The Impact of Simplified Dosing Terminology on Treatment Exposure and Budget Impact Estimates

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Background

Simplified dosing terminology such as ‘monthly’ or ‘bi-weekly’ is frequently used in non-clinical communications and economic models in place of evidence-based interval dosing (e.g., monthly versus every 4 weeks [Q4W]).

This discrepancy can cause confusion among healthcare professionals, resulting in unintended consequences, particularly for fixed-duration regimens where misinterpretation may lead to risk of clinical underdosing or overdosing. For indefinite therapy, the issue primarily affects payers’ budgets.

Objective

To evaluate how simplification of evidence-based dosage schedules in marketing materials affects treatment duration, clinical practice, and costs for fixed-duration and indefinite regimens, and to explore the importance of consistent dosing terminology and harmonized treatment initiation schedules across comparators within economic models.

1 **Simplified dosage terminology:**
‘Monthly’ versus ‘every 4 weeks’

2 **Misinterpretation of bi-weekly:**
‘Q2W’ versus ‘2 dosages per week’

Methodology

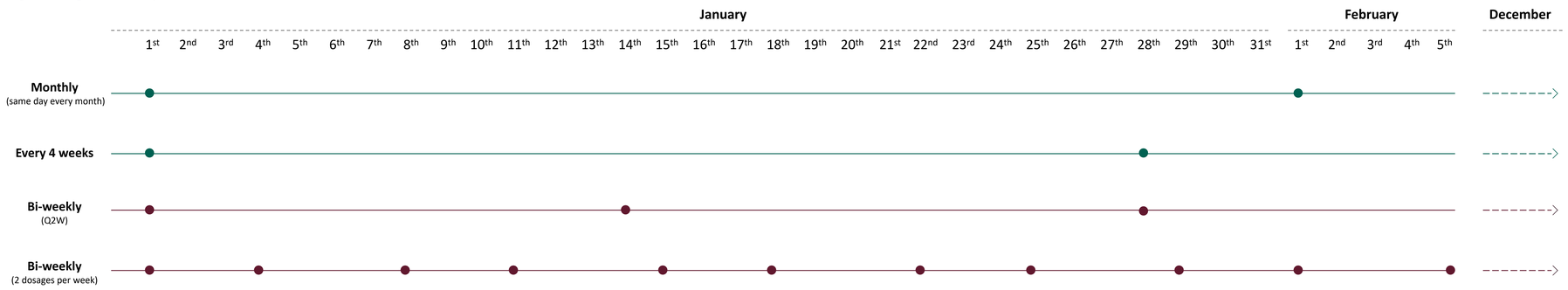
Illustrative case examples were identified in publicly available regulatory and promotional materials in which simplified dosing terminology differed from evidence-based interval dosing. Several examples of where marketing materials diverge from the Summary of Product Characteristics across both oncology and neurodegenerative disease areas were identified. Examples were selected to demonstrate the magnitude of effect rather than to provide a comprehensive audit of promotional practices.

Using Excel®, a deterministic scenario analysis was conducted to isolate the impact of dosing terminology on treatment exposure and drug acquisition costs. Differences in treatment duration and dosing frequency between evidence-based and marketing dosage schedules were modeled over 12 months to evaluate their impact on clinical dosing and budget implications for both fixed-duration and indefinite therapy regimens.

All dosage regimen interpretations were anchored to a start date of January 1st, 2026. ‘Monthly’ dosing was administered on the first calendar day of each month, whilst ‘every 4 weeks’ dosing was administered on a 28-day cycle. For bi-weekly dosing, ‘every 2 weeks’ (‘Q2W’) dosing was administered every 14 days, whilst ‘2 dosages per week’ was administered on the first and fourth day of each weekly cycle (Figure 1).

This analysis focused on drug acquisition costs only. While monitoring, administration, and adverse event management costs may also be affected, these were excluded for simplicity. To capture the magnitude of the effect on payer and institution costs, the percentage difference between the dosages scheduled over a 12-month period was assessed.

Figure 1: Dosage timeline interpretations



Results

For fixed-duration regimens, the simplification of ‘every 4 weeks’ to ‘monthly’ can lead to clinical underdosing, decreased costs, and deviation from trial evidence; resulting in treatment exposure that deviates from trial-evaluated dosing. For indefinite therapy, this discrepancy inflates annual cost projections and may bias cost analysis models. Assuming dosing on Day 1, an ‘every 4-weeks’ dosing results in 14 doses per year (whereas monthly dosing may result in 12 doses), reducing drug acquisition costs by approximately 16.7% and potentially lowering monitoring, administration, and adverse event management costs (Figure 2).

The misinterpretation of bi-weekly meaning ‘every 2 weeks’ as ‘2 dosages per week’ could lead to 105 doses instead of 27 per year, resulting in a 288.9% increase in drug acquisition costs relative to evidence-based Q2W dosing over a 12-month horizon. The clinical implications of overdosing are not quantified in this analysis, but such deviations could influence the efficacy of the treatment (Figure 3).

Figure 2: ‘Monthly’ versus ‘every 4 weeks’

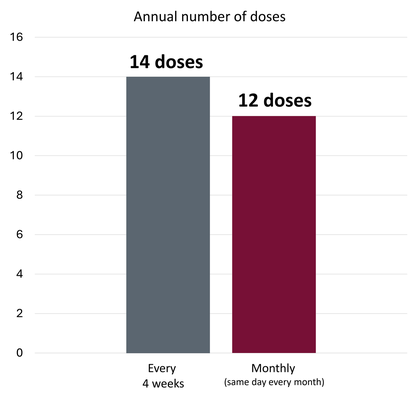
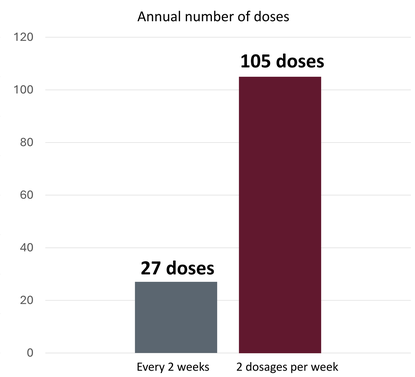


Figure 3: Misinterpretation of bi-weekly



~16.7%
effect on costs

~288.9%
effect on costs

Discussion

The use of ‘monthly’ rather than ‘every 4 weeks’ in economic modeling can introduce bias and should be avoided, as it may cause misleading results and unfounded conclusions. This distinction is particularly important for high-cost drugs, where the 16.7% difference in dosing frequency can significantly affect payer and institutional budgets.

Similarly, misinterpreting bi-weekly can have clinical consequences, potentially exposing patients to unnecessary risk of adverse events or reduced efficacy, as well as creating substantial budgetary impact. In addition, bi-monthly is inherently ambiguous, commonly interpreted as either ‘2 times per month’ or ‘every 2 months’, and could result in comparable, though smaller-scale, clinical impact and financial forecast misalignment.

A final consideration is the importance of aligning dosing terminology and initiation schedules across comparators within economic models. Inconsistent wording or timing assumptions can introduce structural bias and influence cost-comparison outcomes. For instance, even small differences, such as one product initiating at Week 0 and another at Week 1 can result in a different number of doses over a fixed time horizon. With weekly dosing, this equates to 53 vs 52 doses in the first year, a 2% difference, which may meaningfully affect conclusions when drug costs are similar. Ensuring consistent terminology and harmonized initiation points across comparators is therefore essential to maintain the validity and interpretability of budget impact and cost comparison analyses.

Limitations

- No clinical outcome modeling
- Assumes full adherence

Conclusion

Clear and consistent communication of dosage schedules is essential to avoid misrepresentation of costs and resource use, and to prevent biased budget impact analyses. Manufacturers should understand the implications of simplifying terminology before releasing promotional materials to ensure alignment with local guidelines.

Economic models should anchor dosing to evidence-based intervals, explicitly document assumptions, and terminology across comparators. Even small inconsistencies can meaningfully affect dose counts, costs, and conclusions for high-cost therapies.

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Abbreviations
Q2W – Every 2 weeks
Q4W – Every 4 weeks