[Date]

[Payer Contact]

[Title]

[Address]

[City, State, Zip]

**Re: [Patient Identification Number]**

**[Patient Name]**

**[Date of Service]**

Dear [Payer Contact]:

I am writing to request [prior authorization/predetermination] for the treatment of critical carotid artery stenosis using the ENROUTE® Transcarotid Neuroprotection System to perform a TransCarotid Artery Revascularization (TCAR) procedure for the patient listed above.

TCAR is both a unique and a clinically proven procedure combining surgical principles of neuroprotection with minimally invasive endovascular techniques to treat severe stenosis in the carotid artery that may cause subsequent stroke (1,2). The ENROUTE Transcarotid Neuroprotection System (NPS) is the first and only device that allows the physician to directly access the common carotid artery in the neck and initiate high rate temporary blood flow reversal to protect the brain from atherosclerotic debris that could be dislodged during stent placement that may result in procedural stroke.

The ENROUTE Transcarotid NPS used in the TCAR procedure has received FDA marketing authorization. The ENROUTE NPS is intended for patients diagnosed with carotid artery stenosis and who have appropriate anatomy for TCAR. TCAR with the ENROUTE NPS is compatible with FDA-approved carotid stenting systems, including the ENROUTE® Transcarotid Stent System which is indicated for patients considered to be at high risk for adverse events from carotid endarterectomy (CEA).

Clinical Justification:

Carotid artery disease accounts for 20% of all ischemic strokes (3,4,5). Revascularization for carotid artery disease has been shown to reduce stroke and death rates in multiple randomized trials (5,6,7). Current strategies for carotid revascularization include CEA, trans-femoral carotid artery stenting (TF-CAS) and TCAR.

* CEA: CEA has been shown to carry an increased risk of cranial nerve injury (4.7% vs. 0.3%), myocardial infarction (2.3% vs 1.1%) and wound complications relative to TF-CAS (8). The overall 30-day major adverse event rate (stroke, death and myocardial infarction) for CEA and CAS is 4.5% and 5.2%, respectively (8).
* TF-CAS: Although considered to be less invasive than CEA, TF-CAS is associated with twice the stroke risk in the periprocedural (30-day) setting when compared to CEA (4.1% vs. 2.3%, respectively) (8).
* TCAR: In the ROADSTER pivotal study to evaluate TCAR in a high surgical risk patient population who are at higher risk of 30-day stroke, death and myocardial infarction than standard risk patients, the 30-day stroke was 1.4% (2). The cranial nerve injury rate was 0.7% at 30 days and 0% at 6 months (2). The myocardial infarction rate was 0.7% (2). The overall 30-day major adverse event rate (stroke, death and myocardial infarction) was 3.5% (2).

After reviewing the available treatment options, I have determined that TCAR is the best course of therapy for this patient. [Describe patient specific medical history including diagnosis, symptoms, duration, conservative management that may have failed, and why TCAR is the best treatment option for this patient]

I have enclosed pertinent medical records for this patient for your review and ask that you review the information provided and grant coverage for this procedure based on the patient’s medical condition and risk criteria.

Thank you in advance for your prompt attention to this predetermination request. Should you have any questions or require additional information, please feel free to contact me at [555-555-5555].

Sincerely,

[Doctor Name]

[Title/Specialty]

[Email address]

Coding and FDA approvals:

CPT code: 37215, transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection[[1]](#footnote-1).

Approval and indication for use for the ENROUTE® Transcarotid Neuroprotection and Stent:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140026>

Approval and indication for use for the ENROUTE® Transcarotid Neuroprotection System (NPS):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K143072>

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