

# Specialized Provider of Medical Formula Can Improve Dietary Adherence in Inborn Errors of Metabolism

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## OBJECTIVE:

To report on adherence to low protein diet and amino acid (AA) formulas in patients with inborn errors of metabolism (IEM) provided by a specialized provider.

## BACKGROUND:

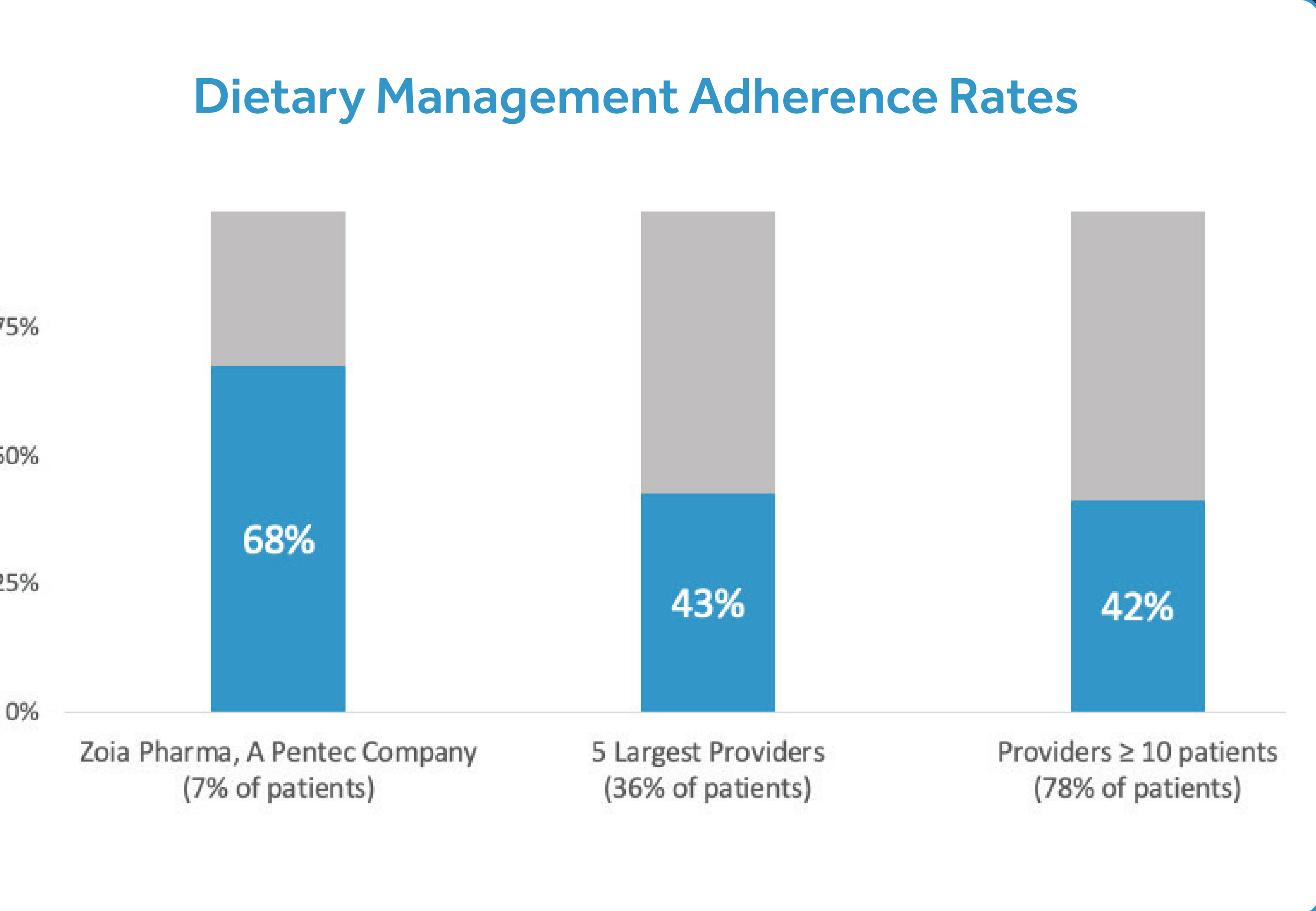
Many IEM, such as phenylketonuria (PKU), result from enzyme deficiencies that hinder amino acid (AA) metabolism. Treatment typically includes some restriction of natural foods while consuming low protein foods and/or medical formulas that omit the AA of concern.

Adhering to this dietary treatment plan is challenging due to unpalatability, inconvenience, high cost, and misinformation.<sup>1</sup> Non-adherence may impair attention, memory, and self-care.<sup>1</sup> Additionally, limited insurance coverage and high out-of-pocket costs further complicate adherence. For example, PKU patients who struggle with diet adherence may use medications like sapropterin. Although the overall cost (patient and insurance) is much higher for sapropterin (\$191,382) than that of medical formulas (\$7,753) and low protein foods (\$1,961), patients usually face lower direct costs for the drug compared to bearing the full expense of dietary management.<sup>2</sup>

## METHODS:

Patient adherence rates to dietary management were estimated across providers of medical formulas by analyzing claims data for the billing codes B4157, B4162, and S9435. These codes are defined as enteral formula and medical foods for special metabolic needs and are the primary codes used to process claims for IEM patients receiving formula and medical foods. Insurance companies and government payers allow only a 30-day supply of medical formulas to be filled each month. Claims data were obtained through Trella Health for dates January 2023 to June 2024. The method of calculating adherence rates was total number of claims processed divided by number of months in the period analyzed.

## CHART 1:



## RESULTS:

Amongst 36,361 claims billed, adherence rates for patients serviced under this provider's service were 25% higher, representing a 50% improvement compared with other national and regional providers. Claims represent a month supply of specialized product shipped to a patient.

## CONCLUSIONS:

Our findings suggest an association between specialized provider services and improved adherence to low protein diets and specialized formulas in patients with IEM. The higher adherence rates with this provider may be due to access to a complete portfolio of low protein foods and medical food formulations, availability of a clinical case management team including dietitians who prioritize monthly interactions to provide consistent support and education, as well as reimbursement experts who navigate complex insurance coverage to ensure patients' out-of-pocket costs are minimized. The limitations of this review include utilization of billing codes in the analysis, the lack of available patient demographics, and inclusion of multiple IEMs in the data set, which may affect the proportion dietary management plays in a patient's overall treatment plan. To confirm these findings, future research should incorporate patient-reported adherence measures obtained through structured surveys and include demographic data to assess differences in adherence. By triangulating this patient-reported data with demographics and existing claims data, we aim to develop a more comprehensive understanding of adherence behaviors and identify interventions to further improve patient outcomes.

## DISCLOSURES:

Authors employed by Zoia Pharma, a Pentec Company and Pentec Health, Inc.

## REFERENCES:

1. MacDonald, A., et al. (2012). Adherence issues in inherited metabolic disorders treated by low natural protein diets. *Annals of Nutrition and Metabolism*, 61(4), 289–295. <https://doi.org/10.1159/000342256>
2. Rose, A. M., et al. (2019). The financial and time burden associated with phenylketonuria treatment in the United States. *Molecular Genetics and Metabolism Reports*, 21, 100523. <https://doi.org/10.1016/j.jymgmr.2019.100523>