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Oregon Prescription Drug Affordability Board (PDAB)
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Re: Comments Regarding Affordability Review of KEYTRUDA® (pembrolizumab) and Drug Review Report Dated July 15, 2026

Members of the Oregon Prescription Drug Affordability Board,

Merck appreciates the opportunity to provide additional comments regarding the Board's selection of KEYTRUDA for affordability review, the process by which the Board is conducting its review, and the draft drug review report for KEYTRUDA.

As Merck has previously communicated to the Board[1], KEYTRUDA is not eligible for selection under the Oregon Prescription Drug Affordability Board review process. ORS 646A.694(2) expressly provides that a drug designated by FDA under 21 U.S.C. § 360bb as a drug for a rare disease or condition "is not subject to review." Oregon's affordability-review rule, OAR 925-200-0020(1)(m), similarly provides that a prescription drug with such an FDA rare-disease designation is not subject to an affordability review.

Accordingly, Merck respectfully maintains that the Board's interpretation is inconsistent with the governing statute and implementing rule. Proceeding with an affordability review of KEYTRUDA notwithstanding the statutory exemption would risk subjecting patients with serious and rare conditions to a process that does not adequately account for their clinical needs, treatment continuity, or potential access implications. Merck therefore urges the Board to apply the exemption as written and refrain from further review of KEYTRUDA under this process.

In addition, the Board's review of KEYTRUDA raises significant concerns that undermine the reliability and fairness of its affordability assessment, including:

- The report contains material data integrity issues.
- The analysis does not reflect KEYTRUDA's full clinical profile.
- The selected therapeutic alternatives do not overlap across all KEYTRUDA indications and may not meet Oregon's standard for therapeutic alternatives.
- The review process lacks sufficient clinical expertise and transparency.
- The "carve out" approach has not been tested, is applied inconsistently and leads to unexplained discrepancies in results.
- The Staff misunderstands the potential for the inclusion of KEYTRUDA in the CMS drug price negotiation process and the Board appears to have used that as a part of the rationale for an affordability review.

[1] See comment letters dated March 13, 2026, April 10, 2026, May 15, 2026, and July 1, 2026.

Draft Affordability Report Contains Numerous Examples of Data Integrity Issues Resulting in Incomplete and Conflicting Data

As noted in prior communications to the Board, the Board's timeline for review is insufficient for the level of complexity required to review a drug like KEYTRUDA. This compressed timeline has led to the publishing of a report that is not only incomplete but also contains numerous errors, inconsistencies, and methodological defects.

We have outlined below some of the most concerning examples:

Incorrect Estimation of 30-Day Supply and Implications on Other Calculations and Analysis Performed

WAC is not an appropriate measure for assessing the cost of KEYTRUDA, as physician administered drugs are reimbursed based upon ASP. Regardless of the price metric used in the assessment, the 30-day supply price of KEYTRUDA was calculated incorrectly. The report overestimates the number of vials needed for a 30-day supply of KEYTRUDA (for adult indications) and therefore inaccurately overestimates the WAC per 30-day supply. The report simultaneously underestimates the number of vials and WAC per 30-day supply for purported therapeutic alternatives and therefore inaccurately suggests that the WAC per 30-day supply for KEYTRUDA is higher than that of the other products considered. These errors occur in Tables 11 and 12 of the Affordability Report.

Table 11 of the affordability review highlights the number of vials or mLs needed, by product, for 30-days of therapy. However, these values are consistently incorrect, leading to further inaccuracies in Table 12, which uses these values to calculate a WAC per 30-day supply. For example, the 30-day supply in Table 11 for Keytruda is listed as 4 vials (which equates to 42 days of therapy). This overestimated value of 4 vials is then used in the calculation of WAC per 30-day supply in Table 12.

Additionally, the 30-day supply estimates in Table 11 for Tecentriq, Libtayo, and Jemperli all correspond to the labelled dosing for 21 days of each drug (1 every 3 week dose), significantly less than the 30 days noted in the table. This results in an underestimate of WAC per 30-day supply of each in Table 12.

This therefore inaccurately suggests that the WAC per 30-day supply for KEYTRUDA is higher than that of the other products considered.

If the PDAB were to use the correct dosing information, which is present in Table 36 of this very report, and normalize those dosing schedules to 30-days of supply, it would be clear that **the WAC for a 30-day supply for these drugs is very similar and that KEYTRUDA does not have the highest WAC per 30-day supply.** To illustrate this, we have provided a table below with corrected estimates for 2025 30-day supply WAC prices.

Product	Incorrect 2025 30-Day Supply WAC Pricing	Incorrect Vial assumptions for 30-day Supply	Correct Weeks of Therapy Based on Vials	Correct Days of Therapy Based on Vials	Corrected 2025 30-Day Supply WAC Pricing
KEYTRUDA (pembrolizumab)	$24,063	4 vials (16 mL)	6	42 days	$17,188
Opdivo (nivolumab)	$16,217	2 vials (48 mL)	4	28 days	$17,375
Tecentriq (atezolizumab)	$11,589	1 vial (20 mL)	3	21 days	$16,556
Libtayo (cemiplimab)	$11,335	1 vial (7 mL)	3	21 days	$16,193
Bavencio (avelumab)	$16,752	8 vials (80 mL)	4	28 days	$17,949
Imfinzi (durvalumab)	$12,884	30 mL	Variable (3-4 depending on indication)	21 days – 28 days	$13,804-$18,406
Jemperli (dostarlimab)	$12,030	10 mL	3	21 days	$17,186
Information Source	*PDAB Affordability Review (Table 12)* *	*PDAB Affordability Review (Table 11)* *	*PDAB Affordability Review Table 36 (confirmed via FDA label)* *	*Calculation (weeks of therapy x 7 = days of therapy)*	*Calculation using (WAC from PDAB Tables 11/12; corrected dosing from Table 12)***

*Keytruda (pembrolizumab) Affordability Review v2.0 https://dfr.oregon.gov/pdab/Documents/Keytruda-2026.pdf

**Note: The products above are administered using 2-, 3-, 4-, or 6-week cycles, not based upon 30-day cycles, and so a calculation was performed to arrive at the 30-day price based on the number of vials and administration cycles in Table 11 and Table 36 and 2025 prices in Table 12. For example, for KEYTRUDA the calculation is as follows: ($24,063 / 42) * 30 = $17,188. We repeated this process for all the products in Table 12.

Misleading Comparison of Products with Materially Different Dosing Schedules

The reports comparison of products on a "per claim" basis produces misleading results when those products have different dosing schedules. A per-claim methodology treats every claim as equivalent, regardless of how much treatment time it covers. KEYTRUDA's every 6-week option, for example, allows 6 weeks between infusions—reducing treatment burden for patients—but a single 6-week claim is counted the same as a 2- or 4-week claim for another product. As a result, less frequently dosed therapies appear more expensive per claim, while more frequently dosed therapies appear less expensive simply because each claim covers a shorter period. A meaningful comparison requires evaluating cost over a common time frame, such as monthly cost or total cost per course of treatment. Absent that adjustment, the analysis penalizes therapies with less frequent dosing and therefore actively penalizes a drug providing the benefits of fewer infusions for the patient and reduced need for chair time.

Ad-Hoc and Untested "Carve Out" Approach that Skews the Affordability Analysis

The "carve out" approach to removing orphan claims in affordability reviews is an ad-hoc workaround that is fundamentally flawed and creates inconsistencies that have not been reconciled. For example, the post-orphan exclusion cohort is reported as 10,715 claims and 1,595 patients in Appendix A that details the Orphan Review Methodology, while tables in the body of the report analyses of 9,851 claims and 1, 591 enrollees across multiple tables.[2] An additional 864 claims and four patients therefore disappear without explanation. This unexplained discrepancy suggests the Board introduced a methodological change midstream without addressing its broader implications for the review.

[2] Appendix A, printed page 42; Tables 2, 4, 6, 8, 9, 10, 16, and 19.

In addition, the "carve out" approach to removing orphan claims does not appear to be utilized with the proposed therapeutic alternative claims. By excluding orphan claims from KEYTRUDA and not applying the same exclusion to the proposed therapeutic alternative products, the analysis risks introducing systematic distortion into the underlying data set, including which claims are counted, which costs are attributed to each product, and how those costs are compared across treatments.

This, when combined with the flawed approach to selecting therapeutic alternatives, may result in incorrectly calculated costs, obscuring clinically meaningful differences among indications and patient populations, and producing results that do not reliably reflect the real-world use, value, or affordability of KEYTRUDA.

Incomplete and Inaccurate Clinical Presentations

There are numerous examples of incomplete or inaccurate representations of KEYTRUDA clinical data. Listed below are a few examples:

- The clinical section presents an incomplete and non-representative set of KEYTRUDA indications and selected efficacy studies without a stated indication or study-selection methodology.
- Results from separate, non-head-to-head trials of KEYTRUDA and the proposed therapeutic alternatives are presented side by side despite acknowledged differences in study design, populations, and follow-up which make comparisons inappropriate.
- The 11.1-month KEYTRUDA progression-free-survival result for the pMMR (proficient mismatch repair) endometrial cancer patient population from Table 31, is presented as the dMMR (deficient mismatch repair) patient population in Table 34, leading to the implication of similar efficacy to a proposed therapeutic alternative.

Conflicting Data Presented Throughout the Report

In addition, there are numerous examples of where the report contains conflicting data to represent the same information without accounting for those differences and how they impact the assessment of affordability.

Listed below are only a few examples:

- Net spending amounts of $46, 012, 562 and $41, 252, 790 are reported for the same displayed carrier-call population of 2, 058 claims and 360 enrollees.
- $132, 020, 415 is represented as total expenditures in one table (Table 2) and as average healthcare costs in another table (Table 16).

The Board's Analysis Fails to Reflect KEYTRUDA's Full Clinical Profile and Market Dynamics

The Board's selective use of data fails to account for the drug's broad clinical profile across 46 indications and differences across those indications, including: patient populations, dosing, treatment length, and setting of care which can lead to variances in the number of claims, payer costs, and patient OOP.

Other PD-1- and PD-L1 Inhibitors are not Therapeutic Alternatives

The Board selected therapeutic alternatives for KEYTRUDA based on drugs being in the same class without considering differences in indications. Oregon's rule[3] requires more than a shared pharmacologic class when selecting therapeutic alternatives. It must be "FDA-approved, compendia-recognized as off-label use for the same indication or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose."

[3] OAR 925-200-0010 (2) (c)

While there may be some overlap of tumor coverage with KEYTRUDA, none of the therapeutic alternatives overlap in all 46 indications. Even in aggregate, the other PD-1 and PD-L1 inhibitors do not cover all of KEYTRUDA's approved indications. In fact, there are multiple indications for which KEYTRUDA is the only PD-1/PD-L1 inhibitor approved. Among currently FDA-approved PD-1/PD-L1 checkpoint inhibitors, KEYTRUDA is the only agent with a U.S. FDA-approved indication in high-risk early-stage triple-negative breast cancer.[4] KEYTRUDA in combination with paclitaxel, with or without bevacizumab, is also the only PD-1/PD-L1 checkpoint inhibitor with an FDA-approved indication for platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, specifically for PD-L1 CPS ≥1 disease after one or two prior systemic regimens. Therefore, none of the proposed therapeutic alternatives meet the above requirements consistent with the statute, and the Board should conclude that there are no therapeutic alternatives to KEYTRUDA.

Affordability Review Relies on Incomplete and Limited Data Sources

The Board's analysis relies heavily on public information, as interpreted by staff, and data submitted by payers, but those sources do not capture the full range of price concessions, discounts, and market dynamics relevant to evaluating affordability. Further complicating the analysis, the PDAB does not have a mechanism to protect voluntarily submitted confidential information. This limits the ability for stakeholders to supplement or correct data represented in the affordability report.

One example of this is the analysis of the average discounts, rebates, and other price concessions considered in the affordability report for KEYTRUDA. The analysis looks only at data provided by commercial payers and does not consider any other price concessions. For example, the report does not account for statutory discounts such as Medicaid and 340B, which can be very substantial but highly confidential.

The current review process also fails to account for the complex distribution, billing, and reimbursement dynamics that distinguish physician administered oncology products from pharmacy benefit drugs. By focusing on PBM or health plan claims data, the analysis overlooks key medical benefit stakeholders—such as wholesalers, distributors, GPOs, and provider groups—and confidential arrangements that may affect acquisition cost and reimbursement. It also relies heavily on WAC without sufficiently considering ASP, site-of-care payment variation, or potential misalignment between NDC pricing units and HCPCS billing units, limiting the reliability of the pricing assessment.

The Approach Utilized to Review KEYTRUDA is Inconsistent with the Complexity of Review

As noted in our July 1, 2026, letter, the Board's review of KEYTRUDA lacks disease-specific clinical expertise—an issue Board staff has acknowledged as a process limitation. Although the Board appears to have taken steps to supplement certain clinical reviews through an external consultant, it has not provided transparency into when or how that consultant is used, and the approach appears to vary by product. Applying different clinical-review standards across 2026 product reviews—using an outside consultant for some products while relying solely on staff for others, including KEYTRUDA—raises concerns about the consistency, reliability, and fairness of the Board's conclusions.

The Board's rubric-based approach appears to apply a common set of variables across all selected products without adequately accounting for meaningful differences, such as whether a product is covered under the pharmacy benefit or the medical benefit, its clinical use, or the availability of data to support the review.

[4] Keytruda PI

For example, there are important differences that need to be considered when comparing pharmacy benefit drugs with medical benefit drugs. These products are distributed, administered, billed, reimbursed, and reported in different ways. Without a methodology that accounts for these differences, the review may treat products and data points as comparable when they are not.

In addition, using a rubric framework that does not account for differences across products is especially problematic for KEYTRUDA, which has 46 approved indications, in contrast to products that may have only one or two indications. Differences in indication breadth, patient populations, dosing patterns, treatment settings, and standards of care can materially affect utilization, spending, value assessment, and affordability considerations. A rubric that does not explain how these differences are weighted or adjusted risks creating misleading comparisons and overstating the significance of product-to-product differences identified through the review.

For all these reasons outlined here and expressed in our prior communications to the Board[5], Merck urges the Board to rescind the current draft affordability review report and withdraw KEYTRUDA from review.

Thank you for considering these comments.

Sincerely,

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[5] See comment letters dated March 13, 2026, April 10, 2026, May 15, 2026, and July 1, 2026.