MS AUSTRALIA
RESEARCH
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Health Technology Assessment Policy and Methods Review

Department of Health and Aged Care

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SUBMISSION

Health Technology Assessment Policy and Methods Review

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MS Australia is Australia's national multiple sclerosis (MS) not-for-profit organisation that empowers researchers to identify ways to treat, prevent and cure MS, seeks sustained and systemic policy change via advocacy, and acts as the national champion for Australia's community of people affected by MS.

MS Australia represents and collaborates with its state and territory MS Member Organisations, people with MS, their carers, families and friends and various national and international bodies to:

- Fund, coordinate, educate and advocate for MS research as part of the worldwide effort to solve MS
- Provide the latest evidence-based information and resources
- Help meet the needs of people affected by MS

Multiple Sclerosis (MS) is the most acquired neurological disease in younger adults around the world with over 2.8 million people affected. More than 33,300 Australians live with MS and over 7.6 million Australians know someone or have a loved one with this potentially debilitating disease.

Symptoms vary between people and can come and go; they can include severe pain, walking difficulties, debilitating fatigue, partial blindness and thinking and memory problems. For some, MS is characterised by periods of relapse and remission, while for others it has a progressive pattern of disability. MS robs people of quality of life, primarily driven by the impact of MS on pain, independent living, mental health and relationships.

Health Technology Assessment Policy and Methods Review

MS Australia welcomes the opportunity to make a submission to the Department of Health and Aged Care on the Health Technology Assessment Policy and Methods Review (HTA Review). MS Australia is pleased to contribute to improving Health Technology Assessments (HTAs) in order to deliver Australians, including those living with MS, health products and services that are equitable, timely, safe, high quality and affordable. MS Australia supports the HTA Review's focus on ensuring that assessment processes keep pace with rapid advances in health technology and barriers to access are minimised. This is particularly important for people living with MS as MS research is moving at a rapid pace and the MS treatment landscape is continuously evolving. Ensuring ease of access to new therapies may slow disease progression and improve symptom management for people living with MS, particularly people who are newly diagnosed.

As the peak body for people affected by MS, MS Australia supports person-centred HTA reforms that enable consumers to access the treatment they need. Consumer and carer engagement in decision-making processes that directly impact their health and healthcare options is essential. MS Australia supports the commitment in the terms of reference "to improve communication and engagement and to better support consumers, patients and carers during the HTA process"[1]. Similarly, MS Australia welcomes the measure to co-design an "Enhanced Consumer Engagement Process" to capture consumer voices in applications to list new medicines on the PBS under clause 6.3 of the Strategic Agreement[2].

MS Australia makes the following recommendations:

MS Australia Recommendations

- Improvements to clinical trials:
    - ❖ Financial incentives for pharmaceutical companies to bring experimental clinical trials to Australia.
    - ❖ Equitable access to clinical trials for a diverse range of people living with MS and transparent feedback processes.
    - ❖ A patient registry with provision for clinical trial recruitment.
- Changes to improve person centredness:
    - ❖ Inform health peak and advisory organisations of intent to register a new medicine with the TGA, including summary information about the eligible patient population, key clinical outcomes and any safety considerations.
    - ❖ Inform health peak and advisory organisations of intent to submit a new medicine to PBAC and provide any additional information not provided through the registration process with the TGA.
    - ❖ Notify health peak and advisory organisations of intent to withdraw or change existing listings on the PBS, so that patients and their health care teams can advocate to pharmaceutical companies or change disease management plans.
    - ❖ Consider an additional section in the PBAC submission process that describes interactions with the patient population such as focus groups, discussions and surveys about the impact of the new medicine on quality of life. Questions could consider the impact on a range of health, social and economic factors including mental health, caring responsibilities and employment. This information should be made available to health peak and advisory organisations as it may have inform their submissions to PBAC.
    - ❖ Provide brief feedback to peak body and representative organisations on the content and value of their submissions.
    - ❖ Ensure consumer consultation sessions and stakeholder meetings include the presence of

a minimum of two people from the impacted patient community, in addition to any delegates from the representative organisation/s.

- Compensate or reimburse any involvement of unpaid volunteer consumers in HTA processes including travel and accommodation costs and ensure protocols for consumer involvement are implemented.

1. Elements and features that are working effectively

Feedback received from MS Australia Members indicates that the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC) approval processes are working effectively and efficiently to evaluate, assess, monitor and approve health technologies. People living with MS in Australia are fortunate to have access to a range of medications to treat all types of MS, with most medications available on the Pharmaceutical Benefits Scheme (PBS). The turnaround between TGA and PBAC approvals is reasonable, meaning there is no unnecessary delay in accessing new health technologies. The PBAC Review process is transparent, and consumers can track how decisions are made. MS Australia acknowledges that the Medicine Status website is a useful tool that enables consumers to search for and monitor the status of medicines as they progress through the PBS listing process[3]. Further information about the processes that lead to a submission being made to PBAC would enhance the consumer information on this site.

2. Current or future barriers to earliest possible access

MS is a chronic, progressive disease that leads to increasing disability in many individuals. The number and type of therapies for treating MS is continually growing. With research making rapid progress in therapies that can improve quality of life and reduce symptoms, it is vital that people living with MS have access to these therapies as early as possible. MS Australia welcomes the HTA Review's focus on clause 5.1 of the Strategic Agreement for "reducing time to access for Australians so that they can access new health technologies as early as possible"[4].

Experimental clinical trials can offer access to therapies that may not yet be accessible in Australia. Due to small patient populations and the high cost of clinical research, there may be inadequate imperatives for pharmaceutical companies to bring these trials to Australia. Under the current system there is little financial incentive for pharmaceutical companies to apply for regulatory approval in Australia.

Access to clinical trials and research is not equitable, people experiencing social and economic disadvantage are more likely to face barriers such as transport or difficulty getting time away from paid work or caring responsibilities. It is important that people who participate in research can interact in a meaningful way with the researchers and be informed of the trial results and any emerging safety concerns. MS Australia members report that participants may not even be informed of the outcome of the trial they participated in. Progress is needed to make research more person-centred and to ensure equitable access.

A patient registry with provision for clinical trial recruitment will improve equity of access to clinical trials. Currently most participation is through clinicians who are involved in or linked to the clinical trial offering their patients the opportunity to take part.

MS Australia recommends the following changes to improve clinical trials:

- Financial incentives for pharmaceutical companies to bring experimental clinical trials to Australia.
- Equitable access to clinical trials for a diverse range of people living with MS and transparent feedback processes.
- A patient registry with provision for clinical trial recruitment.

3. Current or future barriers to equitable access

People with disabilities, and their carers, are among the most socially and economically disadvantaged groups in Australia. This includes people living with progressive, neurological and neuromuscular conditions such as MS. People with disabilities are more likely to live in poverty and may also have difficulty accessing appropriate health care[5]. AIHW data analysis[6] found that 38 per cent of people with disability and 51 per cent of people with severe or profound disability have a low level of personal income, compared to 27 per cent without disability. Research undertaken by UNSW and ACCOSS[7] found that people with disability face an elevated risk of poverty and it is estimated that the rate of poverty among adults with disability is 17 per cent and that people with disability make up 38 per cent of all people in poverty. The true levels of poverty for people with disability are likely to be far higher given the report acknowledges it did not consider the additional costs of living for people with disability.

Many Australians with disability face economic hardship and this impacts on their health and wellbeing and ability to obtain the supports and services they need. Living in poverty creates barriers to accessing new health technologies. People living with MS who don't have private health insurance may be on long public wait lists to see neurologists or MS Nurses or may space out their appointments due to financial concerns or having to travel to see their clinician. If patients aren't regularly seeing their health provider for disease management, they are less likely to get access to new disease modifying therapies or medicines for symptom management. As such, for people living with MS, it is vital that they have access to an MS Nurse who can link them into new health technologies. Access to an MS Nurse contributes to a range of health benefits for people with MS, such as lower disability levels, slower disease progression, less severe symptoms, improved mental health, and higher quality of life[8].

4. Elements and features that detract from person centredness

MS Australia acknowledges there are current opportunities for patient involvement in the PBAC decision-making process. However, MS Australia notes that the process can proceed without any consumer involvement once a submission to PBAC is made.

MS Australia recommends the following changes to improve person centredness:

- Inform health peak and advisory organisations of intent to register a new medicine with the TGA, including summary information about the eligible patient population, key clinical outcomes and any safety considerations.
- Inform health peak and advisory organisations of intent to submit a new medicine to PBAC and provide any additional information not provided through the registration process with the TGA.
- Notify health peak and advisory organisations of intent to withdraw or change existing listings on the PBS, so that patients and their health care teams can advocate to pharmaceutical companies or change disease management plans.
- Consider an additional section in the PBAC submission process that describes interactions with the patient population such as focus groups, discussions and surveys about the impact of the new medicine on quality of life. Questions could consider the impact on a range of health, social and economic factors including mental health, caring responsibilities and employment. This information should be made available to health peak and advisory organisations as it may have inform submissions to PBAC.
- Provide brief feedback to peak body and representative organisations on the content and value of their submissions.
- Ensure consumer consultation sessions and stakeholder meetings include the presence of a minimum of two people from the impacted patient community, in addition to any delegates from the representative organisation/s.
- Compensate or reimburse any involvement of unpaid volunteer consumers in HTA processes including travel and accommodation costs and ensure protocols for consumer involvement are implemented.

References

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[2] Department of Health *2022-2027 Strategic Agreement between the Commonwealth and Medicines Australia* Retrieved from:

https://www.health.gov.au/sites/default/files/2023-03/ma-strategic-agreement.pdf Pg 12.

[3] https://www.pbs.gov.au/medicinestatus/home.html

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[5] World Health Organization (2011). *World report on disability*, WHO, Geneva.

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[7] Davidson, P., Saunders, P., Bradbury, B. and Wong, M. (2018), *Poverty in Australia, 2018. ACOSS/UNSW Poverty and Inequality Partnership Report No. 2*, Sydney: ACOSS.

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