NHS
Commissioning Board

Clinical Commissioning Policy: Intrathecal Baclofen (ITB)

April 2013

Reference : NHSCB/D04/P/c

THE NHS CONSTITUTION
the NHS belongs to us all

NHS Commissioning Board

Clinical Commissioning Policy: Intrathecal Baclofen (ITB)

First published: April 2013

Prepared by the NHS Commissioning Board Clinical Reference Group for Neurosciences

First published April 2013
Published by the NHS Commissioning Board, in electronic format only.

Contents

Policy Statement 4

Equality Statement 4

Plain Language Summary 4

1. Introduction 5

2. Definitions 5

3. Aim and objectives 5

4. Criteria for commissioning 5

5. Patient pathway 6

6. Governance arrangements 7

7. Epidemiology and needs assessment 7

8. Evidence base 7

9. Rationale behind the policy statement 8

10. Mechanism for funding 9

11. Audit requirements 9

12. Documents which have informed this policy 9

13. Links to other policies 9

14. Date of review 9

References 9

Policy Statement

The NHS Commissioning Board (NHS CB) will commission Intrathecal Baclofen (ITB) for patients with spasticity in accordance with the criteria outlined in this document.

In creating this policy the NHS CB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

Plain Language Summary

Spasticity is a disorder of the motor system which causes some muscles to be continuously contracted. Dystonia is a neurological movement disorder in which sustained muscle contractions cause twisting and repetitive movements. Spasms can be debilitating and painful.

Baclofen is a muscle relaxant which can be taken orally or, in more severe and/or generalised spasticity, be delivered directly into the spinal fluid. This is known as intrathecal baclofen or ITB. Much lower doses can be used, avoiding unacceptable side effects while still delivering a therapeutic benefit.

This policy supports the use of ITB for the groups for which it is most cost effective, where other options are exhausted, and where patient and carer evidence shows a real likelihood of success.

Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

1. Introduction

Spasticity is a disorder of the motor system which causes some muscles to be continuously contracted.

Dystonia is a neurological movement disorder in which sustained muscle contractions cause twisting and repetitive movements. Patients may suffer continuous pain, cramping and relentless muscle spasms. Spasms can be debilitating and painful.

Baclofen is a derivative of diazepam; it is a muscle relaxant, antispastic agent and acts at the spinal cord level to inhibit the release of excitatory neurotransmitters. Mild to moderate spasticity can be treated with a combination of physical therapies and oral baclofen. However, patients with more severe and/or generalized spasticity often fail to improve or experience unacceptable side effects on oral drug therapy.

2. Definitions

Oral baclofen is poorly transferred through the blood-brain barrier requiring high doses of the drug to be effective. The use of an implantable pump to deliver the drug intrathecally (directly into the spinal fluid) overcomes this obstacle and facilitates the use of much lower doses, avoiding the unacceptable side effects while still delivering a therapeutic benefit. The pump contains a reservoir for the drug and requires refilling circa every 3 months.

3. Aim and objectives

The overriding goal of therapy is to improve passive and/or active functioning and to prevent deformities resulting from fixed contractures. ITB therapy should not be used simply to reduce tone and improve the range of motion.

4. Criteria for commissioning

In the context of this statement, ITB therapy will be commissioned for adults and paediatrics who meet the following patient selection criteria:

Patient has chronic, severe, diffuse spasticity and/or dystonia of spinal or cerebral origin which renders them a full time wheelchair user or bed bound. Defined as having an Ashworth score of ≥4 in at least two muscle groups, and/or a Penn Spasm score of ≥3, or the equivalent scores using other clinically recognised standard tools e.g. Gross Motor Function Classification System (GMFCS) levels. (This will be reviewed when national guidance for standard practice tools has been produced).

Patient has failed to respond to maximum tolerated or recommended dose of oral anti spasmodic medication or has intolerable side effects

Patient has demonstrated a positive response to a test dose of baclofen delivered via lumbar puncture, defined as a 1 point reduction on the Ashworth and/or Penn Spasm Score 4 to 8 hours after delivery of the test dose

Patient and their carer understand and agree treatment goals

Patient and their carer have demonstrated an explicit commitment to the treatment due to the need for regular return visits for pump refilling

Patient and carers have a good understanding of potential outcomes, side effects and recognition of baclofen withdrawal symptoms

Patient has no indication of renal failure, hepatic or gastrointestinal disease, uncontrolled epilepsy or severe unstable mental disease

Patient has no active infectious problems

Patient has no severe deformities which cannot be corrected by use of orthopaedic surgery

5. Patient pathway

Patients should be seen by a general physician or neurologist prior to referral to the specialist ITB service. Patients can also be referred from Specialised Spinal Injury or Neuro-Rehabilitation services as part of their care pathway. Where possible the above criteria should be applied to determine suitability for onward referral. Referral to the ITB service should be made using a standard referral form to include all necessary information required to confirm adherence to the policy.

A further consultation/selection interview/suitability assessment should be conducted wherever is clinically appropriate e.g. Multi Disciplinary Team (MDT) Spasticity clinic; prior to the test dose appointment being made. The purpose of this appointment is to further assess against criteria and to ensure patients and their carers understand the effects and limitations of baclofen therapy and demonstrate a commitment to the ongoing care and follow up arrangements.

Where indicated, patients will be admitted for a trial dose of ITB. During this trial the patient will undergo a multi disciplinary assessment including physiotherapists, nursing, clinician and patient self assessment to determine effect of test dose. The patient will be discharged.

If the test dose is successful, the patient will be admitted for pump implantation and dose titration

Patients will be reviewed in the neuromodulation day case clinic where dose adjustments and pump refills will take place.

6. Governance arrangements

The governance arrangements fall within those of the Neurosciences service specification.

7. Epidemiology and needs assessment

8. Evidence base

The efficacy of intrathecal baclofen in the treatment of spasticity was first reported in 1985 and since then there have been many published studies demonstrating its effect in reducing spasticity and spasm related pain, and improving ease of care.

Spasticity is reduced whether it is attributable to cerebral palsy, anoxia, trauma or cerebral malformations. Improvements in speech; gait; bladder control and decreased development of musculoskeletal contractures have also been reported; as well as improvements in mental health.[1]The benefits have been shown to persist in the long term.

Whilst reduction in spasticity is well documented, until more recently, evidence of improvement in functionality was scarce. However, such improvement has also now been reported, although a recent review of long term outcomes from 115 patients, showed that ITB did significantly reduce spasticity and the severity of patient reported problems; but its effect on quality of life and functionality were small and non-significant.

Three studies of cost effectiveness were reviewed. However, one was conducted prior to the publication of many of the recent clinical trials to measure effects on functional ability, and makes specific reference to the lack of such evidence. This study concluded that in carefully selected patients, ITB therapy has an acceptable cost/benefit ratio compared with other interventions funded by the health service.

Two more recent articles considering the cost effectiveness of ITB includes a study from the Netherlands. This looked at cost effectiveness alongside the safety and efficacy of ICB treatment. It found that ITB was both more effective and more costly than standard treatment only, gaining one Quality Adjusted Life Year (QALY) cost on average (32, 737 euros). It concluded that based upon the Netherlands threshold willingness to pay for one QALY (80,000 euro) ITB was cost effective. These results also included the cost of a replacement pump after seven years. Similarly an American cost effectiveness analysis concluded that ITB offers “good value for money based on widely accepted measures of cost effectiveness”. The incremental cost effectiveness ratio was calculated to be $42,000 per quality adjusted life year.

The above studies, which include a recent Randomised Control Trial (RCT), show that ITB is an effective treatment for intractable spasticity and is more effective than standard treatments alone. Also, despite direct comparisons with British standards being extremely difficult to make, (due to the problems associated with trying to convert the results of economic evaluations into local currencies), the two most recent cost effectiveness studies find that despite being more expensive than standard treatment; ITB is still cost effective in carefully selected patients.

9. Rationale behind the policy statement

The policy supports the use of ITB for the groups for which it is the most cost effective, where other options are exhausted, and where patient and carer evidence shows a real likelihood of success.

10. Mechanism for funding

From April 2013 the NHS CB will be responsible for commissioning ITB therapy on behalf of the population of England.

11. Audit requirements

Providers will be expected to provide information on activity and outcomes on request.

12. Documents which have informed this policy

East Midlands Specialised Commissioning Group. Clinical Commissioning Policy for intrathecal Baclofen, 2009 http://www.emscg.nhs.uk/Library/P008V2EMSCGPolicyforIntrathecalBaclofen1.pdf Accessed 20/08/2012.

13. Links to other policies

This policy is informed by the generic NHS CB commissioning policies covering experimental treatments and the process by which individual funding requests (IFR) are handled.

14. Date of review

2013/14

References

1. Guillaume D et al. A Clinical study of intrathecal baclofen using a programmable pump for intractable spasticity. *Arch Phys Med Rehabil*, 2005;**86**(11):2165-71.

2. Sampson FC et al. Functional Benefits and cost/benefit analysis of continuous intrathecal baclofen infusion for the management of severe spasticity. *Journal of Neurosurgery,* 2002;**96**:1052-1057.

3. Sindou MP, Mertens P. Decision-making for neurosurgical treatment of disabling spasticity in adults. *Operative Techniques in Neurosurgery*, 2005;**7**:113-119.

4. Sampson FC et al 2000 *The effectiveness of intrathecal baclofen in the management of patients with severe spasticity.* Trent Institute for Health Services Research, Guidance Note for Purchasers 00/01.

5. Dralle D et al. Intrathecal baclofen for spasticity*. Lancet*,1985;**2**:1003.

6. Butler C, Campbell S. Evidence of the effects of intrathecal baclofen for spastic and dystonic cerebral palsy*.* AACPDM Treatment Outcomes Committee Review Panel*. Dev Med Child Neurol*, 2000;**42**:634-645.

7. McClelland, I.S., F.A. Bethoux, et al. Intrathecal Baclofen for spasticity related pain in amyotrophic lateral sclerosis: Efficacy and factors associated with pain relief. *Muscle and Nerve*, 2008;**37**(3) 396-398.

8. Gilmartin R et al. Intrathecal baclofen for management of spastic cerebral palsy: multicenter trial. *J Child Neurol*, 2000;**15**:71-77.

9. Albright AL et al. Long term intrathecal baclofen therapy for severe spasticity of cerebral origin*. J Neurosurg*.2003;**98**:291-295.

10. Albright AL. Neurosurgical Treatment of Spasticity and other paediatric movement disorders. *J Child Neurol*, 2003;**18**(Suppl):67-78.

11. Mason C et al. The effect of intrathecal baclofen on functional intelligibility of speech. *Int J Lang Commun Disord*, 1998;**33**(Suppl):24-25

12. Dan B et al. Effect of intrathecal baclofen on gait control in human hereditary spastic paraparesis. *Neurosci Lett*, 2000;**280**:175-178.

13. Sgouros S, Seri S. The effect of intrathecal baclofen on muscle co-contraction in children with spasticity of cerebral origin. *Pediatr Neurosurg*, 2002;**37**:225-230.

14. Hoving, M.A., E.P.M. van Raak et al. Safety and one year efficacy of intrathecal baclofen therapy in children with intractable spastic cerebral palsy. *European Journal of Paediatric Neurology*, 2009;**13**(3):247-256.

15. Penn RD. Intrathecal baclofen for spasticity of spinal origin: seven years of experience. *J Neurosurg*,1992;**77**:236-240.

16. Awaad Y, et al. Functional assessment following intrathecal baclofen therapy in children with spastic cerebral palsy. *Journal of Child Neurology*, *2003;***18**:26-34.

17. Boviatsis EJ et al. Functional outcome of intrathecal baclofen administration for severe spasticity. *Clin Neurol and Neurosurg, 2005;***107**:289-295.

18. Delhas, E.M.N. Beersen et al. Long term outcomes of continuous intrathecal baclofen infusion for treatment of spasticity. A prospective multi centre follow up study*. Neuromodulation*, 2008;**11**(3):227-236.

19. Sampson C et al. Functional benefits and cost/benefit analysis of continuous intrathecal baclofen infusion for the management of severe spasticity*. J Neurosurg*, 2002;**96**:1052-1057.

20. Hoving, M.A., S.M.A.A. Evers, et al. Intrathecal Baclofen therapy in children with intractable spastic cerebral palsy: A cost effectiveness analysis*. Developmental medicine and child neurology*, 2008;**50**(6):450-455.

21. Lissovy G et al. Cost Effectiveness of intrathecal baclofen therapy for the treatment of severe spasticity associated with cerebral palsy. *Journal of Child Neurology, 2007;***22**:49-59.

22. Hoving, M.A., E.P.M van Raak et al. Efficacy of Intrathecal Baclofen therapy in children with intractable spastic cerebral palsy: A randomised controlled trial*. European Journal of Paediatric Neorology* 2009;**13**(3):240-246.

23. Grunfield, E, Coyle, D. Transferability of the results of economic evaluations to different settings: the example of breast cancer follow-up regimens*. International Society of Technology Assessment in Health Care*,1998;**14**:49.

24. Hoving, M.A., E.P.M. van Raak, et al. Efficacy of intrathecal baclofen therapy in children with intractable spastic cerebral palsy: A randomised control trial. *European Journal of Paediatric Neurology,*2009;**13**(3):240-246.

25. Collins Gem (1994) *English Dictionary, Ninth Edition,* Glasgow, Harper Collins Publishers.

26. Lawrence, E (2000) *Henderson's Dictionary of Biological Terms, 12th Edition,* London, Prentice Hall.