



The Risk Sharing Scheme for Disease Modifying Therapies in MS

What is the Risk Sharing Scheme?

The Risk Sharing Scheme (RSS) is a unique programme which was set up to ensure that anyone with multiple sclerosis (MS) who meets the Association of British Neurologists (ABN) recommended eligibility criteria is able to access disease modifying therapies (DMTs) through the NHS in a cost-effective manner. The scheme is a voluntary partnership between the four UK health departments, the pharmaceutical industry and MS charities.

This leaflet aims to provide an overview of the scheme: who is involved; how it is run; how the data collated will be used and the benefits of the scheme for management of MS in the UK.

Why was the scheme necessary?

A National Institute for Health and Clinical Excellence (NICE) assessment in 2002 concluded that DMTs (see box overleaf), were effective in the treatment of MS. However, it was felt that it was not possible to extrapolate the data available to evaluate their long-term cost-effectiveness, particularly given the unpredictable nature of this relapsing remitting condition and the potential for subsequent disability. The effects of MS can be devastating and its impact is life-long. The data showed that the DMTs had reduced the frequency and severity of MS relapses, slowed the progression of disability, reduced hospitalisations for MS and decreased the need for other drugs such as high dose steroids.

For these reasons, NICE recommended that the Department of Health (DH), National Assembly for Wales and manufacturers consider joint action to allow the drugs to be secured in a cost-effective way. As a result of this the scheme was set up to allow access to treatment and care and to evaluate the long-term cost-effectiveness of DMTs over ten years. The DH in England has underpinned the scheme with a statutory funding requirement which applies to patients eligible for treatment under the scheme, including those newly diagnosed using the ABN's 2001 guidelines, which effectively puts the scheme on a par with positive recommendations from NICE.





Ensuring cost-effectiveness of DMTs

The scheme aims to ensure that the DMTs can be provided to all eligible patients with MS while measuring the cost-effectiveness of these treatments in clinical practice. The cost-effectiveness is monitored via data from a cohort of over 5,000 patients with MS. Clinical outcomes from these treated patients are entered into a health economic model, which allows monitoring of the cost-effectiveness of each of the drugs in the scheme. These data will be assessed at two year intervals over ten years. The price the NHS pays for each drug may be adjusted at the two-yearly analysis points to ensure it is kept at an agreed threshold, thus guaranteeing the NHS continues to acquire the drugs cost-effectively.

Setting up the scheme

In 2002 the details of the scheme were agreed by the DH, National Assembly for Wales, Scottish Executive and Northern Ireland Department for Health, Social Services and Public Safety in conjunction with the four manufacturers of DMTs.

The steering group, which includes representatives from the key stakeholders and independent scientific advisors is responsible for overseeing the project.

To ensure the independence of the scheme an independent Scientific Advisory Group was established and the steering group appointed the MS Trust as the secretariat. The MS Trust manage the contractor who collates and analyses the data.

Initially SchARR (Sheffield School of Health and Related Research) were appointed as the contractor, however they chose not to re-tender when the initial contract expired in 2005. Parexel was then appointed following an open tender process.

Eligibility criteria for the scheme

The ABN recommends beta interferons or glatiramer acetate for all patients with relapsing remitting MS who:

- Can walk independently (beta interferons) or at least 100 metres without assistance (glatiramer acetate)
- Have had at least two clinically significant relapses in the last two years
- Are over 18

The ABN recommends beta interferons (not glatiramer acetate) for patients with secondary progressive MS who:

- Can walk at least ten metres with or without assistance
- Have had two or more disabling relapses in the past two years
- Have had a minimal increase in disability due to gradual progression in the last two years
- Are over 18

When patients are prescribed a DMT by their neurologist the decision on which product is prescribed is taken jointly by the neurologist and the individual. At the time of prescription the patient will receive information and support for the treatments.

How are patients monitored?

For the cohort of patients that are being monitored, data including the patient's Expanded Disability Status Score (EDSS), a method of quantifying disability in MS, are recorded at their initiation into the scheme and re-evaluated and recorded annually. Parexel, who are contracted to implement the scheme, collate and analyse these data. It is a long-term observational study of UK clinical practice rather than a clinical trial.

The initial two year analysis is underway (two years after the last person was recruited to the cohort). While compliance has been good, the Scientific Advisory Group (SAG) has already expressed concerns about the limitations in the measurement of disability and the appropriateness of the natural history comparator. The SAG is currently considering its advice for the DH. The monitoring in the Risk Sharing Scheme will continue over a period of ten years.

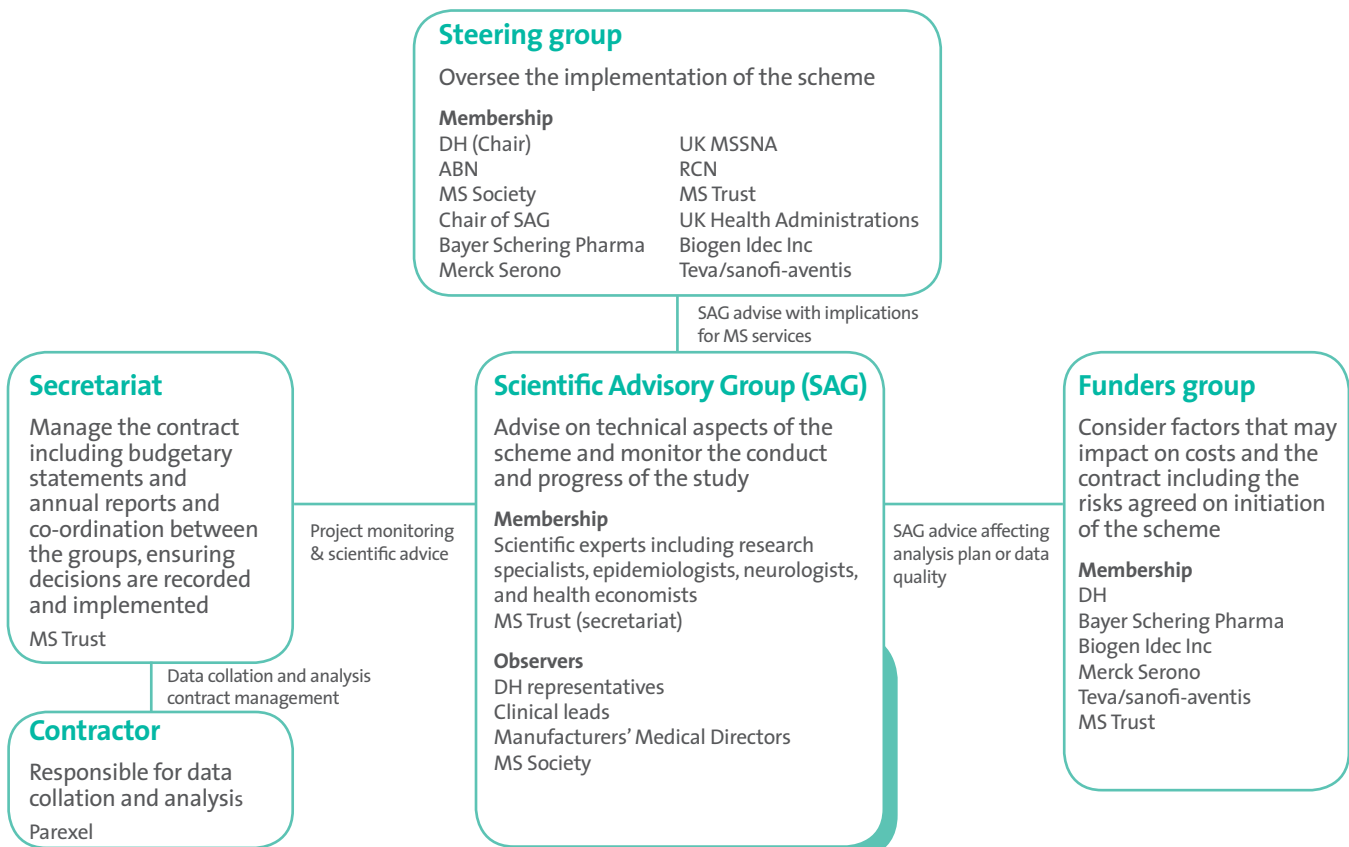
The current position

Over 70 specialist neurology centres are now involved in the scheme across the UK. By April 2005 a cohort of 5,000 patients was being regularly monitored at these centres. Although the target research cohort has been reached all eligible patients should still receive drug therapy on the NHS through the scheme. Currently there are approximately 10,000 people receiving drug therapy in the UK through the scheme.

Which DMTs are available in the RSS?

- Avonex® (interferon-beta 1a) - Biogen Idec Inc
- Betaferon® (interferon-beta 1b) - Bayer Schering Pharma
- Copaxone® (glatiramer acetate) - Teva /sanofi aventis
- Rebif® (interferon-beta 1a) - Merck Serono

Governance of the Risk Sharing Scheme



How is the scheme funded?

The DH and the four manufacturers of DMTs in the UK; Bayer Schering Pharma, Biogen Idec Inc, Merck Serono and Teva/sanofi aventis, provide the funding for the scheme.

The companies have also agreed to provide additional funding to the NHS to improve the quality of care for people with MS. This has included infrastructure support such as specialist nursing, therapy or admin support, training and education for the MS specialist nurses.

The impact of the scheme on MS management in the UK

Since its inception, the scheme has provided more than 10,000 people with relapsing remitting MS, and in some cases with secondary progressive MS, access to DMTs in a cost-effective manner.

The scheme has strengthened the development of a UK-wide network of over 70 MS specialist treatment centres. This has improved the care and support available to people with MS.

The scheme has led to an increase in the number of MS Specialist Nurses in the UK to over 200. Funding from the scheme has been used to support the creation of many of these posts.

Key Milestones

In 2002 NICE suggested the UK health authorities and DMT manufacturers consider joint action to allow DMTs to be secured in a cost-effective way for people with MS

The target cohort to be monitored of 5,000 patients was reached by April 2005

Over 10,000 patients have had access to DMTs through the scheme

Over 200 MS Nurse Specialists are now working in the UK

11.5% of people with MS are now on a DMT

Results from the first two year data analysis are anticipated in early 2008, with further analysis every two years

The scheme is scheduled to run for ten years

References

- 1 HSC 2002/2004. Cost-effective provision of disease modifying therapies for people with multiple sclerosis, Department of Health, 4 February 2002
- 2 Drug treatments for multiple sclerosis (beta interferons and glatiramer acetate); risk-sharing scheme (HSC 2002/2004) briefing note November 2006, Department of Health, 16 November 2006
- 3 NICE Technology Appraisal Guidance No 32. Beta interferon and glatiramer acetate for the treatment of multiple sclerosis, January 2002
- 4 Guidelines for the use of Beta Interferons and Glatiramer Acetate in Multiple Sclerosis, Association of British Neurologists, January 2001

This leaflet is sponsored by Bayer Schering Pharma, Biogen Idec Inc, Merck Serono and Teva/sanofi-aventis.

