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July 1, 2026

Oregon Prescription Drug Affordability Board (PDAB)
350 Winter Street NE
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Re: Statutory Exemption of Orphan Drugs from Affordability Review and Selection of KEYTRUDA® (pembrolizumab) for Affordability Review

Members of the Oregon Prescription Drug Affordability Board,

In follow up to communications submitted to the Board on March 13, 2026[1], April 10, 2026[2], and May 15, 2026[3] , Merck submits the following statement of record of our position that the Board lacks authority to select KEYTRUDA for affordability review based on the statutory exemption for drugs with orphan designation.

The PDAB statute unequivocally states that "[a] drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review . . . ." [4] The Oregon Administrative Rule (OAR) 925-200-0020(1)(m) further underscores this legislative mandate and likewise states that "a drug for a rare disease or condition is not subject to an affordability review." Critically, both the statute and the rule refer to a "drug"—not indication, use, patient population, or claim.

Notwithstanding this legislative mandate, the Board approved OAR 925-200-0020 (2)(n) stating that "[a] prescription drug approved by the FDA for other indications, in addition to a rare disease or condition, is not exempt from an affordability review for those other indications." This rule directly conflicts with both the relevant statute and OAR 925-200-0020(1)(m). The application of OAR 925-200-0020 (2)(n) and subsequent selection of KEYTRUDA for affordability review constitutes an unauthorized narrowing of a categorical exclusion adopted by the Legislature to protect medically vulnerable patients. Because KEYTRUDA is an FDA-designated orphan drug, it is statutorily ineligible for affordability review and should be withdrawn from the 2026 review list.

Sincerely,

Terri Lee
Vice-President,
State Government Affairs & Policy

Christin O' Neill
Associate Vice-President
Market Access Oncology

[1] https://dfr.oregon.gov/pdab/Documents/Letters/Merck-Keytruda-20260313.pdf, accessed June 26, 2026

[2] https://dfr.oregon.gov/pdab/Documents/Letters/Merck-Keytruda-20260410.pdf, accessed June 26, 2026

[3] https://dfr.oregon.gov/pdab/Documents/Letters/Merck-Keytruda-20260515.pdf, accessed June 26, 2026

[4] Or. Rev. Stat. § 646A.694(2)