Hello,

My name is Amy Hale and I'm a pharmacist located in Southern Nevada, attending on behalf of Janssen Scientific Affairs. I would like to thank you for the opportunity to provide testimony regarding Ponvory, or ponesimod, a sphingosine-1-phosphate (S1P) receptor modulator approved for use in adults with relapsing multiple sclerosis, clinically isolated syndrome, and active secondary progression of disease.

Ponvory received FDA approval based off the results of the OPTIMUM study, which was a phase 3 randomized controlled trial comparing teriflunomide (Aubagio) with Ponvory. Ponvory showed an annualized relapse rate reduction of 30.5%, which was statistically significant when compared to Aubagio. This translates to 1 relapse every 5 years for patients receiving Ponvory versus 1 relapse every 3.5 years for those taking Aubagio. Ponvory also demonstrated fewer brain lesions and a lower degree of brain volume loss than Aubagio. Brain volume loss has been shown to be greater in patients who suffer from MS than in those who do not have the disease. Current evidence suggests that patients with greater brain volume loss score lower on cognitive function assessments. Out of the agents available in the US to treat MS, Ponvory shows the lowest degree of brain volume loss. The safety profile of Ponvory was similar to Aubagio and consistent with other medications in its class. In a long-term follow up analysis approximately 60% of patients were still taking Ponvory after 8 years.

The pharmacokinetic data available for Ponvory demonstrate a 33-hour half-life. Lymphocyte counts were shown to return to baseline in 90% of patients by 7 days after the last dose; patients may also attempt pregnancy 7 days after the last dose of Ponvory, which is the shortest interval in its class.

Ponvory has the fewest barriers to initiation among the S1Ps. It requires no genetic testing, has a low potential for drug-drug interactions, no known drug-food interactions, and fewer than 10% of patients should require first-dose cardiac monitoring.

It is our recommendation that Ponvory be allowed open access on the Nevada Medicaid formulary along with other disease-modifying therapies for MS. If prior authorization criteria is imposed, we respectfully advise that patients fail only one agent before starting Ponvory due to the superiority of Ponvory over Aubagio per the OPTIMUM trial (Aubagio is currently listed for use in advance of Ponvory); least amount of restrictions to startup as compared to other S1Ps; and the short half-life allows for quick recovery of lymphocytes in the event of infection, and for pregnancy in a population largely composed of women of childbearing age.

Thank you again for your time today.

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