

Understanding 505(b)(2) drug purchasing patterns within a home infusion and specialty pharmacy group purchasing organization: An osteoporosis case study



Stacey Ness, Pharm.D, CSP, IgCP, MSCS, AAHIVP, Brandon Wilkins, and Jack Donahue
Managed Health Care Associates, Inc. (MHA), Florham Park, NJ



BACKGROUND

In 2019, the United States healthcare system saved an estimated \$313 billion from generics and biosimilar drugs.¹ However, the adoption of specialty generics has been slower, in part because specialty generics are more difficult to develop, obtain approval for, and manufacture.² Most generic products are approved by the US Food and Drug Administration (FDA) through an Abbreviated New Drug Application (ANDA), which necessitates that the proposed generic must be identical to the innovator product with respect to active ingredient, salt form, dosage strength, dosage form, and route of administration. One pathway that manufacturers of specialty products can use to both streamline the approval process and to remove the sameness requirements in order to avoid entering a crowded generics market is the 505(b)(2) new drug application.³ This pathway allows some of the information required for approval of the specialty generic to come from studies that have already been conducted on the reference product, resulting in a less costly and faster route to approval than a New Drug Application (NDA). Unlike an ANDA however, the 505(b)(2) pathway allows for modifications to the proposed product to deviate from the innovator product in many aspects, including the salt form, dosage form, route of administration, strength, new combination product, modified active ingredient, new indications for previously approved drugs, or an over-the-counter switch.^{3,4}

BACKGROUND (CONTINUED)

Given the “Triple Aim” of improving the patient experience of care, improving the health of populations, and reducing the per capita cost of health care,⁵ a 505(b)(2) specialty product can offer cost reduction compared to that of an innovator product, while also allowing for modifications to the drug that may improve the patient’s experience of care. Consistent with the objectives of the Triple Aim, this nationwide home infusion and specialty pharmacy group purchasing organization (GPO) offered a pharmaceutical manufacturer agreement for participating pharmacies to access competitive 505(b)(2) product pricing along with education and support.

OBJECTIVE

The purpose of this case study is to understand changes in purchasing patterns of participating home infusion and specialty pharmacies for a 505(b)(2) product to treat osteoporosis. Purchasing data was analyzed before and after the product was added to this home infusion and specialty pharmacy GPO contract portfolio. Analysis was also completed to compare its market share to the non-contracted reference product.

METHODS

A retrospective analysis of purchasing data from this home infusion and specialty pharmacy GPO was conducted to determine sales growth for the 505(b)(2) product. The baseline for the pre-contracted measurement was average units from July 2020 through November 2020 and sales growth was analyzed quarterly

METHODS (CONTINUED)

in the post-contracting period from Q1 2021 through Q1 2022 and compared to baseline. Market share from November 2020 through March 2022 of the 505(b)(2) product compared to the reference product was also calculated.

RESULTS⁶

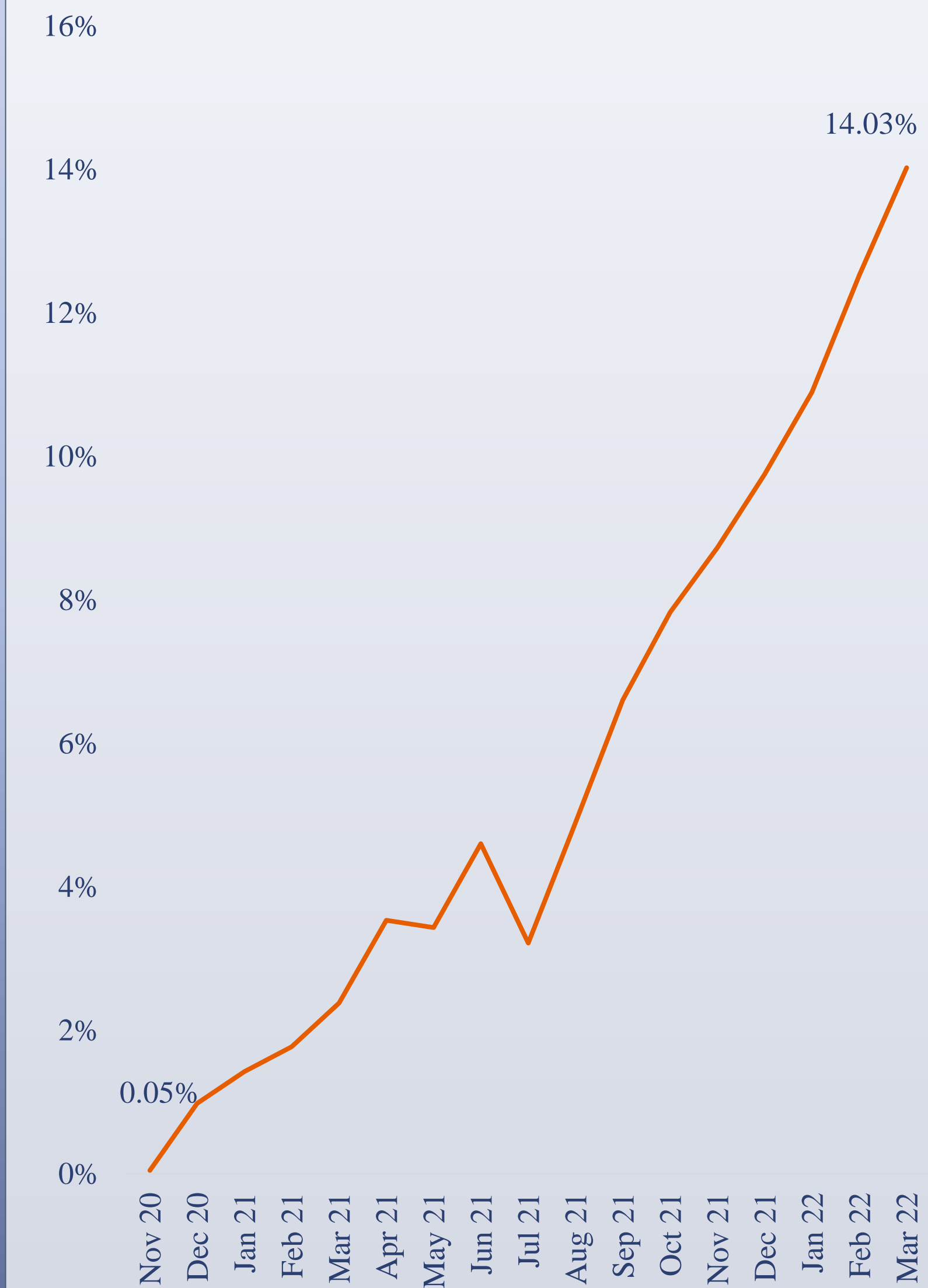
Percent Change of Contracted 505(b)(2) Product Purchases Compared to Baseline



When compared to baseline, contracted 505(b)(2) product purchases grew 688% in Q1 2021, 1348% in Q2 2021, 2942% in Q3 2021, 3355% in Q4 2021, and 3078% in Q1 2022.

RESULTS (CONTINUED)⁶

Market Share of 505(b)(2) Contracted Product



Market share for the 505(b)(2) product as compared to the reference product stood at 0.05% in November 2020 and grew after contract initiation to 14.03% in March 2022.

CONCLUSION

The 505(b)(2) approval pathway may offer manufacturers an option to differentiate their products and diversify their portfolios as the specialty and generic market continues to become crowded and pricing pressures increase.⁷

Although unable to control for confounding factors such as payer formulary, payer reimbursement, and provider adoption, this case study suggests that pharmaceutical manufacturer agreements designed for participating pharmacies to access competitive 505(b)(2) product pricing along with education and support through this home infusion and specialty pharmacy GPO could be one way to help drive adoption of less costly alternative specialty products and continue striving towards the Triple Aim.

REFERENCES

- 2020 Generic Drug & Biosimilar Access and Savings in the US Report. Available at <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf> Accessed 8/30/2022.
- Specialty Generics: Barriers to Uptake. Available at: <https://www.forbes.com/sites/joshuacohen/2018/11/12/specialty-generics-barriers-to-uptake/?sh=7a52331d576f> Accessed 8/30/2022.
- The 505(b)(2) Drug Approval Pathway: A Potential Solution for the Distressed Generic Pharma Industry in an Increasingly Diluted ANDA. Available at: <https://www.sternecker.com/news-insights/publications/505b2-drug-approval-pathway-potential-solution-distressed-generic-pharma> Accessed 8/30/2022.
- What is 505(b)(2)? Available at: <https://premierconsulting.com/resources/what-is-505b2/> Accessed 8/30/2022.
- Institute for Healthcare Improvement Triple Aim Initiative. Available at: <https://www.ihl.org/Engage/Initiatives/TripleAim/Pages/default.aspx> Accessed 8/30/2022.
- Managed Health Care Associates, Inc. (MHA), Data on File. Accessed 6/30/2022.
- 505(b)(2): A Pathway to Competitiveness Through Innovation for Specialty and Generic Companies Available at: <https://www.pharmexec.com/view/505b2-pathway-competitiveness-through-innovation-specialty-and-generic-companies> Accessed 8/30/2022

For additional information, contact info@mhainc.com

Presented at the National Association of Specialty Pharmacy (NASP)

Annual Meeting, Orlando, FL, September 2022.

© 2022 Managed Health Care Associates, Inc All Rights Reserved