MS and Disability: A Resource for Claims Professionals

National
Multiple Sclerosis
Society

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Introduction

The fair and accurate review of disability claims related to multiple sclerosis (MS) should be based on a case-by-case analysis of each claim, with consideration given to all effects of the disease and its management. Claimants (people with MS), health care providers, and claims professionals should understand and accept the role and responsibility each of them has relative to a claim for MS-related disability. This can only occur if each party involved in adjudicating a claim has full and fair access to information about the review process, the claimant's condition, and knowledge of the key terminology and concepts used in disability policies. A basic understanding of the disease, its symptoms and effects, currently available treatment and its limitations, and MS-related disability is essential.

Many people with firsthand knowledge of disability claims involving MS believe that inadequate physician reports, uneven knowledge of the disease among claims professionals and lack of claimant understanding about disability insurance and the adjudication process are commonplace. This can result in arbitrariness in claims review and costly claim disputes, with the burden of proof falling squarely on the person with MS, who may be the least capable of handling this obligation.

As a source of information about MS, the National MS Society (the Society) believes that accurate and unbiased information about MS and MS-related disability can produce:

- Greater understanding of the disease, it's effects and treatments, that can elevate standards for claim evaluations among reviewers and other industry personnel

- The identification and promotion of "best practices" among physicians and their clinical colleagues in documenting MS-related impairments
- Help for people with MS and their caregivers preparing disability claims and knowledge of what to expect about the process in advance
- Improved communications and more realistic expectations about MS-related impairments and disability among all parties
- A reduction in the overall burden of claim disputes initiated by people with MS
- Support for the appropriate use of disability insurance funds and premiums as intended

With this belief in mind, the Society convened a task force of diverse and credible stakeholders, including representatives from the disability insurer community, to identify and characterize the issues related to disability claims involving MS, make recommendations, and help advance opportunities for understanding. The result of these efforts is educational materials targeted to three distinct audiences: claims professionals, clinicians and people with MS.

This particular document was written for claims professionals and others within the insurance industry. It was developed to aid in the evaluation of claims for private disability insurance benefits from policyholders with multiple sclerosis. It is intended to inform the process of claims adjudication with accurate, unbiased information about the diagnosis and treatment of the disease and common symptoms related to it.

These materials, as well as many other resources on multiple sclerosis, are available through your local chapter by calling 1-800-344-4867 or online at **www.nationalmssociety.org/planning**.

Overview of multiple sclerosis

Multiple sclerosis is a chronic, often progressive disease that attacks the central nervous system (the brain and spinal cord). Symptoms may be mild, such as numbness in the limbs, or severe, such as paralysis or blindness. The progress, severity, and specific symptoms of MS in any one person cannot be predicted.

The cause and cure of MS are currently unknown. MS is thought to be an autoimmune disease in which the body's own defense system attacks and damages myelin, the insulating material that surrounds and protects the nerve fibers of the brain and spinal cord. It can also damage the nerve fibers as well. This damage to the myelin and the nerve fibers forms hardened "plaques" and the scattered distribution of these hardened or "sclerotic" areas throughout the brain and spinal cord gave rise to the name multiple sclerosis. When any part of the myelin sheath or nerve fiber is damaged or destroyed, nerve impulses to and from the brain are distorted or interrupted, thereby causing the clinical manifestations of MS. MS is not contagious and is usually not fatal; most affected individuals have normal or near-normal life expectancies.

The symptoms of MS may include tingling, numbness, painful sensations, slurred speech and blurred or double vision. It can also cause muscle weakness, poor balance, poor coordination, muscle tightness or spasticity, or paralysis that may be temporary or permanent. Problems with bladder, bowel, or sexual function are common, although abnormal fatigue is often a major source of disability. MS can cause cognitive changes such as memory loss or difficulty concentrating, as well as mood swings and depression. Symptoms vary greatly in type and severity from one person to another and may come and go, particularly in the exacerbating-remitting form of the disease.

An estimated 400,000 Americans have multiple sclerosis. Most are diagnosed between the ages of 20 and 50 and about two thirds are women. Studies indicate that genetic factors make certain individuals more susceptible to the disease, although MS is not an inherited disease in the usual sense.

Diagnosing MS

There are no laboratory tests, symptoms, or physical findings that can, by themselves, determine if a person has multiple sclerosis. Furthermore, there are many symptoms of MS that can also be caused by other diseases. Therefore, the MS diagnosis can only be made by carefully ruling out all other possibilities.

There are three long-established criteria for diagnosing MS:

1. There must be objective evidence of two attacks (i.e., two episodes of demyelination in the central nervous system). An attack, also known as an exacerbation, flare-up, or relapse, is defined clinically as the sudden appearance or worsening of an MS symptom or symptoms, which lasts at least 24 hours. The objective evidence comes from findings on the neurologic exam and additional tests.
2. The two attacks must be separated in time (by at least one month) and space (indicated by evidence of inflammation and/or damage in different areas of the central nervous system).
3. There must be no other explanation for these attacks or the symptoms the person is experiencing.

In 2001, the International Panel on the Diagnosis of Multiple Sclerosis, chaired by WI McDonald, FRCP (Royal College of Physicians, London), issued a revised set of diagnostic criteria

(*Annals of Neurology 2001; 50:121-127*). In addition to the traditional requirements, the revision provides specific guidelines for using findings on MRI, cerebrospinal fluid analysis, and visual evoked potentials to provide evidence of the second attack in those individuals who have had a single demyelinating episode (called *clinically isolated syndrome*) and thereby confirm the diagnosis more quickly. These guidelines also facilitate the diagnostic process in those patients who have had steady progression of disability without distinct attacks.

Since 2001, the McDonald Criteria for Diagnosis of MS have been used worldwide. The International Panel, chaired by Chris Polman, MD, reconvened in March 2005 to consider extensive data that had been collected since 2001 and to recommend appropriate revisions to the criteria. These revisions, termed the 2005 Revisions to the McDonald Diagnostic Criteria for MS, were published in 2005 (*Annals of Neurology 2005; 58:840-846*). These revisions will help to enhance the speed and accuracy of an MS diagnosis.

MRI Is the Preferred Method of Imaging the Brain

Magnetic Resonance Imaging (MRI) is the preferred method of imaging the brain to detect the presence of plaques or scarring caused by MS. This technology is able to detect lesions in different parts of the central nervous system and differentiate old lesions from those that are new or active.

Still, the diagnosis of MS cannot be made solely on the basis of MRI. There are other diseases that cause lesions—areas of damage in the brain that look like those caused by MS. There are also spots found in healthy individuals, particularly in older persons, which are not related to any ongoing disease process.

On the other hand, a normal MRI cannot rule out a diagnosis of MS. About 5% of people who are confirmed to have MS on the basis of

other criteria, do not show any lesions in the brain on MRI. These individuals may have lesions in the spinal cord or may have lesions that cannot be detected by MRI. Eventually, however, the vast majority of people with MS will have brain and/or spinal lesions on MRI. The longer the MRI remains negative, the more questionable the diagnosis becomes. If the MRI findings continue to be negative more than a year or two after the initial diagnosis is made, every effort should be made to identify another possible cause for the symptoms.

Clinical Exam Includes History and Tests of Function

During the initial clinical examination, the physician takes a careful history to identify any past events that might be indicative of MS-related disease activity and performs a variety of tests. These tests evaluate mental, emotional, and language functions, movement and coordination, vision, balance, and the functions of the five senses. Sex, birthplace, family history, and age of the person when symptoms first began are also taken into consideration.

Other Tests Are Sometimes Needed

It is not usually necessary to do all diagnostic tests for every patient. If, however, a clear-cut diagnosis cannot be made based on the tests above, additional tests may be ordered. These include tests of evoked potentials, cerebrospinal fluid, and blood.

Evoked potential (EP) tests are recordings of the nervous system's electrical response to the stimulation of specific sensory pathways (eg, visual, auditory, general sensory). Because demyelination results in a slowing of response time, EPs can sometimes provide evidence of scarring along nerve pathways that is not apparent on a neurologic exam. *Visual* evoked potentials are considered the most useful for confirming the MS diagnosis.

Cerebrospinal fluid, sampled by a spinal tap, is tested for levels of certain immune system proteins and for the presence of oligoclonal bands. These bands indicate an immune response within the central nervous system. Oligoclonal bands are found in the spinal fluid of about 90-95% of people with MS. Since, however, they are present in other diseases as well, oligoclonal bands cannot be relied on as positive proof of MS.

While there is no definitive blood test for MS, blood tests can rule out other causes for various neurologic symptoms. Some other conditions that cause symptoms similar to those of MS are Lyme disease, a group of diseases known as collagen-vascular diseases, certain rare hereditary disorders, and AIDS.

The McDonald Diagnostic Criteria for MS (revised 2005)

Clinical Presentation	Additional data needed for MS diagnosis
2 or more attacks; objective clinical evidence of 2 or more lesions	• None
2 or more attacks; objective clinical evidence of 1 lesion	• Dissemination in space, demonstrated by: > MRI OR > 2 or more MRI detected lesions consistent with MS plus positive CSF OR > Await further clinical attack implicating a different site

Clinical Presentation	Additional data needed for MS diagnosis
1 attack; objective clinical evidence of 2 or more lesions	• Dissemination in time, demonstrated by: > MRI OR > Second clinical attack
1 attack; objective clinical evidence of 1 lesion (monosymptomatic presentation; clinically isolated syndrome)	• Dissemination in space, demonstrated by: > MRI OR > 2 or more MRI-detected lesions consistent with MS plus positive CSF **AND** • Dissemination in time, demonstrated by: > MRI OR > Second clinical attack
Insidious neurological progression suggestive of MS	• One year of disease progression (retrospectively or prospectively determined) **AND** • Two out of three of the following: a. Positive brain MRI (9 T2 lesions or 4 or more T2 lesions with positive visual evoked potentials) b. Positive spinal cord MRI (two or more focal T2 lesions) c. Positive CSF

Disease Course Classifications

MS is an unpredictable disease. Symptoms vary greatly from person to person, and may vary over time in the same person. Periods of active MS symptoms are called exacerbations, attacks, or relapses, and periods of recovery are called remissions. The disease ranges from very mild to intermittent to steadily progressive. Some people have few attacks and little if any cumulative disability over time. At diagnosis, most people have "relapsing-remitting" disease, with attacks, followed by periods of partial or total remission, which may last months or even years. Others experience a progressive disease course with steadily worsening symptoms. The disease may worsen steadily from the onset ("primary-progressive MS") or may become progressive after a relapsing-remitting course ("secondary-progressive MS").

The charts on the following pages describe the results of an international survey of disease patterns in MS conducted by Fred D. Lublin, MD and Stephen C. Reingold, PhD (1996).

It is important to keep in mind that these disease categories serve primarily as a tool for the development of clinical research protocols, and as a guide for certain types of treatment decisions. The disease categories became a focus of attention for people with MS when they were used by researchers to identify participants for clinical trials, and then by insurance companies, to determine a person's eligibility for reimbursement of disease modifying drugs. Although the categories have come to play a significant role in MS research and management decisions, they were designed to be descriptive in nature rather than a "report card" or rating scale of a person's disease. A particular individual may not fit neatly into one category or another. The categories can, however, provide people with MS, their healthcare providers, and others with useful guides to assist in the understanding of the known courses of the disease.

Relapsing-Remitting MS (RRMS)

RRMS is characterized by clearly defined acute attacks with full recovery (1a) or with residual deficit upon recovery (1b). Periods between disease relapses are characterized by a lack of disease progression. Approximately 85% of people are diagnosed initially with relapsing-remitting MS.

Figure 1a

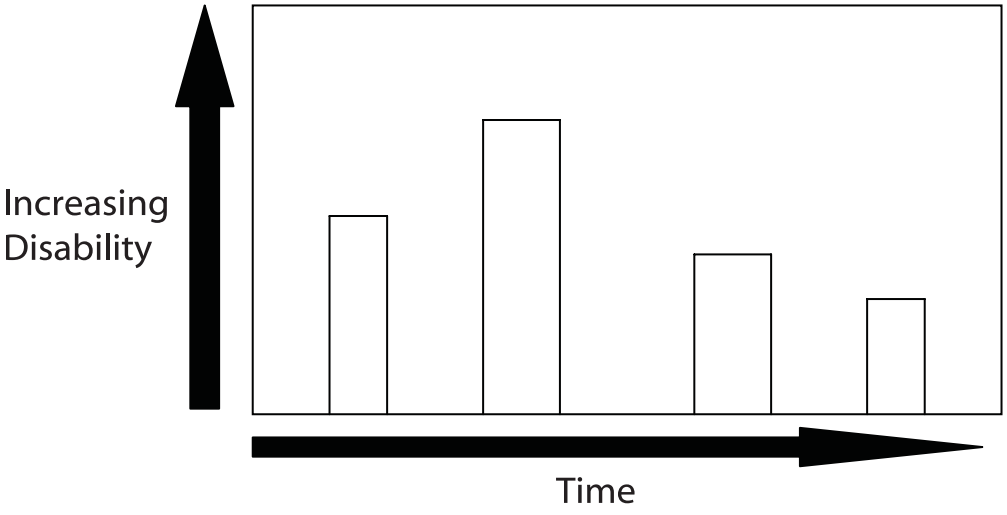
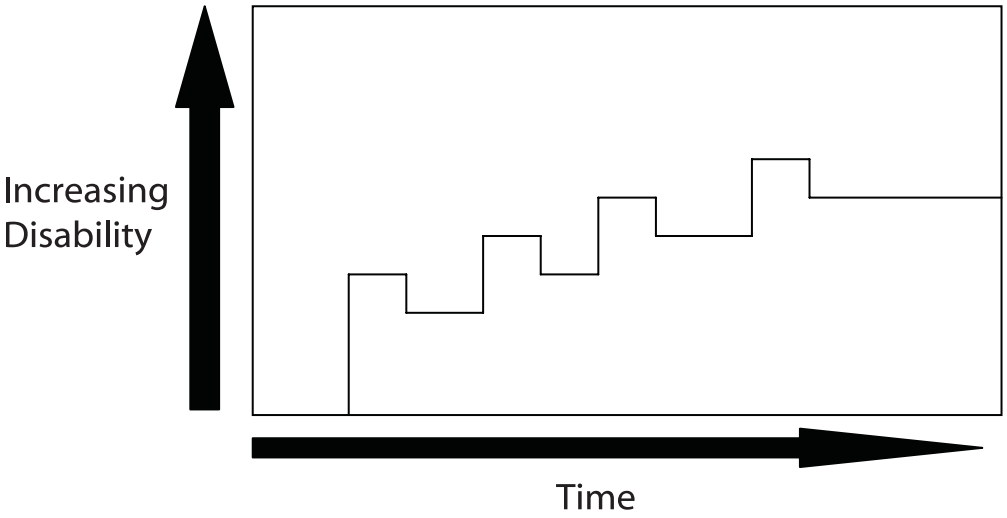


Figure 1b



Secondary-Progressive MS (SPMS)

SPMS begins with an initial relapsing-remitting disease course, followed by progression of variable rate (2a) that may also include occasional relapses and minor remissions and plateaus (2b). Natural history data suggest that of the 85% who start with relapsing-remitting disease, more than 50% will develop SPMS within 10 years; 90% within 25 years. The impact of the disease-modifying therapies on this transition to progressive disease is not yet known.

Figure 2a

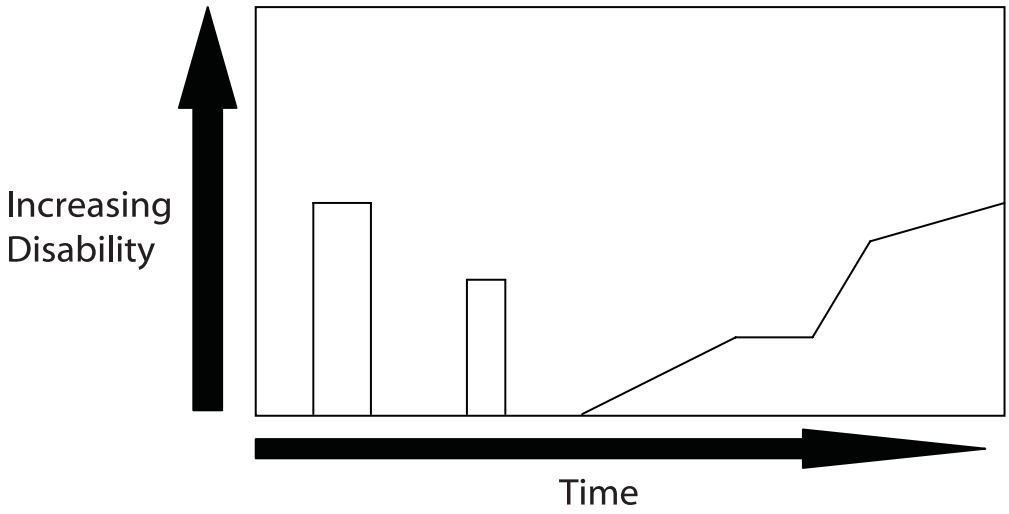
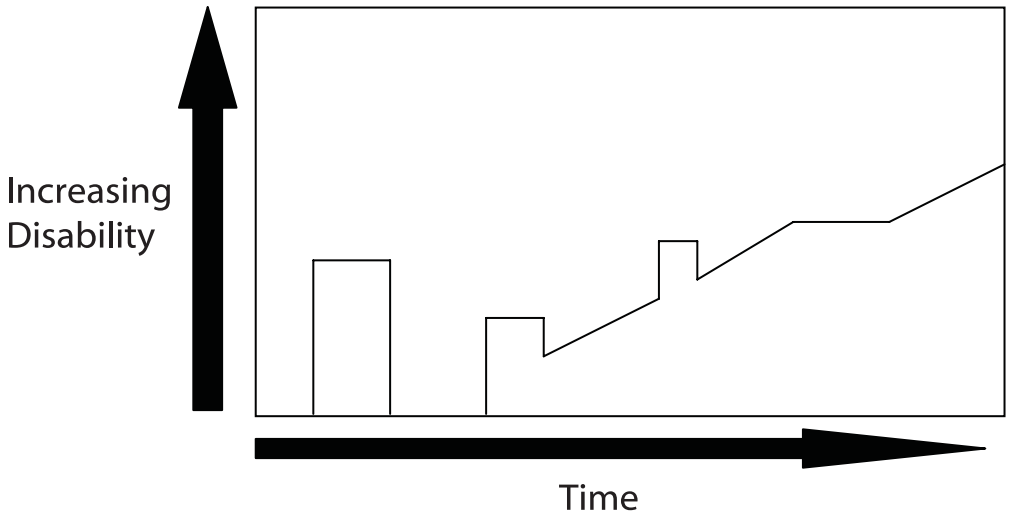


Figure 2b



Primary Progressive MS (PPMS)

PPMS is characterized by progression of disability from onset, without plateaus or remissions (3a) or with occasional plateaus and temporary minor improvements (3b). Approximately 10% of people are diagnosed with PPMS.

Figure 3a

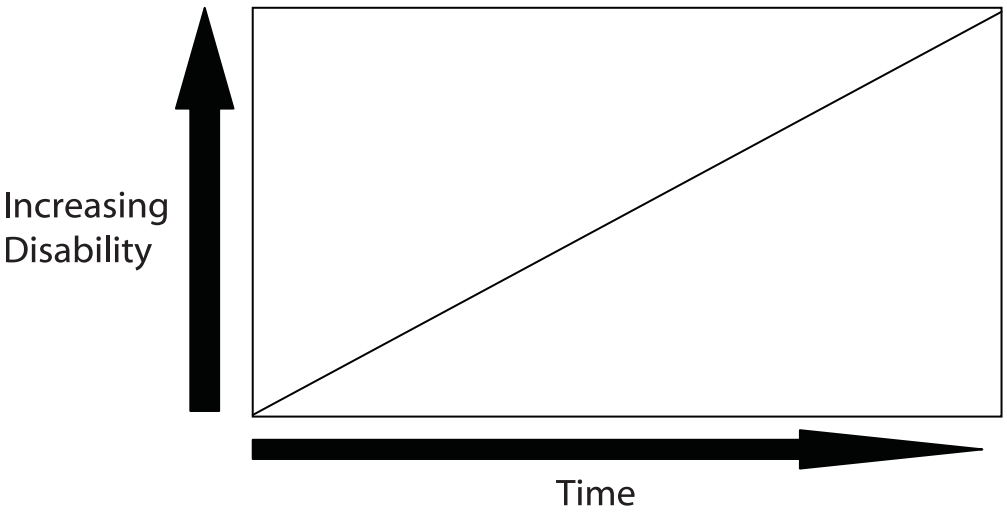
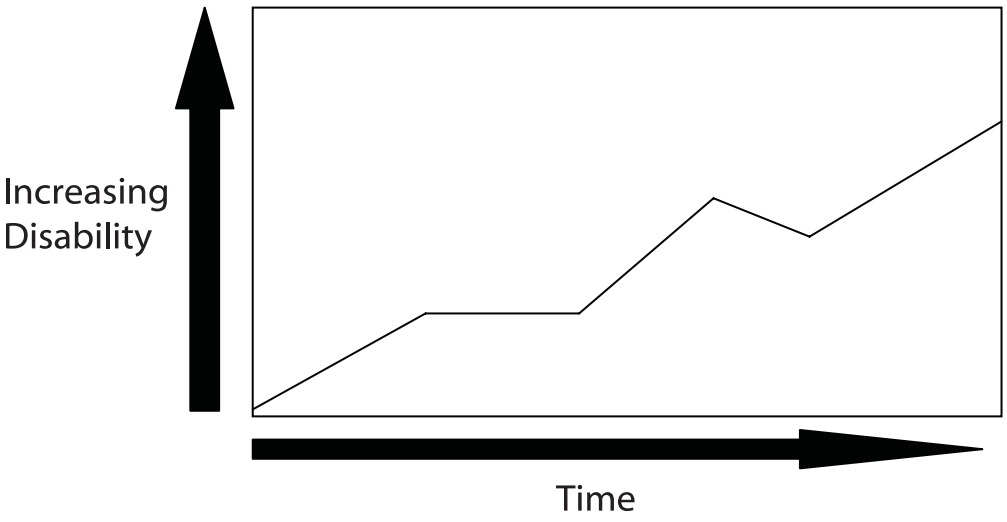


Figure 3b



Progressive-Relapsing MS (PRMS)

PRMS, which is the least common disease course, shows progression from onset but with clear acute relapses, with (4a) or without (4b) full recovery. Approximately 5% of people appear to have PRMS at diagnosis.

Figure 4a

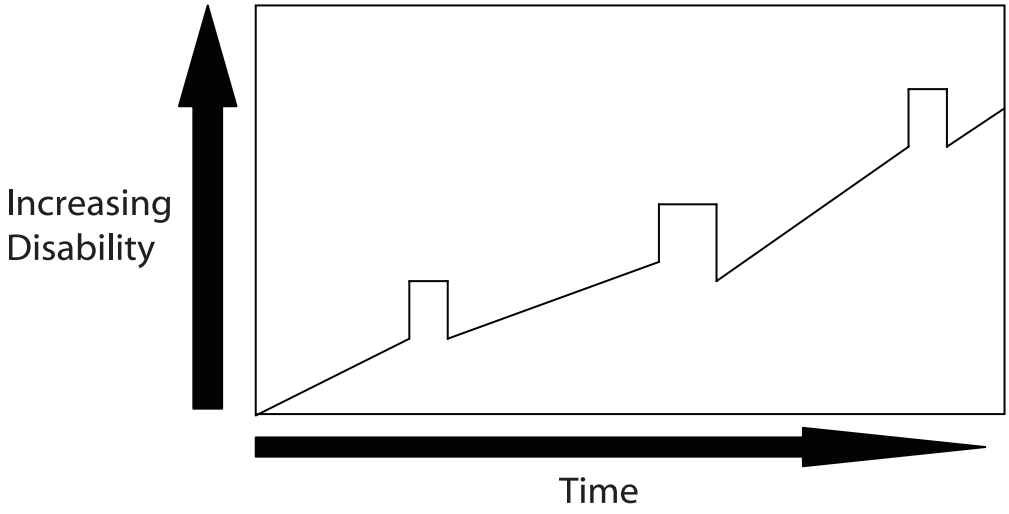
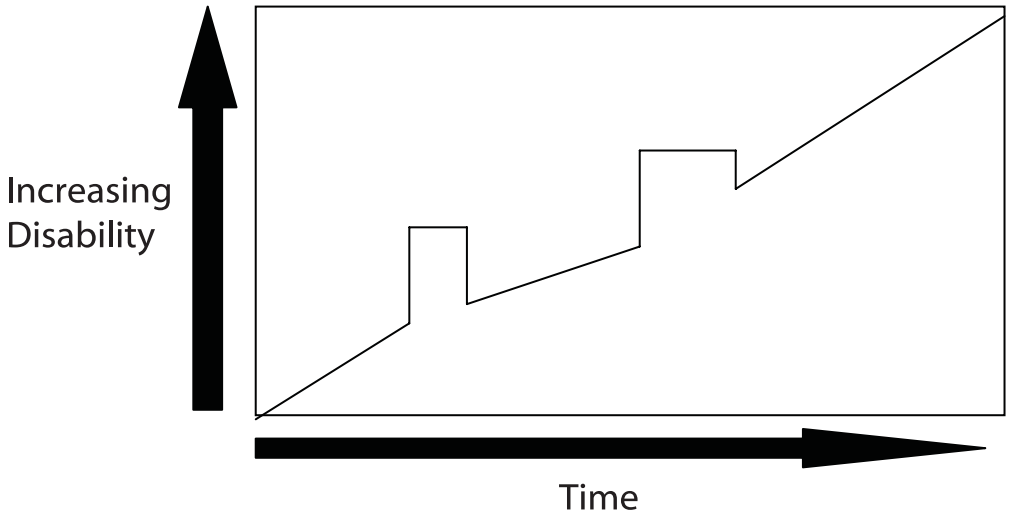


Figure 4b



(Figures 1 through 4 adapted from Fred D. Lublin, M.D., and Stephen C. Reingold, Ph.D., Neurology, April 1996, 46:907–911.)

Symptoms and Prognosis

As a result of the inflammatory process in the central nervous system, people with MS can experience any or all of the following symptoms: fatigue, visual disturbances, paralysis, spasticity, weakness, imbalance, sensory changes, pain, bladder and/or bowel dysfunction, sexual dysfunction, speech impairment (dysarthria), swallowing problems (dysphagia), emotional changes, and cognitive impairment. While any one of these symptoms may become severe enough to cause disability in a person with MS, a combination of mild to moderate deficits from several symptoms, as well as treatment side effects, can also result in MS-related disability.

In a large (n = 697) population-based survey of individuals with MS (Aronson et. al., 1996), the following symptoms were reported as most common by people with MS.

- Fatigue – 88%
- Ambulation problems – 87%
- Bowel/bladder problems – 65%
- Visual disturbances – 58%
- Cognitive problems – 44%
- Tremor – 41%
- Movement problems in the arms – 41%

Fatigue: MS fatigue is characterized by a total lassitude and lack of physical energy. People with MS may experience normal fatigue, fatigue of depression, fatigue from concurrent disease (e.g., arthritis, diabetes), fatigue resulting from sleep disorder (e.g., sleep apnea, restless leg syndrome), or the fatigue of over-exertion. Like other MS

symptoms, fatigue may fluctuate from hour to hour or day to day. An individual with MS may be able to accomplish much in the early part of the day but may require assistance with the same tasks in the afternoon due to MS fatigue. Fatigue is an invisible symptom. Others may misinterpret MS fatigue as laziness, depression, or poor motivation, and it is one of the primary reasons for people with MS to leave the workforce.

Ambulation problems: Difficulty with walking and coordination may be from weakness, spasticity, or loss of normal sensation. Damage to the part of the brain most responsible for posture, the cerebellum, causes problems with directing limb movements individually and in concert. Individuals with MS may experience weakness or paralysis in a part of the body one day and have the ability restored the next. Individuals with progressive forms of MS who have lost the ability to move an area of the body generally do not regain function in that area.

Bowel and/or Bladder problems: Problems with normal bowel and bladder function are common, highly upsetting to those who experience them, and major contributors to social isolation. Bowel problems include constipation and fecal incontinence, and can be related to muscle weakness, loss of sensation, decreased physical activity and side effects of medications. Bladder dysfunction may occur in several forms, from frequency and urgency to urinate to urinary retention—a major cause of infection with potentially life-threatening consequences.

Visual disturbances: Abnormalities in activation of the muscles that move the eyes may result in difficulty focusing on objects, with resultant blurring or even double vision. Damage and inflammation to the optic nerves themselves, known as optic neuritis, results in varying degrees of visual loss ranging from clouding or dimming of vision, to severe and persistent visual loss.

As with other MS symptoms, visual disturbances may increase with fatigue, stress, and high temperatures.

Cognitive problems: Neuropsychological studies have provided evidence of disease-based cognitive loss in a substantial number of people with MS, possibly more than 60%. Symptoms of cognitive loss may include short-term memory problems, difficulty with attention and concentration, slowed processing of information, impaired executive functions (e.g., reasoning, problem-solving, planning and sequencing and impaired word-finding). Without appropriate testing and assessment, cognitive deficits may go undetected by health care professionals, and are a primary cause of early departure from the workforce. People with MS who experience cognitive changes may be in denial and/or lose self-esteem and self-confidence.

Tremor: Tremors involve fine shaking of the arms and hands, and can involve the neck and entire body. Tremors are one of the most disabling symptoms of MS and affect a person's ability to perform activities of daily living. Tremor may worsen with stress.

Movement problems in the arms: Difficulty moving or controlling movement of the upper extremities may stem from weakness, paralysis, tremor, spasticity and/or fatigue, and can have a major impact on ability to perform activities of daily living.

Other: A prevalence study found that 73.1 percent of people with MS reported sexual dysfunction (Zorzon, 1999). Studies of depression in MS indicate that 50 percent of people with MS will experience a major depressive episode at some point in the course of the disease–a higher prevalence than is seen in other, equally disabling chronic illnesses, perhaps resulting in part from the disease process itself (Minden 1987).

Prognosis

Although prognosis in MS is uncertain, there are certain factors that seem to predict a more favorable course.

- Female gender
- Onset before age 35
- Mono-regional (single area of Central Nervous System (CNS) involvement) vs. poly-regional (multiple areas) of attack
- Complete recovery after an exacerbation, leaving little or no residual impairment

Factors that tend to be associated with a poor prognosis include:

- Male gender
- Onset after age 35
- Brainstem symptoms such as nystagmus (rapid, involuntary eye movements) tremor, ataxia (lack of coordination, unsteadiness), and dysarthria (poorly articulated speech)
- Poor recovery following exacerbations
- Frequent attacks

TREATMENT STRATEGIES

The variability of MS poses significant treatment challenges for clinicians and patients alike. The broad scope of currently available treatment strategies described in this section provides an overview of therapeutic options for the clinical care of MS. One or more treatment interventions may be indicated for a person with MS at any time during the course of their disease, or even none at all. The disease-modifying treatments described are known to slow disease activity in many people with MS. However, there is insufficient long-term data to know how these drugs will impact any individual's prognosis or level of disability.

Treatment strategies in MS fall into the following categories as described in this section and include: treatment of acute exacerbations, disease modification (of relapsing disease and progressive disease), symptom management, rehabilitation and psychosocial support.

Treatment of Acute Exacerbations (attacks)

Although the exact protocol may differ, most neurologists use a high-dose intravenous (IV) corticosteroid agent (such as methylprednisolone plus sodium succinate). Most commonly used is a 3–5 day course of treatment, either in the hospital or as an outpatient, which may or may not be followed by a gradually tapering dose of an oral corticosteroid such as prednisone. Steroids work to decrease acute inflammation in the Central Nervous System (CNS), but have no long-term benefits in MS. Many people feel better while taking them, in part because steroids can sometimes have a mood-elevating effect. The chronic use of steroids, however, causes serious side effects including hypertension, diabetes, bone loss (osteoporosis), cataracts, and ulcers.

Short courses of steroids tend to be well-tolerated by most people. Mood changes, however are relatively common, with people reporting feeling "high," energetic, and unable to sleep and/or depressed, particularly as they come off the medication. A small percentage of people may experience quite severe disturbances in mood or behavior. Lithium, divalproex (Depakote®), and carbamazepine (Tegretol®) have all been shown to be effective in preventing or managing these symptoms. Patients should be alerted to these potential side effects before taking corticosteroids, and reminded that a person can react very differently to corticosteroids from one course to the next.

A second option for the treatment of acute exacerbations is H.P. Acthar Gel—repository corticotrophin injection (ACTH). ACTH has been approved by the FDA for this purpose since 1978. Although there was a period when its availability in the US and elsewhere became very restricted due to limited manufacturing production, the product is once again available.

Disease-Modifying Treatments

1. Relapsing Disease

There are currently four *injectable*, and one infused drug that have been approved for the treatment of relapsing forms of MS in the US and Canada. While these drugs are neither a cure for the disease, nor designed to make people feel better, they have each been shown to slow or modify the course of the disease. Betaseron®, Copaxone® and Rebif® are almost always self-administered, often with the aid of a family caregiver. Avonex®, which is an intramuscular interferon, can be self-administered but is more often administered by a clinical professional or family caregiver.

- **Betaseron** has been shown in clinical trials to reduce the frequency and severity of exacerbations and reduce new or

active lesions on MRI. It is approved in the US for use in relapsing forms of MS, including secondary-progressive MS in those individuals who are still experiencing relapses.

Betaseron is administered by subcutaneous injection every other day. Common side effects include flu-like symptoms following injection, which lessen over time for many people; injection site reactions, about 5% of which need medical attention. Less common side effects include depression, elevated liver enzymes, and low white cell counts.

- **Avonex** has been shown to reduce the frequency of relapses, reduce new or active lesions on MRI, and may slow disease or progression. It is approved in the U.S. for the treatment of patients with relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

  Avonex is administered weekly as an intramuscular injection, often with the assistance of a caregiver or in a medical facility. Common side-effects include flu symptoms following injection, which lessen over time for many people. Rarer side effects include depression, mild anemia, elevated liver enzymes, and liver toxicity.

- **Copaxone** has been shown to reduce the frequency of exacerbations and number of new or active lesions on MRI. It is approved in the US for the treatment of relapsing-remitting MS. It is administered as a subcutaneous injection on a daily basis. Common side effects include injection site reactions; less-common side effects include anxiety, chest tightness, shortness of breath, and flushing lasting 5–10 minutes with no known long-term effects.

- **Rebif** has been shown to reduce attack frequency, reduce new or active lesions on MRI, and slow progression of disability. It is administered as a subcutaneous injection three times weekly, with common side effects including flu symptoms following injection, which lessen over time for many people; and injection site reactions. Less common side effects include elevated liver enzymes, liver toxicity, and low white blood cell counts.
- **Tysabri**® was approved by the US Food and Drug Administration in 2006 as a monotherapy (not to be used in combination with another disease-modifying therapy) for the treatment of patients with relapsing forms of MS to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. It is generally recommended for patients who have had an inadequate response to, or cannot tolerate, any of the other disease-modifying therapies that are available for treating MS. Tysabri is given once every four weeks by intravenous infusion, and at present is just emerging as a treatment option for select patients in highly controlled environments.

2. Progressive Disease

A sixth drug, the immunosuppressant **Novantrone**® (mitoxantrone), is approved for use in "worsening relapsing-remitting MS" as well as secondary-progressive and progressive-relapsing forms of the disease.

Novantrone, a potent immunosuppressant already approved for use in adult myeloid leukemia, was shown in secondary-progressive trials to slow progression of disability, reduce the relapse rate, and reduce the numbers of inflammatory lesions in the brain. Based on these trials, the FDA approved Novantrone in October 2000 for "reduction of neurologic disability and/or frequency of clinical relapses in patients with secondary-progressive, progressive-relapsing, or worsening relapsing-remitting MS." Novantrone should

only be used in those with normal cardiac function. Because of possible cumulative cardiac toxicity, the use of this drug is limited to 8–12 doses over 2–3 years, with appropriate monitoring throughout. Novantrone is administered by intravenous infusion.

Other immunosuppressive agents, including azathioprine (Imuran®), cladribine (Leustatin®), cyclophosphamide (Cytoxan®), and methotrexate are also used to treat progressive disease. Although the dosages used in MS are significantly lower than those used for cancer treatment, the short-term side effects (ie, nausea, hair loss) and the long-term side effects (eg, sterility, cardiotoxicity, liver toxicity) are valid concerns. The role of medical and mental health professionals is to help people weigh their options and make informed decisions on their own behalf.

The National MS Society maintains a list of clinical trials (planned, in progress, or recently completed) on the website at **www.nationalmssociety.org/docs/HOM/clinicaltrials.pdf**.

Symptom Management

The table on the following pages presents the symptoms of MS, the treatments recommended to manage them, and the potential emotional and social impact of these symptoms on people's lives.

Symptom management in MS often involves the off-label use of prescription drugs, and many of the medications listed below are used to treat symptoms other than those approved and indicated by the FDA. In most instances, these management strategies have evolved in clinical practice, with MS experts providing information and recommendations of others in the field.

Invisible symptoms can be stressful since they tend to be ignored, misunderstood, or misinterpreted by other people.

Symptom	Treatment	Psychosocial Implications
Ambulation Problems		
• Impaired balance	• Mobility aids	Resistance to use of mobility aids: • Perceptions of self: damaged, weak; giving in • Others' perceptions: less intelligent; less competent
• Weakness	• Mobility aids	
Bladder Dysfunction		
• Failure to store (urgency, frequency, incontinence, nocturia)	Anti-cholinergic agents (oxybutynin (Ditropan®), tolterodine (Detrol®); hyoscyamine sulfate, propantheline bromide (Pro-Banthine®); trospium chloride (Sanctura®); solifenacin succinate (Vesicare®); scheduled voiding; avoidance of diuretics	Fear of drinking liquids; anxiety over loss of control; fear of leaving vicinity of bathroom; embarrassment/shame; fear of incontinence during intercourse; increased fatigue due to interrupted sleep
• Failure to empty (urgency, hesitancy, double voiding, feelings of incomplete emptying)	Intermittent self-catheterization (ISC); may require indwelling catheter	Anxiety about loss of control; fear of ISC
• Combined failure to store/failure to empty	Combination of the above	

Symptom	Treatment	Psychosocial Implications
Bowel Dysfunction		
• Constipation	Bowel training; high-fiber diet; exercise; medication (eg, softeners, mild laxatives, mini-enemas).	• Discomfort; exacerbation of spasticity;
• Fecal impaction	Manual disimpaction	• Discomfort; embarrassment
• Diarrhea (usually from constipation)	Disimpact and relieve constipation	• Discomfort; embarrassment
• Fecal incontinence	Bowel program; anti-cholinergic medication (for hyperreflexic bowel)	• Loss of control; anxiety about leaving home/being around others; shame
Cognitive Symptoms*		
• Memory impairment • Impaired attention/ concentration • Slowed processing speed • Impaired executive functions • Impaired spatial relations • Impaired word-finding ability ** Note: Cognitive deficits are often missed in a standard neurologic exam.*	*Interventions:* cognitive rehabilitation • Restorative approach: direct retraining exercises (have only limited benefit for daily activities) • Compensatory approach: aims to improve function via substitution of compensatory strategies/ tools for the impaired function *Medications:* Donepezil hydrocholoride (Aricept®) may be useful; disease-modifying agents may be beneficial.	*Individual:* denial; anxiety; loss of self-esteem/self-confidence; depression; may interfere with self-care and independence. *Interpersonal:* family strain; marital strain; impaired communication; role shifts within the family *Employment:* major cause of high unemployment rate in people with MS *Healthcare:* may affect communication with providers and compliance with treatment

Symptom	Treatment	Psychosocial Implications
Fatigue • Primary: (neurologic) overwhelming lassitude or tiredness that can strike at any time of day • Secondary: resulting from disturbed sleep; depression; extra exertion due to impairments; medications	*Interventions:* naps; moderate aerobic exercise; work simplification; use of assistive devices (eg, electric scooter); cooling strategies/ devices. *Medications:* amantadine (Symmetrel®); modafinil (Provigil®); fluoxetine (Prozac®).	Inability to carry out activities at home and at work; fatigue of this magnitude is depressing; invisible symptom that is easily misinterpreted by others.
Sensory Problems/ Pain • Sensory Symptoms (from loss of myelin): numbness, tingling, • Primary Pain (from loss of myelin):	No treatment required unless bothersome; medication if necessary	Anxiety, discomfort; clumsiness; fatigue increased by medications and interrupted sleep
• trigeminal neuralgia (sharp facial pain);	*Medications:* (carbamazepine (Tegretol®), gabapentin (Neurontin®), phenytoin (Dilantin®), duloxetine (Cymbalta®); baclofen (Lioresal®). Surgery: radiofrequency rhizotomy; radiofrequency electrocoagulation; glycerol rhizotomy;.	Medications increase fatigue
• dyesthesias (electric shock-like sensations in trunk or extremities);	Medications (same as above, or topical application of capsaic acid cream)	Medications increase fatigue

Symptom	Treatment	Psychosocial Implications
Sensory Problems/Pain (continued) • retro-orbital pain (with optic neuritis)	High-dose IV steroids	Steroids can affect mood
Secondary Pain (musculoskeletal) resulting from poor posture/balance in ambulatory individuals or improper use/fitting of wheelchair	Analgesics; gait training; wheelchair assessment	Discomfort *Note: People often told by doctors that MS does not cause pain*
Spasticity* • Phasic spasms (flexor or extensor) • Sustained increase in muscle tone Spasticity can range from relatively mild to quite severe, and treatment is approached in a step-wise fashion. ** Note: Some degree of spasticity may be required to support weakened limbs.*	1. Rehabilitative PT (stretching) 2. Oral medications (baclofen—Lioresal®; tizanidine—Zanaflex®; diazepam—Valium®) 3. Intrathecal baclofen pump 4. Botulinum toxin injections into individual muscles 5. Surgery	• Oral medications increase fatigue and weakness • Surgical implantation of pump in abdomen can be frightening. • Severing of tendons is irreversible.

Symptom	Treatment	Psychosocial Implications
Sexual Dysfunction*		
• Primary (result of neurologic impairment): impaired arousal, sensory changes, reduced vaginal lubrication, erectile dysfunction, inability to orgasm	Evaluation of medications that might be interfering with sexual function. *Men:* Oral medications (sildenafil-Viagra®; vardenafil-Levitra®; tadalafil-Cialis®); injectable or insertable medication (alprostadil-Prostin VR®, Muse®); prosthetic devices. *Women:* lubricating substances; enhanced stimulation	*Individual:* Significant impact on gratification, self-esteem, self-confidence; difficult/ embarrassing to discuss with healthcare providers *Interpersonal:* Significant impact on all intimate relationships: • Sexual activity can be difficult, exhausting, painful, and unsatisfying. • Lack of arousal can be misunderstood and resented by partner. • Learning new ways to be intimate can be frightening and difficult. • Caregivers may become disinterested in, or uncomfortable with, their disabled partner. • Person with MS may be reluctant to become intimate with new partner.
• Secondary (resulting from other MS symptoms): fatigue, spasticity, bladder/ bowel problems, sensory changes interfere with sexual activity. * *Note: Impaired arousal, erectile dysfunction, and inability to orgasm can also result from medications taken to relieve other symptoms, most notably antidepressants.*	Effective management of MS symptoms to reduce impact on sexual function.	

Symptom	Treatment	Psychosocial Implications
Sexual Dysfunction* (continued) • Tertiary (resulting from disability-related attitudes/feelings): feeling unattractive; unable to attract a partner; believing that sexuality is incompatible with disability	Individual and couple's counseling and education.	Same as Primary and Secondary.
Speech/Swallowing Problems • Dysarthria—poorly articulated, slurred speech • Dysphagia—difficulty in swallowing that can lead to aspiration and/or inadequate nutrition	Assessment, exercise program, training with augmentative or alternative communication devices, if needed. Assessment, exercise program, modified diet, non-oral feeding strategies, if needed.	• Slurring can be misinterpreted as drunkenness or lack of intelligence • Slow, slurred speech interferes with communication • Fear of loss of control, choking • Food needs to be blenderized • Eating is exhausting • Loss of pleasurable mealtimes • Loss of ability to eat orally

Symptom	Treatment	Psychosocial Implications
Tremor Involuntary movements of the arms, legs, or head; tremor can be the least treatable and a debilitating symptom of MS.	*Interventions:* balance/ coordination exercises; weights on limbs or utensils *Medications:* Propanolol; clonazepam-Klonopin®; primidone-Mysoline®; isoniazid-Laniazid®; buspirone-BuSpar®; ondansetron-Zofran®	Fear of loss of control—severe tremor is a major threat to independence. Medications can increase fatigue.
Vertigo • Severe dizziness and nausea caused by inflammation in the brainstem	Oral medication (meclizine-Antivert®); IV fluids and high-dose corticosteroids if nausea prevents the use of oral medications	• Vertigo interferes with functioning at home and at work. • Steroids can impact mood
Visual Impairment • Optic neuritis (temporary loss or disturbance of vision, often accompanied by pain; may also cause a "blind spot" (scotoma) in center of vision.	High-dose corticosteroids	• Visual symptoms can threaten independent functioning (eg, driving), increase fatigue, and interfere with activities at work and at home.
• Diplopia (double vision)	High-dose corticosteroids	• Steroids can impact mood.
• Nystagmus (rhythmic jerkiness or bounce in one or both eyes)	Medication (clonazepam-Klonopin®) if necessary	• Medication can increase fatigue.

Additional Resources on Symptom Management

1. The Society's Clinical Bulletins entitled *Bladder Dysfunction in Multiple Sclerosis* and *Surgical Management of Bladder Dysfunction in Multiple Sclerosis* can be downloaded from the Web site at **www.nationalmssociety.org/docs/HOM/Bladder.pdf** and **www.nationalmssociety.org/docs/HOM/SurgMgmtBladder.pdf**.
2. The Society's Clinical Bulletin entitled *Bowel Management in Multiple Sclerosis* can be downloaded from the Web site at **www.nationalmssociety.org/docs/HOM/Bowel.pdf**.
3. The Society's Expert Opinion Paper entitled *Management of MS-Related Fatigue* can be downloaded from the Web site at **www.nationalmssociety.org/docs/HOM/Expert_Fatigue.pdf**.
4. The Society's Clinical Bulletin entitled *Pain in Multiple Sclerosis* can be downloaded from the Web site at **www.nationalmssociety.org/docs/HOM/Pain.pdf**.
5. The National MS Society's Clinical Bulletin entitled *Spasticity* can be downloaded from the Web site at **www.nationalmssociety.org/docs/HOM/clinicalbulletin_spasticity.pdf**.
6. The Society's Clinical Bulletin entitled *Diagnosis and Management of Vision Problems in MS* can be downloaded from the Web site at **www.nationalmssociety.org/docs/HOM/Vision.pdf**.

Rehabilitation

Although the disease-modifying therapies now available help slow the progression of multiple sclerosis for many living with the disease, most will continue to have limitations. Rehabilitation in MS involves the intermittent or ongoing use of multidisciplinary strategies to promote functional independence, prevent complications, and enhance overall quality of life. It is an active process directed toward helping the person recover and/or maintain the highest possible level of functioning and realize his or her optimal physical, mental, and social potential given any limitations that exist.

Rehabilitation specialists target the following impairments in their work with individuals with MS: fatigue, weakness, spasticity, cognitive impairments, imbalance, sensory loss, ataxia/tremor, pain, paraparesis, speech and swallowing problems, visual disturbances, and bowel and bladder problems. The goal of these rehabilitation interventions is to reduce "disablement," as defined by the World Health Organization (WHO) in the International Classification of Impairments, Activities, and Participation: A Manual of Dimensions of Disablement and Health (ICIDH-2). Disablement is an umbrella term used to describe the consequences of any health condition (disease, disorder, or injury) on a person's body structures or functions, personal activities, and participation in society. Although rehabilitation interventions cannot reverse the neurologic damage caused by MS, they can reduce disablement by:

- Minimizing the impact of existing impairment(s) on day-to-day functioning
- Enhancing the person's ability to carry out daily activities and participate to the fullest extent possible in all of his or her life roles

Restorative and Preventive Goals of Rehabilitation in MS

In multiple sclerosis, rehabilitation has both restorative and preventative goals. Restorative rehabilitation is designed to help the person reach his or her highest physical, emotional, and functional level given the limitations imposed by the illness. Thus, individuals who have recently experienced an exacerbation and accompanying decrease in functional abilities, may require rehab interventions designed to help them regain as much as possible of their previous functional abilities. While total restoration of function may not be possible, the goal is always to maximize independence, productivity, comfort, and self-care while minimizing the impact of the impairment and secondary complications on the person's activities and participation.

When multiple sclerosis has a progressive course, rehabilitation interventions are also designed to help people maintain maximal function in the face of disease progression, and prevent injuries and complications resulting from immobility. Remaining stable, or "holding one's own," replaces improvement as the targeted outcome. It is important to keep in mind that having to accept limitations of function at any point in the disease process can be emotionally devastating. Rehabilitation professionals and mental health professionals play a critical role in helping people with MS modify their expectations and develop realistic goals, while maintaining their self-esteem in the process.

The Society's Expert Opinion Paper entitled *Rehabilitation: Recommendations for Persons with Multiple Sclerosis* can be downloaded from the website at **www.nationalmssociety.org/docs/HOM/ExpOp_Rehab.pdf**.

Psychosocial Support

Psychosocial support is the fifth major category of treatment in MS, encompassing:

1. Disease-related education (more recently termed psychoeducation—a supportive educational process designed to enhance people's understanding of the disease, adaptive coping strategies, and available resources)
2. Diagnosis/treatment of emotional and/or cognitive problems
3. Family interventions designed to support family members' efforts to cope with the intrusion of MS into the household
4. Support for people's efforts to remain productively employed as long as they are able and interested, and to transition out of the workforce when, and if, it is necessary to do so
5. Helping individuals with MS and their families to access available resources

Assessment of MS-Related Disability

Earlier portions of this manual provided claims professionals with information about MS for their general orientation to the disease and its treatment. This section offers information and tools to help address the claims professionals' questions of when, or whether, a claimant with MS is actually disabled by the disease.

The unpredictability of the disease makes even straightforward questions about the severity of its impact on each person difficult to answer. Specialists in the treatment of MS largely rely on their years of experience, knowledge and relationship with each patient (and/or caregiver), their own clinical observations, and patient self reports to assess their MS patients' status. They may also make use of various assessment tools to chart their patients' disease, such as those described below, which were typically developed for use in the research arena. Many of these are useful to document the MS-related impairments that result in the inability to continue working, although *at this time there is no generally accepted battery of tests used or recommended to clinicians to monitor their MS patients' progress*. Several important measurement tools are described in the following pages to inform those who may see reference to one or more of them in a claimant's medical record. However, claims professionals should anticipate wide variation in the habits of neurologists and other MS specialists when it comes to charting their MS patients' progress over time.

See the Appendix for information about the Social Security Administration criteria for MS-related disability under the Social Security Act.

Expanded Disability Status Scale (EDSS)

Description

The Functional System Scores (FSS) and Expanded Disability Status Scale (EDSS) together constitute one of the oldest and probably the most widely utilized assessment instruments in MS. Based on the standard neurological examination, the seven functional systems (pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral) plus "other," are rated. These individual FSS ratings are then used in conjunction with observations and information concerning gait and use of assistive devices to determine the EDSS. Each FSS is an ordinal clinical rating scale ranging from 0 to 5 or 6. As illustrated below, the EDSS is an ordinal clinical rating scale ranging from 0 (normal neurological examination) to 10 (death due to MS) in half-point increments. The EDSS thus provides an overall disability rating for people with MS.

EDSS Scores **The 0 to 10-point score of the EDSS illustrates a patient's status, as follows:**	
0	Normal neurological exam
1.0	No disability, minimal signs in one FS
1.5	No disability, minimal signs in more than one FS
2.0	Minimal disability in one FS
2.5	Mild disability in one FS or minimal disability in two FS
3.0	Moderate disability in one FS, or mild disability in three or four FS. Fully ambulatory
3.5	Fully ambulatory but with moderate disability in one FS and more than minimal disability in several others
4.0	Fully ambulatory without aid, self sufficient, up and about some 12 hours a day despite relatively severe disability; able to walk without aid or rest some 500 meters
4.5	Fully ambulatory without aid, up and about much of the day, able to work a full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability; able to walk without aid or rest some 300 meters

5.0	Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (work a full day without special provisions)
5.5	Ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities
6.0	Intermittent or unilateral constant assistance (cane, crutch, or brace) required to walk about 100 meters with or without resting
6.5	Constant bilateral assistance (canes, crutches, braces) required to walk about 20 meters without resting
7.0	Unable to walk beyond approximately five meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day
7.5	Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; May require motorized wheelchair
8.0	Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms
8.5	Essentially restricted to bed much of day; has some effective use of arms retains some self care functions
9.0	Confined to bed; can still communicate and eat
9.5	Totally helpless bed patient; unable to communicate effectively or eat/swallow
10.0	Death due to MS
*	* Functional Systems are defined as pyramidal; cerebellar; brain stem, sensory; bowel and bladder; visual or optic; cerebral or mental functions.

Multiple Sclerosis Functional Composite (MSFC)

Description

The MSFC is a three-part, standardized, quantitative, assessment instrument, particularly used in clinical trials of MS (Cutter et al, 1999). The three components of the MSFC are: the timed 25 foot walk (T25-FW), which is a mobility and leg function performance test; the 9-Hole Peg Test (9-HPT) which tests coordination of the upper extremities; and the Paced Auditory Serial Addition Test (PASAT) which helps assess auditory information processing speed and flexibility, as well as calculation ability.

The composite MSFC was developed by a special Task Force on Clinical Outcomes Assessment that was appointed by the National Multiple Sclerosis Society's Advisory Committee on Clinical Trials of New Agents in Multiple Sclerosis. (Whitaker et al, 1995; Rudick et al, 1996) It was the consensus of this task force that important clinical dimensions not emphasized in existing rating scales, e.g. cognition, should be measured. The complete *MSFC Administration and Scoring Manual* is available for downloading at no cost at **www.nationalmssociety.org/MUCS_MSFC.asp**.

Administration Time

Administration time will vary depending upon the ability of the patient. Total administration time for all three measures should be approximately 20-30 minutes.

Administration Method

The MSFC measures are administered in person by a trained examiner. The examiner need not be a physician or nurse.

Scoring

The MSFC can produce scores for each of the three individual measures as well as a composite score. In addition, there are a variety of ways to calculate scores depending on the nature of the study and sample.

General Comments

The three component measures of the MSFC have been used for some time in MS prior to their being combined into a composite measure. Analysis of data from studies using these measures had pointed to their reliability, validity, and sensitivity. As a set of objective, quantitative assessment instruments, the MSFC represents a methodological advance over the ordinal clinical rating scales that have been used in MS in the past, e.g., the EDSS and Ambulation Index. A three-part instrument offering both separate and composite scores, the MSFC provides a versatile assessment method for investigational purposes with the ability to measure patients at various levels of disability, i.e., ambulation at less disabled levels of the EDSS, arm function at more disabled levels, and cognitive function at all levels. Since its introduction, the MSFC has seen increasing use in both clinical trials and other clinical studies.

Modified Fatigue Impact Scale (MFIS).

Description

The MFIS is a modified form of the Fatigue Impact Scale (Fisk et al, 1994b) based on items derived from interviews with MS patients concerning how fatigue impacts their lives. This instrument provides an assessment of the effects of fatigue in terms of physical, cognitive, and psychosocial functioning. The full-length MFIS consists of 21 items while the abbreviated version has 5 items. The abbreviated version can be used if time is limited but the full-length version has the advantage of generating subscales. The MFIS is one of the components of the Multiple Sclerosis Quality of Life Inventory (MSQLI).

Administration Time

Administration time is approximately 5-10 minutes for the full-length version and 2-3 minutes for the abbreviated version.

Administration Method

The MFIS is a structured, self-report questionnaire that the patient can generally complete with little or no intervention from an

interviewer. However, patients with visual or upper extremity impairments may need to have the MFIS administered as an interview. Interviewers should be trained in basic interviewing skills and in the use of this instrument.

Scoring

The total score for the MFIS is the sum of the scores for the 21 items. Individual subscale scores for physical, cognitive, and psychosocial functioning can also be generated by calculating the sum of specific sets of items. See the MSQLI: A User's Manual for details.

General Comments

The MFIS is easy to administer and focuses on the ways in which MS-related fatigue affects everyday life. As such it has high face validity for patients. The availability of the three subscales, physical, cognitive, and psychosocial functioning, may be useful to investigators interested in testing hypotheses concerning these different areas of function. However, the three subscales tend to correlate highly with one another, which limits their usefulness to some extent.

Multiple Sclerosis Quality of Life Inventory (MSQLI)

Description

The MSQLI is a battery consisting of 10 self-report questions that provide a quality of life measure that is both generic and MS-specific. (Fischer et al. 1999) The MSQLI consists of the following individual scales, 5 of which have both a standard and a short form. The 10 individual scales are as follows:

- **Health Status Questionnaire (SF-36)**, one of the most widely used generic measures of health-related quality of life and has been shown to discriminate between subjects with different chronic conditions and between subjects with different severity levels of the same disease

- **Modified Fatigue Impact Scale (MFIS)**, an assessment of the effects of fatigue in terms of physical, cognitive, and psychosocial functioning
- **MOS Pain Effects Scale (PES)**, an assessment of the ways in which pain and unpleasant sensations interfere with mood, ability to walk or move, sleep, work, recreation, and enjoyment of life
- **Sexual Satisfaction Scale (SSS)**, an indicator of overall sexual adjustment
- **Bladder Control Scale**, a brief assessment of bladder control and the extent to which bladder problems have an impact on everyday activities
- **Bowel Control Scale (BWCS)**, a brief assessment of bowel control and the extent to which bowel problems have an impact on everyday activities
- **Impact of Visual Impairment Scale (IVIS)**, an assessment of difficulties with simple visual tasks such as reading and watching television
- **Perceived Deficits Questionnaire (PDQ)**, a self-report measure of cognitive dysfunction. This instrument provides an assessment of several domains of cognitive functioning that are frequently affected in MS: attention, retrospective memory, prospective memory, and planning and organization
- **Mental Health Inventory (MHI)**, an assessment of several domains of mental health including anxiety, depression, behavioral control, positive affect, and general distress
- **MOS Modified Social Support Survey (MSSS)**, an assessment of several domains of social support including tangible support, emotional support, affective support, and positive support

Administration Time

If the standard, longer forms are used, the MSQLI takes approxi-

mately 45 minutes to administer. Using all 5 of the short forms, the time can be reduced to approximately 30 minutes. In addition, individual scales can be omitted to save additional time.

Administration Method
The MSQLI consists of a set of 10 self-report questionnaires that the patient can generally complete with little or no intervention from an interviewer. However, patients with visual or upper extremity impairments may need to have the MSQLI administered as an interview. Interviewers should be trained in basic interviewing skills and in the use of this instrument.

Scoring
Each of the individual scales generates a separate score. In addition, some of the scales generate subscales, e.g., the SF-36, the MFIS, the PDQ, and the MSSS. There is no global composite combining all the scales into a single score.

General Comments
The MSQLI addresses the concerns most relevant to the MS population. Although the standard version of the MSQLI is somewhat lengthy, short forms of many of the individual scales have been developed and these have psychometric properties comparable to the longer versions.

Clinical Trial Measures

To present much of this information in another way, the following chart lists the most common symptoms of MS (listed in order of reported prevalence) and tools commonly used by clinicians to measure their impact on the patient's progress. Again, the common practices of clinicians may or may not include the clinical trial measures described here, but are included here to illustrate their applicability to specific symptoms. This will help the claims reviewer better understand how the physician assesses the severity or impact of the most common symptoms of MS over time.

Symptom	Measurement Tool	Administration
Fatigue	1) Patient self report including discussion of fatigue level, possible causal factors (eg heat, unusual physical demands), compensatory actions/behaviors (eg greater use of mobility devices, naps) and impact on daily activities, including interruption in work schedule. 2) Modified Fatigue Impact Scale (MFIS) is a modified form of the Fatigue Impact Scale (Fisk et al, 1994b) based on items derived from interviews with MS patients concerning how fatigue impacts their lives. **This instrument provides an assessment of the effects of fatigue in terms of physical, cognitive, and psychosocial functioning.** The full-length MFIS consists of 21 items while the abbreviated version has 5 items. The abbreviated version can be used if time is limited but the full-length version has the advantage of generating subscales. The MFIS is one of the components of the MSQLI.	MFIS administration time is approximately 5-10 minutes for the full-length version and 2-3 minutes for the abbreviated version. The MFIS is a structured, self-report questionnaire that the patient can generally complete with little or no intervention from an interviewer. However, patients with visual or upper extremity impairments may need to have the MFIS administered as an interview. Interviewers should be trained in basic interviewing skills and in the use of this instrument.

Symptom	Measurement Tool	Administration
Ambulation	1) The 25' Timed Walk (T25-FW): The T25 -FW is a quantitative mobility and leg function performance test based on a timed 25' walk. It is the first component of the Multiple Sclerosis Functional Composite (MSFC) to be administered at each visit. The patient is directed to one end of a clearly marked 25-foot course and is instructed to walk 25 feet as quickly as possible, but safely. The time is calculated from the initiation of the instruction to start and ends when the patient has reached the 25-foot mark. The task is immediately administered again by having the patient walk back the same distance. Patients may use assistive devices when doing this task. 2) Clinical observation over time 3) Kurtzke Functional System Scores (FSS) and Expanded Disability Status Scale (EDSS) described at the beginning of this section.	Administration time of the T25-FW will vary depending upon the ability of the patient. Total administration time should be approximately 1-5 minutes. **Administration Method** The T25-FW is administered in person by a trained examiner. The examiner need not be a physician or nurse. **Scoring** The score for the T25-FW is the average of the two completed trials. This score can be used individually or used as part of the MSFC composite score. See the MSFC Administration and Scoring Manual for details. The FSS and EDSS are in the context of a standard neurological examination by neurologists, nurse practitioners and/or others specifically trained for this purpose. The time to administer such an exam will vary depending upon the ability of the patient.

Symptom	Measurement Tool	Administration
Bowel/ bladder problems	Patient self report including effect of bowel/bladder control problems on normal activities, sleep, mood, etc. 1) The Bladder Control Scale (BLCS) is based on items from the Bowel-Bladder Function Scale (Turnbull et al, 1992) and the Sickness Impact Profile. This four-item instrument provides a brief assessment of bladder control and the extent to which bladder problems have an impact on everyday activities. The BLCS is one of the components of the MSQLI.	BLCS administration time is approximately 2-3 minutes. **Administration Method** The BLCS is a structured, self-report questionnaire that the patient can generally complete with little or no intervention from an interviewer. However, patients with visual or upper extremity impairments may need to have the BLCS administered as an interview. Interviewers should be trained in basic interviewing skills and in the use of this instrument. **Scoring** The total score for the BLCS is the sum of the scores for the 4 items. See the MSQLI: A User's Manual for details. **General Comments** The BLCS is easy to administer and focuses on the basics of bladder control. Given the high frequency of bladder dysfunction among MS patients, the BLCS has high face validity. However, the scale was not designed as a comprehensive assessment of neurogenic bladder dysfunction and does not address issues such as urinary hesitancy and retention, detrusor-sphincter dyssnergia, etc.

Symptom	Measurement Tool	Administration
Bowel/ bladder problems (continued)	2) The Bowel Control Scale is based on items from the Bowel-Bladder Function Scale (Turnbull et al, 1992) and the Sickness Impact Profile. This five-item instrument provides a brief assessment of bowel control and the extent to which bowel problems have an impact on everyday activities. The BWCS is one of the components of the MSQLI.	2) Administration time is approximately 2-3 minutes. The BWCS is a structured, self-report questionnaire that the patient can generally complete with little or no intervention from an interviewer. However, patients with visual or upper extremity impairments may need to have the BWCS administered as an interview. Interviewers should be trained in basic interviewing skills and in the use of this instrument
Visual Disturbances	1) Standard of practice would include a clinical evaluation by a neuro- ophthalmologist to assess visual field defects, loss of acuity, and nystagmus (uncontrolled eye movements) 2) Impact of Visual Impairment Scale (IVIS) The IVIS was based on items derived from the Functional Capacities Assessment developed by the Michigan Commission for the Blind. This five-item instrument provides an assessment of difficulties with simple visual tasks such as reading and watching television. The IVIS is one of the components of the MSQLI.	2) Administration time is approximately 2-3 minutes. The IVIS is a structured, self-report questionnaire that the patient can generally complete with little or no intervention from an interviewer. However, patients with visual or upper extremity impairments may need to have the IVIS administered as an interview. Interviewers should be trained in basic interviewing skills and in the use of this instrument

Symptom	Measurement Tool	Administration
Cognitive Problems	1) Patient Self Report, which may include responses to physicians' questions regarding problems with memory, reasoning, concentrating, participating in workplace discussions, tolerating stress, anxiety or interruptions and more. 2) Minimal Assessment of Cognitive Function in MS (MACFIMS) 7 neuro-psychological tests covering five cognitive domains commonly impaired in MS (processing speed/ working memory, learning and memory, executive functional, visual-spatial processing, and word retrieval)	As a tool specific to MS, MACFIMS is usually administered by a MS specialist. Time = 90 mins
Tremor	1) clinical evaluation 2) 9 Hole Peg Test The 9-HPT is a brief, standardized, quantitative test of upper extremity function. It is the second component of the MSFC to be administered at each visit. Both the dominant and non-dominant hands are tested twice. The patient is seated at a table with a small, shallow container holding nine pegs and a wood or plastic block containing nine empty holes. On a start command when a stopwatch is started, the patient picks up the nine pegs one at a time as quickly as possible, puts them in the nine	2) Administration time will vary depending upon the ability of the patient. Total administration time should be approximately 10 minutes or less. The 9-HPT is administered in person by a trained examiner. The examiner need not be a physician or nurse.

Symptom	Measurement Tool	Administration
Tremor (continued)	holes, and, once they are in the holes, removes them again as quickly as possible one at a time, replacing them into the shallow container. The total time to complete the task is recorded. Two consecutive trials with the dominant hand are immediately followed by two consecutive trials with the non-dominant hand.	

Appendix A — Social Security Administration's Determination of Disability from MS

Claims reviewers and other professionals involved in the adjudication of disability benefits may be aware of the procedures used by the Social Security Administration (SSA) in their evaluations of claims for benefits administered by this federal agency. In comparison with private insurers, the SSA's procedures for evaluating claims and determining disability are standardized and codified in the federal law. The Social Security Act defines disability as "the inability to engage in any substantial gainful activity (SGA) by reason of any medically determinable physical or mental impairment(s) which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months."

Additionally, the SSA recognizes a number of physical and mental impairments whose presence in an applicant provides the basis for eligibility for disability benefits. At this writing, four such impairments due to MS are recognized, although a revision (and likely expansion) of them is currently underway. At present, the four recognized areas are as follows:

1) Disorganization of motor function, described as a significant and persistent disorganization of motor function in two extremities, resulting in sustained disturbance of gross and dexterous movements, or gait and station.

2) Impairment of visual acuity, including:

- remaining vision in the better eye after best correction is 20/200 or less;

- contraction of peripheral visual fields in the better eye
  - to 10 degrees or less from the point of fixation; or
  - so the widest diameter subtends an angle no greater than 20 degrees; or
  - to 20% or less visual field efficiency

3) Mental impairment, described as psychological or behavioral abnormalities associated with a dysfunction of the brain. History and physical examination or laboratory tests demonstrate the presence of a specific organic factor judged to be etiologically related to the abnormal mental state and loss of previously acquired functional abilities.

The required level of severity for these disorders are met when the requirements in both A and B are satisfied, or when the requirements in C are satisfied.

A. Demonstration of a loss of specific cognitive abilities or affective changes and the medically documented persistence of at least one of the following:

1. Disorientation to time and place; or
2. Memory impairment, either short-term (inability to learn new information), intermediate, or long-term (inability to remember information that was known sometime in the past); or
3. Perceptual or thinking disturbances (e.g., hallucinations, delusions); or
4. Change in personality; or
5. Disturbance in mood; or
6. Emotional lability (e.g., explosive temper outbursts, sudden crying, etc.) and impairment in impulse control; or

7. Loss of measured intellectual ability of at least 15 I.Q. points from premorbid levels or overall impairment index clearly within the severely impaired range on neuropsychological testing, e.g., Luria-Nebraska, Halstead-Reitan, etc;

AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or
2. Marked difficulties in maintaining social functioning; or
3. Marked difficulties in maintaining concentration, persistence, or pace; or
4. Repeated episodes of decompensation, each of extended duration;

OR

C. Medically documented history of a chronic organic mental disorder of at least two years duration that has caused more than a minimal limitation of ability to do basic work activities, with symptoms or signs currently attenuated by medication or psychosocial support, and one of the following:

1. Repeated episodes of decompensation, each of extended duration; or
2. A residual disease process that has resulted in such marginal adjustment that even a minimal increase in mental demands or change in the environment would be predicted to cause the individual to decompensate; or
3. Current history of one or more years' inability to function outside a highly supportive living arrangement, with an indication of continued need for such an arrangement.

4) Fatigue, described as significant, reproducible fatigue of motor function with substantial muscle weakness on repetitive activity, demonstrated on physical examination, resulting from neurological dysfunction in areas of the central nervous system known to be pathologically involved by the multiple sclerosis process.

Appendix B — Qualifications of Reviewing Clinicians

When a disability review requires input from a health care professional with experience in MS, either for clinical assessment of an application or to conduct an examination of a claimant as a second opinion, the National MS Society strongly recommends that clinicians with demonstrable expertise in MS be utilized. While neurologists or physiatrists may have a general familiarity with multiple sclerosis, its relatively low prevalence in the United States, and its complex and unique clinical dimensions, means that even board certified neurologists may not have a truly up-to-date and comprehensive knowledge of the disease.

Recently, in order to improve its adjudication process, the Social Security Administration asked the National MS Society to define what constitutes 'MS expert' with regard to physicians, psychologists, and nurses. Below are our listings of suggested qualifications for each of these professions as shared with the Social Security Administration. We hope these listings can be helpful to the private disability insurer community as well.

- Physicians should be board certified, preferably in neurology or rehabilitation medicine, and with at least one of the following additional qualifications:
  - A member of the Medical Advisory Board of the Society
  - A member of a Clinical Advisory Committee of a chapter of the Society
  - A physician working at a Society affiliated facility
  - A physician working at a MS center that is a member of the Consortium of MS Centers

- A member of the Multiple Sclerosis Section of the American Academy of Neurology

- In order to qualify, MS specialty nurses must be at the RN level or above, have at least a bachelor's degree, be licensed in the United States, and with at least one of the following additional qualifications:
  - A member of the International Organization of MS Nurses
  - A member of a Clinical Advisory Committee of a chapter of the Society
  - A nurse working at a Society affiliated facility
  - A nurse working at a MS center that is a member of the Consortium of MS Centers
  - Certified in MS nursing by the Multiple Sclerosis International Credentialing Board

- Psychologists must have a Ph.D. in a relevant psychological specialty, must be licensed to practice in the United States and with at least one of the following additional qualifications:
  - A member of a Clinical Advisory Committee of a chapter of the Society
  - A psychologist working at a Society affiliated facility
  - A psychologist working at a facility that is a member of the Consortium of MS Centers

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The National MS Society Task Force on Private Disability Insurance

Mark Battista, MD
Mary Fuller
Howard Kessler, Ph.D.
Deborah Miller, LISW, Ph.D.
April Paul, MD
Bonnie G. Rafel, Esq.
Mark Scherzer, Esq.

National MS Society Staff

Kimberly Calder, MPS
Nicholas LaRocca, Ph.D.
Dorothy Northrop, MSW, ACSW
John Richert, MD