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Oregon Prescription Drug Affordability Board (PDAB)
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Re: Concerns with the Selection Process for Affordability Reviews and Consideration of KEYTRUDA® (pembrolizumab) for Affordability Review

Members of the Oregon Prescription Drug Affordability Board,

Merck appreciates the opportunity to submit the following comments as written testimony for the upcoming meeting on March 18, 2026. We are writing to express our concerns regarding the Board's process for selecting drugs for prescription drug affordability reviews and the potential implications in the assessment of whether a drug is considered affordable. We are committed to supporting policies that reduce or eliminate barriers to patient affordability and offer the following commentary to ensure the process utilized by the Board to assess affordability is robust, accurate, and consistent with its statutory obligations

We provide more details and supporting documentation on the concerns below in the sections that follow:

- We are deeply concerned that the Board intends to review drugs with orphan designations, as this is inconsistent with the PDAB statute.
- The Board intends to review drugs with orphan designations without having the necessary data or technical capabilities to distinguish between orphan and non-orphan utilization of the drug.
- The data being used to represent the patient out of pocket cost is not an accurate representation of true Patient Out-of-Pocket (OOP) burden.
- We are concerned that changes to PDAB policies and procedures preventing the PDAB from accepting confidential information will limit its ability to make accurate affordability assessments.
- We are concerned that the potential selection of KEYTRUDA for an affordability review may overlook the immense clinical value of the drug.
- We feel our approach to pricing/affordability reflects the value of our medicines to the healthcare system and patients and supports patient access by limiting OOP burden for many patients.

Review of Drugs with Orphan Indications

We disagree with the Board's interpretation[1] that the statute allows the consideration of orphan-designated drugs also approved for non-orphan indications for an affordability 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.[2] The statute 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" under the PDAB process.

Complexity and Challenges of Separating Utilization Associated with Orphan Indications vs Non-Orphan Indications

Should the Board proceed with reviewing drugs with orphan indications, the consideration of those orphan designated drugs approved for non-orphan indications raises implementation concerns. The Board not only lacks statutory authority to review drugs with orphan indications but also the technical capability to separate orphan utilization from non-orphan utilization. As outlined below, there is a great deal of complexity associated with any attempt to identify and separate utilization associated with orphan indications vs non orphan indications for any given drug, especially in the treatment of patients with cancer.

In oncology, the same medicine can be used across different cancers and patient subgroups, but the "why" behind its use is rarely visible in administrative claims data. Claims data are essentially receipts: they can show that the drug was given, on what date, and what it cost, but the drug's billing code (e.g., National Drug Code for pharmacy dispensed drugs or Healthcare Common Procedure Coding System Level II J code for physician-administered drugs) is the same regardless of *which* cancer the drug was treating. Physician-administered drug claims include diagnosis codes, yet these codes don't include the details that define the clinical use in cancer care. Specific indications for use often involve detailed clinical information—things like histology, how advanced the cancer is, whether treatment is curative vs. palliative, or whether the patient met biomarker criteria. This information is not available in the diagnosis codes. These details are critical for distinguishing utilization for non-orphan from orphan indications. For example, KEYTRUDA received an orphan drug designation for "Treatment of Stage IIB through IV malignant melanoma" on 11/19/2012.[3] The ICD-10 diagnosis codes for malignant melanoma of the skin - C43 - support details only about the location of the cancer, not the necessary stage information.[4] The result is that trying to sort utilization by indication using claims alone quickly turns into inference and guesswork, with a high risk of misclassifying which patients (and which uses) are being counted.

To attribute oncology drug use to a specific indication with confidence, linked, patient-level clinical information that goes well beyond pharmacy and medical claims is needed. At minimum, that means: a confirmed diagnosis with tumor site and histology/subtype (typically from pathology), stage and metastatic status (often based on oncology notes and imaging), biomarker/genomic test results and the timing of those tests (from laboratory and pathology systems), a clear picture of the patient's treatment history (line of therapy and prior regimens, captured from the paper or electronic patient record), treatment intent (adjuvant/curative vs. metastatic/palliative), and the full regimen context (whether the drug was used alone or in combination, and why it was started, changed, or stopped).

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[1] Or. Admin. Code §925-200-0020(2)(n)
[2] Or. Rev. Stat. § 646A.694(2)
[3] U.S Food & Drug Administration. Search Orphan Drug Designations and Approvals: pembrolizumab. https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=381012 , accessed March 10, 2026.
[4] ICD10Data.com. ICD-10-CM Codes: Malignant melanoma of skin C43-. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C43-C44/C43- , accessed March 10, 2026.

Just as importantly, the data must be reliably linkable across settings, so the drug administration/dispensing event can be tied to the contemporaneous clinical and test information that justified that specific use. Without access to detailed clinical records, pathology, and laboratory data—and the ability to connect the data—indication level measurement for multiuse oncology drugs is not just difficult; it is prone to systematic error.

As a practical matter, Oregon's PDAB has stated that its drug review work relies on aggregated, de-identified information drawn from the state's Drug Price Transparency reporting, the Oregon Health Authority's All Payer All Claims (APAC) reporting program, and a data call to Oregon insurance carriers[5]. APAC is, by design, an administrative claims database (medical, pharmacy, and dental claims plus related enrollment/demographic/provider fields), and does not contain clinical or electronic health record data[6]. That limitation matters when trying to operationalize "orphan versus nonorphan" sorting: FDA orphan drug designation is granted for a specified rare disease or condition that must be identified with specificity—it is not a blanket status applied to the drug across all cancers and uses[7]. Without access to the underlying chart-level pathology, laboratory, staging, and treatment information that defines those specific diseases/subsets, which are not contained in the available databases, any attempt by the Board to separate orphan from non-orphan utilization will be based on guesswork and prone to significant error, leading to a flawed affordability review.

Utilizing Total Annual Net of Rebate Spend per Enrollee as Proxy for Patient Out-of-Pocket (OOP) Burden

We are also concerned that the Board is utilizing the metric "total annual net of rebate spend per enrollee" as a proxy for patient out-of-pocket burden. We agree that patient OOP burden is an important variable to consider when assessing potential affordability challenges and should be a priority when selecting drugs for an affordability review. However, we disagree with the use of a metric that represents the plan spend per enrollee as the basis for determining the OOP burden for a drug. Patient OOP costs are determined by the individual plan design and are variable within and between insurance carriers. We encourage the Board to leverage other available data sources to better understand the real OOP cost burden for drugs being considered for potential selection.

Limitations to Manufacturer Ability to Provide Information into the Process

We are also concerned about the recent changes made to the PDAB Policies and Procedures that prevent the Board from accepting, reviewing, or retaining information voluntarily submitted by manufacturers or any stakeholder, if that information is designated as trade secret, confidential, or proprietary. If stakeholders are unable to voluntarily provide information beyond what is in the public domain, this will limit their ability to provide information that could provide additional context or correct data inaccuracies. And as a result, it will hamper the Board's ability to accurately assess affordability and identify potential contributing factors. We urge the Board to continue to look for ways to receive voluntarily submitted information designated as trade secret, confidential, or proprietary while ensuring this information is adequately protected and used only for this intended purpose.

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[5] Data for drug reviews: 2026 Drug review data. Oregon Prescription Drug Affordability Board. https://dfr.oregon.gov/pdab/pages/data.aspx , Accessed March 10, 2026.
[6] All Payer All Claims Reporting Program. Oregon Health Authority. https://www.oregon.gov/oha/hpa/analytics/pages/all-payer-all-claims.aspx , Accessed March 10, 2026.
[7] § 316.20 Content and format of a request for orphan-drug designation. 21 CFR 316.20 https://www.ecfr.gov/current/title-21/section-316.20 , accessed March 10, 2026.

Concerns Regarding Selection of KEYTRUDA

At Merck, our goal is to help extend and improve the lives of people with cancer. We are extremely proud that KEYTRUDA has helped to transform the way physicians treat some of the deadliest forms of cancer. We are concerned that the process for selecting drugs for affordability review may not adequately account for the significant clinical value of KEYTRUDA and the important benefits it provides to patients.

Today, KEYTRUDA is foundational in the treatment of many advanced cancers. In the United States, KEYTRUDA has 44 FDA-approved indications across 19 different tumor types and 2 tumor agnostic indications.[8] These include indications for melanoma, non-small cell lung cancer, malignant pleural mesothelioma , head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large b-cell lymphoma, urothelial cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, biliary tract cancer, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, cutaneous squamous cell cancer, triple-negative breast cancer, and ovarian cancer. KEYTRUDA is also indicated in the treatment of two tumor site-agnostic cancer types: microsatellite instability-high or mismatch repair deficient cancer and tumor mutational burden-high cancer.

In addition to the drug's substantial breadth of approved uses, KEYTRUDA has demonstrated improved survival outcomes in 14 tumor types.[9] Importantly, improved survival outcomes has been demonstrated in certain patients with early-stage non-small cell lung cancer, intermediate-high or high-risk resectable renal cell carcinoma, and early-stage high-risk triple-negative breast cancer – cancers that have been difficult to treat. It is illustrative that, prior to immunotherapy, 5-year survival was 24% for all patients with non-small cell lung cancer and 5.5% for those with distant metastases.[10] Since the introduction of immuno-oncology therapies like KEYTRUDA, there has been a four-fold increase in survival in metastatic non-small cell lung cancer.[11] Additionally, KEYTRUDA has demonstrated significant improvements in overall survival in five earlier stage cancer settings – perioperative (before and after surgery) non-small cell lung cancer, adjuvant (after surgery) renal cell carcinoma, perioperative triple-negative breast cancer, locally advanced cervical cancer, and perioperative cisplatin ineligible muscle-invasive bladder cancer.
Many of the 44 indications for KEYTRUDA address high unmet need in small subpopulations or in populations with rare cancers. Limited treatment options in these settings are reflected in the 10 orphan drug[12] and 16 breakthrough therapy designations[13] that KEYTRUDA has received. Overall, the extensive clinical evidence, broad utility across tumor types, and meaningful survival benefits of KEYTRUDA for certain indications reinforce its value as a foundational oncology therapy and reflect Merck's commitment to helping improve and extend the lives of patients with cancer.

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[8] KEYTRUDA® (pembrolizumab) injection. Prescribing information. Merck & Co., Inc.; revised 2026. U.S. Food and Drug Administration. Accessed March 2026.
[9] KEYTRUDA® (pembrolizumab) injection. Prescribing information. Merck & Co., Inc.; revised 2026. U.S. Food and Drug Administration. Accessed March 2026.
[10] Noone AM, Howlader N, Krapcho M, et al: SEER Cancer Statistics Review, 1975-2015. Bethesda, MD, National Cancer Institute, 2018.
[11] KEYTRUDA® (pembrolizumab) injection. Prescribing information. Merck & Co., Inc.; revised 2026. U.S. Food and Drug Administration. Accessed March 2026.
[12] U.S. Food and Drug Administration; Search Orphan Drug Designations and Approvals; https://www.accessdata.fda.gov/scripts/opdlisting/oopd/ , Accessed March 10, 2025.
[13] U.S. Food and Drug Administration; Center For Drug Evaluation And Research; https://www.fda.gov/drugs/nda-and-bla-approvals/breakthrough-therapy-approvals , current as of February 27, 2026.

Our Approach to Pricing/Affordability

Merck stands behind the pricing of our products. Merck has a long history of responsibly pricing our medicines and vaccines to reflect the benefit they provide to people and society – and the price of KEYTRUDA reflects its value to patients and healthcare systems.

The amount that any patient ultimately pays for a medicine is determined by the terms of the patient's insurance policy or by the government program in which the patient participates (e.g., Medicare). Merck does not control this, but we do have national level data on these costs. For example, for patients with commercial insurance who received a 200 mg dose, 59% of patients paid no out-of-pocket costs for KEYTRUDA. For those patients who did have out-of-pocket costs, approximately 80% of patients paid between $0.01 and $375 per infusion, after satisfying their deductible.[14]

At Merck, we have a long-standing commitment to developing and delivering life-changing medicines and vaccines, and to prioritizing access and affordability for our patients. We believe that no one should go without the medicines or vaccines they need. Merck is committed to helping Americans access the medicines they rely on while protecting the innovation that makes future breakthroughs possible.

That is why the Merck Patient Assistance Program provides certain medicines – including KEYTRUDA – for free to people who do not have prescription drug or health insurance coverage and who, without our assistance, cannot afford their Merck medicine and vaccines. Additionally, we maintain the Merck Access Program (MAP), a patient support program for KEYTRUDA. MAP supports patients and their healthcare providers through various means, including but not limited to: determining patient coverage and benefits information, providing information on affordability options such as the Merck Co-pay Assistance Program, referring patients to the Merck Patient Assistance Program, Inc. for eligibility determination, and helping answer questions about billing and coding, the prior authorizations and appeals process, and product distribution. These programs are consistent with Merck's long-held values and traditions of putting patients first.

In addition to the concerns outlined herein, we continue to have broader concerns about the potential for the Board's work and future actions to adversely impact patient access to medicines and future innovations.

We thank the Board for the opportunity to provide written comments and look forward to engaging in the future.

Sincerely,

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[14] Merck & Co., Inc. (2026). Cost, insurance, and financial help with KEYTRUDA® (pembrolizumab). https://www.keytruda.com/financial-support/