Quality ID #257 (NQF 1519): Statin Therapy at Discharge after Lower Extremity Bypass (LEB) – National Quality Strategy Domain: Effective Clinical Care

2018 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Process

DESCRIPTION:
Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge

INSTRUCTIONS:
This measure is to be submitted **each time** an infra-inguinal lower extremity is performed during the performance period. 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: *ANY registry that includes anatomic details or CPT procedure codes and captures prescription of statin at hospital discharge as well as documented reasons for not prescribing statin medication is required to identify patients for numerator inclusion or denominator exclusion. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of New England (VSGNE) are examples of registries that capture detailed anatomic information, but the measure is not limited to these registries.*

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-based submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR:
Patients who received an infra-inguinal lower extremity bypass

Denominator Criteria (Eligible Cases):
All patients aged 18 years and older
AND
Patient procedure during the performance period (CPT): 35556, 35566, 35570, 35571, 35583, 35585, 35587, 35656, 35666, 35671

NUMERATOR:
Patients prescribed a statin medication at discharge

Numerator Options:

Performance Met:	Statin medication prescribed at discharge **(G8816)**
OR	
Denominator Exception:	Documented reason in the medical record for why the statin therapy was not prescribed (i.e. lower extremity bypass was for a patient with non-artherosclerotic disease) **(G8815)**
OR	
Performance Not Met:	Statin therapy not prescribed at discharge, reason not given **(G8817)**

RATIONALE:

Patients who require lower extremity revascularization procedures are at high risk of subsequent cardiovascular morbidity and mortality because of their widespread atherosclerotic disease. Statin therapy in this patient population has been associated with a significant decrease in cardiovascular events. Hospitalization for lower extremity revascularization provides an opportunity for initiating statin therapy on patients without contraindications who are not already on statin therapy.

CLINICAL RECOMMENDATION STATEMENTS:

Patients who present with lower extremity ischemia bear a large systemic burden of atherosclerotic disease, and therefore face not only the immediate risk of limb loss (Dormandy/Rutherford, TASC, 2000) but also an increased risk for cardiovascular events. (Criqui, et al., N Engl J Med, 1992; McKenna/Wolfson/Kuller, Atherosclerosis, 1991; Howell, et al., J Vasc Surg, 1989) The benefits of statin therapy for cardiovascular risk reduction in the PAD population have been demonstrated in several studies, most notably the Heart Protection Study.

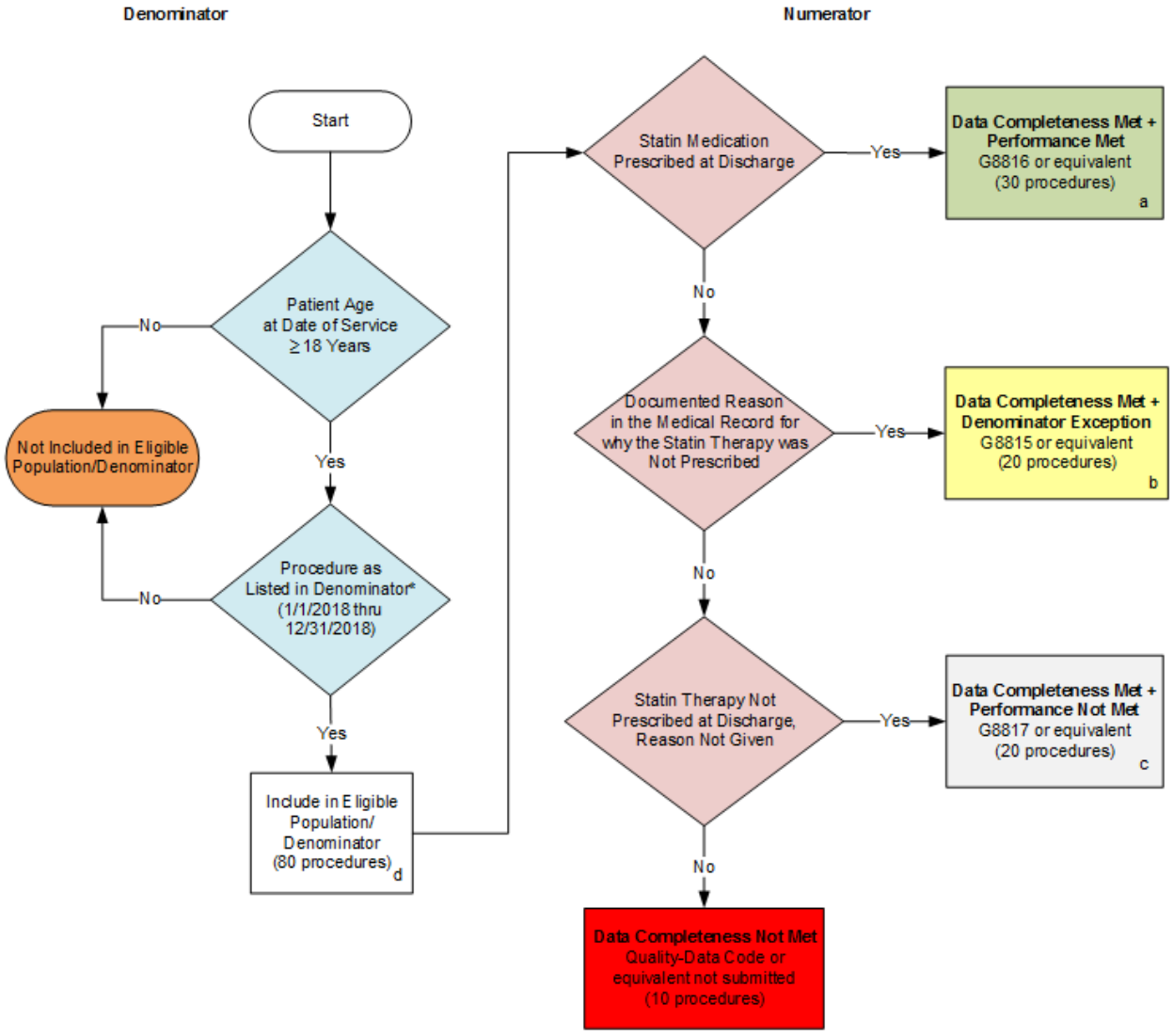
(MRC/BHF, Lancet, 2002) The Heart Protection Study (HPS) is the largest trial to assess the effects of statins on major morbidity and mortality. The investigators enrolled over 20,000 patients deemed to be at high risk for cardiovascular events and randomized them to receive either 40mg of simvastatin or placebo. On survival analysis, they demonstrated that treatment with a statin was significantly associated with a decrease in all-cause mortality (12.9% vs. 14.7%, p=.0003) and that this effect was primarily driven by the reduction in death from vascular causes (7.6% vs. 9.1%, $p < .0001$). A recently published subgroup analysis (Randomized trial, J Vasc Surg, 2007) focusing specifically on patients with documented PAD (n=6748) did not include mortality data. However, the authors demonstrated a significant reduction in the rate of first major vascular event in the simvastatin treatment arm (relative reduction of 22%; $p < .0001$), when compared to placebo.

The PREVENT III trial was a prospective, randomized, double-blinded, multicenter trial designed to examine the efficacy of a novel pharmacologic agent (edifoligide) in preventing autogenous vein graft failure in 1404 patients who underwent infra-inguinal vein bypass at 83 hospitals exclusively for the treatment of critical limb ischemia. (Conte, et al., J Vasc Surg, 2006) This LEB trial, with its high-risk critical limb ischemia (CLI) population, provides another relevant database for examination of the role of statins. The salient finding from this study is that the use of statin drugs was associated with a significant one-year survival benefit in patients undergoing surgical bypass for CLI.(Schanzer, et al., J Vasc Surg, 2008) The Kaplan-Meier analysis also suggested that the benefit continues to increase with time, and might be even greater with longer term follow-up. In these 1404 patients, those not receiving statins experienced a 40% increase in the risk of death at one year. This effect was demonstrated both in the propensity score weighted analysis (HR 1.40, CI 1.02-1.92), and in the Cox proportional hazards model (HR 1.47, CI 1.11-1.96). These findings are consistent with prior observational studies that have examined the effects of statins, albeit, in heterogeneous PAD populations. (Feringa HH, et al., J Vasc Surg, 2007; Ward RP, et al., Int J Cardiol, 2005; Kertai MD, et al., Am J Med, 2004) The largest of these observational studies, conducted by Feringa and colleagues, enrolled 1374 patients with PAD and followed them for a mean duration of 6.4 years. The authors demonstrated a strong independent association between statin use and all-cause mortality (HR 1.41 for non-users, $p < 0.0001$). (Feringa HH, et al., J Vasc Surg, 2007)

The DECREASE study randomized 497 patients who had not previously been treated with a statin to receive either 80 mg of extended-release fluvastatin or placebo once daily before undergoing major non-cardiac vascular surgery. (Schouten O, et al., N Engl J Med, 2009) On evaluation of the primary endpoint, statin therapy conferred a 45% decreased hazard ratio (10.8% versus 19%, p=0.01) for peri-operative myocardial infarction. Furthermore, death from cardiovascular causes or myocardial infarction occurred in 4.8% of patients in the fluvastatin group and 10.1% of patients in the placebo group (hazard ratio, 0.47; 95% CI, 0.24 to 0.94; p= 0.03). Fluvastatin therapy was not associated with a significant increase in the rate of adverse events. Several additional studies in patients undergoing LEB have shown similar reductions in peri-operative morbidity and mortality associated with statin use. (Ward RP, et al., Int J Cardiol, 2005; Poldermans O, et al., Circulation, 2003; O'Neil-Callahan K, et al., J Am Coll Cardiol, 2005)

Recent studies have also demonstrated a specific benefit in graft patency after LEB in patients on statin therapy. (Christenson J, Cardiovasc Surg, 2001; Abbruzzese TA, et al., J Vasc Surg, 2004; Henke PK, et al., J Vasc Surg, 2004) Abbruzzese et al. observed that statin use was associated with improved secondary patency (3-fold increased risk compared to non-users) among 197 patients who had undergone lower extremity bypass using saphenous vein, in a single-center retrospective analysis. (Abbruzzese TA, et al., J Vasc Surg, 2004)

2018 Registry Flow for Quality ID #257:
Statin Therapy at Discharge after Lower Extremity Bypass (LEB)



SAMPLE CALCULATIONS:

Data Completeness=

Performance Met (a=30 procedures) +Denominator Exception (b=20 procedures) + Performance Not Met (c=20 procedures) / Eligible Population / Denominator (d=80 procedures) = 70 procedures / 80 procedures = **87.50%**

Performance Rate=

Performance Met (a=30 procedures) / Data Completeness Numerator (70 procedures) – Denominator Exception (b=20 procedures)= 50 procedures = 30 procedures = **60.00%**

* See the posted Measure Specification for specific coding and instructions to submit this measure.
NOTE: Submission Frequency: Procedure

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2018 Registry Flow for Quality ID
#257: Statin Therapy at Discharge after Lower Extremity Bypass (LEB)

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 Patient Age:
    a. If Patient Age at Date of Encounter is equal to or greater than 18 years equals No during the performance period, do not include in Eligible Patient Population. Stop Processing.
    b. If Patient Age at Date of Encounter is equal to or greater than 18 years equals Yes during the performance period, proceed to check Procedure Performed.
3. Check Procedure Performed:
    a. If Procedure as Listed in Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Procedure as Listed in Denominator equals Yes, include in the 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 Statin Medication Prescribed at Discharge:
    a. If Statin Medication Prescribed at Discharge equals Yes, include in Data Completeness Met and Performance Met.
    b. Data Completeness Met and Performance Met is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 30 procedures in Sample Calculation.
    c. If Statin Medication Prescribed at Discharge equals No, proceed to Statin Therapy Not Prescribed for Documented Reasons.
7. Check Statin Therapy Not Prescribed for Documented Reasons:
    a. If Statin Therapy Not Prescribed for Documented Reasons equals Yes, include in the Data Completeness Met and Denominator Exception.
    b. Data Completeness Met and Denominator Exception is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b equals 20 procedures in the Sample Calculation.
    c. If Statin Therapy Not Prescribed for Documented Reasons equals No, proceed to Statin Therapy Not Prescribed at Discharge, Reason Not Given.

8. Check Statin Therapy Not Prescribed at Discharge, Reason Not Given:

    a. If Statin Therapy Not Prescribed at Discharge, Reason Not Given equals Yes, include in the Data Completeness Met and Performance Not Met.

    b. Data Completeness Met and Performance Not Met 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 Statin Therapy Not Prescribed at Discharge, Reason Not Given equals No, proceed to Data Completeness Not Met.

9. Check Data Completeness Not Met:

    a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 procedures have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met (a=30 procedures) + Denominator Exception (b=20 procedures) + Performance Not Met (c=20 procedures)}}{\text{Eligible Population / Denominator (d=80 procedures)}} = \frac{70 \text{ procedures}}{= 80 \text{ procedures}} = \mathbf{87.50\%}$$

Performance Rate=

$$\frac{\text{Performance Met (a=30 procedures)}}{\text{Data Completeness Numerator (70 procedures) – Denominator Exception (b=20 procedures)}} = \frac{30 \text{ procedures}}{50 \text{ procedures}} = \mathbf{60.00\%}$$