

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S3-02-01  
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality

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Zachary J Woodson  
VP of Regulatory Affairs & Quality  
2934 Scott Boulevard  
Santa Clara, CA 95954

July 28, 2022

Dear Mr. Woodson:

Thank you for submitting your Medicare coverage Category B IDE study review request. We have completed our review of the IDE study protocol entitled Percutaneous Deep Vein Arterialization for the Treatment of Late-Stage Chronic Limb-Threatening Ischemia: The PROMISE III Trial [G160156-NCT05313165]. CMS believes that the IDE study is consistent with the conditions specified in the IDE regulations (42 CFR 405 Subpart B). The device, related and routine items and services are approved for purposes of Medicare coverage. We will post limited information about this study on the CMS IDE webpage at <http://www.cms.gov/Medicare/Coverage/IDE/index.html>. Approval of this IDE study does not guarantee future Medicare coverage of your device.

Because this study is approved for purposes of Medicare coverage across all Medicare Administrative regions, study sites are not required to obtain approval from local Medicare Administrative Contractors (MACs). However, MACs may require additional documentation. To facilitate Medicare reimbursement, we suggest you provide your study sites with appropriate billing instructions. Additional information is available on the CMS IDE webpage at <http://www.cms.gov/Medicare/Coverage/IDE/index.html> and in a MLNMatters article at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8921.pdf>. Please contact [clinicalstudynotification@cms.hhs.gov](mailto:clinicalstudynotification@cms.hhs.gov) if you have any questions or need additional information.

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Sincerely,

Tamara Syrek Jensen, JD  
Director, Coverage and Analysis Group