NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Multiple sclerosis: management of multiple sclerosis in primary and secondary care

1.1 Short title

Multiple sclerosis

2 The remit

This guideline is a full replacement for multiple sclerosis (NICE clinical guideline 8).

3 Clinical need for guidance

3.1 Epidemiology

a) Multiple sclerosis (MS) is thought to be an acquired chronic immune-mediated inflammatory condition which affects the central nervous system (CNS), and is characterised by demyelination and axonal degeneration. People with MS typically develop multiple neurological dysfunctions (for example, visual and sensory disturbances, limb weakness, gait problems, and bladder and bowel symptoms) that are followed by recovery or progressive functional disability over time.

b) The cause of MS is unknown, but it is believed that the condition develops in people who are genetically predisposed and that environmental factors play a central role in the disease process through immune-mediated mechanisms. It is thought that abnormal

immune responses to self or foreign antigens initiate and perpetuate inflammation.

c) Estimates suggest that approximately 100,000 people in the UK have MS. The prevalence rate varies with latitude (that is, prevalence is lower in the tropics and higher in northern Europe).

d) MS is a chronic and potentially highly disabling disorder that has considerable personal, social and economic consequences. People with MS live for many years following diagnosis. The condition may have a significant impact on a person's ability to work, as well as an adverse and often highly debilitating effect on quality of life (QoL) of people with MS and their families.

3.2 Current practice

a) The McDonald criteria are used to make a diagnosis of multiple sclerosis, and include (1) evidence of damage in at least two separate areas of the CNS (2) the damage occurred at least one month apart and (3) exclusion of other possible diagnoses. These criteria (which were revised in 2010) suggest the term MS is used if there is no better explanation for the clinical presentation, and the term 'possible MS' when the diagnosis is suspected but the criteria are not completely met. There is variation in how widely these criteria are applied and limited consensus on which techniques are most effective to achieve diagnosis. Diagnostic techniques include magnetic resonance imaging (MRI), visual evoked potential (VEP) and cerebrospinal fluid analysis.

b) Different types of disease pattern are recognised including relapsing-remitting MS and primary-progressive MS. Relapsing-remitting MS occurs when the person experiences an average of one or two relapses per year, with good or complete remission in between. Primary-progressive MS is when people experience gradual disability over time without remission. Some people with relapsing-remitting MS will develop secondary-progressive MS

which is characterised by worsening disability over time rather than relapses followed by recovery.

c) The medical management of people with MS includes both disease-modifying therapies and symptom alleviation.

d) Most disease-modifying therapies aim to reduce the frequency and severity of relapses in people with relapsing-remitting MS. They may also be given to slow the progression of disability in people in progressive stages of the disease.

e) Symptoms that require management can include fatigue, pain, spasticity, cognitive impairments, urinary symptoms and mood disorder. Pharmacological treatments or programmes such as exercise or cognitive training can be tailored to meet the person's symptoms and are given in a hospital or community setting. Coordinating assessment and treatment of often complex needs and symptoms is pivotal for high quality care.

f) Since the publication of NICE guidance on Multiple sclerosis (NICE clinical guideline 8) more information has become available on the diagnosis of MS, including the revised McDonald Criteria, and on management of symptoms such as fatigue and spasticity, oral versus intravenous administration of steroids, promoting exercise, and on complementary therapies for MS.

g) A recent national audit highlighted wide variability in access to specialist services and poor integration of services for people with MS. Access to neurological rehabilitation was particularly poor.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, ‘Further information’).

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

Adults who have a diagnosis of MS or possible MS, or are being investigated for MS.

4.1.2 Groups that will not be covered

Children and young people under the age of 18 years who have a diagnosis of MS or possible MS, or are being investigated for MS.

4.2 Healthcare setting

Any setting that provides primary and secondary NHS care.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

Diagnosis, assessment and information

a) Diagnostic criteria for MS and possible MS including the revised McDonald criteria for MS, diagnostic criteria for neuromyelitis optica and the appropriate investigation for people with clinically isolated syndrome.

b) Structured review of people with MS including assessment of:

- their disability and functional problems (for example. activities of daily living, vocational activities)
- the impact of disability and functional problems on carers.

c) Information and support for people with MS and their carers including advance decision-making and end-of-life care.

d) Modifiable risk factors such as immunisations and pregnancy.

Disability management and rehabilitation

e) Non-pharmacological management programmes (including self management) for fatigue, spasticity, mobility and pain.

f) Pharmacological management of fatigue involving amantadine, B12 injections and selective serotonin reuptake inhibitors (SSRIs).

g) Pharmacological management of spasticity using baclofen, tizanidine, gabapentin, dantrolene, benzodiazepines, botulinum toxin, pregabalin and Sativex.

h) Pharmacological management of mobility with fampridine.

i) Management of visual problems including nystagmus,

j) Management of ataxia and tremor.

k) Management of emotionalism, memory and cognitive impairments, including the use of anti-depressants, neuropsychological rehabilitation.

l) Setting of rehabilitation.

m) Coordination of care and support including the role of the MS nurse.

Other treatments

n) Intravenous versus oral administration of steroids for acute relapse.

o) Vitamin D.

p) Omega-3 and omega-6.

q) Acupuncture.

4.3.2 Clinical issues that will not be covered

a) Treatment of contractures at joints.

b) Disease-modifying therapies.

4.3.3 The following areas are covered by technology appraisals or other NICE guidance, to which the new guideline will cross-refer

a) Communication and emotional support:

- Patient experience in adult NHS services. NICE clinical guideline CG138 (2012).

b) Pharmacological treatment with disease modifying treatments including interferon beta, glatiramer acetate and natalizumab:

- Fingolimid for the treatment of highly active relapsing-remitting multiple sclerosis. NICE technology appraisal TA254 (2012).
- Natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis, NICE technology appraisal TA127 (2007).
- Guidance on beta interferon and glatiramer acetate for the treatment of multiple sclerosis. NICE technology appraisal TA32 (2002).

c) The management of pressure ulcers:

- The management of pressure ulcers in primary and secondary care. NICE clinical guideline CG29 (2005). (Update currently in progress).

d) Bladder problems:

- Urinary incontinence in neurological disease:. NICE clinical guideline: Publication expected October 2012.

e) Urinary tract infections:

- Infection control. NICE clinical guideline 139. (2012)

f) Bowel problems:

- Faecal incontinence. NICE clinical guideline CG49 (2007).

g) Neuropathic pain:

- Neuropathic pain, NICE clinical guideline 96 (2010). (Update currently in progress)

h) Depression:

- Depression in adults. NICE clinical guideline CG90 (2009).
- Depression in adults with a chronic physical health problem. NICE clinical guideline CG91 (2009).

i) Anxiety:

- Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults. NICE clinical guideline CG113 (2011).

j) Swallowing difficulties and nutrition support:

- Nutrition support in adults. NICE clinical guideline CG32 (2006).

4.4 Main outcomes

a) Health-related Quality of Life, for example EQ-5D, SF-36, Leeds MS quality of life scale, MS Impact Scale.

b) Patient-reported outcomes, for example symptoms, activities.

c) Impact on carers.

d) Functional scales that quantify level of disability, such as the Expanded Disability Status Scale (EDSS), the Multiple Sclerosis Functional Composite (MSFC), the Cambridge Multiple Sclerosis

Basic Score (CAMBS), the Functional Assessment of Multiple Sclerosis (FAMS) or the National Fatigue Index (NFI).

e) Mobility, for example the MS walking scale.

f) Cognitive functions, such as memory and concentration, and physical symptoms including fatigue, spasticity, spasms, , assessed by validated and disease-specific scales, questionnaires or similar instruments, for instance the Scripps Neurologic Rating scale (SNRS) or the Krupp Fatigue Severity Scale (FSS).

g) Psychological symptoms assessed by validated and disease-specific scales, questionnaire or similar instruments.

h) Adverse effects of treatment.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in September 2012.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be replaced

This guideline will fully replace the following NICE guidance:

- Multiple sclerosis. NICE clinical guideline 8 (2003).

5.1.2 NICE guidance to be incorporated

There is no specific guidance to be incorporated.

5.1.3 Other related NICE guidance

- Patient experience in adult NHS services. NICE clinical guideline CG138 (2012).
- Percutaneous venoplasty for chronic cerebrospinal venous insufficiency for multiple sclerosis. NICE interventional procedure guidance IPG420 (2012).
- Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults. NICE clinical guideline CG113 (2011).
- End of life care for adults. NICE Quality Standard (2011).
- Neuropathic pain. NICE clinical guideline CG96 (2010)
- Medicines adherence. NICE clinical guideline CG76 (2009).
- Depression in adults. NICE clinical guideline CG90 (2009).
- The treatment and management of depression in adults with chronic physical health problems. NICE clinical guideline CG91 (2009).
- Functional electrical stimulation for drop foot of central neurological origin. NICE interventional procedure guidance IPG278 (2009).
- Faecal incontinence. NICE clinical guideline CG49 (2007).
- Natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis. NICE technology appraisal TA127 (2007).
- Dementia. NICE clinical guideline CG42 (2007).
- Nutrition support in adults. NICE clinical guideline CG32 (2006).
- Deep brain stimulation for tremor and dystonia (excluding Parkinson's disease). NICE interventional procedure IPG188 (2006).

- The management of pressure ulcers in primary and secondary care. NICE clinical guideline CG29 (2005). (Update currently in progress).
- Infection control. NICE clinical guideline CG2 (2003). (Update currently in progress)
- Pressure relieving devices. NICE clinical guideline CG7 (2003).
- Guidance on beta interferon and glatiramer acetate for the treatment of multiple sclerosis. NICE technology appraisal TA32 (2002).
- Guidance on the use of computerised cognitive behavioural therapy for anxiety and depression. NICE technology appraisal TA51 (2002).

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

- Cladribine for the treatment of relapsing remitting multiple sclerosis. NICE technology appraisal guidance (Note: this technology appraisal is currently suspended because cladribine has not been granted a marketing authorisation for multiple sclerosis).
- Urinary incontinence in neurological disease. NICE clinical guideline. Publication expected August 2012.
- The prevention and management of pressure ulcers in primary and secondary care (update). Publication date to be confirmed.
- Percutaneous venoplasty for chronic cerebrospinal venous insufficiency (CCSVI) in multiple sclerosis. NICE interventional procedure guidance. Publication date to be confirmed.

6 Further information

Information on the guideline development process is provided in:

- ‘How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS’
- ‘The guidelines manual’.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).