

12 September 2023

PBAC Secretariat
MDP 952
Office of Health Technology Assessment Branch
Department of Health and Ageing
GPO Box 9848
Canberra ACT 2601

By email to: pbac@health.gov.au

**Re: Submission of herpes zoster (shingles) vaccine (Shingrix®) to PBAC meeting
November 2023**

MS Australia is writing to the Pharmaceutical Benefits Advisory Committee (PBAC) to support the inclusion of Shingrix® on the Pharmaceutical Benefits Scheme (PBS) for the broader population of immunocompromised individuals over the age of 18 years at increased risk of herpes zoster (shingles).

MS Australia is Australia's national 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 champion for Australia's community of people affected by MS. MS Australia is the largest Australian not-for-profit organisation dedicated to funding, coordinating, educating and advocating for MS research as part of the worldwide effort to solve MS. MS Australia collaborates closely with our member organisations and various national and international bodies to help meet the needs of people affected by MS.

Declaration of interest

MS Australia is making this submission as we have an interest in the health and wellbeing of all people with MS. MS Australia is the national peak body for people living with MS in Australia. We work with governments at all levels, engaging on the issues that concern the lives of people living with MS, their families and carers, the community, and the economy. We declare that we have in the past received funding support from pharmaceutical companies (2% of total revenue for FY2022), with an interest in MS in the form of grants for projects and support of our national MS research scientific conference.

About MS

As the national peak body for people with MS, we are proud to advocate on behalf of our state member organisations and the MS community. One area we are particularly passionate about



is the provision of more affordable and accessible treatments that can improve the lives of people with MS.

MS is the most common acquired chronic neurological disease affecting young adults, often diagnosed between the ages of 20 to 40 and, in Australia, affects three times more women than men. In MS, the body's own immune system mistakenly attacks and damages the fatty material, called myelin, around the nerves. This results in a range of symptoms that can include a loss of motor function (e.g., walking and hand and arm function, loss of sensation, pain, vision changes and changes to thinking and memory).

There is currently more than 33,000 people living with MS across the country and over 7.6 million Australians know or have a loved one with this disease. MS can be particularly debilitating and has an unpredictable disease course. No two cases of MS are the same. MS affects everyone differently and people also respond to treatments and their potential side effects differently. Life circumstances, such as family planning, career and travel, as well as other health conditions, can also greatly affect treatment options and decisions. Even geography can affect treatment choices with close access to hospitals and health professionals for treatment, administration and monitoring being a big consideration relating to some medications for people with MS living outside of major metropolitan areas. There is no one-size fits all treatment for people living with MS and to date, there is no known cure.

About Shingrix®

Shingrix® is a non-live vaccine for the prevention of herpes zoster (shingles) and related complications. Shingles causes significant morbidity, especially in those over the age of 50 and patients who are immunocompromised or immunosuppressed.

Clinical trials for Shingrix®

Two large phase 3 clinical trials showed that Shingrix® had an efficacy of 90% in people aged 70 and older and 97% in people aged 50 and older^{1,2}. The safety of Shingrix® was consistent between both studies and previous phase studies, with pain at the injection site and systemic reactions being the most common adverse events. The reactions were generally mild-to-moderate in intensity and were transient.

Several clinical trials showed that Shingrix® provided good protection against herpes zoster in people who were severely immunocompromised, including those who have undergone autologous haematopoietic stem cell transplantation and exhibited haematological malignancies^{3,4}.

Impact on MS patients

Currently, the Zostavax vaccine is provided for free to adults over the age of 70 under the National Immunisation Program. The Zostavax vaccine, which is a live-attenuated vaccine, is contraindicated in people who are immunocompromised. Some people with MS are deemed to be severely immunocompromised because of medications they may be receiving to treat their MS. Currently, this group includes ocrelizumab (Ocrevus), ofatumumab (Kesimpta), rituximab (various trade names), alemtuzumab (Lemtrada), fingolimod (various trade names), ozanimod (Zeposia) and siponimod (Mayzent), some other immunosuppressive medications (such as high dose corticosteroids to treat a relapse), as well as people who have undergone autologous haematopoietic stem cell transplant or have other co-existing diseases

Currently, Shingrix[®] has been recommended for listing on the PBS for indigenous people aged 50 years and over, non-indigenous people aged 65 years and over and people aged 18 years and over with conditions at high risk of herpes zoster infection, including those who have undergone autologous haematopoietic stem cell transplant. While this is excellent news, there is a pressing need to consider a wider immunocompromised population over the age of 18, which includes people with MS on certain disease modifying therapies (DMTs).

Shingrix[®] offers an effective, inactivated vaccine suitable for the wider immunocompromised population over the age of 18, including individuals with MS on specific DMTs. We strongly support its inclusion on the PBS for the broader immunocompromised population over the age of 18 years.

1. Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, Hwang SJ, Levin MJ, McElhaney JE, Poder A, Puig-Barberà J, Vesikari T, Watanabe D, Weckx L, Zahaf T, Heineman TC; ZOE-50 Study Group. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med*. 2015 May 28;372(22):2087-96.
2. Cunningham AL, Lal H, Kovac M, Chlibek R, Hwang SJ, Díez-Domingo J, Godeaux O, Levin MJ, McElhaney JE, Puig-Barberà J, Vanden Abeele C, Vesikari T, Watanabe D, Zahaf T, Ahonen A, Athan E, Barba-Gomez JF, Campora L, de Looze F, Downey HJ, Ghesquiere W, Gorfinkel I, Korhonen T, Leung E, McNeil SA, Oostvogels L, Rombo L, Smetana J, Weckx L, Yeo W, Heineman TC; ZOE-70 Study Group. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. *N Engl J Med*. 2016 Sep 15;375(11):1019-32.
3. Bastidas A, de la Serna J, El Idrissi M, Oostvogels L, Quittet P, López-Jiménez J, Vural F, Pohlreich D, Zuckerman T, Issa NC, Gaidano G, Lee JJ, Abhyankar S, Solano C, Perez de Oteyza J, Satlin MJ, Schwartz S, Campins M, Rocci A, Vallejo Llamas C, Lee DG, Tan SM, Johnston AM, Grigg A, Boeckh MJ, Campora L, Lopez-Fauqued M, Heineman TC, Stadtmauer EA, Sullivan KM; ZOE-HSCT Study Group Collaborators. Effect of Recombinant

- Zoster Vaccine on Incidence of Herpes Zoster After Autologous Stem Cell Transplantation: A Randomized Clinical Trial. *JAMA*. 2019 Jul 9;322(2):123-133.
4. Dagnew AF, Ilhan O, Lee WS, Woszczyk D, Kwak JY, Bowcock S, Sohn SK, Rodriguez Macías G, Chiou TJ, Quiel D, Aoun M, Navarro Matilla MB, de la Serna J, Milliken S, Murphy J, McNeil SA, Salaun B, Di Paolo E, Campora L, López-Fauqued M, El Idrissi M, Schuind A, Heineman TC, Van den Steen P, Oostvogels L; Zoster-039 study group. Immunogenicity and safety of the adjuvanted recombinant zoster vaccine in adults with haematological malignancies: a phase 3, randomised, clinical trial and post-hoc efficacy analysis. *Lancet Infect Dis*. 2019 Sep;19(9):988-1000.
5. *Health Economic Impact of MS in Australia in 2021*
https://www.msaustralia.org.au/wp-content/uploads/2018/08/executive-summary_health-economic-impact-of-ms-in-australia-in-2017-report_ms-research-australia.pdf