

Quality ID #437: Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure – National Quality Strategy Domain: Patient Safety

2018 OPTIONS FOR INDIVIDUAL MEASURES:

REGISTRY ONLY

MEASURE TYPE:

Outcome

DESCRIPTION:

Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure

INSTRUCTIONS:

This measure is to be submitted each time an endovascular lower extremity revascularization procedure is performed during the performance period. There is no diagnosis associated with this measure. This measure may be submitted by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

NOTE: Include only patients undergoing an endovascular lower extremity revascularization procedure through December 29 of the performance period. This will allow the evaluation of at least 48 hours of the procedure within the performance period.

Measure Submission:

The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR:

Patients undergoing endovascular lower extremity revascularization

Denominator Criteria (Eligible Cases):

All patients, regardless of age

AND

Patient procedure during the performance period (CPT): 37220, 37221, 37224, 37225, 37226, 37227, 37228, 37229, 37230, 37231

AND NOT

DENOMINATOR EXCLUSION:

Documentation of planned hybrid or staged procedure: G9640

NUMERATOR:

Number of patients undergoing major amputation or open surgical bypass within 48 hours of the index endovascular lower extremity revascularization procedure

Definition:

Major Amputation – An amputation at the level of the ankle or above

NUMERATOR INSTRUCTIONS:

INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that is trends

closer to 0%, as quality increases. For inverse measures, a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control.

Numerator Options:

Performance Met:

Major amputation or open surgical bypass required within 48 hours of the index endovascular lower extremity revascularization procedure (**G9641**)

OR

Performance Not Met:

Major amputation or open surgical bypass not required within 48 hours of the index endovascular lower extremity revascularization procedure (**G9639**)

RATIONALE:

Conversions from a planned lower extremity endovascular revascularization procedure to an unanticipated surgical procedure indicates either poor patient assessment/procedural assignment, or procedural failure. Patients who undergo unplanned surgical conversion have a higher cost of care and higher morbidity and mortality. In addition, there is a higher expense for dual procedures, with use of endovascular tools and surgical procedural time and equipment, as well as longer length of stay and rehabilitation. Physicians performing endovascular revascularization for arterial insufficiency should assess patient suitability for such interventions, involving their surgical colleagues in treatment planning when appropriate.

CLINICAL RECOMMENDATION STATEMENTS:

Studies show higher rates of limb salvage in patients with foot ulcers after surgical or catheter based restoration of arterial blood flow than with medical therapy alone, but there is insufficient robust data to indicate better outcomes with endovascular or open bypass treatment of arterial insufficiency in this patient group. Both amputation-free survival and quality of life outcomes have been shown to be comparable for patients with critical limb ischemia treated with either open bypass or endovascular repair, but the bypass-first strategy has been shown to be more costly. There are many studies suggesting benefit of an endovascular-first approach to limb salvage because of the proposed patient benefits, including ability to avoid general anesthesia for these procedures, avoidance of a surgical incision and attendant healing time, shorter length of hospital stay with endovascular revascularization when compared to bypass, strong patient preference for endovascular approaches, and decreased cost of a successful endovascular approach.

Although long term limb salvage outcomes are equivalent regardless of the initial strategy adopted, some data indicate a high rate of early technical failure of endovascular treatment of critical limb ischemia, but high secondary patency rates and high limb conservation rates in spite of initial technical failures, indicating that repeat procedures, both endovascular and open, tend to be successful in this patient group. A meta-analysis of 30 studies of below knee angioplasty showed a higher technical failure rate of endovascular treatment than that seen with open (bypass) repair. This same meta-analysis reports that repeat procedures in patients with endovascular-first failures were more likely to be bypass procedures than repeated endovascular procedures. Another study of 1023 patients undergoing either endovascular or open surgical treatment for critical limb ischemia demonstrated a higher rate of secondary surgical procedures in the endovascular group compared with the surgical group, but again showed comparable 5-year limb salvage rates in the two groups.

Notably, it has been demonstrated that the difference in patency rates and differences in rates of conversion to bypass appear to be partly related to the specialty of the operator, based on studies of procedural failure and open conversion rates in different physician groups. Two large studies of extracted data, one of Medicare claims data assessing mortality, transfusion rates, intensive care unit use, length of stay, and subsequent repeat revascularization procedures or amputation, and one of National Inpatient Sample (NIS) data reviewing in-hospital mortality and iatrogenic arterial injuries, showed statistically significant differences in outcomes across physician groups. One of these studies (Zafar, et al) suggested that there may be a higher use of repeat intervention, including adjunctive, unplanned surgical bypass, and a higher rate of amputation following a primary endovascular procedure in some physician cohorts. The reasons for this discrepancy are unclear, and may represent patient selection, operator bias towards endovascular revascularization in all comers, technical ability, or other factors.

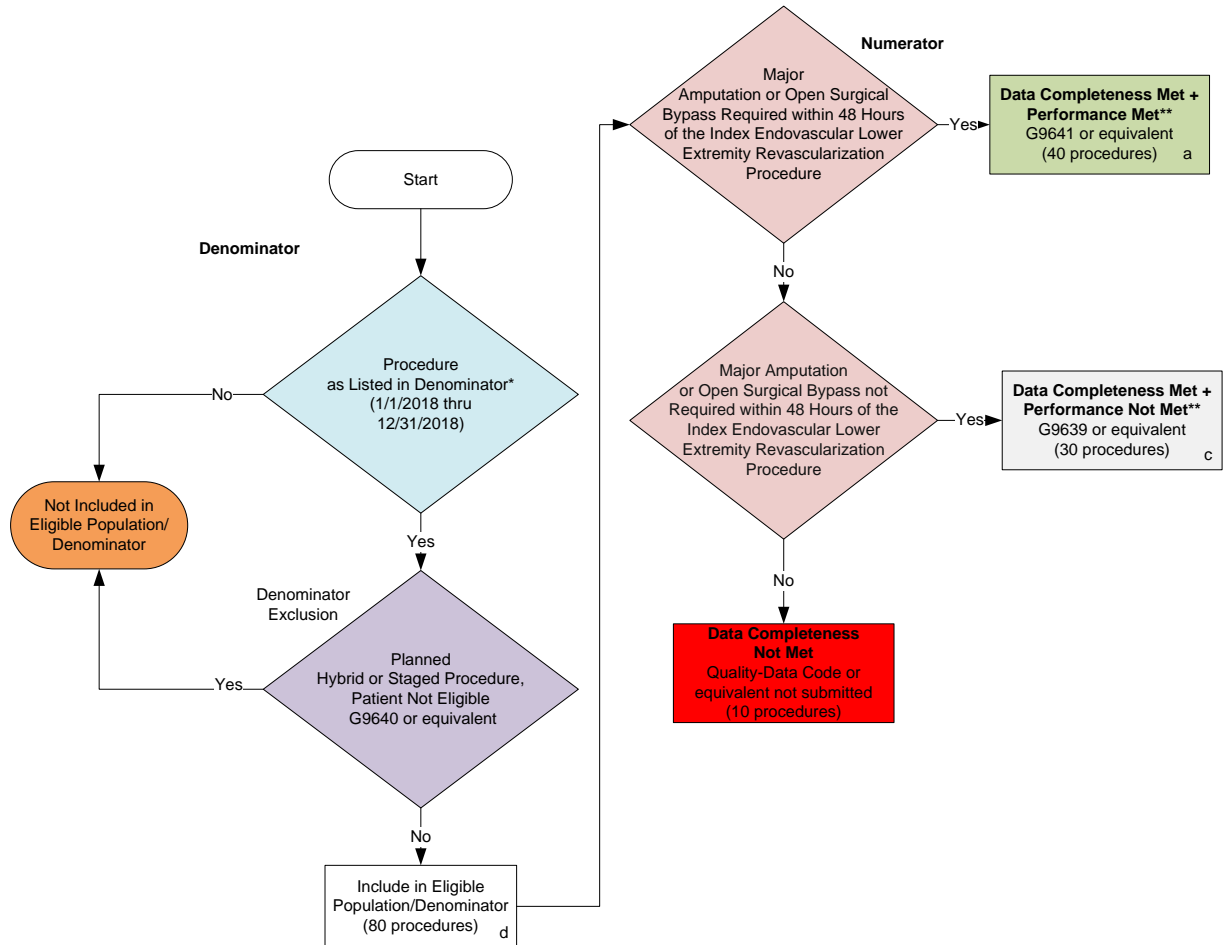
The newly-approved NHLBI trial, Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia, proposes to look at outcomes, including open conversions and amputations, in a cohort of patients randomized to open vs endovascular therapy. This trial will be multidisciplinary, evaluating all specialists involved in procedural care of this group of patients, and will ultimately provide guidance for physicians in terms of patient assignment to open vs endovascular care, and will establish solid data to support thresholds for conversion and amputation. However, data will not be available for years to come.

This measure proposes, based on the data available in the existing literature, to track use of repeat or unplanned adjunctive surgical (bypass or amputation) procedures in patients undergoing revascularization procedures for lower extremity arterial insufficiency. It is expected that this rate should be equivalent across all physician groups performing endovascular procedures when adjusted for specific patient risk factors. With establishment of a baseline benchmark rate for conversion to surgical therapy based on existing data from the Medicare sample, rates of conversion may be tracked to encourage appropriate patient selection or referral to expert operators to improve patient outcomes and reduce excessive resource use by selection of the most appropriate procedure and procedural operator.

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2018 Registry Flow for Quality ID #437: Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure



SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met (a=40 procedures)} + \text{Performance Not Met (c=30 procedures)}}{\text{Eligible Population / Denominator (d=80 procedures)}} = \frac{70 \text{ procedures}}{80 \text{ procedures}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a=40 procedures)}}{\text{Data Completeness Numerator (70 procedures)}} = \frac{40 \text{ procedures}}{70 \text{ procedures}} = 57.14\%$$

*See the posted Measure Specification for specific coding and instructions to submit this measure.

**A lower calculated performance rate for this measure indicates better clinical care or control.

NOTE: Submission Frequency: Procedure

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The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.

v2

2018 Registry Flow for Quality ID

#437: Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure

Please refer to the specific section of the specification to identify the denominator and numerator information for use in submitting this Individual Specification. This flow is for registry data submission.

1. Start with Denominator
2. Check Procedure Performed:
 - a. If Procedure as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
 - b. If Procedure as Listed in the Denominator equals Yes, proceed to check Planned Hybrid or Staged Procedure.
3. Check Planned Hybrid or Staged Procedure:
 - a. If Planned Hybrid or Staged Procedure equals Yes, do not include in Eligible Patient Population. Stop Processing.
 - b. If Planned Hybrid or Staged Procedure equals No, include in Eligible Population.
4. Denominator Population:
 - a. Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 procedures in the Sample Calculation.
5. Start Numerator
6. Check Major Amputation or Open Surgical Bypass Required within 48 hours of the Index Endovascular Lower Extremity Revascularization Procedure:
 - a. If Major Amputation or Open Surgical Bypass Required within 48 hours of the Index Endovascular Lower Extremity Revascularization Procedure equals Yes, include in Data Completeness Met and Performance Met.
 - b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 procedures in the Sample Calculation.
 - c. If Major Amputation or Open Surgical Bypass Required within 48 hours of the Index Endovascular Lower Extremity Revascularization Procedure equals No, proceed to Major Amputation or Open Surgical Bypass not Required within 48 Hours of the Index Endovascular Lower Extremity Revascularization Procedure.
7. Check Major Amputation or Open Surgical Bypass not Required within 48 Hours of the Index Endovascular Lower Extremity Revascularization Procedure:
 - a. If Major Amputation or Open Surgical Bypass not Required within 48 Hours of the Index Endovascular Lower Extremity Revascularization Procedure equals Yes, include in Data Completeness Met and Performance Not Met.

- b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 procedures in the Sample Calculation.
 - c. If Major Amputation or Open Surgical Bypass not Required within 48 Hours of the Index Endovascular Lower Extremity Revascularization Procedure equals No, proceed to Data Completeness Not Met.
8. Check Data Completeness Not Met:
- a. If Data Completeness Not Met equals No, Quality Data Code not submitted. 10 procedures have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met (a=40 procedures)} + \text{Performance Not Met (c=30 procedures)}}{\text{Eligible Population / Denominator (d=80 procedures)}} = \frac{70 \text{ procedures}}{80 \text{ procedures}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a=40 procedures)}}{\text{Data Completeness Numerator (70 procedures)}} = \frac{40 \text{ procedures}}{70 \text{ procedures}} = 57.14\%$$