

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## SCOPE

### 1 Guideline title

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

#### 1.1 *Short title*

Multiple sclerosis

### 2 The remit

This new guideline is a replacement for Multiple sclerosis: management of multiple sclerosis in primary and secondary care, NICE clinical guideline CG8 (2003), available from <http://guidance.nice.org.uk/CG8>.

### 3 Clinical need for guidance

#### 3.1 *Epidemiology*

- a) Multiple sclerosis (MS) is an acquired chronic immune mediated inflammatory condition of the central nervous system, characterized by demyelination and axonal degeneration. It clinically manifests with multiple neurological dysfunctions (e.g. visual and sensory disturbances, limb weakness, gait problems and bladder and bowel symptoms) followed by recovery or by an increasing disability because of irreversible functional disability over time.
- b) Although the aetiology is largely unknown, it is believed that MS develops in genetically predisposed individuals and that environmental factors play a central role in its pathogenesis based on immune-mediated mechanisms. It is thought that aberrant

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

- c) Estimates suggest that approximately 100,000 in the UK have MS. The prevalence rate varies with latitude (e.g., lower rates in tropics and higher rates in northern Europe).
- d) MS is a chronic and potentially highly disabling disorder with considerable personal and social impact and economic consequences. The disease has an adverse and often highly debilitating impact on the quality of life (QoL) of people with MS and their families.

### **3.2 Current practice**

- a) Several criteria have to be met in order to make a diagnosis of multiple sclerosis, such as (1) evidence of damage in at least two separate areas of the central nervous system (CNS); (2) the damage occurred at least one month apart and (3) exclusion of other possible diagnoses. An array of techniques is used to gather information, such as magnetic resonance imaging (MRI), visual evoked potential (VEP) and cerebrospinal fluid analysis. The criteria for diagnosis of MS are referred to as the McDonald Criteria which had a recent revision in 2010. The criteria 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.
- b) Different types of disease pattern are recognised including relapsing-remitting MS and primary progressive MS. Relapsing-remitting is when the person experiences on average one or two relapses per year, with good or complete remission in between. Primary progressive is when people experience gradual disability

over time without remission. Some people with relapse-remitting MS will develop secondary progressive MS.

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

Most disease-modifying therapies aim to reduce the frequency and severity of relapses in people with relapsing remitting MS. An additional aim would be to slow the progression of disability, in patients in progressive stages of the disease.

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 individual person's specific symptoms and are implemented in a hospital or community setting. The co-ordination of the assessment and treatment of often complex needs and symptoms is pivotal for high quality care.

- d) Since publication of CG8 more literature has become available on the diagnosis of MS with the revised McDonald criteria, management of symptoms such as fatigue among people with MS, the promotion of exercise; management of spasticity; oral versus intravenous administration of steroids; and studies on complementary therapies for MS.
- e) A recent national audit has 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 and young people (aged 16 years or over), 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 16 years)

## **4.2      *Healthcare setting***

Any setting where NHS care is provided

## **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, including 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 disability and functional problems e.g. bladder function, cognitive impairment, activities of daily living, vocational activities
- c)      Information and support for patients and carers including advanced decision making.
- 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 (e.g. physical therapy).
- f) The pharmacological management of fatigue with, amantadine, B12 injections and selective serotonin reuptake inhibitors (SSRIs)
- g) The pharmacological management of spasticity with baclofen, tizanidine, gabapentin, dantrolene, benzodiazepines, botulinum toxin, and Sativex
- h) The pharmacological management of mobility with fampridine
- i) The management of visual problems including nystagmus,
- j) Management of ataxia and tremor
- k) The management of emotionalism, memory and cognitive impairments including anti-depressants and neuropsychological rehabilitation
- l) Home versus hospital rehabilitation

**Specialist nurse**

- m) The role of the specialist nurse including support over time and the coordination of care.

**Other treatments**

- n) Administration of steroids (intravenous versus oral) for acute relapse
- o) Vitamin D for the management of MS
- p) Use of complementary or alternative therapies such as linoleic acid and acupuncture.

#### **4.3.2 Clinical areas not covered**

- a) Acetylcholinesterase inhibitors for the management of memory and cognitive impairments
- b) Contractures at joints

#### **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
  - Patient experience in adult NHS services, 2012. NICE clinical guideline CG138. Available from [www.nice.org.uk/CG138](http://www.nice.org.uk/CG138)
- b) Emotional support
  - Patient experience in adult NHS services, 2012. NICE clinical guideline CG138. Available from [www.nice.org.uk/CG138](http://www.nice.org.uk/CG138)
- c) Pharmacological treatment with disease modifying treatments including interferon beta, glatiramer acetate and natalizumab
  - Guidance on beta interferon and glatiramer acetate for the treatment of multiple sclerosis, 2002. NICE technology appraisal TA32. Available from [www.nice.org/TA32](http://www.nice.org/TA32)
  - Natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis, 2007. NICE technology appraisal TA127. Available from [www.nice.org.uk/TA127](http://www.nice.org.uk/TA127)
- d) The management of pressure ulcers

- The management of pressure ulcers in primary and secondary care, 2005. NICE clinical guideline CG29. Currently in progress. Available from [www.nice.org/CG29](http://www.nice.org/CG29)
  
- e) Bladder problems
  - Clinical guideline: Management of incontinence in neurological disease. NICE public health guidance. NICE clinical guideline: currently in progress. Expected date of publication October 2012.
  
- f) Urinary tract infections
  - Infection control, 2003. NICE clinical guideline CG2. Available from [www.nice.org/CG2](http://www.nice.org/CG2) - update currently in progress
  
- g) Bowel problems
  - CG49: Faecal incontinence: The management of faecal incontinence in adults, 2007. NICE clinical guideline CG49. Available from [www.nice.org.uk/CG49](http://www.nice.org.uk/CG49)
  
- h) Neuropathic pain
  - CG96: Neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings, 2010. NICE clinical guideline CG96. Available from [www.nice.org.uk/CG96](http://www.nice.org.uk/CG96)
  
- i) Depression
  - Depression: the treatment and management of depression in adults (update), 2009. NICE clinical guideline CG90. Available from [www.nice.org/CG90](http://www.nice.org/CG90)

- The treatment and management of depression in adults with chronic physical health problems (partial update CG23), 2009. NICE clinical guideline CG91. Available from [www.nice.org/CG91](http://www.nice.org/CG91)
  
- j) Anxiety
  - CG113: Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults, 2011. NICE clinical guideline CG113. Available from [www.nice.org.uk/CG113](http://www.nice.org.uk/CG113)
  
- k) Swallowing difficulties
  - Nutrition support in adults, 2006. NICE clinical guideline CG32. Available from [www.nice.org.uk/CG32](http://www.nice.org.uk/CG32)

#### **4.4 Main outcomes**

- a) Health related Quality of Life for example EQ-5D, SF-36
- b) Impact on carers
- c) 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).
- d) Cognitive functions: memory, concentration (Physical symptoms: fatigue, spasticity, spasms, bladder function, bowel symptoms) (better, worse or no change) assessed by validated and disease specific scales, questionnaire or similar instruments, for instance the Scripps Neurologic Rating scale (SNRS) or the Krupp Fatigue Severity Scale (FSS).



- e) Psychological symptoms (better, worse or no change) assessed by validated and disease specific scales, questionnaire or similar instruments
- f) 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 consultation draft of the scope. The consultation dates are 8<sup>th</sup> May to 7<sup>th</sup> June 2012.

##### **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 replace the following NICE guidance: Multiple Sclerosis. NICE clinical guideline 8 (2003). Available from <http://guidance.nice.org.uk/CG8>

### 5.1.2 NICE guidance to be incorporated

There is no specific guidance to be incorporated.

### 5.1.3 Other related NICE guidance

- Guidance on beta interferon and glatiramer acetate for the treatment of multiple sclerosis, 2002. NICE technology appraisal TA32. Available from [www.nice.org/TA32](http://www.nice.org/TA32)
- Guidance on the use of computerised cognitive behavioural therapy for anxiety and depression, 2002. NICE technology appraisal TA51. Available from [www.nice.org/TA51](http://www.nice.org/TA51)
- Infection control, 2003. NICE clinical guideline CG2. Available from [www.nice.org/CG2](http://www.nice.org/CG2) - update currently in progress
- Natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis, 2007. NICE technology appraisal TA127. Available from [www.nice.org.uk/TA127](http://www.nice.org.uk/TA127)
- Pressure relieving devices, 2003 NICE clinical guideline CG7. Available from [www.nice.org/CG7](http://www.nice.org/CG7) - currently being considered for an update.
- The management of pressure ulcers in primary and secondary care, 2005. NICE clinical guideline CG29. Available from [www.nice.org/CG29](http://www.nice.org/CG29) - currently in progress. Available from [www.nice.org/CG29](http://www.nice.org/CG29)
- Nutrition support in adults, 2006. NICE clinical guideline CG32. Available from [www.nice.org.uk/CG32](http://www.nice.org.uk/CG32)
- Deep brain stimulation for tremor and dystonia (excluding Parkinson's disease), 2006. NICE interventional procedure IPG188. Available from [www.nice.org.uk/IPG188](http://www.nice.org.uk/IPG188)
- Dementia, 2007. NICE clinical guideline CG42. Available from [www.nice.org.uk/CG42](http://www.nice.org.uk/CG42)
- Medicines adherence, 2009. NICE clinical guideline CG76. Available from [www.nice.org/CG76](http://www.nice.org/CG76)
- Depression: the treatment and management of depression in adults (update), 2009. NICE clinical guideline CG90. Available from [www.nice.org/CG90](http://www.nice.org/CG90)

- The treatment and management of depression in adults with chronic physical health problems (partial update CG23), 2009. NICE clinical guideline CG91. Available from [www.nice.org/CG91](http://www.nice.org/CG91)
- Functional electrical stimulation for drop foot of central neurological origin, 2009. NICE interventional procedure guidance IPG278. Available from [www.nice.org.uk/guidance/IPG278](http://www.nice.org.uk/guidance/IPG278)
- CG96: Neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings, 2010. NICE clinical guideline CG96. Available from [www.nice.org.uk/CG96](http://www.nice.org.uk/CG96)
- CG113: Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults, 2011. NICE clinical guideline CG113. Available from [www.nice.org.uk/CG113](http://www.nice.org.uk/CG113)
- Patient experience in adult NHS services, 2012. NICE clinical guideline CG138. Available from [www.nice.org.uk/CG138](http://www.nice.org.uk/CG138)
- Percutaneous venoplasty for chronic cerebrospinal venous insufficiency for multiple sclerosis, 2012. NICE interventional procedure guidance IPG420. Available from [www.nice.org/guidance/IPG420](http://www.nice.org/guidance/IPG420)
- CG49: Faecal incontinence: The management of faecal incontinence in adults, 2007. NICE clinical guideline CG49. Available from [www.nice.org.uk/CG49](http://www.nice.org.uk/CG49)
- Fingolimod for the treatment of highly active relapsing-remitting multiple sclerosis, 2012. NICE Technology Appraisal TA254 available from [www.nice.org.uk/TA254](http://www.nice.org.uk/TA254)

## **5.2 Guidance under development**

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

- Multiple sclerosis – cladribine for the treatment of relapsing remitting multiple sclerosis. Technology Appraisal: currently suspended since cladribine has not been granted a marketing authorisation.

- Clinical guideline: Management of incontinence in neurological disease. NICE public health guidance. NICE clinical guideline: currently in progress. Expected date of publication October 2012.
- Clinical guideline: The prevention and management of pressure ulcers in primary and secondary care (update).
- Percutaneous venoplasty for chronic cerebrospinal venous insufficiency (CCSVI) in multiple sclerosis. NICE interventional procedure guidance IP891. Currently in progress at scoping stage.

## 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](http://www.nice.org.uk/GuidelinesManual)). Information on the progress of the guideline will also be available from the NICE website ([www.nice.org.uk](http://www.nice.org.uk)).