

# ARTICLE IN REVIEW:

## ViviGen® 24-month clinical performance in lumbar fusions comparable to Infuse™, yet with significantly lower follow-up hospitalization charges

**PUBLICATION:** Journal of Orthopaedic Surgery and Research, November 2021.

**TITLE:** A 24-month retrospective update: follow-up hospitalization charges and readmissions in US lumbar fusion surgeries using a cellular bone allograft (CBA) versus recombinant human bone morphogenetic protein-2 (rhBMP-2).<sup>1</sup>

**AUTHORS:** Wetzell B, McLean JB, Dorsch K, Moore MA.

**STUDY DESIGN:** Retrospective cohort follow-up study using data from the Premier Healthcare Database.

**SUMMARY:** The objective of this study was to build upon previously-reported 12-month follow-up findings.<sup>2</sup> Of 16,172 patients who underwent lumbar fusion surgery in the original study, there were 1,522 patients (23.1%) from the ViviGen group and 2,270 patients (23.7%) from the Infuse group identified in the full cohort of the current study with all-cause hospital readmissions during the 24-month follow-up period. For the single-level cohort, there were 1,076 ViviGen patients (18.9%) and 1,531 Infuse patients (18.0%). The adjusted cumulative mean follow-up hospitalization charges in the full cohort were significantly lower in the ViviGen group (\$99,087) versus the Infuse group (\$124,389;  $P < 0.0001$ ), and this pattern remained in the single-level cohort (ViviGen = \$104,906 vs Infuse = \$125,311;  $P = 0.0006$ ). There were no differences between groups in adjusted cumulative mean lengths of stay in either cohort. Differences in the rates of potentially-relevant follow-up readmissions aligned with baseline comorbidities originally reported for the initial procedure.<sup>2</sup> Subsequent lumbar fusion procedure rates were significantly lower for ViviGen patients in the full cohort (10.1% vs 12.0%;  $P = 0.0002$ ) and similar between groups in the single-level cohort, in spite of ViviGen patients having significantly higher rates of baseline comorbidities that could negatively impact clinical outcomes, including bony fusion. The authors conclude that use of ViviGen for lumbar fusion surgeries performed in the US is associated with substantially lower 24-month follow-up hospitalization charges versus Infuse, with both exhibiting similar rates of subsequent lumbar fusion procedures and potentially-relevant readmissions.

### Similar clinical performance between ViviGen and Infuse:

Rates of subsequent lumbar fusions were significantly lower among ViviGen patients in the full cohort but similar between groups in the single-level cohort (Figure A).

### Significantly lower follow-up hospitalization charges in ViviGen patients:

ViviGen patients in the full cohort had \$25.3K lower average hospitalization charges than Infuse patients and \$20.4K lower charges in the single-level cohort (Figure B).

### Aligns ViviGen's clinical performance with the reported attribute that makes Infuse cost-effective:

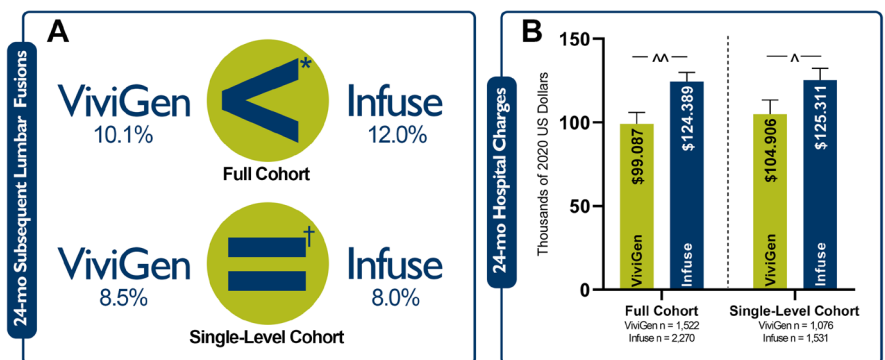
24-month rate of revisions reportedly makes Infuse cost-effective.<sup>3</sup> ViviGen's clinical performance was similar in this study, yet it is associated with substantial reductions in index<sup>2</sup> and follow-up<sup>1</sup> hospitalization charges, suggesting that ViviGen is the more cost-effective option

### References:

1. Wetzell B, McLean JB, Dorsch KA, Moore MA. A 24-month Retrospective Update: Follow-up Hospitalization Charges and Readmissions in US Lumbar Fusion Surgeries Using a Cellular Bone Allograft (CBA) versus Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2). J Orthop Surg Res. 2021; 16(680). doi: [10.1186/s13018-021-02829-0](https://doi.org/10.1186/s13018-021-02829-0)
2. Wetzell B, McLean JB, Moore MA, Kondragunta V, Dorsch KA. A Large Database Study of Hospitalization Charges and Follow-up Diagnoses in US Lumbar Fusion Surgeries Using a Cellular Bone Allograft (CBA) versus Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2). J Orthop Surg Res. 2020; 15(544). doi: [10.1186/s13018-020-02078-7](https://doi.org/10.1186/s13018-020-02078-7)
3. Jain A, Yeramaneeni S, Kebaish KM, et al. Cost-Utility Analysis of rhBMP-2 Use in Adult Spinal Deformity Surgery. Spine (Phila Pa 1976). 2020; 45(14):1009-1015. doi: [10.1097/brs.0000000000003442](https://doi.org/10.1097/brs.0000000000003442)

## Rates of Subsequent Fusions and Follow-up Hospitalization Charges

(A) Rates of 24-month subsequent lumbar fusions were significantly lower among ViviGen patients in the full cohort (10.1% vs 12.0%,  $*P = 0.0002$ ), but similar in the single-level cohort (8.5% vs 8.0%, †not statistically different; figure created from data presented in Table 2). (B) Cumulative 24-month follow-up hospitalization charges were significantly lower for the ViviGen patients in both cohorts ( $^{**}P < 0.0001$ ,  $^{*}P = 0.0006$ ; figure adapted from Figure 2 with permission under an [open access license](#).<sup>1</sup>)



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