



Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting – JA6839

Related CR Release Date: March 5, 2010

Date Job Aid Revised: March 12, 2010

Effective Date: December 9, 2009

Implementation Date: April 5, 2010

Key Words	MM6839, CR6839, R1925CP, Percutaneous, Transluminal, Angioplasty, PTA, Carotid, Artery, Stenting
Contractors Affected	<ul style="list-style-type: none"> • Medicare Carriers • Fiscal Intermediaries (FIs) • Part A/B Medicare Administrative Contractors (A/B MACs)
Provider Types Affected	Provider types affected are physicians and providers who submit claims to Medicare Carriers, FIs and A/B MACs for PTA with stenting of the carotid arteries.



- Change Request (CR) 6839 announces that for claims with dates of service on and after December 9, 2009, there is revised language specific to embolic protection devices (EPDs) for PTA concurrent with carotid artery stenting (CAS) system placement in Food and Drug Administration (FDA)-approved post-approval studies, and PTA Concurrent with CAS system placement in patients at high risk for carotid endarterectomy.
- The revised language specific to EPDs is located in Pub. 100-03, *National Coverage Determination (NCD) 20.7.B.3* and 20.7.B.4, and Pub. 100-04, Chapter 32, Section 160.

Provider Needs to Know...

- The Centers for Medicare & Medicaid Services (CMS) internally generated a reconsideration of Section 20.7B4 of the *Medicare NCD Manual*.
- CMS made no changes in the covered patient groups for PTA of the carotid artery concurrent with stenting, but slightly revised the language regarding EPDs.

- In the final decision, effective December 9, 2009, CMS retained existing coverage for the following with a slight revision to the language regarding EPDs:
 - For patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis ≥ 70 percent, coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or FDA-cleared EPDs;
 - For patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50 percent and 70 percent, in accordance with the Category B Investigational Device Exemption (IDE) clinical trials regulation (42 Code of Federal Regulations (CFR) 405.201), as a routine cost under the clinical trials policy (*Medicare NCD Manual 310.1*), or in accordance with the NCD on CAS post-approval studies (*Medicare NCD Manual 20.7B*), coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or FDA-cleared EPDs. (If deployment of the EPD is not technically possible, and not performed, then the procedure is not covered); and
 - For patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥ 80 percent, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (*Medicare NCD Manual 310.1*), or in accordance with the NCD on CAS post-approval studies (*Medicare NCD Manual 20.7B*), coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or FDA-cleared EPDs.

Note: The use of an FDA-approved or cleared EPD is required. If deployment of the EPD is not technically possible and not performed, then Medicare does not cover the procedure. This CR does not require new or revised claims processing instructions.

Background

- Under the previous NCD policy, patients at high risk for CEA who have symptomatic carotid artery stenosis ≥ 70 percent are covered for procedures performed using FDA-approved CAS systems with EPDs in facilities approved by CMS to perform CAS procedures.
- Patients at high risk for CEA with symptomatic carotid artery stenosis between 50 percent and 70 percent and patients at high risk for CEA with asymptomatic carotid artery stenosis ≥ 80 percent are covered in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (*Medicare NCD Manual 310.1*), or in accordance with the NCD on CAS post-approval studies (*Medicare NCD Manual 20.7B*).
- If deployment of the EPD is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection.

Operational Impact	N/A
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The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6839.pdf> on the CMS website.

Reference Materials	The official instruction (CR6839) issued can be found at http://www.cms.hhs.gov/Transmittals/downloads/R1925CP.pdf on the CMS website.
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The CAS facilities “approved facilities” website link in Publication 100-03, *The National Coverage Determinations Manual*, may be found at <http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp> on the CMS website.
