Botulinum Toxin A for Urinary Incontinence, Chronic Migraine, and Spasticity

1. **Bladder dysfunction**

   a. **Overactive bladder in women**: botulinum toxin type A **WILL BE** funded as an option for the secondary management of overactive bladder refractory to conservative and non-interventional medical treatment providing that:

      • Patients have been managed and treated in line with:
        - NICE clinical guideline 171: management of urinary incontinence in women.
      • Patients have been supported with behavioural and lifestyle advice and a trial of at least two medications but have not had an adequate response to these interventions. Details of what has been tried and the outcomes must be clearly documented in the notes.
      • A multidisciplinary team has fully reviewed current management and all other options and considers Botulinum Toxin to be the most appropriate treatment. Clear treatment goals and outcome measures have been agreed with the patient and **WILL BE** monitored and evaluated in determining whether to continue treatment with botulinum toxin.
      • Detrusor overactivity **HAS BEEN** confirmed by urodynamic studies.
      • Patients **ARE WILLING** and able to self-catheterise
      • Informed consent **HAS BEEN** obtained

      Compliance with the above criteria must be documented in the notes.

   b. **Patients with spinal cord disease (spinal cord injury or multiple sclerosis) in children, young people and adults**: botulinum toxin type A will be funded as an option for patients with:

      • Symptoms of overactive bladder where antimuscarinic drugs have been ineffectual or poorly tolerated; OR
      • Impaired bladder storage confirmed on urodynamic investigation where antimuscarinic drugs have been ineffectual or poorly tolerated.

      Patients **MUST BE** managed in line with NICE clinical guideline 148: urinary incontinence in neurological disease: assessment and management. Clear treatment goals and outcome measures **HAVE BEEN** agreed with the patient and/or carers and **WILL BE** monitored and evaluated in determining whether to continue treatment with botulinum.

      **Use of botulinum toxin A for bladder dysfunction in patients who do not meet the criteria in sections 1 a or b above will not be funded.**
Where a patient is considered to have exceptional need for and capacity to benefit from a procedure that is not routinely funded, a request for individual funding may be made to the Individual Funding Requests Panel. The patient must be made aware that the Panel may not support the request and must not be added to the waiting list until a decision to fund has been received in writing from the Panel.

Further information can be obtained here www.gov.im/IFRP

2. **Chronic Migraine**: botulinum toxin A **WILL BE** funded as an option for the prophylaxis of headaches in adults with chronic migraine in line with NICE Guidance for the Prophylaxis of Headaches in Adults with Chronic Migraine, TA26 (2012). For the purposes of this policy, chronic migraine is defined as headaches on at least 15 days per month of which at least 8 days are with migraine.

Patients will be eligible for botulinum toxin A if:

- they **HAVE NOT** responded to at least three prior pharmacological prophylaxis therapies
  
  AND
  
  - their condition is appropriately managed for medication overuse.

Treatment (and funding) **WILL CEASE** if the patient’s condition:

- **IS NOT** adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles) or

- **HAS CHANGED** to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months.

In all other clinical circumstances, Botulinum toxin type A is not funded for chronic migraine treatment.

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3. **Spasticity**

   a. **Children and young people with spasticity**

   Botulinum toxin A will be funded as an option in the management of children and young people under the age of 19 provided assessment and treatment is in line with NICE clinical guideline 145 (updated November 2016).
Treatment with botulinum **WILL ONLY** be funded in conjunction with an adaptive physical therapy programme delivered within an integrated care network which allows treatment (physiotherapy, paediatrics, nursing and occupational therapy) within local services with access to specialist expertise (orthotics, paediatric neurosurgery/specialist orthopaedics, paediatric neurology) from an appropriate tertiary/specialist centre as required.

Treatment **MUST BE** linked to clear goals agreed with the child/young person and carers as appropriate.

Assessment of muscle tone, range of movement and motor function **MUST BE** made at baseline (pretreatment), at 6-12 weeks post treatment to assess response and at 12-26 weeks post treatment to inform decisions about further injections.

All patient goals, assessments and outcomes **MUST BE** recorded clearly in the notes.

**b. Spasticity in adults:**

Botulinum toxin A **WILL BE** funded as a treatment option in adults with spasticity in line with Royal College of Physicians/British Society of Rehabilitation Medicine evidence based guidelines\(^1\).

Treatment **MUST BE** initiated within a multidisciplinary team including local professionals supported by access to specialist expertise in an appropriate tertiary/specialist centre. Treatment **MUST BE** linked to clear goals agreed with the patient, and carers if appropriate. Treatment **WILL ONLY BE** funded when it forms part of an integrated multidisciplinary approach and is accompanied by a rehabilitation programme.

Pre and post-treatment assessments and reviews **MUST BE** carried out in accordance with the RCP/BSRM guideline and used to determine future need for treatment.

Botulinum toxin used as part of rehabilitation in the post-acute setting **WILL NOT** normally be funded beyond a total of four treatments.

Intermittent treatment over a longer period can be appropriate in patients with severe and long-standing spasticity, where it can contribute to symptom control or passive outcomes (eg enabling hygiene/avoidance of skin breakdown in severe flexion deformity of the fingers). Such use should be supported by tailored physical management (eg splinting) to reduce the frequency of repeat botulinum injections.

A patient core data-set and treatment/outcome proforma (as per the example proforma included in Appendix 5 of the RCP/BSRM guideline) **MUST BE** completed for each patient and a copy kept in the notes.

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\(^1\) NICE has a multiple technology appraisal for botulinum toxin A in upper and lower limb focal spasticity associated with stroke within its current work programme. As of February 2017, no timelines have been confirmed for this piece of work [https://www.nice.org.uk/guidance/indevelopment/gid-tag499].
Use of botulinum toxin A for spasticity in patients who **DO NOT** meet the criteria in 3a or b above **WILL NOT** be funded. Where a patient is considered to have exceptional need for and capacity to benefit from a procedure that is not routinely funded, a request for individual funding may be made to the Individual Funding Requests Panel. The patient must be made aware that the Panel may not support the request and must not be added to the waiting list until a decision to fund has been received in writing from the Panel.

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<th>Clinical Effectiveness</th>
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<td><strong>Comment</strong></td>
<td>See summaries of evidence of clinical and cost effectiveness set out in NICE CGs 148, 171; TA260; and RCP/BSRM guideline.</td>
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**Summary of evidence**


**Reason for requesting a policy recommendation:**

Reviewed as part of the Effective Use of Resources project.

Replaces part of Clinical Recommendations Committee Recommendation 09/12.

Further information contact:

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