Botulinum Toxin for the treatment of chronic anal fissure

NHS Devon

Commissioning policy

The routine commissioning of botulinum toxin is accepted in Devon for the treatment of chronic anal fissure in adults, following failure of conservative management and topical treatment (to include glyceryl trinitrate (GTN) and diltiazem) and where surgery is considered as the only other treatment option. The decision to offer botulinum toxin is at the discretion of the treating clinician and the patient must be made fully aware and give informed consent to the 'off-label' use of botulinum toxin.

Rationale for the decision

Botulinum toxin is recommended by professional societies in the management of chronic anal fissure. There is evidence that it is less effective than surgery with lateral internal sphincterotomy. In randomised controlled trials botulinum toxin is associated with healing in around 60% of cases compared to around 90% with sphincterotomy. However, lateral internal sphincterotomy is also associated with a significantly greater risk of incontinence; reports have suggested that up to 30% of patients have difficulty controlling flatus, 3-10% have episodes of leakage and up to 5% of patients experience anal incontinence.

Topical GTN is the only product licensed in the management of chronic anal fissure. Botulinum toxin is more invasive than applying topical treatments and more expensive when the costs of administration are considered. Since evidence suggests that it is not more effective than topical treatments as a first line treatment, it should not be used unless a patient has failed treatment with topical therapy. There is a paucity of high quality evidence to determine the optimal second line treatment. A prospective non-randomised trial found that failure to achieve healing with topical GTN as first line occurred in 54% of patients; the majority of unhealed patients then choose botulinum toxin over surgery and healing was demonstrated in 85%.

Botulinum toxin represents an established treatment option in the management pathway for chronic anal fissure. It is effective in a proportion of patients and

therefore if used following treatment failure with conservative management and topical GTN and diltiazem, can prevent the need for surgical intervention, which is associated with an increased risk of adverse events.

Guidance notes on exceptionality

Where the circumstances of treatment for an individual patient do not meet the criteria described above exceptional funding can be sought. Individual cases will be reviewed by the appropriate panel of the ICB upon receipt of a completed application from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally.

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