Position Statement

Autologous Haematopoietic Stem Cell Transplant (AHSCT) for MS

Background

Autologous Haematopoietic Stem Cell Transplant (AHSCT) is a procedure that has been used to treat a small percentage of people with multiple sclerosis (MS) in Australia and internationally. The procedure comprises a number of stages performed over several weeks. Drugs are first used to mobilise haematopoietic (blood and immune system) stem cells from the bone marrow into the blood. Blood is then collected from the patient, and the stem cells are separated and frozen.

The patient then receives a 'conditioning' treatment with chemotherapy agents which destroys the cells of the immune and blood system. The extent and duration of immune system suppression can vary depending on the chemotherapy protocol used (for more information visit here). The patient's own (autologous) haematopoietic stem cells are then thawed and reinfused to overcome the effects of the chemotherapy, resulting in a recovery of blood and immune cells over several months. During this time, the patient has severely reduced immune function and is vulnerable to infections and bleeding problems as white blood cells and platelets are affected.

AHSCT is thought to 'reset' the immune system to a less inflammatory state, reducing the autoimmune attack on the central nervous system. There is no evidence that the procedure initiates stem cell-mediated repair of the nervous system.

Key points – Summary of MS Australia's position

- AHSCT is an intensive immunosuppressive treatment that continues to be evaluated for its role in the management of MS.
- AHSCT is not recommended as routine therapy for MS.
- Current Australian and international specialist clinical guidance indicate that, in selected circumstances, AHSCT may be considered for a small number of people with active inflammatory MS, particularly where:
    - high-efficacy disease-modifying therapies (DMTs) have failed, or
    - such therapies are contraindicated.
- Decisions about AHSCT should be made on an individual basis, through careful discussion between a person with MS and their treating neurologist, with referral to specialised transplant centres experienced in delivering AHSCT.
- The provision of AHSCT remains at the discretion of treating hospitals, and eligibility criteria and clinical pathways may vary between centres.
- Ongoing data collection through clinical trials and registries, including the Australasian Haematopoietic Stem Cell Transplant Registry, is essential to improving understanding of the long-term safety and effectiveness of AHSCT in MS.

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Evidence for efficacy in relapsing remitting MS

Only a single randomised phase 3 trial of AHSCT versus 'standard of care' DMT has been published – the MIST trial[1]. The study revealed a 5.7% occurrence of disability worsening in AHSCT patients, in contrast to the 66.7% observed in the DMT patient cohort. However, only approximately 50% of the DMT cohort had received high-efficacy therapy. Ongoing randomised phase 3 clinical trials comparing AHSCT to high efficacy DMTs are expected in Q3 of 2026[2].

Multiple phase 2 trials and propensity matched retrospective analyses support the results of the MIST trial.

The largest Australian study, a phase 2 single centre trial published in 2019, reported remission from relapses, freedom from new MRI lesions and no disability progression in 60% of individuals at three years post-AHSCT (70% of the cohort had relapsing remitting MS)[3].

A study published in 2021 following people with MS treated at multiple Italian centres for up to 10 years found that 78.1% of people with relapsing remitting MS remained relapse free five years following treatment[4]. After ten years, this dropped to 63.5%. After five years, 85.5% of people with relapsing remitting MS had no disability worsening, decreasing to 73.1% after 10 years.

Another 2021 study of more than 500 people treated between 2003 and 2019 at a single centre in the US reported that 80.1% of people with relapsing remitting MS remained relapse-free five years after treatment[5]. After four years, 95% did not experience disease progression, and on average, there was significant improvement in disability at five years post-treatment[5].

Retrospective observational studies published between 2023 and 2025[6–12] suggest that AHSCT is a high-efficacy treatment option for relapsing remitting MS, with efficacy comparable to other high-efficacy therapies.[13] A large multicentre, multinational retrospective cohort study published in 2023 compared AHSCT with fingolimod, natalizumab and ocrelizumab in 4,915 people with relapsing remitting MS treated between 2006 and 2021. The study found AHSCT to be superior in preventing relapses and facilitating disability recovery compared with fingolimod, marginally superior to natalizumab, and equivalent to ocrelizumab [14]. Over five years, AHSCT was associated with fewer relapses than fingolimod (ARR 0.09 versus 0.20 respectively) but a similar risk of disability worsening (HR 1.70, 95% CI 0.91-3.17) and higher chance of disability improvement (HR 2.70, 95% CI 1.71-4.26). AHSCT was also associated with a slightly lower ARR than natalizumab (0.08 vs 0.10 respectively), similar risk of disability worsening (HR 1.06, 95%CI 0.54-2.09) and higher chance of disability improvement (HR 2.68, 95%CI 1.72-4.18) over five years. AHSCT and ocrelizumab were associated with similar ARR (0.09 vs 0.06), disability worsening (HR 1.77, 95%CI 0.61-5.08) and disability improvement (HR, 1.37, 95%CI 0.66-2.82) over three years. AHSCT-related mortality was 0.6%.

Current evidence supports the use of AHSCT for people with highly active, inflammatory relapsing MS who continue to experience disease activity despite treatment with at least one high-efficacy DMT. This positioning is reflected in guidelines from the European Committee for Treatment and Research in Multiple

Sclerosis[2] and American Society for Transplant and Cellular Therapies[15]. This is echoed in the recommendations the United Kingdom's National Health Service[16].

Evidence for efficacy in progressive MS

In contrast, evidence for benefit in progressive MS is limited and less consistent than in relapsing remitting MS. In a multicentre Italian cohort with long-term follow-up, outcomes in progressive MS were less favourable than in relapsing remitting MS. Among people with progressive MS, 71% had no disability worsening at five years, decreasing to 57.2% at 10 years[4].

In a large single-centre US cohort, outcomes in secondary progressive MS suggested that some individuals may experience short-term stabilisation; 66% did not experience disease progression up to four years post-transplant. However, while there was some improvement in disability up to one year post-transplant, longer follow-up did not continue to show improvement[5].

More recent comparative evidence does not demonstrate a disability benefit in predominantly secondary progressive MS. In a 2024 retrospective cohort study comparing AHSCT (n=39) with natalizumab (n=65), there was no difference found between treatment groups in disability worsening or improvement over up to four years, and relapse rates were similarly low in both groups. The study concluded that AHSCT did not demonstrate benefit for disability control in people with progressive MS who had advanced disability and low relapse activity.[13].

Patient characteristics associated with better outcomes

Overall, the data shows that people who are relatively young, with shorter disease duration and still in the active inflammatory phase of the disease (new and active lesions on MRI scans and/or relapses) appear to respond better to AHSCT in comparison to people who are older and/or have no active inflammatory lesions[5,17–22]. This is similar to what is seen for some moderate to high efficacy DMTs, such as fingolimod[23], alemtuzumab[24,25] and natalizumab[26].

Safety and treatment-related mortality

The intense immune suppression of the procedure is associated with severe and potentially life-threatening complications, predominantly due to infections. However, the risk of death has declined in recent years with advances in supportive care. Experience with AHSCT in people with blood cancers in Australia suggests a transplant-related mortality (TRM) rate of around 1% within the first 100 days following transplant[4]. Data from the EBMT registry shows that TRM in people with MS has improved significantly over time[2], decreasing from 3.4% in those treated before 2005 to 0.3% in those who were treated after 2005[2,21].

Data from the single-centre US study of people treated between 2003 and 2019 reported a TRM of 0.19%[5]. A systematic review found that 12 out of 15 studies published from 2014 to 2021 reported no deaths[27] (see here for more information). Data from the EBMT registry showed that overall, 2.0% of patients conditioned with BEAM/ATG and 1.0% with CYC/ATG died within 100 days from HSCT in 2010-2019[28]. To date, there have been no deaths among people with MS who have received AHSCT in Australian teaching hospitals[3], based on data from the Australian MS

AHSCT Registry.

The risk of infections from bacteria, viruses and fungi remains significant[29]. These infections can result in prolonged hospital stays and may also be associated with neurological worsening[20]. Chemotherapy can be neurotoxic and often those treated will become worse in the immediate post-transplant period due to a combination of infection, deconditioning, and the chemotherapy itself. Experience with treating blood cancers over many years, as well as autoimmune disorders, suggests that there may also be longer term adverse effects of AHSCT, such as effects on heart, liver, kidney and bone health, reduction in fertility, premature menopause, secondary cancers and secondary autoimmunity[29].

Conditioning regimens

The risks associated with AHSCT vary depending on the chemotherapy regimen used, which may vary slightly between centres and should be discussed with the treating transplant centre. Over recent years, there has been a shift towards the use of lower intensity chemotherapy regimens for the treatment of autoimmune diseases, which appear safer and better tolerated, but still highly efficacious.

Over the past decade, the myeloablative BEAM with anti-thymocyte globulin (ATG) regimen and the non-myeloablative, immunoablative cyclophosphamide (Cyclo) ATG regimen have become the primary conditioning protocols.[30] Both regimens are currently recommended by European guidelines, with the Cyclo-ATG now the most commonly used[28].

A Swedish observational study published in 2024 compared the two conditioning regimens in 231 people with relapsing remitting MS who had received AHSCT[30]. There was no difference between the regimens in efficacy. However, the Cyclo-ATG regimen was associated with a more favourable safety profile, with significantly fewer severe adverse events per patient than BEAM-ATG. Infectious complications, such as febrile neutropenia, sepsis and septicaemia, as well as anorexia, diarrhoea and hypokalaemia, were more common in people treated with BEAM-ATG. This likely reflects the higher intensity and greater gastrointestinal toxicity of the BEAM-ATG regimen. Hyperglycaemia occurred only in people conditioned with Cyclo-ATG, likely due to the high doses of methylprednisolone used in this regimen. The study noted that the two groups were not directly comparable, as indications for AHSCT and treatments for relapsing remitting MS have changed over time. However, the study suggested that the Cyclo-ATG regimen is the preferred conditioning protocol for relapsing remitting MS due to its favourable safety profile[30].

In contrast, an observational study of EBMT registry data including 1,114 people with MS treated with AHSCT found no clear difference between BEAM-ATG and Cyclo-ATG in terms of efficacy and toxicity[28]. In this analysis, disease type rather than conditioning regimen was the major determinant of neurological outcomes, with significantly worse outcomes observed in people with progressive MS[28].

Overall interpretation of the evidence

Overall, most studies show that the risk of disease activity returning gradually increases over time following treatment[4,5,11,12,18,28] (see here for more information). As with other MS therapies, in some people undergoing AHSCT, there may be a reversal of disability, but it is rare[5,18]. Whilst people with early, relapsing MS may experience stability in their symptoms, many day-to-day symptoms of MS persist post-AHSCT. People with progressive MS are likely to continue to experience disability progression.

While the long-term effects of AHSCT on the course of MS are still being investigated, the growing evidence base indicates that people with inflammatory MS and who are still experiencing disease activity (relapses or new MRI lesions) despite treatment with available high efficacy DMTs may benefit from AHSCT. There are, however, still significant risks associated with the procedure, and careful consideration and planning are required in consultation with the patient's healthcare team. Treatment should be accompanied by long-term follow-up through registries or clinical trials to contribute to ongoing understanding of the safety and efficacy of AHSCT as an intervention for MS.

Australian context and registry data

MS Australia (with initial support of the MS Society of Western Australia) is funding the Australian MS AHSCT Registry and working with haematologists and neurologists to gather and analyse further data on Australians with MS treated with this procedure. This will contribute to the continuing international effort to better understand the role that AHSCT may play in the range of treatments available for MS.

In the interim, MS Australia provides the guidelines below, to assist those who may be considering AHSCT for the treatment of MS.

Clinical practice guides developed for specific jurisdictions, such as the NSW *Autologous Haematopoietic Stem Cell Transplant for Multiple Sclerosis*, may adopt a more directive stance to support service delivery within specialised centres, whereas this MS Australia position statement reflects a national, evidence-weighing perspective intended to inform people with MS, clinicians and policymakers.

Recommendations

MS Australia does not recommend specific treatments for MS. Decisions about whether to pursue AHSCT should be made through careful consultation between an individual and their treating neurologist, taking into account the potential benefits, risks, uncertainties, and the person's individual clinical circumstances.

The clinical role of AHSCT continues to be evaluated and is not currently recommended as routine therapy for MS. Current international and Australian guidance suggests that, in selected circumstances, particularly where people with active inflammatory MS continue to experience disease activity despite available high efficacy DMTs, or where such therapies are contraindicated, AHSCT may be considered within specialised centres.

The criteria outlined below are drawn from the July 2025 *Autologous Haematopoietic Stem Cell Transplant for Multiple Sclerosis Clinical Practice Guide,* which reflects current practice within specialised AHSCT services in Australian public hospitals [31]. They should not be interpreted as a recommendation by MS Australia that AHSCT is appropriate or available for all people who meet these criteria. Eligibility decisions remain the responsibility of specialist multidisciplinary transplant teams and may vary between jurisdictions and centres.

Considerations currently used by specialist AHSCT services in Australia

- Aged 18 to 65 years with a diagnosis of active relapsing MS made by a neurologist, according to the 2024 revised McDonald's criteria AND an Expanded Disability Status Scale (EDSS) score of 0 to 6.5.
    - Those with an EDSS score of 6.5 to 8 may be considered eligible if an increase in EDSS >2 points occurred in the preceding 3 months in the context of an acute, radiologically proven MS relapse.
- People with active MS, despite using high efficacy DMTs for >3 months prior to the relapse.
- Individuals with highly active, relapsing MS where continuation of high-efficacy therapy is contraindicated (e.g., people who are stable on natalizumab but have recent John Cunningham virus seroconversion may be considered for AHSCT).
- People with adequate organ function to be considered fit for AHSCT.
- Not pregnant at the time of screening and conditioning.
- Patients of childbearing potential must agree to use a form of effective contraception during treatment and for 6 months after AHSCT.
- Able to provide valid consent.
- AHSCT is deemed an appropriate high-intensity immunotherapeutic treatment in the opinion of the transplant physicians and transplant neurologist.

Definition of active MS

Active MS is defined as occurring within the previous 12 months:

- One or more clinical relapses in the opinion of the referring neurologist; AND/OR
- Evidence of radiological disease activity (new and/or persistent gadolinium-enhancing lesions), with evidence that this new activity did not precede the start of high-efficacy DMT within 3 months.

Contraindications to AHSCT

The following factors would be considered as being reasons against considering AHSCT (contraindications):

- Active neoplasm or concomitant myelodysplasia.
- Acute or chronic infection.
- Uncontrolled psychiatric disease.
- People with a predominantly progressive form of MS (primary or inactive secondary progressive MS).
- Those where MS mimics have not been adequately excluded.
- Anyone deemed not otherwise suitable for transplant by the Bone Marrow Transplant multidisciplinary team at participating hospitals

Referral and service considerations

MS Australia recommends that people considering AHSCT are referred by their treating neurologist for assessment within an experienced multidisciplinary specialist transplant centre, where neurologists and haematologists jointly evaluate suitability for transplant.

Assessment should occur at specialist transplant centres with established clinical governance arrangements, ethics approval, and participation in clinical trials and/or registries to enable long-term follow-up and monitoring, and to contribute to ongoing understanding of AHSCT as an intervention for MS.

These centres should operate as multidisciplinary Haematology-Neurology services, based in major Australian teaching hospitals, with demonstrated experience in the use of AHSCT for autoimmune disorders, including MS. International evidence indicates that treatment in experienced centres is associated with lower TRM in people with MS[17,32].

In circumstances where AHSCT is considered an appropriate therapy for an individual, neurologists experienced in the management of MS should be able to advise on appropriate specialist transplant centres for referral and further evaluation. Final eligibility and treatment decisions remain the responsibility of the assessing multidisciplinary transplant team.

In some jurisdictions, AHSCT for MS is delivered through designated specialist services within major Australian teaching hospitals. Referral and assessment occur through neurologist-led multidisciplinary team processes within these centres, informed by jurisdiction-specific clinical practice guidance, including the *Autologous Haematopoietic Stem Cell Transplant for Multiple Sclerosis Clinical Practice Guide*. Service models and referral pathways may vary between states and centres.

Important notes

The above criteria are guidelines aimed at assisting people with MS in understanding the factors that may be taken into consideration by treating clinicians. Provision of AHSCT for MS or other autoimmune disorders in Australia remains entirely at the discretion of the treating hospital and the criteria for treatment may differ to the recommendations in this document.

MS Australia has developed this Position Statement in consultation with clinicians and members of the research and MS communities, drawing on current Australian clinical practice guidelines and the available evidence base (see below).

As the MS Australia-supported Australian MS AHSCT Registry continues its analysis of Australian data and further data becomes available from international registries and trials, this position will be revised.

MS Australia will continue to advocate for Australian neurologists and haematologists to work together to deepen our understanding of the safety and efficacy of AHSCT for MS.

For more information and references please visit https://www.msaustralia.org.au/ahsct/autologous-haematopoietic-stem-cell-transplant

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