The majority of supporting evidence is for upper limb spasticity following stroke. There is less evidence for lower limb spasticity. How study results translate into changes at the level of activity or participation in the real-life setting is uncertain. Effects on functional ability are more uncertain but studies have mainly reported benefits in terms of improved global outcomes. A variety of studies have shown that botulinum toxin reduces muscle tone when administered to patients with focal spasticity following stroke. Effects on functional ability are more uncertain but studies have mainly reported benefits in terms of improved global patient/physician ratings and passive functional tasks. How study results translate into changes at the level of activity or participation in the real-life setting is uncertain. The majority of supporting evidence is for upper limb spasticity following stroke. There is less evidence for lower limb spasticity or spasticity due to other neurological conditions.

**Hertfordshire Medicines Management Committee recommends the use of Botulinum Toxin Type A as a treatment option for restricted use in adults to treat:**

- Upper limb focal spasticity due to stroke (*in-patients only*) or non-stroke neurological disease

*stroke patients being treated in out-patient setting should be referred to the Northwick Park Rehabilitation service as part of the block commissioned pathway.

This recommendation is made on the basis that patients were being referred to tertiary care centres and there is no additional cost pressure.

Such treatment will be commissioned in line with:

- The criteria outlined (Appendix 1) for service requirements, specifications and competencies.
- On receipt of a notification form.
- More than one injection will not be routinely commissioned. Clinicians are asked to submit a request with rationale for on-going injections and evidence of benefit from previous injections.
- Outcomes of patients treated are reported to HMMC in April 2014.

**Dysport®** (up to 500 units for upper limb focal spasticity) selected as botulinum toxin type A product choice as there are no head to head comparisons of different products and this was the product and dose the applicant (Dr Wilkinson (Consultant Neurologist, East and North Herts NHS Trust)) was most familiar with. It is lower cost than Xeomin® & Botox®.

**Assessment against Ethical Framework**

**Clinical Effectiveness**

- A variety of studies have shown that botulinum toxin reduces muscle tone when administered to patients with focal spasticity following stroke.
- Effects on functional ability are more uncertain but studies have mainly reported benefits in terms of improved global patient/physician ratings and passive functional tasks.
- How study results translate into changes at the level of activity or participation in the real-life setting is uncertain.
- The majority of supporting evidence is for upper limb spasticity following stroke. There is less evidence for lower limb spasticity or spasticity due to other neurological conditions.

**Cost Effectiveness**

- SMC considered Botox® and Xeomin® to be cost-effective treatment options for upper limb spasticity post stroke despite weaknesses in the economic case. The economic case was not demonstrated for Dysport®.
- There does not appear to be cost-effectiveness analysis available for lower limb spasticity or spasticity due to other neurological conditions.

**The needs of the population**

- There are limited options for the treatment of focal spasticity inadequately controlled by physiotherapy. This need is for a small group of patients.

**The needs of the community**

- The needs of the community are small as this will benefit a very small number of patients. Resulting opportunity costs are small.

**Equity**

- Cambridgeshire, Bedfordshire & Luton, Mid-Essex & Suffolk PCTs do not commission the treatment. Norfolk PCT does.

**Policy Drivers**

- NICE Clinical Guideline only.
- SMC has approved certain products for upper limb spasticity post stroke.

**Implementability**

- Royal College guidelines outline competencies required and service specification.

**Selected References** (all references available in HMMC application)

- Scottish Medicines Consortium Advice; botulinum toxin type A (Xeomin®) (Sep 2011). [http://www.scottishmedicines.org.uk/SMC_Advice/Advice/731_11_botulinum_toxin_type_A_Xeomin](http://www.scottishmedicines.org.uk/SMC_Advice/Advice/731_11_botulinum_toxin_type_A_Xeomin)
- Scottish Medicines Consortium Advice; clostridium botulinum type A neurotoxin (Botox®) (Feb 2011). [http://www.scottishmedicines.org.uk/SMC_Advice/Advice/Clostridium_botulinum_type_A_neurotoxin_Botox](http://www.scottishmedicines.org.uk/SMC_Advice/Advice/Clostridium_botulinum_type_A_neurotoxin_Botox)
- Scottish Medicines Consortium Advice; clostridium botulinum type A haemagglutinin complex (Dysport®) (Feb 2007). [http://www.scottishmedicines.org.uk/SMC_Advice/Advice/Clostridium_botulinum_type_A_toxin_haemagglutinin_complex_Dysport](http://www.scottishmedicines.org.uk/SMC_Advice/Advice/Clostridium_botulinum_type_A_toxin_haemagglutinin_complex_Dysport)
Appendix 1

**Service Requirements, Specifications and Competencies**

These have been adapted from the Royal College of Physicians National guidelines for spasticity in adults: management using botulinum toxin; Jan 2009 which should be referred to for full details (http://bookshop.rcplondon.ac.uk/details.aspx?e=272).

1.1 Training and General requirements

- Botulinum toxin (BT) injections should only be used by appropriately trained and competent personnel experienced in the assessment and management of spasticity.
- Clinician(s) need to be trained in neurological rehabilitation and spasticity management in general, with specific additional training in BT treatment (including muscle selection, injection, dosing and management of complications).
- Appropriate settings, facilities and equipment need to be in place to aid assessment, selection and treatment planning. It may be appropriate for outpatient clinic settings to be used which would allow:
  - more convenient, cost-effective assessment
  - MDT follow up
  - minimal wastage of BT
  - easier access to equipment
  - availability of nursing staff trained to assist in the care of patients.
- Appropriately trained and competent staff in integrated physiotherapy, rehabilitation nursing and occupational therapy services are needed, with roles that include:
  - selecting appropriate patients for review for treatment.
  - arranging for delivery of targeted physiotherapy after injection including posture management, exercise, muscle stretch and ensuring appropriate provision of splinting and orthoses.
  - assessing outcomes
- appropriate surgical advice should be available as needed (eg orthopaedic, neurosurgical, plastics).

1.2 Product choice and documentation

- Only one BT preparation should be used (eg Dysport) in order to prevent confusion over different products and doses and to ensure knowledge of the product characteristics.
- The product given, dose, dilution and muscles injected should be recorded.

1.3 Evaluation, assessment and documentation

The following should all be in place:

- Clear, concise documentation (also see below).
- Standardised evaluation and assessment (see below).
- A system for obtaining informed consent.
- Provision of appropriate patient and carer information and leaflets.
- Arrangements for prescribing, supply and administration.
- Appropriate arrangements for follow up (appropriate review periods for assessment for orthotics/splinting, assessment of response and future management plan).

Standardised evaluation and assessment criteria should be documented, used and completed for each patient:

- patient selection criteria (to include appropriate physical management programme, that the spasticity has a significant component of focal muscle over-activity (spastic component not contracture) and ensuring any aggravating factors addressed).
- Goals for treatment and anticipated functional gains (clear, achievable, realistic and measurable goals).
- Outcome measures (use of assessment tools (eg rating scales) to review baseline and outcome response) including stopping criteria, continuation criteria and adverse effects.

1.4 Service Evaluation/Audit

Regular audit of the use of, and documentation of the use of, BT should be in place. Audit assessments to include:

- numbers of patients treated.
- product given, dose, dilution and muscles injected.
- use of, and compliance with, standardised evaluation and assessment criteria.
- outcomes from treatment, in particular achievement of treatment goals.
- quality of documentation and recording.