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Via Electronic Submission

August 28, 2026

Shelley Bailey, Board Chair
Oregon Prescription Drug Affordability Board
pdab@dcbs.oregon.gov

Re: Public Comment on the Draft Drug Review Report for TREMFYA® (guselkumab)

Dear Board Chair Bailey:

Thank you for the opportunity to comment on the draft Drug Review Report for TREMFYA ("Report") developed by the Oregon Prescription Drug Affordability Board ("PDAB" or "Board"). Johnson & Johnson shares the Board's commitment to ensuring that Oregonians can access and afford the medicines they need.

We have reviewed the Report and reached the following conclusions:

- TREMFYA should not have been selected for review under the Board's governing rule.
- The Report contains multiple inconsistencies, undermining confidence in its reliability and accuracy for the purpose of evaluating affordability.
- The Report's own data show that TREMFYA does not create an affordability challenge for Oregon patients or the health care system.

Therefore, we respectfully ask the Board to end its affordability review of TREMFYA and remove it from the list of drugs included in the Board's annual report to the Legislature.

A. TREMFYA should not have been deemed eligible for affordability review.

As a threshold matter, OAR 925-200-0010 provides that the Board "will select from the list of eligible prescription drugs, provided by the Department of Consumer and Business Services [DCBS] pursuant to ORS 646A.694."[1] TREMFYA did not appear on any list of eligible drugs provided by DCBS pursuant to ORS 646A.694 for the applicable review period. Accordingly, it was not eligible for selection, a point J&J raised in our June 15, 2026 submission and again at the Board's August 19, 2026 meeting.[2]

At that meeting, staff stated that instead of using the aggregate Top 25 list published by DCBS when selecting drugs for review, the PDAB selected TREMFYA because it appeared on "either the greatest increase, most costly, or most prescribed drug" submission from "six or more"

[1] ORS 743.025; OAR 925-200-0010(1)
[2] https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx; https://dfr.oregon.gov/drugtransparency/data/Pages/new-drug-reports.aspx#drug; https://dfr.oregon.gov/pdab/Documents/Letters/Johnson-Johnson-Tremfya-20260615.pdf

individual reporting carriers.[3] That methodology is inconsistent with OAR 925-200-0010. The rule does not establish, reference, or authorize a "six or more carrier" threshold.[4] Nor does the statutory or regulatory framework authorize the Board to substitute an unpublished carrier-count methodology for DCBS's consolidated and published list pursuant to ORS 646A.694.[5]

The proposed "six-or-more carrier" methodology also lacks transparency. Given that carrier submissions are confidential, neither manufacturers nor the public can determine whether the methodology was applied consistently, whether the same carriers were counted across drugs, or whether differences in enrollment and benefit design affected selection. As a result, the methodology cannot be independently verified and is difficult to reconcile with the transparency goals of the Drug Price Transparency program and the Board's commitment to using aggregated, de-identified information.[6]

B. The Report contains errors that undermine its reliability.

The Report contains several substantive data inconsistencies that undermine reliability and raise significant concerns about the accuracy of its conclusions. The examples below are representative and, in some cases, materially affect the Report's assessment of TREMFYA's price trajectory, spending, patient burden, and affordability.

- **Conflicting price data.** Figure 1 and Table 12 report materially different wholesale acquisition cost (WAC) figures. The Report erroneously uses the same value as both the WAC per-unit list price (Figure 1) and the WAC per 30-day supply (Table 12). Due to this mistake, Table 12 shows ***a single-year artificial increase of approximately 110%***, conflicting with the Report's finding of an approximately 5% average annual increase.
- **Conflicting spending data.** The total payer spend for TREMFYA is also materially different throughout the report. For example, TREMFYA's gross total payer spend in the narrative text on page 19 is over $11 million higher than the gross total payer spend listed in Tables 2, 16, 21, and 24. The narrative appears to convert a per-enrollee figure into a total measured in millions, thereby overstating system-level spending and potentially changing perceived budget impact or comparative ranking.
- **Conflicting price concessions.** Page 17 appears to conflate a percentage of dollars with a percentage of claims. It states that "68.5 percent of claims received some form of price concessions, leaving 59.3 percent at full gross cost." If 68.5 percent of claims received a price concession, only 31.5 percent (not 59.3 percent) could remain at full gross cost.
- **Conflicting out-of-pocket (OOP) figures.** The OOP amounts in Tables 3 and 7 do not appear consistent with the enrollee burden figure in Table 4. Other cost figures also vary across Tables 2, 16, and 24. These inconsistencies make it difficult to determine actual patient cost-sharing and may materially overstate the financial burden experienced by

[3] https://www.youtube.com/watch?v=5GDmlQ9Hh7c
[4] ORS 743.025; OAR 925-200-0010(1)
[5] OAR 925-200-0010(1)
[6] https://dfr.oregon.gov/drugtransparency/pages/index.aspx; https://dfr.oregon.gov/pdab/pages/data.aspx

patients.

- **Potentially misleading 30-day calculations.** TREMFYA is not administered monthly. For plaque psoriasis and psoriatic arthritis, it is administered at weeks 0 and 4 and every eight weeks thereafter. Converting this regimen to a 30-day supply may distort comparisons with therapies that have different dosing schedules.
- **Misaligned therapeutic alternatives by indication.** The claims analysis appears to aggregate TREMFYA use across indications, while the 11 selected alternatives are not each approved for all the same indications. Comparing aggregated TREMFYA claims with alternatives that treat different patient populations may produce misleading conclusions.
- **Clinical review limitations.** The clinical review explicitly recognizes the complexity of autoimmune diseases and acknowledges that it does not evaluate key components of patient management, including treatment sequencing, treatment failure, comorbidities, complications, and individualized patient considerations. Consequently, the review provides only a partial view of a patient's treatment journey. Because these omitted factors can significantly influence treatment utilization, outcomes, and healthcare costs, the Board cannot appropriately determine affordability based on an analysis that does not capture the full scope of real-world patient care.
- **Typographical errors.** Several misspellings and typographic errors further underscore the need for careful review.

Collectively, these issues create a materially inaccurate picture of TREMFYA's price trajectory, budget impact, patient burden, and relative affordability. The consequences may extend far beyond this review. The Report is in the public domain and may be relied upon by policymakers and researchers nationwide. Yet, many of the Report's conclusions rely on proprietary, subscription-based data that cannot be accessed or independently verified by those using it. The Report also includes methodologies and comparative analyses involving numerous therapies, including additional Johnson & Johnson products that may be subject to review elsewhere. ***As states increasingly look to one another's affordability reviews and as public reports are incorporated into analytical tools, databases, and artificial-intelligence-enabled research platforms, any errors may be perpetuated, amplified, and relied upon by others without independent validation.*** For these reasons, we respectfully urge the Board to withdraw the Report, correct all errors throughout, and refrain from relying on it in any affordability determination.

C. The Report's data show that TREMFYA is affordable.

Affordability should be based on what patients and payers actually pay, not list price alone. The Report's net-price, patient-cost, and coverage findings do not support a conclusion that TREMFYA creates an affordability challenge.

1. Net costs are substantially below list price.

The Report finds that Oregon payers receive average price concessions of approximately 40.7% on TREMFYA, with manufacturers providing about 80% of that total concession. As the Report

acknowledges, this figure excludes total price concessions to pharmacy benefit managers, meaning the true manufacturer concession may be larger still. Given that list price does not reflect these concessions, WAC overstates the cost borne by payers and the health care system and should not be considered in affordability determinations.

2. **Actual patient out-of-pocket costs are low and are further supported by assistance.**

The Report shows a median enrollee OOP cost of $0 per claim (Tables 3 and 7). The difference between the median and mean suggests that higher average costs may be driven by a relatively small number of claims rather than the typical patient experience. These figures also do not fully reflect manufacturer programs that may further reduce costs for eligible patients, including:

- The TREMFYA withMe Savings Program, through which eligible commercially insured patients may pay as little as $0 per dose; and
- J&J's Patient Assistance Program that provides TREMFYA at no cost to eligible patients who are uninsured.

The Board should evaluate the experience of the typical patient and avoid allowing a limited number of higher-cost claims to characterize overall affordability.

3. **TREMFYA is priced competitively.**

The Report's comparative data show that TREMFYA's cost is lower than many of the named therapeutic alternatives. Several alternatives have higher total payer spending, average cost per enrollee, total patient spending, or median patient OOP costs (see Tables 2, 3). These comparisons should be interpreted cautiously because the products do not share identical indications, patient populations, dosing schedules, or utilization. Even so, the Report does not establish that TREMFYA presents an unusual or disproportionate affordability burden.

4. **Access is already broad, and additional restrictions could harm patients**

The Report shows strong formulary acceptance and access: TREMFYA is covered by 100% of reporting plans, with no plans requiring step therapy and none declining to cover it. This is generally an indicator that payers view the product as a necessary or appropriate treatment option. Its value is further underscored by the lack of step therapy—payers are not actively steering patients to alternatives. Patients in Oregon are accessing this medicine today. We respectfully caution that policy actions premised on list price could disrupt this stable access, push plans toward more restrictive utilization management, and interrupt care for patients whose disease is well controlled.

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J&J remains committed to engaging constructively with stakeholders to improve patient access and affordability to innovative medicines. We know that patients are counting on us to develop

and bring medicines to market. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Sincerely,

Michael Valenta
Chief Strategic Customer Officer, Strategic Customer Group
Johnson & Johnson Health Care Systems, Inc.