

Reply to: DUOPA[®] is an Excellent Alternative Treatment but with Some Caveats

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A full issue of the Journal of the American Medical Association was recently devoted to the important topic of industry influence on biomedical publishing.¹ Financial relationships are sources of bias that warrant special attention, and we adhered closely to MDCP's disclosure policies to ensure transparency in this regard.² Dr. Lamichhane's letter³ highlights the success of these efforts.

Authors with consulting income from Abbvie are among those who gained early experience with carbidopa/levodopa enteral suspension (CLES) in the US through involvement in the clinical trials that led to FDA approval. A central intention of the authors was to share insights from first-hand experience that cannot be readily gleaned from clinical trial data and the FDA-approved marketing information derived from these trials. Sponsored writing and editorial assistance was a catalyst that mitigated time and energy constraints faced by academic clinicians, but in the absence of such support, the content would have been identical. The first author, who has no financial relationship with Abbvie, vetted the utility and truthfulness of every word in the document, and the peer review process validated the content.

Implementation of any intervention in clinical practice includes reimbursement considerations, and we agree that these realities can create barriers to access for patients who otherwise could benefit from CLES. Solutions to these challenges are highly specific to local factors that influence the allocation of resources in each practice environment. Many elements of good clinical care are not directly reimbursed, and every practice makes choices about whether and how this unreimbursed care is provided. Advocacy by clinicians and professional associations, patients and support organizations, and industry are important forces for influencing reimbursement policies.

With respect to specific reimbursement challenges: (1) although there is no CPT code for drug titration, there is significant counseling and education that occurs concurrently with drug titration that could support time-based billing; (2) in Medicare Part A inpatient environments, medications are not reimbursed separately

from other care costs, but rather must be covered by the fixed daily rate for the diagnosis-related group (DRG). When drug costs exceed the DRG reimbursement, as is currently the case for CLES, justification of this expenditure must be made on a case-by-case basis. We highlight impending skilled nursing facility placement as a relative contraindication to initiation of CLES for precisely this reason. For a brief inpatient stay, facility policies often permit patients to use their home supply of non-formulary drugs, with institutional pharmacy oversight. For longer inpatient hospital or rehabilitation admissions, a provider may need to communicate with the facility director to highlight the clinical impact of CLES relative to oral therapy (e.g., improved motor function can translate to earlier discharge).

The impact of a publication is ultimately the result of collaboration between authors, editors, reviewers, and readers. The presence of financial conflicts of interest from industry support should not derail endeavors that can ultimately benefit patients; transparency is what ensures the integrity of the content. We are grateful to all parties involved in the scrutiny of this work.

Author Roles

1. Research Project: A. Conception, B. Organization, C. Execution;
2. Statistical Analysis: A. Design, B. Execution, C. Review and Critique;
3. Manuscript Preparation: A. Writing the First Draft, B. Review and Critique.

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Relevant disclosures and conflicts of interest are listed at the end of this article.

Received 10 December 2018; accepted 14 December 2018.

Published online 27 March 2019 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/mdc3.12738

Disclosures

Ethical Compliance Statement: The authors confirm that the approval of an institutional review board was not required for this work. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

Funding Sources and Conflicts of Interest: M.B. has no relevant disclosures to report. J.A. has served as a consultant for AbbVie and has participated in AbbVie speakers' bureaus. C.Z. has served as an advisor and received honoraria and educational grants from AbbVie. A.V. has served as a consultant for AbbVie and is a member of the Pharmacy and Therapeutics Committee for CVS/Caremark. K.K. has served as a consultant for AbbVie and has participated in AbbVie speakers' bureaus. B.B. has no disclosures to report. H.H.F. has served as a consultant for and has received research grants from AbbVie. D.G.S. has served as a consultant to AbbVie.

Financial Disclosures for the previous 12 months: M.B. owns stock in Novartis, and has received scientific advisory honoraria from Lundbeck and speaker's honoraria from Onandaga County Department of Adult and Long Term Care Services. J.A. has received research support from US World Med, AbbVie, National Institutes of Neurological Disorders and Stroke, National Parkinson Foundation, Biogen, Boehringer Ingelheim, Lundbeck, and Impax, and has been a speaker for US World Meds, TEVA, Lundbeck, and AbbVie. C.Z. has served as an advisor for AbbVie, Teva, Cynapsus, Lundbeck, UCB, and Merz; has received honoraria from Teva, UCB, US World Meds, Cynapsus, AbbVie, Acadia, Lundbeck, and Merz. She has also received educational grants from AbbVie, Teva, and Allergan. A.V.: has no disclosures to report. K.K. has received research support and funding from US World Meds, Pfizer Pharmaceuticals, Neuroderm Ltd, Merz, Cynapsus Therapeutics Inc., Solstice Neurosciences LLC, Intec Pharma, Ltd., Adamas Pharmaceuticals, Biotie Therapeutics, Inc., and AUSPEX Pharmaceuticals. He has served as an advisor and received honoraria on the speaker bureau for AbbVie and UCB pharmaceuticals. B.B. has no disclosures to report. H.H.F. has received

research support from AbbVie, Acadia, Teva, Biotie/Acorda Therapeutics, Civitas, Kyowa/Prostrakan, Michael J. Fox Foundation, Movement Disorders Society, NIH/NINDS, Parkinson Study Group, Rhythm, and Synosia, and has received a stipend from the International Parkinson and Movement Disorders Society for serving as Medical Editor of the MDS website. He has served as a consultant for Biogen, GE Health Care, Inventiv, Kyowa Hakko Kirin, Lundbeck, Medscape, Merz Pharmaceuticals, Voyager, Sunovion, and Pfizer Pharmaceuticals, and has received honoraria from Prime Education Inc., International Parkinson and Movement Disorders Society, Carling Communications, and Medscape. He has received royalties for publications from Demos Publishing. D.S. is a member of the faculty of the University of Alabama at Birmingham and is supported by endowment and University funds. He is an investigator in studies funded by AbbVie, Inc., the American Parkinson Disease Association, Michael J. Fox Foundation for Parkinson Research, Alabama Department of Commerce, and NIH grants P01NS087997, P20NS087997, R25NS079188, P2CHD086851, and P30NS047466. He has a clinical practice and is compensated for these activities through the University of Alabama Health Services Foundation. In addition, since January 1, 2016 he has served as a consultant for or received honoraria from, Serina Therapeutics, AbbVie, Voyager Therapeutics, Michael J. Fox Foundation for Parkinson Research, The International Parkinson Disease and Movement Disorder Society, the National Institutes of Health, The American Institute for Biological Sciences, Rush University, Huntsville Hospital, UCSD, Voyager Therapeutics, and he has received royalties for publications from McGraw Hill, Inc.

References

1. Conflict of Interest Theme Issue. *JAMA* 2017;317:1707–1812.
2. Burack M, Aldred J, Zadikoff C, et al. Implementing levodopa-carbidopa intestinal gel for Parkinson disease: insights from US practitioners. *Mov Disord Clin Pract* 2018;5:383–393.
3. Lamichhane D. DUOPA[®] is an excellent alternative treatment but with some caveats, *Mov Disord Clin Pract* 2019. <https://doi.org/10.1002/mdc3.12739>.