

Neurology RESEARCH REVIEW™

SUPPLEMENT:
MULTIPLE SCLEROSIS

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Issue 89 – 2025

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Abbreviations used in this issue

AQP4 = aquaporin-4
EDSS = Expanded Disability Status Scale
JCV = John Cunningham virus
MRI = magnetic resonance imaging
MS = multiple sclerosis
NMOSD = neuromyelitis optica spectrum disorder
PIRA = progression independent of relapse activity
pwMS = people with MS
RRMS = relapsing-remitting MS

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Welcome to the latest issue of Neurology Research Review, focusing specifically on MS.

In this issue, Swedish investigators report the impact of progression independent of relapse activity (PIRA) on quality of life in people with RRMS, a review of postmarketing data confirms an association between fumaric acid ester drugs and serious gastrointestinal adverse events, analysis of a multicentre cohort evaluates the significance of trigeminal neuralgia within the disease course of MS, and Japanese investigators report the utility of satralizumab for relapse prevention in patients with NMOSD. Also in this issue, a local study looks at the prevalence of MS in NZ.

We hope you find these and the other selected studies interesting, and welcome your feedback.

Kind regards,

Dr Jennifer Pereira

jenniferpereira@researchreview.co.nz

Quality of life is decreased in persons with relapsing-remitting multiple sclerosis experiencing progression independent of relapse activity

Authors: Lindberg S et al.

Summary: This prospective observational study in Sweden investigated the impact of progression independent of relapse activity (PIRA) on quality of life in patients with RRMS. A total of 125 newly diagnosed individuals with RRMS were assessed over 5 years using the EuroQoL-5-Dimension-3-level (EQ-5D-3L), EQ-visual analogue scale (EQ-VAS) and 29-item MS-Impact-Scale (MSIS-29). Patients were grouped according to whether they had PIRA (worsening EDSS independent of relapses) or not. At 5 years, 19.2% of patients had PIRA. Linear mixed-effects models showed that non-PIRA patients had better quality of life than PIRA patients over the 5-year study period (EQ-5D-3L: $p < 0.001$; EQ-VAS: $p < 0.001$; MSIS-29-PHYS: $p < 0.001$; and MSIS-29-PSYCH: $p < 0.001$).

Comment: As novel therapies for the treatment of PIRA become available, identifying those patients who will benefit and as early as possible will be an important part of our clinical practice. Our current strategy is to look for progressive neurological symptoms and signs despite high-efficacy disease-modifying therapy and analyse MRI scans for slowly expanding lesions (SELs) or magnetic rim lesions (MRLs). The most promising treatment for PIRA is tolebrutinib – a Bruton tyrosine kinase inhibitor administered as a daily pill which can cross the blood-brain barrier and target smouldering immunological disease. Studies such as this quality of life study identify other measures that will likely also be useful.

Reference: *Mult Scler.* 2025;31(5):548–57

[Abstract](#)

Severe gastrointestinal adverse reactions including perforation, ulceration, hemorrhage, and obstruction: A fumaric acid ester class new safety risk

Authors: Kim T et al.

Summary: This study reviewed the FDA Adverse Events Reporting System database and published medical literature to identify cases of serious gastrointestinal (GI) events in patients taking fumarate acid ester (FAE) drugs for the treatment of MS. Forty-nine cases of GI adverse reactions (perforation, ulceration, haemorrhage, and obstruction) causally associated with FAE drugs were identified. Most of them occurred within 4 months of drug initiation and required hospitalisation. Ten cases required red blood cell transfusions, nine required surgical intervention, and two patients died.

Comment: In NZ, dimethyl fumarate (Tecfidera®) is funded by PHARMAC. It is administered as a twice-daily tablet. Due to the known side effects of flushing and GI upset, patients starting this drug are advised to start with 120mg once daily in a "Tecfidera® Sandwich" which means – eat food, take tablet, eat more food – to minimise these side effects. The dose is slowly increased to 240mg twice daily. In clinical practice as per the clinical trials, most patients will tolerate dimethyl fumarate well when this strategy is followed. Given the potential for serious harm detailed in this study (GI perforation, ulceration, haemorrhage and obstruction), 75% of which occurred within the first 4 months of starting treatment, consider further investigations when significant GI symptoms are reported and an early switch to an alternative treatment is advised.

Reference: *Mult Scler.* 2025;31(5):578–86

[Abstract](#)

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Trigeminal neuralgia within the disease course of MS: Diagnostic and therapeutic implications from a multicenter cohort

Authors: Laakso SM et al.

Summary: This study examined the diagnostic and therapeutic implications of trigeminal neuralgia in pwMS. Of 171 pwMS at three international sites, 0.9–1.9% were diagnosed with trigeminal neuralgia. It was the first potential demyelinating symptom in 9.9% of patients, but in most (86%) of them it occurred after their MS diagnosis (median 13–16 years). One-fifth of patients had a clinical relapse within 6 months of trigeminal neuralgia onset.

Comment: In a stretched public healthcare system where MRI imaging is a precious resource and the most common cause of trigeminal neuralgia is neurovascular compression, this article acts as a reminder that MRI imaging should be undertaken to identify those with trigeminal neuralgia as a presenting symptom of MS. Fifteen percent of patients in this study experienced trigeminal neuralgia prior to a formal diagnosis of MS and 20% of pwMS had a relapse within 6 months of trigeminal neuralgia.

Reference: *Mult Scler.* 2025;31(5):607–11

[Abstract](#)

Hypnosis and mindfulness audio recordings for reducing fatigue in individuals with multiple sclerosis

Authors: Jensen MP et al.

Summary: This randomised controlled trial evaluated the impact of therapeutic hypnosis and mindfulness meditation on fatigue in pwMS. 333 pwMS and fatigue were randomised 1:1:1 to receive access to therapeutic hypnosis audio recordings, access to mindfulness meditation audio recordings, or no access to recordings (treatment as usual) for 28 weeks. Individuals that were assigned to the hypnosis or mindfulness meditation groups reported significantly greater reductions in fatigue impact, sleep disturbance, and depressive symptom severity than controls after 4 weeks. These improvements were maintained at 16 and 28 weeks after treatment assignment.

Comment: Fatigue is a disabling symptom in MS. It is the most common reason that pwMS reduce working hours or stop paid employment. Management of fatigue remains a common topic of discussion in MS clinics. Here is another non-medical strategy to suggest to your patients that may offer some symptomatic improvement – the authors are considering developing software to enable the delivery of the recordings used in this trial to pwMS via smartphones.

Reference: *Mult Scler.* 2025; published online Apr 17

[Abstract](#)

The team at Research Review want to take this opportunity to thank Dr Jennifer Pereira for her valuable contributions to Neurology Research Review over the years. We wish her well with future plans.



INDEPENDENT COMMENTARY BY
Dr Jennifer Pereira BHB, MBChB, FRACP, MD

After undergraduate training in medicine at the University of Auckland, Jennifer trained in neurology at Auckland City Hospital. Postgraduate training consisted of an MS research fellowship, with the Therapeutic Immunology Group in the Department of Clinical Neurosciences, University of Cambridge (UK). **For full bio** [CLICK HERE](#).

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Effectiveness of satralizumab in a real-world clinical setting in Japan: Interleukin-6 receptor inhibition in neuromyelitis optica spectrum disorder: A six-month interim analysis of a multicenter medical chart review

Authors: Fujihara K et al.

Summary: This real-world study evaluated the efficacy of satralizumab for relapse prevention in AQP4-positive patients with NMOSD. The medical charts of 124 patients with NMOSD (mean age 51.1 years, 93.5% female; mean disease duration 7 years) who initiated satralizumab at one of 25 sites in Japan were reviewed. 120 patients (96.6%) were relapse-free at 26 weeks. The annualised relapse rate was 0.069 at week 26 compared with 0.445 in the year prior to satralizumab initiation. Treatment with satralizumab permitted dose reduction of concomitant oral glucocorticosteroids and immunosuppressants over 26 weeks.

Comment: In NZ, rituximab is available for the treatment of NMOSD if patients meet criteria required in a Special Authority. They must have a severe relapse or a relapse despite mycophenolate and prednisone. Access to funded satralizumab would need to be through a named patient application (NPPA) and this treatment would be appropriate for those failing rituximab. This would occur rarely; relapse rates in the small clinical trials of rituximab for AQP4-positive NMOSD were analysed in a 2022 meta-analysis and showed 70–90% of patients will be relapse free on rituximab.

Reference: *Mult Scler Relat Disord.* 2025;98:106384

[Abstract](#)

High-dose vitamin D in clinically isolated syndrome typical of multiple sclerosis: The D-Lay MS randomized clinical trial

Authors: Thouvenot E et al., for the D-Lay MS Investigators

Summary: The D-Lay MS trial investigated the effects of high-dose cholecalciferol on disease activity in patients with clinically isolated syndrome (CIS) typical of MS. At 36 MS centres in France, 316 untreated patients aged 18–55 years with CIS duration <90 days and serum vitamin D levels <100 nmol/L were randomised 1:1 to receive oral cholecalciferol 100,000 IU or placebo every 2 weeks for 24 months. The primary outcome was disease activity, defined as occurrence of a relapse and/or MRI activity (new and/or contrast-enhancing lesions) over 24 months of follow-up. Disease activity was observed in 60.3% of patients in the vitamin D group and 74.1% in the placebo group at 24 months (hazard ratio 0.66, 95% CI 0.50–0.87; $p=0.004$), and median time to disease activity was longer in the vitamin D group (432 vs 224 days; $p=0.003$).

Comment: Low vitamin D has a role in immune regulation, and it is via this mechanism that low vitamin D acts as a risk factor for the development of MS. It has been postulated that vitamin D supplementation might be beneficial to pwMS. In an earlier attempt to answer this question, the PrevANZ study published in *Brain* in 2024 was undertaken in Australia and NZ and found no reduction in MS disease activity with daily dosing of vitamin D – either 1000, 5000 or 10,000 IU over the 48 weeks of the study. The major differences between the PrevANZ and the D-Lay study reported here, are that the D-Lay study used a dosing of 100,000 IU every fortnight, and those enrolled in the PrevANZ study were not vitamin D deficient – whereas the D-Lay study recruited only pwMS with low vitamin D levels. The current recommendations stand: replace vitamin D to the normal range and start disease-modifying therapy in those with RRMS.

Reference: *JAMA* 2025;333(16):1413–22

[Abstract](#)

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*In the open-label, observational RRMS TOP study, with analysis up to 10 years, **TYSABRI® consistently demonstrated reductions in both ARR and CDW that were maintained long-term.**^{1-3†}

†ARR decreased from 1.99 at baseline to 0.24 at 1 year of treatment and remained ≤0.20 from 2 to 10 years of treatment; at 10 years follow-up, the cumulative probability of 24-week CDW was 27.8%; secondary endpoints (n=6,148). Findings from open-label, observational studies should be interpreted with caution. The TOP study is based on TYSABRI IV.¹



Long-term safety in the 10-year TOP study was consistent with TYSABRI's known safety profile and no new safety findings were identified (primary endpoint).^{1,3}

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WARNING: TYSABRI is associated with an increased risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that may lead to death or severe disability. Healthcare professionals should closely monitor patients on TYSABRI for any new or worsening signs or symptoms that may be suggestive of PML. TYSABRI dosing should be withheld immediately at the first signs or symptoms suggestive of PML. For diagnosis, an evaluation that includes a gadolinium-enhanced magnetic resonance imaging (MRI) scan of the brain, neurological assessment and cerebrospinal fluid analysis for JC viral DNA are recommended (see section 4.3 CONTRAINDICATIONS and section 4.4 PRECAUTIONS, Progressive Multifocal Leukoencephalopathy).

INDICATIONS: Monotherapy for the treatment of patients with relapsing remitting multiple sclerosis (MS) to delay the progression of physical disability and to reduce the frequency of relapse. **DOSE:** 300 mg by IV infusion or two subcutaneous injections every four weeks. IV infusion over approx. 1 hour with 1 hour observation. Subcutaneous injections within 30 minutes with 1 hour observation. **CONTRAINDICATIONS:** Known hypersensitivity to natalizumab, its excipients, or murine derived proteins. History of, or current, progressive multifocal leukoencephalopathy (PML). Patients with increased risk for opportunistic infections, including those immunocompromised due to current or recent immunosuppressive therapies or systemic medical conditions. TYSABRI should not be administered in combination with immunomodulatory agents. **PRECAUTIONS:** TYSABRI has been associated with PML, other opportunistic infections (including herpes infections with CNS manifestations and acute retinal necrosis), hypersensitivity reactions and liver injury. If any of these adverse events occur discontinue therapy. Patients should be regularly monitored, with continued vigilance for PML for 6 months following cessation of TYSABRI. Early diagnosis, clinical and MRI monitoring and stopping therapy are important in managing PML. Annual MRI recommended; consider more frequent MRIs in patients at higher risk of PML. The following risk factors are associated with an increased risk of PML: (i) presence of anti-JCV antibodies, (ii) treatment duration especially beyond 2 years in anti-JCV antibody positive patients, (iii) immunosuppressant use prior to receiving TYSABRI. Patients who have all three risk factors have a significantly higher risk of PML and the benefit-risk of continuing treatment with TYSABRI should be carefully considered. In patients not previously treated with immunosuppressants, index value further stratifies risk of developing PML. Anti-JCV antibody testing should be performed prior to initiating TYSABRI therapy or in patients already receiving TYSABRI in whom antibody status is unknown. Anti-JCV antibody assays should not be used to diagnose PML and should not be performed for at least two weeks following plasma exchange or 6 months following use of IVIG. If symptoms suggestive of PML occur, immediate dose suspension is required until PML is excluded. If initial investigations prove negative, but clinical suspicion for PML still remains, TYSABRI should not be restarted and repeat investigations should be undertaken. If a patient develops PML, permanently discontinue TYSABRI to enable restoration of immune function. In patients that develop PML, monitor for development of Immune Reconstitution inflammatory Syndrome (IRIS) after removal of TYSABRI (e.g. via plasma exchange (PLEX)). IRIS presents as a worsening in neurological status that may be rapid, which can lead to serious neurological complications and may be fatal. No difference was observed on 2-year survival after PML diagnosis between patients who received PLEX and those who did not. Symptoms of JCV granule cell neuronopathy are similar to PML. Careful consideration is required before commencing other therapies following discontinuation of TYSABRI. Use in Pregnancy Category C. TYSABRI has been detected in human milk. **ADVERSE EFFECTS:** Very Common: nasopharyngitis, dizziness, nausea. Common: urinary tract infection, urticaria, headache, vomiting, arthralgia, rigors, pyrexia, fatigue. Serious: Opportunistic infections, hypersensitivity reactions, liver injury, uncommon thrombocytopenia and immune thrombocytopenic purpura, rare haemolytic anaemia. **NAME AND ADDRESS OF SPONSOR:** Biogen NZ Biopharma Limited, Auckland. **REVISION DATE:** November 2023. TYSABRI is a Prescription Medicine. TYSABRI solution for infusion, 300mg/15mL natalizumab in a sterile, single use vial free of preservatives (pack of 1 vial). TYSABRI solution for infusion is funded on the Pharmaceutical Schedule - Special Authority Criteria apply. TYSABRI solution for pre-filled injection, 150mg/mL natalizumab, pre-filled syringe (pack of 2 syringes). TYSABRI solution for pre-filled injection is not available in New Zealand. CDW was defined as an increase, confirmed 24 weeks later, of ≥0.5 point from a baseline EDSS score of ≥6.0, ≥1.0 point from a baseline EDSS score of ≥1.0 to <6.0, or ≥1.5 points from a baseline EDSS score of 0.0.¹

ARR=annualised relapse rate; CDW=confirmed disability worsening; EDSS=Expanded Disability Status Scale; IV=intravenous; RRMS=relapsing-remitting multiple sclerosis; TOP=TYSABRI Observational Program. **References:** 1. Butzkueven H *et al.* *J Neurol Neurosurg Psychiatry* 2020;91(6):660–668. 2. Butzkueven H *et al.* *J Neurol Neurosurg Psychiatry*. 2014;85(11):1190–1197. 3. Trojano M *et al.* TYSABRI Observational Program: Long-term Safety and Effectiveness in Relapsing-Remitting Multiple Sclerosis over 15 years. Poster presented at the 9th Congress of the European Academy of Neurology; 1-4 July 2023, Budapest, Hungary. Poster EPO-658. 4. TYSABRI New Zealand Data Sheet. 5. Rolak L and Fleming J. *Neurologist* 2007;13:57–72. 6. Butzkueven H *et al.* Brain health – time matters. 2024 Report. MS Brain Health. Oxford Health Policy Forum. Available at: <https://www.msbrainhealth.org/wp-content/uploads/2024/09/Brain-Health-Time-Matters-2024.pdf> (Accessed January 2025). Biogen® and TYSABRI® are registered trademarks of Biogen MA Inc. ©2025. Biogen-257913. TAPS BG4607. BIOG1258/EMBC. Date of preparation: January 2025.



Long-term disability trajectories in multiple sclerosis: A group-based trajectory analysis of the AusLong cohort

Authors: Zarghami A et al., for the AusLong Investigator Group

Summary: This analysis of the AusLong cohort evaluated long-term disability trajectories in pwMS. Data for 263 pwMS over a 10-year follow-up period were analysed. Three distinct disability trajectories based on EDSS were identified: no/minimal, moderate and severe. Patients with a no/minimal disability trajectory had no significant progression of EDSS over 10 years, while those with a moderate or severe disability trajectory had disability worsening (median time to reach EDSS 4 was 9 and 7 years in the respective groups). Older individuals and those with more relapses in the first 5 years after clinical diagnosis or a higher number of comorbidities at baseline were more likely to have a worse disability trajectory. Neither baseline MRI nor anatomical site of initial symptoms had a significant impact on long-term outcomes.

Comment: Data on disability trajectories in pwMS can inform clinical decisions, particularly the use of high-efficacy therapies in high-risk subgroups. Although these treatments carry risks – such as infusion reactions, opportunistic infections, and reduced vaccine efficacy – patients with risk factors like older age, frequent early relapses, and multiple comorbidities are both more susceptible to complications and more likely to experience disability progression. In such cases, the potential benefits of high-efficacy therapy may outweigh the risks.

Reference: *J Neurol Neurosurg Psychiatry* 2025;96(5):424–34
[Abstract](#)

Low natalizumab trough concentrations are associated with reduced seroconversion of the John Cunningham virus in natalizumab-treated patients with multiple sclerosis

Authors: Gelissen LMY et al.

Summary: Natalizumab-treated pwMS who are JCV seropositive are at increased risk for progressive multifocal leukoencephalopathy (PML). This study assessed whether lower natalizumab trough concentrations are associated with less JCV seroconversion than higher natalizumab trough concentrations. Two cohorts of patients treated with intravenous natalizumab in the Netherlands were combined to assess JCV seroconversion rates during periods of high (≥ 15 µg/mL) and low (< 15 µg/mL) natalizumab trough concentrations. Overall, 357 patients from 21 hospitals in the Netherlands were included. The annual JCV seroconversion rate was 8.4% during periods of high natalizumab trough concentrations compared with 4.8% during periods of low trough concentrations ($p=0.0035$).

Comment: Most infusion centres in NZ are administering natalizumab using an extended dosing regimen to reduce the PML risk. Approximately 50% of pwMS will be JCV-negative prior to starting treatment. For those who are JCV-negative the quoted risk of seroconversion is 4–10% per annum. Remaining JCV-negative in NZ is advantageous as we only have two high efficacy agents available, natalizumab and ocrelizumab. Natalizumab trough levels are known to be high in those with low BMI. It may be that in the future we take a personalised approach as is being studied in a further trial called SUPER-NEXT in which enrolled patients start with a dosing interval of 6 weeks and then the dosing interval is increased based on trough levels.

Reference: *J Neurol Neurosurg Psychiatry* 2025; published online Mar 25
[Abstract](#)

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Subcutaneous ocrelizumab in patients with multiple sclerosis: Results of the phase 3 OCARINA II study

Authors: Newsome SD et al.

Summary: The OCARINA II trial compared ocrelizumab drug exposure after subcutaneous (SC) versus intravenous (IV) administration. A total of 236 ocrelizumab-naïve patients aged 18–65 years with relapsing and primary progressive MS and an EDSS score of 0–6.5 were randomised 1:1 to initially receive a single ocrelizumab IV dose (administered as two 300mg infusions, 2 weeks apart) or a single ocrelizumab SC dose (920mg injection on Day 1). At week 24, patients who received the initial ocrelizumab IV dose switched to ocrelizumab SC 920mg every 24 weeks until week 96; patients who received the initial ocrelizumab SC dose remained on SC ocrelizumab every 24 weeks until week 96. The primary end-point was ocrelizumab area under the serum concentration-time curve from day 1 to week 12 (AUC_{W1-12}). The study demonstrated that ocrelizumab SC 920mg was non-inferior to ocrelizumab IV 600mg for the primary end-point (geometric mean ratio 1.29) and also for AUC_{W1-24} (geometric mean ratio 1.27).

Comment: SC ocrelizumab has recently been approved by Medsafe, and we await the outcome of ongoing PHARMAC negotiations regarding funding. Its availability will significantly ease the burden on overstretched infusion centres, reducing administration time from several hours to a 10-min SC injection. Notably, the initial dosing – traditionally administered as two 300mg IV infusions on Day 1 and Day 15 – can now be given as a single subcutaneous dose on Day 1, alleviating pressure on limited infusion slots.

Reference: *Neurology* 2025;104(9):e213574
[Abstract](#)

Identifying multiple sclerosis in linked administrative health data in Aotearoa New Zealand

Authors: Boven N et al.

Summary: This study used linked administrative health records to update the findings of the 2006 NZ National MS Prevalence study. MS cases were identified from hospital records, pharmaceutical dispensing records, needs assessments for older adults, and disability support records between Jan 1988 and Jun 2022. A total of 7890 people (73% female) with MS were identified, and the crude national prevalence was estimated to be 96.6 per 100,000 in 2022 compared with 72.4 per 100,000 in 2006. Age-adjusted prevalence (per 100,000) was highest for Europeans (124.7), followed by Middle Eastern/Latin American/African (85.5), Māori (41.8), Asian (16.8) and Pacific peoples (11.1).

Comment: This study of MS prevalence in NZ suggests, as has been identified globally, that the prevalence of MS is increasing with time (providing the data are accurate) from 72 per 100,000 in 2006 to 96 per 100,000 in 2022. This trend is thought to be due to increased diagnostic accuracy and awareness, longer life expectancy and lifestyle factors such as reduced sun exposure and other MS risk factors.

Reference: *N Z Med J*. 2025;138(1612):71–82
[Abstract](#)

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