The Risk Sharing Scheme for Disease Modifying Therapies in MS

The purpose of this leaflet is to give an update on progress with the Risk Sharing Scheme for Disease Modifying Therapies (DMTs) in Multiple Sclerosis. The first edition of the leaflet was published in November 2007 and gives the full background to the scheme (available at www.doh.gov.uk)

We would like to take this opportunity to thank all the NHS staff involved in the scheme for their hard work and good will in continuing to collect data on all patients involved in the scheme, and the patients themselves for agreeing to be part of it.

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.

The current position

The Multiple Sclerosis Risk Sharing Scheme (MS RSS) is in its fifth year of collecting data from a cohort of over 5,000 patients with MS. Currently we estimate that there are approximately 12,000 people receiving drug therapy in the UK through the scheme.

Data from the first two years of follow-up have now been collected, analysed and interpreted by a group independent of the study funders. Their paper (published in the British Medical Journal and accessible at www.bmj.com) concludes that it is premature to reach any conclusion about the cost-effectiveness of the drugs used to treat relapsing remitting multiple sclerosis from this first interim analysis.

Important methodological issues, including the need for an alternative comparator dataset, the potential bias resulting from missing data, and the impact of the 'no improvement' rule (utilising the conventions of the current dataset, patients are constrained to remain stable or worsen, improvements are not possible) are being addressed and long-term follow up of all patients is essential to secure meaningful results. It is anticipated that future analyses will be more informative.

Multiple Sclerosis Trust MS

ABPI

DH Department of Health

The Scientific Advisory Group to the RSS have discussed the first two year results of the MS RSS and have identified an alternative comparator dataset that will match more closely the patient population that is now being treated in the UK. To this end the Neurology Department of the University of British Columbia have agreed to share data and information with the Scientific Advisory Group to the UK Multiple Sclerosis Risk Sharing Scheme. This arrangement will provide the alternative comparator dataset that is required to get useful analyses from the scheme in the future.

Ensuring cost effectiveness of DMTs

DMTs are currently purchased at a cost effective price as assessed by the NICE model. The scheme aims to ensure 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 are assessed at two year intervals over ten years. Actual and expected benefits of the drugs are compared and if there is a significant shortfall in actual compared to expected benefit for a particular product, the price of the product is reduced for the following 2-year period. (See 'Current position' for details of the results of the first two year analysis).

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.

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

How is the scheme funded?

The Scheme is equally funded by DH and the four manufacturers of DMTs in the UK; Bayer Schering Pharma, Biogen Idec Inc., Merck Serono and Teva/sanofi aventis.

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.

Why was the scheme necessary?

The Risk-Sharing Scheme is the mechanism that makes the DMTs, interferon beta and glatiramer acetate, available on the NHS to people with certain types of MS. It was established as a voluntary partnership between the four UK health departments, the pharmaceutical industry, the MS charities and professional bodies.

Prior to the scheme, provision varied widely between areas. The scheme was set up by the Department of Health in 2002 to address these inequalities and also in the light of an assessment by the National Institute of Health and Clinical Excellence (NICE), which in the absence of longer term data, judged the drugs not to be cost effective.

The scheme allows access to treatment and care and evaluates the long-term cost-effectiveness of DMTs over 10 years.

Under the scheme, all those with relapsing/remitting MS, and those with secondary progressive MS in which relapses are the dominant feature, who meet the criteria laid down by the Association of British Neurologists (ABN) in 2001 are eligible for the drugs. The eligibility criteria for the scheme are set out in detail at www.dh.gov.uk

The 'risk' element of the scheme involves a sharing of the financial risk between the NHS and the participating pharmaceutical companies.

Current Governance of the Risk Sharing Scheme

Steering group

Oversee the implementation of the scheme

Membership

DH (Chair)
ABN
Chair of SAG
Bayer Schering Pharma
Merck Serono
UK MSSNA
RCN
MS Trust
UK Health Administrations
Biogen Idec Inc
Teva/sanofi-aventis

Secretariat

Manage the contract including budgetary statements and annual reports and co-ordination between the groups, ensuring decisions are recorded and implemented

MS Trust

Project monitoring & scientific advice

Data collation and analysis contract management

Contractor

Responsible for data collation and analysis

Parexel

Scientific Advisory Group (SAG)

Advise on technical aspects of the scheme and monitor the conduct and progress of the study

Membership

Scientific experts including research specialists, epidemiologists,and health statisticians
MS Trust (secretariat)

Observers

DH representatives
Clinical leads
Manufacturers' Medical Directors
NICE and MS Trust (secretariat)

SAG advice affecting analysis plan or data quality

Funders group

Consider factors that may impact on costs and the contract including the risks agreed on initiation of the scheme

Membership

DH
Bayer Schering Pharma
Biogen Idec Inc
Merck Serono
Teva/sanofi-aventis
MS Trust (observers)'

The impact of the scheme on MS management in the UK

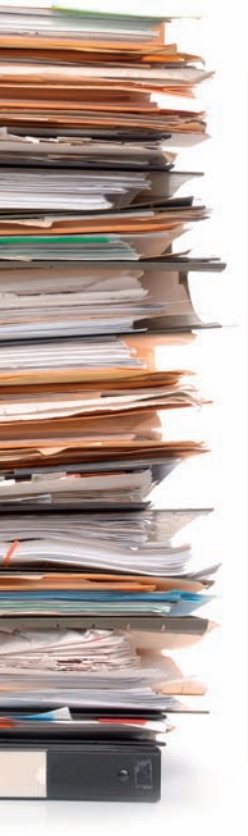
The scheme has improved the care and support offered to all people with MS. Since its inception, it has provided more than 12,000 people with relapsing remitting MS and in some cases with secondary progressive MS, access to DMTs in a cost-effective manner.

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.

The data are also valuable for other reasons. For example, one benefit of the scheme is that clinics have access to their patients' updated data. This is extremely useful to the clinicians and to academic and clinical researchers.

It should be noted that the value of the data collected from this large 'cohort' will become more useful, the longer we collect it. This will give us a better idea of how the disease progresses over the longer-term and how cost-effective the drugs are in treating it.



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 12,000 patients have had access to DMTs through the scheme

Over 200 MS Nurse Specialists are now working in the UK

Around 12% of people with MS are now on a DMT

Results from the first two year data analysis were published in the British Medical Journal in 2009

2010 - Potential switch to use of British Columbia comparator dataset to enable more accurate/informed analyses to be made from the scheme in the future.

Summer 2010 - The scheme's Scientific Advisory Group to sign off the revised Statistical Analysis Plan

The scheme is scheduled to run until 2015

References

- HSC 2002/2004. Cost-effective provision of disease modifying therapies for people with multiple sclerosis, Department of Health, 4 February 2002
- Drug treatments for multiple sclerosis (beta interferons and glatiramer acetate); risk-sharing scheme (HSC 2002/04) briefing note November 2006, Department of Health, 16 November 2006
- NICE Technology Appraisal Guidance No 32. Beta interferon and glatiramer acetate for the treatment of multiple sclerosis, January 2002
- 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.

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Date of preparation: October 2010

Stock code: UK.PH.H&N.BET.2010.109