**Sample Prior Authorization Letter for High Surgical Risk or Standard Surgical Risk – Transcarotid Artery Revascularization**

This is a sample template to be used by physicians’ offices to request coverage for the ENROUTE® Transcarotid Stent System in conjunction with the ENROUTE® Transcarotid Neuroprotection System.

**Instructions for completing the sample prior authorization:**

* The template should be tailored by the physician to the patient’s condition and clinical history as well as any specific high risk (physiological or anatomic characteristics) or standard risk payer requirements. Fields highlighted in yellow need to be customized.
* It is important to ensure all information provided is accurate and medical necessity of the procedure is clearly documented in the patient’s medical record.
* Optional enclosures include FDA approval letters for the ENROUTE® Transcarotid Stent System and Transcarotid Neuroprotection System, and CMS approval letters for high risk and standard risk patients.

[Date]

[Payer Name]

[Street Address]

[City, State, Zip Code]

[Phone Number]

[Patient Name]

[Policy Holder]

[ID #]

[Group #]

[Social Security or Patient Identification]

[Date of Birth]

Dear [Payer Contact]:

I am writing on behalf of my patient, [Patient Name], to request [prior authorization/ predetermination] for the treatment of carotid artery stenosis using the ENROUTE® Transcarotid Stent System (TSS) in conjunction with the ENROUTE® Transcarotid Neuroprotection System (NPS) to perform a TransCarotid Artery Revascularization (TCAR) procedure.

TCAR has been commercially available in the U.S. for the treatment of carotid artery disease since 2015. TCAR is both a unique and 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.1-3 The ENROUTE Transcarotid NPS and TSS used in the TCAR procedure have both received FDA approval.4,5 The ENROUTE Transcarotid NPS is intended for patients diagnosed with carotid artery stenosis and who have appropriate anatomy for TCAR. It 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 TSS is the only stent indicated for use in conjunction with the ENROUTE Transcarotid NPS and is indicated for the treatment of patients at high risk and standard risk for adverse events from carotid endarterectomy and who require carotid revascularization.

**Clinical Justification**

I have determined that TCAR is the best course of therapy for my patient. [Explain why the patient is a good candidate for the therapy and how they meet FDA indications for use. Personalize the letter for the specific patient addressing each of the following points in the body of the letter or in an attached report.]

* Document current findings/status, including detailed diagnostic description and ICD-10 diagnosis codes.
* Describe the patient’s specific medical history, including the following:
  + Applicable high-risk criteria (physiological or anatomic characteristics).
  + Any diagnostic work-up studies and results.
  + Anatomical location of the stenosis and degree of stenosis.
  + Symptomatic vs asymptomatic status. If patient is symptomatic, describe the symptoms (when they started), duration, any prior diagnosis (when), conservative management that may have failed, drug therapies (drug prescribed, dosage, when).
* Document why TCAR is the best treatment option for this patient.
* State how patient meets FDA indications for use.

**Treatment Options**

Carotid artery disease accounts for 20% of all ischemic strokes.6-8 Revascularization for carotid artery disease has been shown to reduce stroke and death rates in multiple randomized trials.8-10 Current strategies for carotid revascularization include surgical revascularization using carotid endarterectomy (CEA) or endovascular revascularization using carotid artery stenting (CAS), such as transfemoral (TF-CAS), transradial (TR-CAS), or transcarotid (TCAR).

CEA carries a higher risk of adverse events in patients presenting with certain anatomic and/or physiologic risk factors.11,12 Schermerhorn, et al.13 reported outcomes from the Society for Vascular Surgery (SVS) Vascular Registry in high surgical risk patients as defined by the Centers for Medicare and Medicaid Services (CMS) criteria that were published in the National Coverage Determination for Percutaneous Transluminal Angioplasty (20.7).14 In this “real world” analysis, in symptomatic high-risk patients, the 30-day stroke and death rate for CEA was 6.4%.13 In asymptomatic high-risk patients, the 30-day stroke and death rate for CEA was 3.7%.13 These stroke and death rates, stratified by symptom status, exceed the risk/benefit thresholds of 6% (symptomatic) and 3% (asymptomatic) set by the American Heart Association.13,15

CAS is endorsed by all relevant medical societies as an appropriate treatment option for carotid artery disease.8 Although TF-CAS is 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).16

TCAR is a hybrid approach to carotid revascularization that combines the protection of surgery with the benefits of a minimally invasive procedure. Multiple clinical trials and studies have been performed to evaluate the safety and performance of TCAR for the treatment of patients with carotid stenosis. These studies demonstrated high rates of procedural success and low rates of perioperative stroke or death as well as low rates of perioperative cardiac and stroke complications.2,3,17-19 With over 45,000 procedures performed to date, TCAR has been validated as a safe, less invasive standard in stroke prevention treatment options. Please reference Appendix A for a listing of TCAR clinical studies and publications.

The ROADSTER study2 was a prospective, single-arm, multi-center clinical trial of the TCAR procedure using the ENROUTE Transcarotid NPS in high surgical risk patients with carotid artery stenosis. The overall stroke rate of 1.4% was the lowest reported to date for any prospective multi-center trial of carotid stenting. The cranial nerve injury rate was 0.7% at 30 days and 0% at 6 months. The myocardial infarction rate was 0.7%. The overall 30-day major adverse event rate (stroke, death, and myocardial infarction) was 3.5%. ROADSTER demonstrated that the ENROUTE Transcarotid NPS, used in conjunction with commercially approved stents, is safe and effective at preventing stroke during carotid artery stenting.

The ROADSTER study2 was followed by the larger, post-market ROADSTER 2 study3 which evaluated the safety and efficacy of TCAR with the ENROUTE TSS when used in conjunction with the ENROUTE Transcarotid NPS. This study showed excellent outcomes with a stroke rate of 0.6% in the per protocol population which may be the lowest reported rate after any carotid intervention. The death rate was 0.2%. The stroke/death rate was 0.8%. The adverse event rate for stroke/death/myocardial infarction was 1.7%. ROADSTER 2 demonstrated that TCAR is a safe and effective procedure in a broad user base with varying TCAR experience levels and that excellent outcomes, such as low stroke and death rates, are achievable if you follow the protocol and society guidelines (patient/lesion selection, drug regimen, procedure technique).

The SVS Vascular Quality Initiative (VQI) is a collaborative effort to improve the quality, safety, effectiveness, and cost of vascular healthcare. The initiative sponsors several registries, one of which is the TCAR Surveillance Project (TSP) designed to monitor the safety and effectiveness of stents placed in the carotid artery while reversing blood flow within the carotid artery using a transcarotid approach to reduce stroke risk. An analysis of the TSP registry showed TCAR had significant reductions in the risk of postoperative myocardial infarction (TCAR, 0.5% vs. CEA, 0.9%, P<0.005) and cranial nerve injury (0.4% vs. 2.7%, P<0.001) compared to CEA.18 In another study using data from the VQI TSP, TCAR was associated with a significantly lower risk of stroke or death compared to TF-CAS (TCAR, 1.6% vs. TF-CAS, 3.1%, P<0.001).19 Results from these studies support the decisions by the 2021 SVS guidelines that TCAR is recommended over CEA or TF-CAS in certain patient populations.20 Refer to the Appendix B for a summary of additional clinical outcomes from the VQI TSP registry database.

**Medicare Coverage for TCAR21**

On September 1, 2016, CMS granted coverage for the TCAR procedure in both symptomatic and asymptomatic patients at high risk for traditional carotid artery surgery, as part of the VQI TSP. CMS also covers the TCAR procedure for standard risk patients (not at risk for traditional surgery) as part of the CREST 2 Registry. On May 31, 2022, CMS determined that patients participating in the VQI-TSP, including the new population at standard surgical risk, continue to be included in the currently covered population of patients participating in FDA-approved post approval studies (Pub. 100-03, 20.7, B3).

I have enclosed pertinent medical records for this patient for your review and kindly ask that you review the information provided and grant coverage for the TCAR procedure based on the patient’s medical condition. This request for coverage includes the primary CPT codes 37215 and 76937. TCAR has been scheduled at [name of facility] on [date].

Thank you in advance for your prompt attention to this [prior authorization/predetermination] request. If you have any questions or require additional information, please feel free to contact me at [phone].

Sincerely,

[Physician Name]

[Title/Specialty]

[Institution]

[Email address]

[You may decide to use the following letters as part of the submission for TCAR prior authorization.]

Enclosures:

* FDA approval letter for ENROUTE® Transcarotid Stent System
* FDA approval letter for ENROUTE® Transcarotid Neuroprotection System
* CMS approval letter for high risk
* CMS approval letter for standard risk

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**Appendix A: TCAR Clinical Studies and Publications**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **PROOF**1,2 | **ROADSTER**3,4 | **TCD**5  CEA v TCAR vs TF-CAS | **TCAR vs TF-CAS**  **VQI**6 | **TCAR vs CEA**  **VQI**7 | **ROADSTER 2**8 |
| **Study type** | First In Man &  DW-MRI Sub-Study | US Pivotal IDE + Continued Access | Single Center Transcranial Doppler | TCAR  Surveillance Project | TCAR  Surveillance Project | US Post-Market  Registry |
| **Patients** | 75 | 219 | 34 | 3286 pairs of matched patients | 6,384 pairs of matched patients | 632 |
| **Profile** | All-comers | HSR  Sym & Asx | CEA vs TCAR  vs TF-CAS | HSR  Sym & Asx | HSR  Sym & Asx | HSR  Sym & Asx |
| **TCAR**  **Outcomes** | * 0.0% Major S/D/MI * 1.3% Minor contralateral stroke * 17.9% New ipsilateral DWI lesions | * 1.4% All stroke (ITT) * 0.7% All stroke (PP) * 0.0% Major stroke * 0.7% MI * 0.0% CNI at 6 months | * No significant differences in number of emboli and seconds of embolic showers btw TCAR and CEA | * 1.6% (vs. 3.1%) In-hospital stroke * 1.3% (vs. 2.4%) Stroke * 0.4% (vs. 1.0%) Death * 5.1% (vs. 9.6%) Ipsilateral S/D at 1 yr | * 1.4% In-hospital stroke * 1.6% Stroke/ death (statistically similar between TCAR & CEA) * TCAR shorter procedure * 0.4% CNI | * 1.7% S/D/MI * 0.6% In-hospital stroke * 0.1% Death * 0.9% MI * 0.5% CNI at 6 mths |
| **Procedural**  **Data & Conclusions** | * NA | * 53% Local anesthesia * 76 min OR time * 99% Tech success | * TF-CAS showed significantly higher emboli rates compared with CEA or TCAR (p<0.001) | * TCAR was associated with significantly lower risk of stroke or death, less radiation, less contrast, and lower risk of ipsilateral stroke or death at 1 yr vs TF-CAS. | * Propensity-score matched analysis showed significant reduction in risk of postoperative MI and CNI after TCAR vs CEA, with no differences in stroke/death. | * 25% Local anesthesia * 75 min Skin to skin time * 98% Procedural Success |

Definitions: Asx – Asymptomatic, CEA – Carotid endarterectomy, CNI – Cranial Nerve Injury, DW-MRI – Diffusion-weighted magnetic resonance imaging, DWI – Diffusion weighted imaging,   
HSR – High standard risk, ITT – Intention to treat, MI – Myocardial Infarction, PP – Per Protocol, S/D – Stroke/Death, S/D/MI – Stroke/Death/Myocardial Infarction, Sym – Symptomatic,   
TCAR – Transcarotid revascularization, TF-CAS – Transfemoral carotid artery stenting, VQI – Vascular Quality Initiative

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**Appendix B: Clinical Outcomes from VQI TSP Registry Database Articles**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Article/Study Design and Objective** | **Condition** | **Patients (N)** | **Safety** | | | **Performance** | |
| **Stroke (%) In-hospital** | **DSMI (%)**  **30-dayooo** | **Ipsilateral Stroke 31–365 days** | **In-hospital stroke rates (TCAR vs TF-CAS) OR RR** | |
| Dakour et al., 2021[[1]](#footnote-2)  Nonrandomized, retrospective analysis of patients undergoing TCAR, TF-CAS or CEA | Contralateral carotid artery occlusion | Asymptomatic: 937 | 1.1% | NR | NR | 1.1% vs 1.4% OR: 0.65  P=0.3 |
| Symptomatic: 207 | 3.4% | NR | NR | 3.4% vs 3.9%  OR: 0.8  P=0.63 | |
| Liang et al., 2021[[2]](#footnote-3)  Multi-center retrospective cohort. Sept 2016 to Sept 2019 | Asymptomatic (46.4%) or  Symptomatic (53.6%) | 7,633 | 0.75%[ppp](#_bookmark188) | NR | NR | NR |
| Columbo et al., 2021[[3]](#footnote-4)  Retrospective study from 2015 to 2019 | Symptomatic (48.8%) and  Asymptomatic (51.2%) | 7,664 | 1.4% | NR[qqq](#_bookmark189) | NR | NR |
| Healy et al., 2021[[4]](#footnote-5)  Retrospective analysis of EEG monitoring from 2 hospitals (from May 2017 to Jan 2020) | Symptomatic >50% stenosis  (41.6%)  Asymptomatic >80% stenosis | 89 | 1.12%[rrr](#_bookmark190) | 6.7% | NR | NR |

ooo Hierarchical composite

ppp Of all stroke events, 58 were identified either intraoperatively or within 6 hours of the procedure. So, the in-hospital stroke rate is 58/7663 =0.75%.

qqq 30-day MAE rate was defined as in-hospital stroke, 30-day MI, 30-day death, so was not included because 30-day strokes were not reported.

rrr Among the 3 patients, two patients presented with stroke after the discharge of which only one was re-admitted. Only one patient reported post-operative (day 1) stroke and as there is no mention of discharge so, the presumption is it is in-hospital.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Article/Study Design and Objective** | **Condition** | **Patients (N)** | **Safety** | | | **Performance** | |
| **Stroke (%) In-hospital** | **DSMI (%)**  **30-dayooo** | **Ipsilateral Stroke 31–365 days** | **In-hospital stroke rates (TCAR vs TF-CAS) OR RR** | |
| Liang et al., 2020[[5]](#footnote-6)  Retrospective study (September 2016 to April 2019). Propensity-score matched cohort of patients receiving protamine vs patients who did not receive protamine. | Protamine: Symptomatic 48.2% and Asymptomatic  51.8% | 944 | 2.0% | NR | NR | NR |
| No protamine: Symptomatic 46.5% and Asymptomatic  53.5% | 944 | 1.1% |
| Liang et al., 2020[[6]](#footnote-7)  Retrospective, multicenter study of propensity matched cohort of TCAR with flow reversal | Symptomatic 54.9% | 357 | 0.8% | NR | NR | 0.8% vs 2.5%  RR: 3.0  P=0.08 |
| Malas et al., 2020[[7]](#footnote-8)  Retrospective study of propensity score-matched cohort of TCAR and CEA | Symptomatic (26%)  and Asymptomatic (74%) | 6,384 | 1.4% | NR | NR | NR |
| Dakour et al., 2020[[8]](#footnote-9)  Analysis of patients undergoing TCAR, and TF-CAS stratified by age | Symptomatic (39.1%) and  Asymptomatic (60.9%) | ≤70 years  TCAR: 1,153  TF-CAS: 5,404 | 1.1% | NR | NR | 1.1% vs 1.5%  OR: 1.0  P=0.99 |
| 71-79 years  TCAR: 1,191  TF-CAS: 3,333 | 1.6% | NR | NR | 1.6% vs 2.0%  OR: 1.05  P=0.87 | |
| ≥80 years  TCAR: 808  TF-CAS: 1,644 | 1% | NR | NR | 1% vs 4.7%  OR: 0.3  P<0.01 | |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Article/Study Design and Objective** | **Condition** | **Patients (N)** | **Safety** | | | **Performance** | |
| **Stroke (%) In-hospital** | **DSMI (%)**  **30-dayooo** | **Ipsilateral Stroke 31–365 days** | **In-hospital stroke rates (TCAR vs TF-CAS) OR RR** | |
| Conway et al., 2020[[9]](#footnote-10)  Retrospective study of patients who underwent TF-CAS versus TCAR with simple and complex aortic arches | Simple Aortic arch anatomy Symptomatic (56.6%) and  Asymptomatic (43.4%) | TCAR: 1,619 | 1.6% | NR | NR | 1.6% vs 1.7%  OR: 0.96 P=0.8836 |
| TF-CAS: 1,917 | 1.7% |
| Complex Aortic arch anatomy Symptomatic (41.9%) and  Asymptomatic (58.1%) | TCAR: 1,156 | 1.2% | NR | NR | 1.2% vs 2.6%  OR: 0.46 P=0.0132 |
| TF-CAS: 1,416 | 2.6% |
| Dakour et al., 2020[[10]](#footnote-11)  Retrospective study of patients who underwent TCAR or CEA between 2016 and April 2019 | Symptomatic (39.8%) and  Asymptomatic (60.2%). | 4,122 | 1.4% | NR | NR | NR |
| Schermerhorn et al., 2020[[11]](#footnote-12)  Retrospective study of patients  undergoing TCAR with flow reversal and CEA | Symptomatic (2.7%) and  Asymptomatic (97.3%) | 1,182 | 1.4% | NR | NR | NR |
| Malas et al., 2019[[12]](#footnote-13)  Retrospective study | Symptomatic 34% and  Asymptomatic 66% | 638 | 1.4% | NR | NR | 1.4% vs 2%  OR: 1.62[sss](#_bookmark191)  P=0.18 |
| Schermerhorn et al., 2019[[13]](#footnote-14)  Retrospective propensity-score matched study | Symptomatic carotid stenosis 55.4%  Asymptomatic carotid stenosis 44.6% | 3,286 | 1.3% | NR | NR | 1.3% vs 2.4%  RR: 0.54 P=0.001 |

sss Multivariable logistic regression analysis.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Article/Study Design and Objective** | **Condition** | **Patients (N)** | **Safety** | | | **Performance** | |
| **Stroke (%) In-hospital** | **DSMI (%)**  **30-dayooo** | **Ipsilateral Stroke 31–365 days** | **In-hospital stroke rates (TCAR vs TF-CAS) OR RR** | |
| Kashyap et al., 2020[[14]](#footnote-15)  Learning curve of surgeons adopting TCAR based on data was examined | Novice cases 1-5: 37.9% vs  62.1% | 1,426 | 1.2% | NR | NR | NR |
| Intermediate cases 6-20: 38%  vs 62% | 1,375 | 1.2% |
| Advanced cases 21-30: 42.7%  vs 57.3% | 307 | 1.0% |
| Expert cases >30): 44.3% vs  55.7% | 348 | 1.2% |
| Cappellini et al., 2021[[15]](#footnote-16)  Retrospective review, patients undergoing TCAR or CEA | Symptomatic >50% internal carotid artery stenosis (54.5%) and Asymptomatic ≥80% internal carotid artery stenosis (45%) | 66 | 0% | NR | NR | NR |
| Marmor et al., 2021[[16]](#footnote-17)  Retrospective review of the patients undergoing TCAR and CEA | Symptomatic carotid artery stenosis (LRA) (33.9%) and asymptomatic carotid artery stenosis (62.2%). | 933 (Propensity score match) | 1.6% | NR | NR | NR |
| Symptomatic carotid artery stenosis (GA) (37.8%) and asymptomatic carotid artery stenosis (66.1%) | 5,238  (Propensity score match) | 1.4% | NR | NR | NR | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Article/Study Design and Objective** | **Condition** | **Patients (N)** | **Safety** | | | **Performance** | |
| **Stroke (%) In-hospital** | **DSMI (%)**  **30-dayooo** | **Ipsilateral Stroke 31–365 days** | **In-hospital stroke rates (TCAR vs TF-CAS) OR RR** | |
| Dakour et al., 2021[[17]](#footnote-18)  Multicenter retrospective analysis of patients undergoing TCAR | Symptomatic stenosis (No CCO) (25.1%) and  Asymptomatic stenosis (74.9%) | 4,892 | 1.2% | 1.8% | NR | NR |
| Symptomatic stenosis (CCO) 16.4% and Asymptomatic  stenosis (83.6%) | 593 | 1.7% | 2.3% | NR | NR |
| **Range** |  |  | **0%-3.4%** | **1.8%-6.7%** | **NR** | **NR** | |

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