



UG3A-94
351 N. Sumneytown Pike
North Wales, PA 19454

[Merck.com](https://www.Merck.com)

October 16, 2026

Oregon Prescription Drug Affordability Board (PDAB)
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Comments Regarding Affordability Review of KEYTRUDA® (pembrolizumab)

Members of the Oregon Prescription Drug Affordability Board,

Merck appreciates the opportunity to provide comments regarding the Board's affordability review of KEYTRUDA.

As stated in our prior communications to the Board¹, KEYTRUDA is not eligible for selection for review under the Oregon Prescription Drug Affordability review process as ORS § 646A.694 (2) expressly provides that a drug designated by FDA under 21 U.S.C. § 360bb for a rare disease or condition "is not subject to a review". Any selection of a drug with an orphan designation, even if the drug is also approved for non-orphan indications, violates the PDAB's statute, which expressly exempts orphan-designated drugs from affordability review.

The Orphan Drug Act was established to address the lack of treatments for rare diseases by creating incentives where small patient populations otherwise made development economically challenging.² Since 1983, this framework has contributed to FDA approval of more than 500 orphan drugs.³ Efforts to circumvent these protections through affordability review and potential price or utilization limits could weaken the incentives supporting rare-disease innovation and jeopardize patient access to treatments developed under this successful federal framework.

The categorical exemption adopted by the Legislature is a provision to protect patients with rare diseases, who often face life-threatening conditions, few or no approved therapies, and significant barriers to treatment access. The federal orphan drug framework underscores the need for this protection by recognizing the extraordinary scientific and economic challenges of developing treatments for small patient populations. Attempts by the Board to more narrowly define or interpret this exemption undermine this clear legislative policy and expose vulnerable patients with limited treatment options to even greater access risks.

Furthermore, the "Orphan drug review refinements" Policy Memorandum dated October 13, 2026⁴ acknowledges that the Board lacks clear statutory authority to review a drug designated by the U.S. Food and Drug Administration for a rare disease or condition. Accordingly, the Board's adoption of OAR 925-200-0020(2)(n), as well as any review conducted pursuant to that rule, conflicts with the Board's statutory authority because it subjects orphan-designated drugs to affordability review for non-orphan indications.

¹ See Merck comment letters dated March 13, 2026, April 10, 2026, May 15, 2026, July 1, 2026, and September 4, 2026

² Orphan Drug Act, Pub. L. No. 97-414, § 1(b), 96 Stat. 2049 (1983)

³ Congressional Research Service, *The Orphan Drug Act: Legal Overview and Policy Considerations* (Mar. 5, 2024)

⁴ Oregon PDAB orphan drug review refinement draft policy recommendation,
<https://dfr.oregon.gov/pdab/Documents/PDAB-Orphan-Drug-Review-Refinement-Recommendation.pdf>



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For the reasons outlined here and the numerous concerns expressed in prior comments regarding the accuracy, reliability, and fairness of the affordability review, which have not been addressed in the most recent materials shared, we urge the Board to rescind the current draft affordability report and withdraw KEYTRUDA from review.

Thank you for considering these comments.

Sincerely,

A handwritten signature in black ink that reads "Denise Tucker".

Denise Tucker
Executive Director
State Government Affairs & Policy

A handwritten signature in black ink that reads "Joanne McMahon".

Joanne McMahon
Associate Vice President
Market Access Oncology