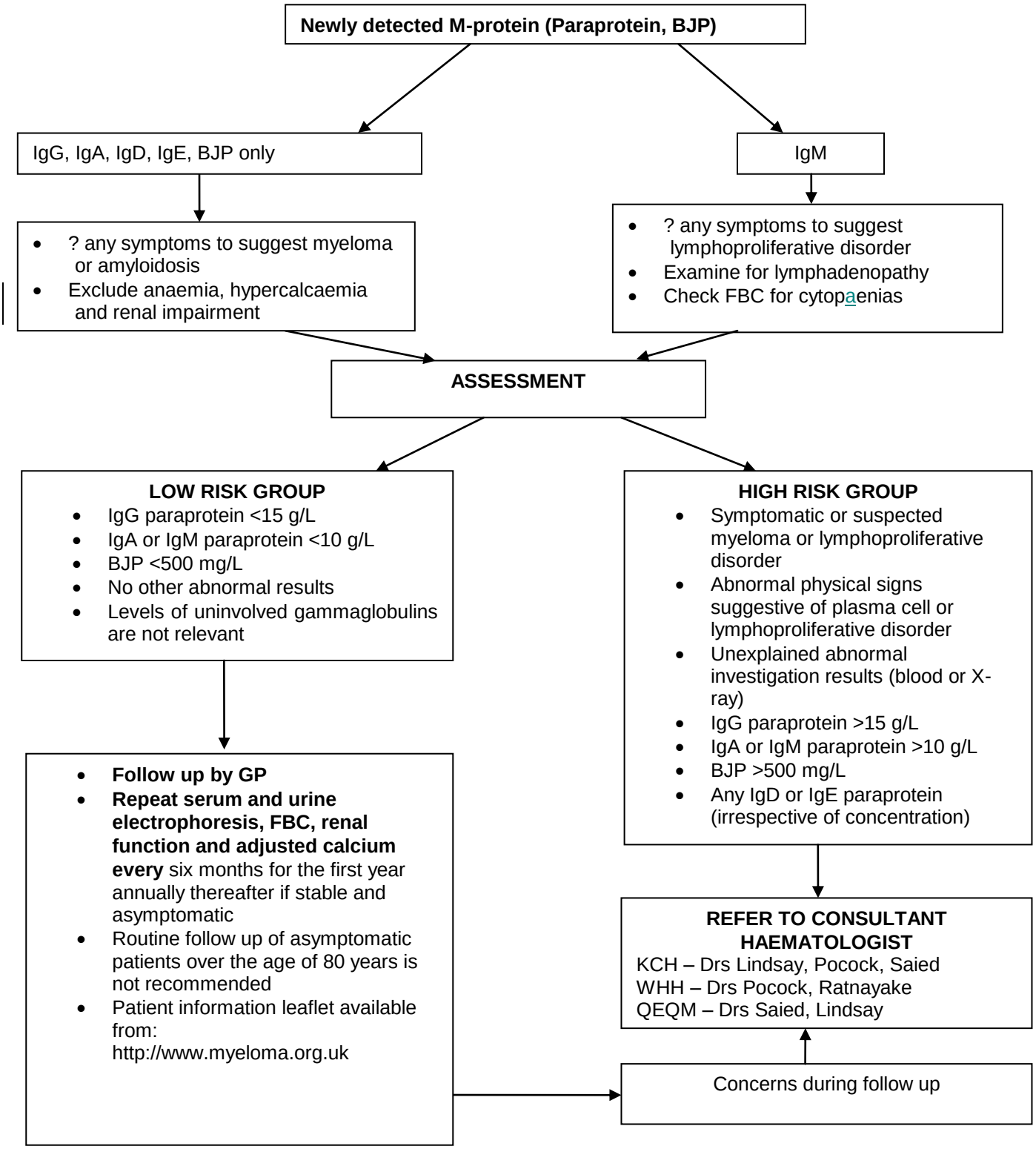
MGUS is indicated if there is no progression in an asymptomatic patient; serum and urine electrophoresis must be repeated annually.

Cryoglobulins

Cryoglobulins are proteins that precipitate at temperatures below 37^{o}C. This phenomenon is particularly associated with IgM paraproteins. Cryoglobulin precipitation *in vivo* is a rare cause of Raynaud's syndrome. Cryoglobulin precipitation *in vitro* is more common and may lead to underestimation of the paraprotein concentration.

Samples for "?cryoglobulin" must be taken by phlebotomists in the Out-patient department to ensure the rigorous sampling handling requirements are followed

Figure 1 Algorithm New Paraprotein Bands



7 Key Stakeholders, Consultation, Approval and Ratification Process

East Kent Hospitals University NHS Foundation Trust is the key stakeholder for this policy.

Consultation has been through e-mail and face-to-face communication between clinical biochemistry staff, Trust consultant Haematologist (Dr J Lindsay). Copies of correspondence are on "T" Pathology/Clinical Biochemistry/Communications with users/Paraprotein Guidelines

8 Review and Revision Arrangements

Three years from implementation date, by author.

9 Dissemination and Implementation

SharePoint, by proactive implementation through the Divisions by appropriate clinical leads and by proactive dissemination to primary care partners.

10 Document Control including Archiving Arrangements

Archive of this document will be through QPulse.

11 Monitoring Compliance

Within the Trust, compliance with this policy must rest with the requesting Divisions with vetting of requests in Clinical Biochemistry. Compliance will also be subject to occasional audit within Clinical Biochemistry.

12 References

Brit J Haematol. 2005; 132, 683–697. Guidelines on the management of Waldenström macroglobulinaemia

UK Myeloma Forum (UKMF) and Nordic Myeloma Study Group (NMSG): Guidelines for the investigation of newly detected M-proteins and the management of Monoclonal Gammopathy of Undetermined Significance (MGUS) British Journal of Haematology, 2009, **147**,22-42Guidelines for the diagnosis and management of Multiple Myeloma 2103 Haemato-oncology Task force of the British Committee for Standards in Haematology, UK Myeloma Forum
BCSH (http://www.bcshguidelines.com/) and UKMF (http://www.ukmf.org.uk/)

Patient information is available at http://www.myeloma.org.uk

13 Associated Documentation

Not applicable

Appendix A - Equality Impact Assessment

Equality and Human Rights Impact Analysis (EHRIA)

Part One – Screening Tool

Name of the policy, strategy, function or methodology:	Paraprotein bands – Management of Patients

Details of person completing the EHRIA	
Name	Mr Edward Kearney
Job Title	Consultant Clinical Scientist
Department/Specialty	Laboratory Medicine/Clinical Biochemistry
Telephone Number	Ext 62404

1. Identify the policy, strategy, function or methodology aims

What are the main aims, purpose and outcomes of the policy, strategy, function or methodology?
To ensure appropriate follow up of patients with a newly detected paraprotein band across the health service in East Kent.
Does it relate to our role as a service provider and/or an employer?
Service provider.

2. Assess the likely impact on human rights and equality

Use this table to check if the policy, strategy, function or methodology:

- could have a negative impact on human rights or on any of the equality groups, or
- could have a positive impact on human rights, contribute to promoting equality, equal opportunities or improve relations.

It is not necessary to complete each box, nor to mark whether it is positive or negative, although you can do this if you find it helpful.

	Protected Characteristic								
	Race	**Sex**	**Disability**	**Sexual Orientation**	**Religion or belief**	**Age**	**Gender reassignment**	**Marriage & Civil Partnership**	**Pregnancy & Maternity**
Could this policy, procedure, project or service affect this group differently from others? **YES/NO**									
Could this policy, procedure, project or service promote equal opportunities for this group? **YES/NO**									
Right to life *e.g. decisions about life-saving treatment, deaths through negligence in hospital*									
Right not to be tortured or treated in an inhuman or degrading way *e.g. dignity in care, abuse or neglect of older people or people with learning disabilities.*									
Right to respect for private and family life e.g. *respecting lgb relationships, confidentiality*									
Right to freedom of thought, conscience and religion *e.g. respect for cultural and religious requirements*									
Right to freedom of expression *e.g. access to appropriate communication aids*									
Right to freedom of assembly and association *e.g., right to representation, to socialise in care settings*									
Right to education *e.g. access to basic knowledge of hygiene and sanitation*									
Right to liberty e.g. informal detention of patients who do not have capacity									

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3. How does it impact on people's human rights and equality?

Using the table above, explain anticipated impacts. If a full EHRIA is recommended, you can summarise the impacts - it is not necessary to set these out in detail,

Could people's human rights be impacted negatively? Could the policy, strategy, function or methodology result in inequality or discrimination?
No. The prevalence for an M protein without plasma cell disease as approx. 1% of people older than 50 years. The presence of any band in the less than 50 years age group is very rare and has not been fully studied. The average age for a MGUS diagnosis is 70 years with a 1.5 % conversion p/a. This equates to an actuarial rate of progression of 17% at 10 years, 34% at 20 years and 39% at 25 years. The younger a patient presents with MGUS the greater the likelihood he/she will convert to MM in their life time and hence closer monitoring and assessment may be beneficial.
Could this policy, strategy, function or methodology result in positive impacts on people's human rights or equality? Could it present opportunities to promote equality?
No

4. Recommendations

Is a full EHRIA recommended? If not, give reasons
No. The policy has equal impact.

5. Publication of EHRIA

Give details of where Screening Tool or the full EHRIA will be published and when this will take place
With document.

Details of person completing the EHRIA	
Name	Mr Edward Kearney, Consultant Clinical Scientist

Signed …… Date: ……

Approval and sign-off	Name
Head of Department/Director	Dr Edmund Lamb, Head of Service Clinical Biochemistry

Signed …… Date: ……

	Name
Trust Board approval and sign-off	not applicable

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Signed …… Date: ……

Appendix B – Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

POLICY:

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

	Requirement:	Compliant Yes/No/ Unsure	Comments
1.	**Style and format**	Yes	
2.	**An explanation of any terms used in documents developed**	Yes	
3.	**Consultation process**	Yes	
4.	**Ratification process**	Yes	
5.	**Review arrangements**	Yes	
6.	**Control of documents, including archiving arrangements**	Yes	
7.	**Associated documents**	n/a	
8.	**Supporting references**	Yes	
9.	**Relevant NHSLA criterion specific requirements**	n/a	
10.	**Any other requirements of external bodies**	n/a	
11.	**The process for monitoring compliance with NHSLA and any other external and/or internal requirements**	n/a	

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