

Distal Symmetric Polyneuropathy

Performance Measurement Set

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Distal Symmetric Polyneuropathy

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Executive Summary: Toward Improving Outcomes for Patients with Distal Symmetric Polyneuropathy

The American Academy of Neurology (AAN) formed a Neuropathy Work Group to identify and define quality measures towards improving outcomes for patients with neuropathy. The majority of the available evidence that would meet a gap in care focused on distal symmetric polyneuropathy (DSP), therefore this measurement set is focused on measures for patients with a diagnosis of DSP.

Reasons for Prioritizing Improvement in Distal Symmetric Polyneuropathy

High Impact Topic Area

- DSP represents a significant health problem because it is a chronic, high-cost disease and is often linked to severe neuropathic pain and significant morbidity, increased mortality and impaired quality of life.¹
- The onset of DSP is insidious and without appropriate intervention the course of the disease is progressive and debilitating.²
- Peripheral neuropathy is estimated to affect more than 20 million Americans.³
- DSP is the most common variety of neuropathy and type of diabetic neuropathy.^{1,4} Approximately 30% of neuropathies are caused by diabetes and 30% are idiopathic (or unknown cause).³ Other common causes of neuropathy include autoimmune disorders, tumors, hereditary conditions, nutritional imbalances, infections or toxins.³
- The most important etiological factors that have been associated with DSP are poor glycemic control, diabetes duration, visceral obesity and height, with possible roles for hypertension, age, smoking, hypoinsulinemia, and dyslipidemia.^{5,6}
- Neuropathies affect up to 50% of patients with diabetes.⁷ DSP affects at least one in four diabetic patients.¹ Diabetes is one of the five major chronic conditions that affect 25% of the US community population⁸ and amounted to more than \$62.3 billion health care costs in 1996.⁹
- The distal symmetric sensory or distal sensorimotor polyneuropathy represents the most relevant clinical manifestation, affecting 30% of the hospital-based population and 25% of community-based samples of diabetic patients.⁶
- The incidence of DSP is 2% per year.⁶
- A 1999 survey found that 8-9% of Medicare recipients have peripheral neuropathy as their primary or secondary diagnosis.³ The annual cost to Medicare exceeds \$3.5 billion.³
- Neuropathies also cause great morbidity because the symptoms severely decrease patients' quality of life. Pain associated with diabetic neuropathy exerts a substantial impact on sleep and enjoyment of life.^{10,11} Patients describe pain-related interference in multiple health related quality of life (HR-QOL) and functional domains, as well as reduced ability to work and reduced mobility due to their pain. The substantial costs to society of DSP derive from direct medical costs, loss of the ability to work, loss of caregivers' ability to work and possibly greater need for institutionalization or other living assistance.¹⁰ The secondary complications of neuropathy such as falls, foot ulcers (estimated that foot ulcers occurs in approximately 2.5% of patients with diabetes⁷), cardiac arrhythmias, and ileus are significant and can lead to fractures, amputations, and even death in patients with diabetes.⁷ Despite this significant impact, 25% and 39% of the diabetic patients, respectively, had no treatment for their pain in two surveys.^{12,13}
- Therapy is aimed at treating the underlying disease or cause. Proper management of medications can also improve the symptoms. An experienced neurologist can help patients feel more comfortable, improve the patient's quality of life, and help prevent further permanent damage.¹⁴

Demonstrated Opportunity for Improvement

- DSP is often difficult to diagnose reliably. It is often misdiagnosed or erroneously associated as the side effect of another disease like kidney failure.³ Undiagnosed and untreated neuropathy may lead to disability and poor quality of life. Neuropathy needs to be diagnosed early to prevent complications, such as neuropathic pain or the diabetic foot.
- Since DSP is the major contributory factor for diabetic foot ulcers and the lower-limb amputation rates in diabetic subjects are 15 times higher than in the non-diabetic population, an early detection of DSP by screening and appropriate diagnosis are of utmost importance¹⁵. This is even more imperative because many patients with DSP are asymptomatic or have only mild symptoms.
- Neuropathic pain is often more difficult to treat than many other types of chronic pain. Patients with neuropathic pain have great medical co-morbidity burden than age- and sex-adjusted controls.¹⁰ Data collected between 1988 and 1995 (derived from the Center for Disease Control's population-based Behavioral Risk Factor Surveillance System [BRFSS], as well as the National Health and Nutrition Examination [NHANES] surveys) reveal significant quality gaps in the treatment of diabetes and in screening for diabetes-related complications.⁷ Diabetics also do not receive appropriate screening measures: only 55% obtain annual foot examinations.¹⁶

Disparities

- There is currently no consistent data that shows disparities between minorities and whites for diabetes-related neuropathy and peripheral vascular disease.¹⁷ DSP is more common in older adults. Older people are among the top spenders on healthcare. They make up 13% of the US population in 2002, yet they consumed 63% of health care expenses.⁶ Improving the effectiveness of diagnosis and optimizing patient outcomes will become increasingly important as the population of the United States ages.

Rigorous Clinical Evidence Base

Evidence-based clinical practice guidelines and consensus papers are available for the management of distal symmetric polyneuropathy. This measurement set is based upon guidelines or consensus papers from:

- American Academy of Neurology
- American Diabetes Association
- United States Preventive Services Task Force
- National Quality Forum Consensus Standards
- International Association for the Study of Pain (IASP) Neuropathic Pain Special Interest Group with additional support provided by the Neuropathic Pain Institute
- American Geriatrics Society

Distal Symmetric Polyneuropathy Outcomes

The work group attempted to develop measures of outcomes along with measures of processes that may improve patient outcomes for DSP patients. Due to the lack of standardized diagnostics for DSP and measures already developed by outside organizations for outcomes of untreated DSP (eg foot ulcerations), the work group felt there were no specific outcomes that could be focused on. The Work Group decided to focus on performance measures based upon processes that may achieve desired outcomes and reflect high quality care.

Desired outcomes for DSP include:

1. Establish and define appropriate DSP diagnostic criteria to ensure appropriate disease diagnosis
2. Promote appropriate testing and studies for DSP and related complications
3. Screen for underlying causes of DSP (diabetes, unhealthy alcohol use, etc.) to promote appropriate treatment of DSP patients.
4. Assist patients in managing their pain and improving their quality of life

5. Promote patient safety and reduce falls
6. Reduce DSP complications (eg foot ulcers)

Distal Symmetric Polyneuropathy Work Group Recommendations

Process measures: Several processes of care demonstrated to improvement outcomes for patients with distal symmetric polyneuropathy are recommended:

Distal Symmetric Polyneuropathy Measures

Measures addressing appropriate diagnosis

Measure #1: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria: DSP Symptoms and Signs

Measure #2: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria: Electrodiagnostic Studies

Measures addressing underuse of effective services (evaluation and treatment services)

Measure #3: Diabetes/Pre-Diabetes Screening for Patients with DSP

Measure #4: Screening for Unhealthy Alcohol Use

Measure addressing quality of life/morbidity

Measure #5: Querying about Pain and Pain Interference with Function

Measures addressing safety

Measure #6: Querying about Falls for Patients with DSP

These measures are designed for individual practitioner level quality improvement. Unless otherwise indicated the measures are appropriate for accountability if the appropriate methodological, statistical, and implementation rules are followed.

Other Potential Measures

The Work Group considered several other potential measures, though ultimately decided they were not appropriate for inclusion in the measurement set.

Measure Harmonization

When existing measures are available for the same measurement topic, the AAN attempts to harmonize the measures to the extent it is feasible. The AAN works to ensure there is no duplication of existing measures. The AAN reaches out to partner organizations for input on the measures, involves key stakeholders on the measure development workgroups and posts the measures during a 30 day public comment period for comment by any interested individual or group. For example, the DSP workgroup considered the addition of a measure on foot care as it relates to distal symmetric polyneuropathy. The workgroup worked with the American Diabetes Association (ADA) to develop this measure; however, ultimately this measure was not included in the measurement set as there was significant overlap with the existing ADA measure.

Existing Quality Improvement (QI) Initiative or Collaborative for Measure Implementation

The American Academy of Neurology has developed a performance in practice program for maintenance of certification (MOC), NeuroPI¹⁸, which meets the American Board of Psychiatry and Neurology (ABPN) requirements for MOC Performance in Practice requirements. The NeuroPI will contain a new module for distal symmetric polyneuropathy based upon the measures developed in this measurement set. The measures will be used as the basis of the module content. A separate formal testing effort for reliability and validity is also planned for this measurement set.

Technical Specifications Overview

The AAN develops technical specifications for multiple data sources, including:

- Electronic Health Record (EHR) Data

- Electronic Administrative Data (Claims)
- Expanded (multiple-source) Administrative Data
- Paper Medical Record/Retrospective Data Collection Flow Sheet

Because administrative claims are currently the only available sources of data, specifications to collect and report on the neuropathy measures for administrative claims are included in this document.

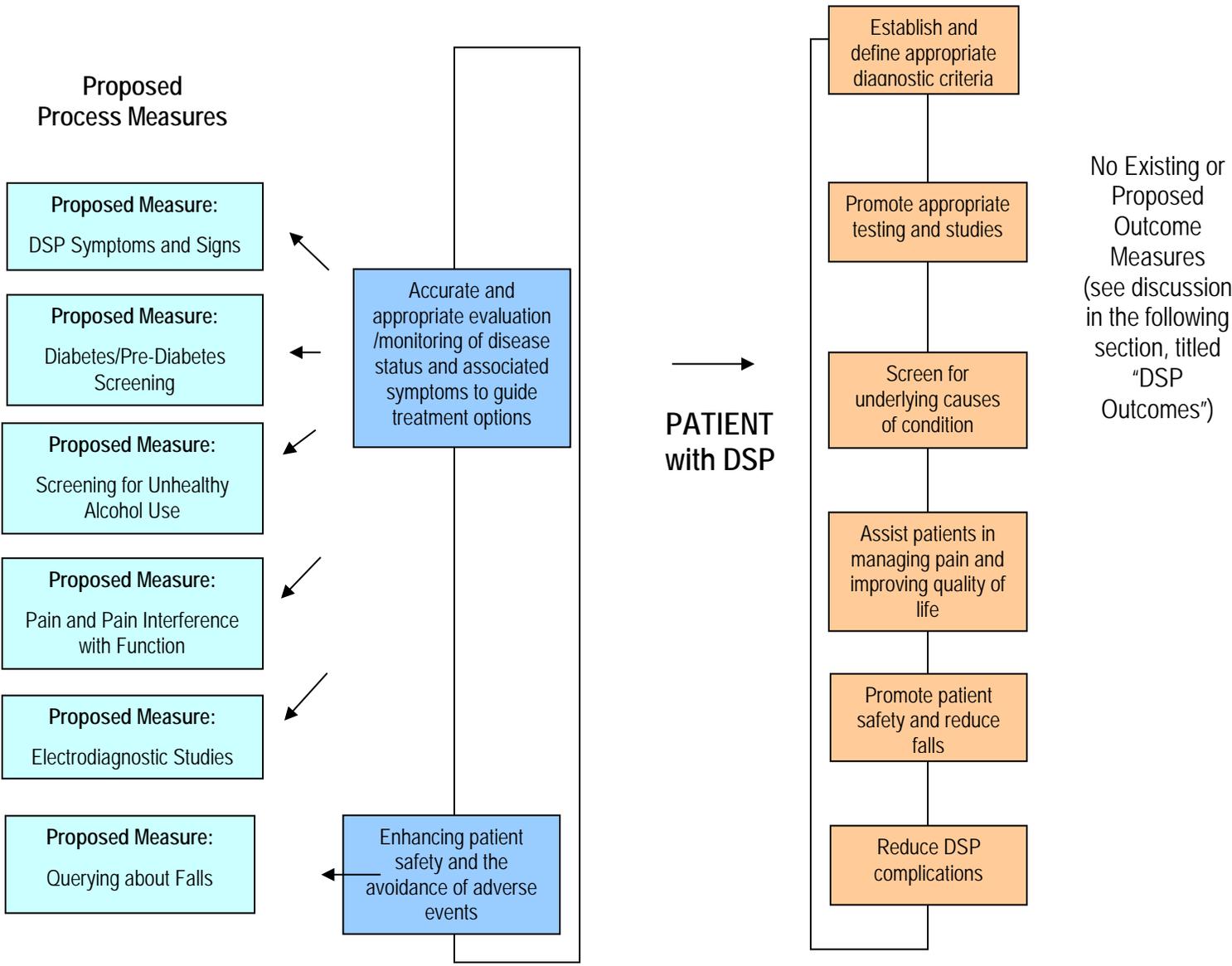
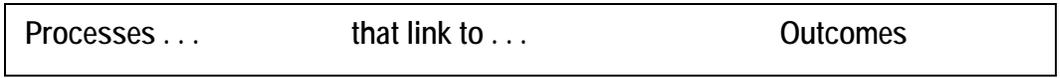
The AAN is in the process of creating data elements required for electronic capture with Electronic Health Records (EHRs). A listing of the data elements for each of the DSP measures will be made available at a later date.

Testing and Implementation of the Measurement Set

The measures in the set are being made available without any prior testing. The AAN welcomes the opportunity to promote the initial testing of these measures and to ensure that any results available from testing are used to refine the measures before implementation.

Desired Outcomes for Patients with DSP

Setting: Ambulatory and residential care (nursing facility, domiciliary, home care)



Purpose of Measurement Set

The American Academy of Neurology (AAN) formed a Neuropathy Work Group to identify and define quality measures towards improving outcomes for patients with distal symmetric polyneuropathy (DSP). The majority of the available evidence that would meet a gap in care focused on distal symmetric polyneuropathy (DSP), therefore this measurement set is focused on measures for patients with a diagnosis of DSP. The Work Group sought to develop measures to support the delivery of high quality care for patients with DSP. The Work Group developed measures that were focused on the gaps in care in need of significant improvement and the available rigorous clinical evidence for DSP. The Work Group considered the development of outcome, process, structural, composite, bundled, and group or system-level measures where it was appropriate.

The Work Group focused on measures that would be applicable to patients with an established diagnosis of distal symmetric polyneuropathy. However, an important aspect of care is to ensure that an appropriate diagnosis of DSP has been made. Thus there is a paired measure that focuses on ensuring that the appropriate diagnosis criteria were followed and electrodiagnostic testing was completed.

Importance of Topic

Prevalence and Incidence

- DSP is the most common variety of neuropathy and a type of diabetic neuropathy.^{1,4}
- Peripheral neuropathy is estimated to affect more than 20 million Americans.³ The overall prevalence is approximately 2,400 (2.4%) per 100,000 population, but in individuals older than 55 years, the prevalence rises to approximately 8,000 (8%) per 100,000.^{19,20} Older people are among the top spenders on healthcare. They make up 13% of the US population in 2002, yet they consumed 63% of health care expenses.⁶ Improving the effectiveness of diagnosis and optimizing patient outcomes will become increasingly important as the population of the United States ages.
- Neuropathies affect up to 50% of patients with diabetes.⁷ DSP affects at least one in four diabetic patients.¹ Diabetes is one of the five major chronic conditions that affect 25% of the US community population¹⁴ and amounted to more than \$62.3 billion health care costs in 1996.⁹
- The incidence of DSP is 2% per year.⁶

Mortality and Morbidity

- Neuropathies also cause great morbidity because the symptoms severely decrease patients' quality of life. The secondary complications of neuropathy such as falls, foot ulcers, cardiac arrhythmias, and ileus are significant and can lead to fractures, amputations, and even death in patients with diabetes.⁷
- Pain associated with diabetic neuropathy exerts a substantial impact on the quality of life, particularly by causing considerable interference in sleep and enjoyment of life.¹¹ Despite this significant impact, 25% and 39% of the diabetic patients, respectively, had no treatment for their pain in two surveys.^{12,13}
- Another complication in diabetic neuropathy is the development of foot ulcers, and some reports have estimated that this occurs in approximately 2.5% of patients with diabetes.⁷

Office Visits and Hospital Stays

- The distal symmetric sensory or distal sensorimotor polyneuropathy represents the most relevant clinical manifestation, affecting 30% of the hospital-based population and 25% of community-based samples of diabetic patients.⁶

Family Caregiving

- Patients describe pain-related interference in multiple health related quality of life (HR-QOL) and functional domains, as well as reduced ability to work and reduced mobility due to their pain. The substantial costs to

society of DSP derive from direct medical costs, loss of the ability to work, loss of caregivers' ability to work and possibly greater need for institutionalization or other living assistance.¹⁰

Cost:

- A 1999 survey found that 8-9% of Medicare recipients have peripheral neuropathy as their primary or secondary diagnosis.³ The annual cost to Medicare exceeds \$3.5 billion.³

Opportunity for Improvement

- DSP is often difficult to diagnose reliably. It is often misdiagnosed or erroneously associated as the side effect of another disease like kidney failure.³ Undiagnosed and untreated neuropathy may lead to disability and poor quality of life. Neuropathy needs to be diagnosed early to prevent complications, such as neuropathic pain or the diabetic foot.
- Since DSP is the major contributory factor for diabetic foot ulcers and the lower-limb amputation rates in diabetic subjects are 15 times higher than in the non-diabetic population, an early detection of DSP by screening and appropriate diagnosis is of utmost importance.¹⁵ This is even more imperative because many patients with DSP are asymptomatic or have only mild symptoms.
- Neuropathic pain is often more difficult to treat than many other types of chronic pain. Patients with neuropathic pain have great medical co-morbidity burden than age- and sex-adjusted controls.¹⁰ Data collected between 1988 and 1995 (derived from the Center for Disease Control's population-based Behavioral Risk Factor Surveillance System [BRFSS], as well as the National Health and Nutrition Examination [NHANES] surveys) reveal significant quality gaps in the treatment of diabetes and in screening for diabetes-related complications.⁷ Diabetics also do not receive appropriate screening measures: only 55% obtain annual foot examinations.¹⁶

Disparities

- There is currently no consistent data that shows disparities between minorities and whites for diabetes-related neuropathy and peripheral vascular disease.¹⁷ DSP is more common in older adults. Older people are among the top spenders on healthcare. They make up 13% of the US population in 2002, yet they consumed 63% of health care expenses.⁶ Improving the effectiveness of diagnosis and optimizing patient outcomes will become increasingly important as the population of the United States ages.
- No definite racial predilection has been demonstrated for diabetic neuropathy. However, members of minority groups (eg, Hispanics, African Americans) have more secondary complications from diabetic neuropathy, such as lower-extremity amputations, than whites.^{17,21} They also have more hospitalizations for neuropathic complications.
- Men with type 2 diabetes may develop diabetic polyneuropathy earlier than women, and neuropathic pain causes more morbidity in women than in men.²²

Clinical Evidence Base

Clinical practice guidelines and peer-reviewed consensus papers serve as the foundation for the development of performance measures. There are relatively few guidelines that have been developed for distal symmetric polyneuropathy. Guidelines or consensus papers from the American Academy of Neurology^{4,23-26}, American Diabetes Association²⁷, United States Preventive Services Task Force²⁸, National Quality Forum Consensus Standards²⁹, International Association for the Study of Pain (IASP) Neuropathic Pain Special Interest Group with additional support provided by the Neuropathic Pain Institute³⁰, and the American Geriatrics Society³¹ were used as the foundation for the measures in this measurement set. In addition, recommendations from other groups were considered including the American Association of Clinical Endocrinologists, European Federation of Neurological Societies, American Association of Neuromuscular and Electrodiagnostic Medicine, American Association of Physical Medicine and Rehabilitation, and the Peripheral Nerve Society.

Selected guidelines met all of the required elements outlined in the American Medical Association convened Physician Consortium for Performance Improvement® framework for consistent and objective selection of clinical practice guidelines from which measures may be derived.³²

Distal Symmetric Polyneuropathy Outcomes

The work group attempted to develop measures of outcomes along with measures of processes that may improve patient outcomes for DSP patients. Due to the lack of standardized diagnostics for DSP and measures already developed by outside organizations for outcomes of untreated DSP (eg foot ulcerations), the work group felt there were no specific outcomes that could be focused on. The Work Group decided to focus on performance measures based upon processes that may achieve desired outcomes and reflect high quality care.

Desired outcomes for DSP include:

1. Establish and define appropriate DSP diagnostic criteria to ensure appropriate disease diagnosis
2. Promote appropriate testing and studies for DSP and related complications
3. Screen for underlying causes of DSP (diabetes, unhealthy alcohol use, etc.) to promote appropriate treatment of DSP patients.
4. Assist patients in managing their pain and improving their quality of life
5. Promote patient safety and reduce falls
6. Reduce DSP complications (eg foot ulcers)

Intended Audience, Care Setting, and Patient Population

The AAN encourages use of the measures by physicians and other health care professionals, where appropriate, to manage the care for all patients with distal symmetric polyneuropathy 18 years and older. These measures are intended to be used to calculate performance or reporting at the practitioner level. Performance measurement may not achieve the desired goal of improving patient care by itself. Measures have their greatest impact when they are used appropriately and linked directly to operational steps that clinicians, patients, and health plans can apply in practice to improve care.

Distal Symmetric Polyneuropathy Work Group Recommendations

The measurement set includes measures that focus on accurate and appropriate diagnosis of disease status and associated symptoms to guide treatment, effective using of, improving quality of life, and enhancing patient safety. The DSP Work Group identified several desired outcomes for patients with DSP (see “Link to Outcomes” diagram in the preceding section). Current quality gaps in DSP care emphasize the need to improve specific processes that have been demonstrated to improve DSP patient outcomes. As a result, many of the measures in the DSP measurement set focus on the provision of effective and efficient patient-centered care. These performance measures are designed for practitioner level quality improvement to achieve better outcomes for patients with DSP. Unless otherwise indicated, the measures are also appropriate for accountability if the appropriate methodological, statistical, and implementation rules are achieved.

Distal Symmetric Polyneuropathy

Measures addressing appropriate diagnosis

Measure #1: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria: DSP Symptoms and Signs

Measure #2: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria: Electrodiagnostic Studies

Measures addressing underuse of effective services (evaluation and treatment services)

Measure #3: Diabetes/Pre-Diabetes Screening for Patients with DSP

Measure #4: Screening for Unhealthy Alcohol Use

Measure addressing quality of life/morbidity

Measure #5: Querying about Pain and Pain Interference with Function

Measures addressing safety

Measure #6: Querying about Falls for Patients with DSP

Distal Symmetric Polyneuropathy

These measures are designed for individual practitioner level quality improvement. Unless otherwise indicated the measures are appropriate for accountability if the appropriate methodological, statistical, and implementation rules are followed.

Institute Of Medicine Domains of Health Care Quality

Measure	Safe	Effective		Patient-Centered	Timely	Efficient	Equitable
		Underuse	Overuse				
Measure #1: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria: DSP Symptoms and Signs	X	X				X	
Measure #2: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria: Electrodiagnostic Studies	X		X			X	
Measure #3: Diabetes/Pre-diabetes Screening for Patients with DSP	X	X				X	
Measure #4: Screening for Unhealthy Alcohol Use	X	X		X		X	
Measure #5: Querying about Pain and Pain Interference with Function	X	X		X		X	
Measure #6: Querying about Falls for Patients with DSP	X	X		X		X	

Where possible the measures in this measurement set were focused to address one or more of the IOM's Domains of Health Care Quality. Please refer to each measure for which domain(s) it addresses.

Other Potential Measures

The Work Group considered several other potential measures, though ultimately decided they were not appropriate for inclusion in the measurement set.

Measure Harmonization

When existing measures are available for the same measurement topic, the AAN attempts to harmonize the measures to the extent it is feasible. The AAN works to ensure there is no duplication of existing measures. The AAN reaches out to partner organizations for input on the measures, involves key stakeholders on the measure development workgroups and posts the measures during a 30 day public comment period for comment by any interested individual or group. For example, the DSP workgroup considered the addition of a measure on foot care as it relates to distal symmetric polyneuropathy. The workgroup worked with the American Diabetes Association (ADA) to develop this measure; however, ultimately this measure was not included in the measurement set as there was significant overlap with the existing ADA measure.

Potential for future measure development in the National Priorities Partnership Priority Areas

Care coordination: Multiple specialties treat patients with distal symmetric polyneuropathy. Care coordination between primary care physicians, diabetes specialists, neurologists, physical therapists and many other clinicians is paramount to providing optimal care to the patient with neuropathy.

Patient Safety: There are significant safety concerns associated with distal symmetric polyneuropathy. Neuropathy often leads to the loss of feeling in feet, hands, and other parts of the body, and may lead to dizziness and impaired balance. This may lead to significant falls risks and related safety issues. Medications used to treat neuropathies can have side effects that need to be recognized and managed appropriately. Frequently, neuropathy is the first

symptom of an underlying disorder such as diabetes or nutritional deficiency. The early recognition of these disorders is important not only to treat the neuropathy but also the underlying disorder.

Patient and family engagement: Involving patients in their own care, particularly with regard to education and self-management, can improve health outcomes, as well as the patient's quality of life.⁸ Spouses of neuropathy patients have been shown to have negative adverse outcomes socially because of their partner's neuropathic pain.¹⁰ Involving both the patient and family members in the diagnosis and treatment of DSP may lead to improved quality of life.

Palliative/End of Life Care: Ulcers or bed sores due to diabetes and diabetic neuropathy are a significant issue for patients with DSP. In the future, there may be the potential to create a measure to focus on this end of life issue for DSP patients. Pain management is an integral part of neuropathy treatment.

Existing Quality Improvement (QI) Initiative or Collaborative for Measure Implementation

The American Academy of Neurology has developed a performance in practice program for maintenance of certification (MOC), NeuroPI¹⁸, which meets the American Board of Psychiatry and Neurology (ABPN) requirements for MOC Performance in Practice requirements. The NeuroPI will contain a new module for distal symmetric polyneuropathy based upon the measures developed in this measurement set. The measures will be used as the basis of the module content. A separate formal testing effort for reliability and validity is also planned for this measurement set.

Technical Specifications: Overview

The AAN develops technical specifications for multiple data sources, including:

- Electronic Health Record (EHR) Data
- Electronic Administrative Data (Claims)
- Expanded (multiple-source) Administrative Data
- Paper Medical Record/Retrospective Data Collection Flow Sheet

Because administrative claims are currently the only available sources of data, specifications to collect and report on the DSP measures for administrative claims are included in this document.

The AAN is in the process of creating data elements required for electronic capture with Electronic Health Records (EHRs). A listing of the data elements for each of the DSP measures will be made available at a later date.

Measure Exceptions

For *process measures*, the AAN follows the PCPI's three categories of reasons for which a patient may be excluded from the denominator of an individual measure:

- Medical reasons (examples)
 - not indicated (absence of organ/limb, already received/performed, other)
 - contraindicated (patient allergic history, potential adverse drug interaction, other)
- Patient reasons (examples)
 - patient declined
 - social or religious reasons
 - other patient reasons
- System reasons (examples)
 - resources to perform the services not available
 - insurance coverage/payor-related limitations
 - other reasons attributable to health care delivery system

These measure exception categories are not available uniformly across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. For some measures, examples have been provided in the measure exception language of instances that would constitute an exception. Examples are intended to guide clinicians and are not all-inclusive lists of all possible reasons why a patient could be excluded from a measure. The exception of a patient may be reported by appending the appropriate modifier to the CPT Category II code designated for the measure:

- Medical reasons: modifier 1P
- Patient reasons: modifier 2P
- System reasons: modifier 3P

Although this methodology does not require the external reporting of more detailed exception data, the AAN follows the PCPI's recommendation that physicians document the *specific* reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness.³² The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception.

Please refer to documentation for each individual measure for information on the acceptable exception categories and the codes and modifiers to be used for reporting.

Testing and Implementation of the Measurement Set

The draft measures in the set were made available for public comment without any prior testing. The AAN recognizes the importance of testing all of its measures and encourages testing of the DSP measurement set for feasibility and reliability by organizations or individuals positioned to do so. The AAN welcomes the opportunity to promote the initial testing of these measures and to ensure that any results available from testing are used to refine the measures before implementation.

Measure #1: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria: DSP Symptoms and Signs

Distal Symmetric Polyneuropathy
This is a paired measure with measure #2.

Measure Description

Percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy who had their neuropathic symptoms and signs* reviewed and documented at the initial evaluation for distal symmetric polyneuropathy.

**Neuropathic symptoms*: numbness, altered sensation, or pain in the feet. *Neuropathic Signs*: decreased or absent ankle reflexes, decreased distal sensation, and distal muscle weakness or atrophy.

Measure Components

Numerator Statement	<p>Patients who had their neuropathic symptoms and signs* reviewed and documented at the initial evaluation for distal symmetric polyneuropathy.</p> <p>Definitions: <i>*Neuropathic Symptoms</i>: numbness, altered sensation, or pain in the feet. <i>Neuropathic Signs</i>: decreased or absent ankle reflexes, decreased distal sensation, and distal muscle weakness or atrophy</p>
Denominator Statement	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p>
Denominator Exceptions	<ul style="list-style-type: none"> • Documentation of a medical reason for not reviewing and documenting neuropathic symptoms and signs (eg, patient has profound mental retardation, patient has a language disturbance, or patient is cognitively impaired)
Supporting Guideline & Other References	<p>The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines:</p> <ul style="list-style-type: none"> • Symptoms alone have relatively poor diagnostic accuracy in predicting the presence of polyneuropathy. Multiple neuropathic symptoms are more accurate than single symptoms and should be weighted more heavily. (Level B)²³ • Signs are better predictors of polyneuropathy than symptoms and should be weighted more heavily. (Level B)²³ • A single abnormality upon examination is less sensitive than multiple abnormalities in predicting the presence of polyneuropathy; therefore, an examination for polyneuropathy should look for a combination of signs. (Level B)²³ • Relatively simple examinations are as accurate in diagnosing polyneuropathy as complex scoring systems; therefore, the case definition can use simple examinations without compromising accuracy. (Level B)²³ • The combination of neuropathic symptoms, signs, and abnormal electrodiagnostic studies provides the most accurate diagnosis of distal symmetric polyneuropathy. (Formal Consensus)²³

Measure Importance

Relationship to desired outcome Appropriate diagnosis of DSP can lead to improved patient outcomes and can prevent complications (i.e., neuropathic pain). The accurate criteria for the diagnosis of DSP in debatable. The exact criteria for diagnosis are needed to aid clinicians in the diagnosis of DSP.

Distal symmetric polyneuropathy can be asymptomatic in its early stages. Asymptomatic detection is more likely when dyskinesia or paresthesias are lacking or when only motor deficits are the presenting factors. There are many signs that need to be examined including primary sensory modalities, examining for sensory motor loss, and examining for motor signs.²³

Neuropathy is often misdiagnosed or not diagnosed at all due to a misunderstanding or lack of presentation of symptoms; it can be mistaken for another condition. This leads to a delay in treatment or no treatment at all for those afflicted by the condition.³

Correct diagnosis may reduce hospitalizations for neuropathic complications, lower morbidity in females, slow or control the progression of neuropathy in diabetics, and reduce variability in symmetric diabetic polyneuropathy prevalence data. Peripheral neuropathy has not been adequately recognized. It is often misdiagnosed or erroneously associated as the side effect of another disease like kidney failure.³

DSP is one of the most common neurological complications of HIV/AIDS and its treatment.³³

Clinicians caring for patients with HIV infection need recognize the importance in becoming familiar with the diagnosis and treatment of DSP³⁴, as this may provide significant improvement in the quality of life in these patients.

Opportunity for Improvement	The lack of consistent criteria for diagnosis of DSP has supported a wide variability in prevalence data for the condition. Moreover, because many patients with DSP are initially asymptomatic, detection is extremely dependent on careful neurologic examination by the primary care clinician or other provider.
	Peripheral neuropathy is estimated to affect more than 20 million Americans. ³ 1 in 3 patients with diabetes are affected by DSP. ³⁵ Neuropathy is estimated to be present in 7.5% of patients at the time of diabetes diagnosis. More than half of cases are distal symmetric polyneuropathy. ³⁵
	Approximately 30% of neuropathies are caused by diabetes and 30% are idiopathic (or unknown cause). ¹ Other common causes of neuropathy include autoimmune disorders, tumors, hereditary conditions, nutritional imbalances, infections or toxin.

IOM Domains of Health Care Quality Addressed	<ul style="list-style-type: none"> • Safe • Effective • Efficient
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Exception Justification	Evaluation for neuropathy involves taking a patient history regarding symptoms of pain, numbness, tingling, weakness, balance impairment etc. The neurological exam of these patients includes sensory testing where patient input regarding reduced sensation and co-operation for motor testing is required in addition to objective evidence of atrophy or reflex loss which can be detected by the examiner. In patients who are profoundly mentally retarded, have language impairments (eg aphasia), or other significant cognitive impairment they cannot provide the required information for diagnosis of distal symmetric polyneuropathy.
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Harmonization with Existing Measures	There are no other measures currently available that are similar to this measure or need to be harmonized with this measure.
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Measure Designation

Measure purpose	<ul style="list-style-type: none"> • Quality improvement • Accountability
Type of measure	<ul style="list-style-type: none"> • Process
Level of Measurement	<ul style="list-style-type: none"> • Individual practitioner

Care setting	<ul style="list-style-type: none"> • Ambulatory care
Data source	<ul style="list-style-type: none"> • Electronic health record (EHR) data • Administrative Data/Claims (outpatient claims) • Administrative Data/Claims Expanded (multiple-source) • Paper medical record

Technical Specifications: Administrative/Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

The specifications listed below are those needed for performance calculation. Additional CPT II codes may be required depending on how measures are implemented in reporting programs versus performance assessment programs.

Denominator (Eligible Population)	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy</p> <p>ICD-9 –CM Diagnosis Codes: 250.6, 250.60, 250.61, 250.62, 250.63, 356.4, 356.8, 356.9, 357.1, 357.2, 357.3, 357.4, 357.5, 357.6, 357.7, 357.8, 357.89, 357.9</p> <p>AND</p> <p>CPT E/M Service Code: 99201, 99202, 99203, 99204, 99205 (office-new patient), 99211, 99212, 99213, 99214, 99215 (office-established patient), 99241, 99242, 99243, 99244, 99245 (outpatient consult), 99304, 99305, 99306, 99307, 99308, 99309, 99310 (nursing facility), 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337 (domiciliary), 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 (home visit).</p>
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Numerator	<p>Patients who had their neuropathic symptoms and signs* reviewed and documented at the initial evaluation for distal symmetric polyneuropathy.</p>
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Definitions:

**Neuropathic Symptoms:* numbness, altered sensation, or pain in the feet.

Neuropathic Signs: decreased or absent ankle reflexes, decreased distal sensation, and distal muscle weakness or atrophy.

Reporting Instructions:

- For all patients meeting the denominator criteria, report either **1119F** for *initial evaluation for condition* or **1501F** for *not initial evaluation for condition*.
- When **1119F** is reported, also report the CPT Category II, **1500F** *Signs and symptoms of distal symmetric polyneuropathy reviewed and documented*.

1500F *Symptoms and signs of distal symmetric polyneuropathy reviewed and documented*

1119F *Initial evaluation for condition*

1501F *Not initial evaluation for condition*

Denominator Exceptions	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy</p> <ul style="list-style-type: none"> • Documentation of a medical reason(s) for not reviewing and documenting neuropathic symptoms and signs (eg profound mental retardation, patient has a language disturbance, or patient cognitively impaired)
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Reporting Instructions:

- For patient with appropriate exclusion criteria, report **1500F-1P**.
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Measure #2: Distal Symmetric Polyneuropathy (DSP) Diagnosis Criteria-Electrodiagnostic Studies

Distal Symmetric Polyneuropathy
This is a paired measure with measure #1.

Measure Description

Percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy who had electrodiagnostic studies (EDX) conducted, documented and reviewed within 6 months of initial evaluation for distal symmetric polyneuropathy.

Measure Components

Numerator Statement	<p>Patients who had electrodiagnostic (EDX) studies conducted, documented, and reviewed within 6 months of initial evaluation for distal symmetric polyneuropathy.</p> <p>Note: It may be necessary to look for findings in the patient medical record or request studies previously conducted from another physician office which may require additional time. Another electrodiagnostic study should not be performed if a satisfactory study has already been done and can be reviewed.</p>
Denominator Statement	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p>
Denominator Exceptions	<ul style="list-style-type: none"> • Documentation of a medical reason for not conducting, documenting and reviewing EDX studies (eg patient has a skin conditions which contraindicates EDX) • Documentation of a patient reason for not conducting, documenting and reviewing EDX studies (eg patient declines to undergo testing) • Documentation of a system reason for not conducting, documenting and reviewing EDX studies (eg patient does not have insurance to pay for the testing)
Supporting Guideline & Other References	<p>The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines or consensus papers:</p> <ul style="list-style-type: none"> • The combination of neuropathic symptoms, signs, and abnormal electrodiagnostic studies provides the most accurate diagnosis of distal symmetric polyneuropathy. (Formal Consensus)²³ • Electrodiagnostic studies are recommended as part of the clinical research case definition since they are objective and validated tests of peripheral nerve function. Abnormal electrodiagnostic studies increase the likelihood of the presence of distal symmetric polyneuropathy and provide a higher level of specificity to the case definition. Electrodiagnostic studies should not be used alone to make the diagnosis since their sensitivity and specificity are not perfect. (Formal Consensus).²³ • The simplified minimal requirements for Nerve Conduction Study (NCS) protocol is as follows: <ol style="list-style-type: none"> 1. Sural sensory and peroneal motor NCSs are performed in one lower extremity. Taken together, these NCSs are the most sensitive for detecting a distal symmetric polyneuropathy. If both studies are normal, there is no evidence of typical distal symmetric polyneuropathy. In such a situation, no further NCSs are necessary.(Formal Consensus)²³ 2. If sural sensory or peroneal motor NCSs are abnormal, the performance of additional NCSs is recommended. This should include NCS of at least the ulnar sensory, median sensory, and ulnar motor nerves in one upper extremity. A contralateral sural sensory and one tibial motor NCS may also be performed according to the discretion of the examiner. Caution is

	<p>warranted when interpreting median and ulnar studies since there is a possibility of abnormality due to compression of these nerves at the wrist or ulnar neuropathy at the elbow. (Formal Consensus)²³</p> <ol style="list-style-type: none"> 3. If a response is absent for any of the nerves studied (sensory or motor, a NCS of the contralateral nerve should be performed. (Formal Consensus)²³ 4. If a peroneal motor response is absent, an ipsilateral tibial motor NCS should be performed.(Formal Consensus)²³ <ul style="list-style-type: none"> • Electrodiagnostic studies are not required for field or epidemiologic studies, but the likelihood of diagnosis must be downgraded accordingly. (Formal Consensus)²³
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Measure Importance

Relationship to desired outcome	Appropriate diagnosis is critical to ensuring that the patient receives the best possible treatment. Electrodiagnostic studies are one of the three main criteria used for the most accurate diagnosis of distal symmetric polyneuropathy. Electrodiagnostic studies provide a higher level of specificity for the diagnosis. ³⁶⁻³⁹ Electrodiagnostic studies are sensitive, specific, and validated measures of the presence of polyneuropathy. ²³
Opportunity for Improvement	<p>Gorson and Ropper⁴⁰ found that electrodiagnostic studies, specifically, nerve conduction studies showed a distal, axonal loss pattern affecting predominantly sensory fibers in the majority of patients studied. However, nine of 98 patients (9%) had three or more demyelinating features, and 6% had conduction block. These findings are virtually identical to a previous study of diabetic polyneuropathy,⁴¹ but lower compared to another study (17%).⁴² This discrepancy may be related to patient selection. In the latter study patients were selected from electrodiagnostic records without considering the clinical phenotype.¹⁶ Nonetheless, because some patients may have an immune demyelinating neuropathy detected only by electrodiagnostic evaluation^{24,43}, electrodiagnostic studies remain an integral element of the evaluation of diabetic patients with DSP.</p> <p>Approximately 55% of patients have a potential for other causes of DSP with 9% having 3 or more demyelinating features found on an EMG study.⁴²</p>
IOM Domains of Health Care Quality Addressed	<ul style="list-style-type: none"> • Safe • Effective • Efficient
Exception Justification	If patients have a severe neuropathy clinically in the presence of an apparent cause, the electrodiagnostic studies may not add additional information (medical exception). The patients have the right to refuse any testing (patient exception) or decline the testing for financial or other related reasons (system exception).
Harmonization with Existing Measures	There are no other measures currently available that are similar to this measure or need to be harmonized with this measure.

Measure Designation

Measure purpose	<ul style="list-style-type: none"> • Quality improvement • Accountability
Type of measure	<ul style="list-style-type: none"> • Process
Level of Measurement	<ul style="list-style-type: none"> • Individual practitioner
Care setting	<ul style="list-style-type: none"> • Ambulatory care
Data source	<ul style="list-style-type: none"> • Electronic health record (EHR) data

- Administrative Data/Claims (outpatient claims)
- Administrative Data/Claims Expanded (multiple-source)
- Paper medical record

Technical Specifications: Administrative/Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

The specifications listed below are those needed for performance calculation. Additional CPT II codes may be required depending on how measures are implemented in reporting programs versus performance assessment programs.

Denominator (Eligible Population)	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p> <p>ICD-9 –CM Diagnosis Codes: 250.60, 250.61, 250.62, 250.63, 356.4, 356.8, 356.9, 357.1, 357.2, 357.3, 357.4, 357.5, 357.6, 357.7, 357.8, 357.89, 357.9 AND</p> <p>CPT E/M Service Code: 99201, 99202, 99203, 99204, 99205 (office-new patient), 99211, 99212, 99213, 99214, 99215 (office-established patient), 99241, 99242, 99243, 99244, 99245 (outpatient consult), 99304, 99305, 99306, 99307, 99308, 99309, 99310 (nursing facility), 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337 (domiciliary), 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 (home visit)</p>
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Numerator	<p>Patients who had electrodiagnostic (EDX) studies conducted, documented, and reviewed within 6 months of initial evaluation for distal symmetric polyneuropathy</p>
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Note: It may be necessary to look for findings in the patient medical record or request studies previously conducted from another physician office which may require additional time. Another electrodiagnostic study should not be performed if a satisfactory study has already been done and can be reviewed.

Reporting Instructions:

- For all patients meeting the denominator criteria, report either **3751F**, *Electrodiagnostic studies for distal symmetric polyneuropathy conducted (or requested), documented, and reviewed within 6 months of initial evaluation for condition* or **3752F** *Electrodiagnostic studies for distal symmetric polyneuropathy not conducted (or requested), documented, or reviewed within 6 months of initial evaluation for condition* or **3753F** *Patient has clear clinical symptoms and signs that are highly suggestive of neuropathy AND cannot be attributed to another condition, AND has an obvious cause for the neuropathy*

3751F *Electrodiagnostic studies for distal symmetric polyneuropathy conducted (or requested), documented, and reviewed within 6 months of initial evaluation for condition*

3752F *Electrodiagnostic studies for distal symmetric polyneuropathy not conducted (or requested), documented, or reviewed within 6 months of initial evaluation for condition*

3753F *Patient has clear clinical symptoms and signs that are highly suggestive of neuropathy AND cannot be attributed to another condition, AND has an obvious cause for the neuropathy*

**Denominator
Exceptions**

All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy

- Documentation of a medical reason for not conducting, documenting and reviewing EDX studies (eg patient has clear clinical symptoms and signs that are highly suggestive of neuropathy AND cannot be attributed to another condition, AND has an obvious cause for the neuropathy; OR has skin conditions which contraindicate EDX)
 - Append modifier to CPT II code: **3751F-1P**
- Documentation of a patient reason for not conducting, documenting and reviewing EDX studies (eg patient declines to undergo testing)
 - Append modifier to CPT II code: **3751F-2P**
- Documentation of a system reason for not conducting, documenting and reviewing EDX studies (eg patient does not have insurance to pay for the testing)
 - Append modifier to CPT II code: **3751F-3P**

Measure #3: Diabetes/Pre-Diabetes Screening for Patients with DSP

Distal Symmetric Polyneuropathy

Measure Description

Percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy who had screening tests for diabetes (eg fasting blood sugar test, a hemoglobin A1C, or a 2 hour Glucose Tolerance Test) reviewed, requested or ordered when seen for an initial evaluation for distal symmetric polyneuropathy.

Measure Components

Numerator Statement	Patients who had screening tests for diabetes (eg, fasting blood sugar test, hemoglobin A1C, or a 2 hour Glucose Tolerance Test) reviewed, requested, or ordered when seen for an initial evaluation for distal symmetric polyneuropathy.
Denominator Statement	All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.
Denominator Exceptions	<ul style="list-style-type: none"> • Documentation of a medical reason for not reviewing, requesting or ordering diabetes screening tests (eg patient has a diagnosis of diabetes, patient has a known medical condition to cause neuropathy, patient had previous diabetes screening) • Documentation of a patient reason for not reviewing, requesting or ordering diabetes screening tests (eg patient declines to undergo testing) • Documentation of a system reason for not reviewing, requesting or ordering diabetes screening tests (eg patient does not have insurance to pay for testing)
Supporting Guideline & Other References	<p>The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines:</p> <ul style="list-style-type: none"> • Screening laboratory tests may be considered for all patients with polyneuropathy. (Level C)²⁷ • Those tests that provide the highest yield of abnormality are blood glucose, serum B12 with metabolites (methylmalonic acid with or without homocysteine), and serum protein immunofixation electrophoresis. (Level C)²⁷ • If there is no definite evidence of diabetes mellitus by routine testing of blood glucose, testing for impaired glucose tolerance may be considered in distal symmetric sensory polyneuropathy. (Level C)²⁷ • All patients should be screened for distal symmetric polyneuropathy(DSP) at diagnosis and at least annually thereafter, using simple clinical tests. (Level B)²⁴

Measure Importance

Relationship to desired outcome Early intervention and control of diabetes in DSP patients can improve care. DSP patients screened for pre-diabetes or diabetes may reduce complications over time. Patients with painful diabetic neuropathy sensory polyneuropathy are more likely to have impaired glucose tolerance tests (GTT) than those with painless sensory polyneuropathy.⁴⁴

DSP is the most common variety of neuropathy and type of diabetic neuropathy.^{1,4} Approximately 30% of neuropathies are caused by diabetes.³ Neuropathies affect up to 50% of patients with diabetes.⁷ Since DSP is the major contributory factor for diabetic foot ulcers and the lower-limb amputation rates in diabetic subjects are 15 times higher than in the non-diabetic population, an early detection of DSP by screening and appropriate diagnosis is of utmost importance.¹⁵

Opportunity for Approximately 1.9 million people 20 years and older were newly diagnosed with diabetes in

Improvement 2010. In 2005–2008, based on fasting glucose or hemoglobin A1c levels, 35% of U.S. adults aged 20 years or older had pre-diabetes (50% of adults aged 65 years or older). Applying this percentage to the entire U.S. population in 2010 yields an estimated 79 million American adults aged 20 years or older with prediabetes.⁴⁴

DSP affects at least one in four diabetic patients.¹ Diabetes is one of the five major chronic conditions that affect 25% of the US community population¹⁴ and amounted to more than \$62.3 billion health care costs in 1996.⁹

Data collected between 1988 and 1995 (derived from the Center for Disease Control's population-based Behavioral Risk Factor Surveillance System [BRFSS], as well as the National Health and Nutrition Examination [NHANES] surveys) reveal significant quality gaps in the treatment of diabetes and in screening for diabetes-related complications.⁷ Diabetics also do not receive appropriate screening measures: only 55% obtain annual foot examinations.¹⁶

The UK Prospective Diabetes Study showed the effects of different treatment therapies and the associated outcomes over time. The group studied the effects of diet alone and deterioration of glycemic control; this shows the importance of early intervention and control of diabetes.⁴⁵

IOM Domains of Health Care Quality Addressed

- **Safe**
- **Effective**
- **Efficient**

Exception Justification If patients already have an underlying diagnosis of diabetes, the testing would include evaluation of degree of glycemic control, rather than tests for initial diagnosis of diabetes. If patients have already been diagnosed with diabetes, has a diagnosed cause of their neuropathy or has previously completed testing they do not need to undergo additional testing as this would be unnecessary. Patients have a right to refuse testing for personal (patient exception) or financial reasons (system exception).

Harmonization with Existing Measures There are no other measures currently available that are similar to this measure or need to be harmonized with this measure.

Measure Designation

Measure purpose	<ul style="list-style-type: none"> • Quality improvement • Accountability
Type of measure	<ul style="list-style-type: none"> • Process
Level of Measurement	<ul style="list-style-type: none"> • Individual practitioner
Care setting	<ul style="list-style-type: none"> • Ambulatory care
Data source	<ul style="list-style-type: none"> • Electronic health record (EHR) data • Administrative Data/Claims (outpatient claims) • Administrative Data/Claims Expanded (multiple-source) • Paper medical record

Technical Specifications: Administrative/Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based

on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

The specifications listed below are those needed for performance calculation. Additional CPT II codes may be required depending on how measures are implemented in reporting programs versus performance assessment programs.

Denominator (Eligible Population)	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p> <p>ICD-9 –CM Diagnosis Codes: 356.4, 356.9, 357.1, 357.2, 357.3, 357.4, 357.5, 357.6, 357.7, 357.8, 357.89, 357.9, AND</p> <p>CPT E/M Service Code: 99201, 99202, 99203, 99204, 99205 (office-new patient), 99211, 99212, 99213, 99214, 99215 (office-established patient), 99304, 99305, 99306, 99307, 99308, 99309, 99310 (nursing facility), 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337 (domiciliary), 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 (home visit)</p>
Numerator	<p>Patients who had screening tests for diabetes (eg, fasting blood sugar test, hemoglobin A1C, or a 2 hour Glucose Tolerance Test) reviewed, requested, or ordered when seen for an initial evaluation of distal symmetric polyneuropathy.</p> <p>Reporting Instructions:</p> <ul style="list-style-type: none">• For all patients meeting the denominator criteria, report CPT Category II code 1119F, <i>initial evaluation for condition</i> <u>or</u> 1501F, <i>not initial evaluation for condition</i>.• When 1119F is reported, also report 3754F <i>Screening tests for diabetes mellitus reviewed, requested, or ordered</i>.• <p>3754F Screening tests for diabetes mellitus reviewed, requested, or ordered 1119F Initial evaluation for condition 1501F Not initial evaluation for condition</p>
Denominator Exceptions	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p> <ul style="list-style-type: none">• Documentation of a medical reason for not reviewing, requesting or ordering diabetes screening tests (eg patient already had diagnosis of diabetes or patient has a known medical condition to cause neuropathy, patient had previous diabetes screening)<ul style="list-style-type: none">○ Append modifier to CPT II code: 3754F -1P• Documentation of a patient reason for not reviewing, requesting or ordering diabetes screening tests (eg patient declines to undergo testing)<ul style="list-style-type: none">○ Append modifier to CPT II code: 3754F -2P• Documentation of a system reason for not reviewing, requesting or ordering diabetes screening tests (eg patient does not have insurance to pay for testing)<ul style="list-style-type: none">○ Append modifier to CPT II code: 3754F -3P

Measure #4: Screening for Unhealthy Alcohol Use

Distal Symmetric Polyneuropathy

Measure Description

Percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy who were screened with a validated screening instrument for unhealthy alcohol use* when seen for an initial evaluation for distal symmetric polyneuropathy.

**Unhealthy alcohol use covers a spectrum that is associated with varying degrees of risk to health. Categories representing unhealthy alcohol use include risky use, problem drinking, harmful use, and alcohol abuse, and the less common but more severe alcoholism and alcohol dependence.*

Measure Components

Numerator Statement	<p>Patients who were screened with a validated screening instrument for unhealthy alcohol use* when seen for an initial evaluation for distal symmetric polyneuropathy.</p> <p><i>*Unhealthy alcohol use covers a spectrum that is associated with varying degrees of risk to health. Categories representing unhealthy alcohol use include risky use, problem drinking, harmful use, and alcohol abuse, and the less common but more severe alcoholism and alcohol dependence.</i></p> <p>Unhealthy alcohol use can be assessed using one of a number of available valid and reliable instruments available from medical literature. Examples include, but are not limited to:</p> <ul style="list-style-type: none"> • CAGE-AID (Cut-down, Annoyed, Guilty, Eye-opener)⁴⁶ • AUDIT C (Alcohol Use Disorders Identification Test – Consumption)⁴¹ <p>A systematic method of assessing for unhealthy alcohol use should be utilized. Please refer to the National Institute on Alcohol Abuse and Alcoholism publication: <i>Helping Patients Who Drink Too Much: A Clinician's Guide</i> for additional information regarding systematic screening methods.⁴⁷</p>
Denominator Statement	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p>
Denominator Exceptions	<ul style="list-style-type: none"> • Documentation of a medical reason for not screening the patient with a validated screening instrument for unhealthy alcohol use (eg patient diagnosed with alcoholism) • Documentation of a patient reason for not screening the patient with a validated screening instrument for unhealthy alcohol use (eg patient declines to answer questions/complete the screening)
Supporting Guideline & Other References	<p>The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines or consensus papers.</p> <ul style="list-style-type: none"> • The USPSTF strongly recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings. (Level B)²⁸ • During new patient encounters and at least annually, patients in general and mental healthcare settings should be screened for at-risk drinking, alcohol use problems and illnesses, and any tobacco use. (Consensus Standard)²⁹ • All patients identified with alcohol use in excess of National Institute on Alcohol Abuse and Alcoholism guidelines and/or any tobacco use should receive brief motivational counseling intervention by a healthcare worker trained in this technique. (Consensus Standard)²⁹

Measure Importance

Relationship to desired Reduction in alcohol dependence varies with referral for treatment. Alcohol dependence often goes undetected and in a recent study in primary care patients with alcohol dependence,

outcome they received the recommended quality of care including a referral for treatment approximately 10% of the time.⁴⁸

Chronic unhealthy alcohol use leads to metabolic changes of nerve cells, these metabolic changes lead to break down in the nerve cells which in turn cause neuropathies in patients who chronically misuse alcohol. It is therefore important to monitor patients for alcohol consumption and misuse.⁴⁷

Epidemiological data indicate that not only increased alcohol consumption but also the traditional cardiovascular risk factors such as hypertension, smoking, and cholesterol play a role in development and progression of diabetic neuropathy and hence need to be prevented or treated.¹

Opportunity for Improvement In patients with alcohol dependence, only 10% received the recommended quality of care including a referral for treatment.⁴⁸ Unhealthy alcohol use can be assessed using one of a number of available valid and reliable instruments available from medical literature. Examples include, but are not limited to: CAGE-AID⁴⁶ and Audit C (Alcohol Use Disorders Identification Test – Consumption).⁴¹

- IOM Domains of Health Care Quality Addressed**
- **Safe**
 - **Effective**
 - **Efficient**
 - **Patient-Centered**
-

Exception Justification In patients with documented alcoholism, it would be unnecessary to rescreen them for unhealthy alcohol use. Patients may refuse to be screened (patient exception) for unhealthy alcohol use.

Harmonization with Existing Measures There is one other measure that refers to screening for unhealthy alcohol use. This measure has been adapted to capture those patients with a diagnosis of distal symmetric polyneuropathy screened for unhealthy alcohol use as these patients are not necessarily captured by the existing screening measures for unhealthy alcohol use. Existing literature supports specifically screening these patients for this condition. The existing PCPI measure is a general measure meant to be used for all patients 18 years or older, this measure applies to those diagnosed with distal symmetric polyneuropathy due to risk identified for these patients.

Measure Designation

- | | |
|-----------------------------|--|
| Measure purpose | <ul style="list-style-type: none"> • Quality improvement • Accountability |
| Type of measure | <ul style="list-style-type: none"> • Process |
| Level of Measurement | <ul style="list-style-type: none"> • Individual practitioner |
| Care setting | <ul style="list-style-type: none"> • Ambulatory care |
| Data source | <ul style="list-style-type: none"> • Electronic health record (EHR) data • Administrative Data/Claims (outpatient claims) • Administrative Data/Claims Expanded (multiple-source) • Paper medical record |

Technical Specifications: Administrative/Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible

population/denominator criteria.

The specifications listed below are those needed for performance calculation. Additional CPT II codes may be required depending on how measures are implemented in reporting programs versus performance assessment programs.

Denominator (Eligible Population)	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p> <p>ICD-9 –CM Diagnosis Codes: 250.60, 250.61, 250.62, 250. 63, 356.4, 356.9, 357.1, 357.2, 357.3, 357.4, 357.5, 357.6, 357.7, 357.8, 357.89, 357.9</p> <p>AND</p> <p>CPT E/M Service Code: 99201, 99202, 99203, 99204, 99205 (office-new patient), 99212, 99213, 99214, 99215 (office-established patient), 99241, 99242, 99243, 99244, 99245 (outpatient consult), 99304, 99305, 99306, 99307, 99308, 99309, 99310 (nursing facility), 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337 (domiciliary), 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 (home visit),</p>
Numerator	<p>Patients who were screened with a validated screening instrument for unhealthy alcohol use* when seen for an initial evaluation for distal symmetric polyneuropathy.</p> <p><i>*Unhealthy alcohol use covers a spectrum that is associated with varying degrees of risk to health. Categories representing unhealthy alcohol use include risky use, problem drinking, harmful use, and alcohol abuse, and the less common but more severe alcoholism and alcohol dependence.</i></p> <p>Unhealthy alcohol use can be assessed using one of a number of available valid and reliable instruments available from medical literature. Examples include, but are not limited to:</p> <ul style="list-style-type: none">• CAGE-AID (Cut-down, Annoyed, Guilty, Eye-opener)⁴⁶• AUDIT C (Alcohol Use Disorders Identification Test – Consumption)⁴¹ <p>A systematic method of assessing for unhealthy alcohol use should be utilized. Please refer to the National Institute on Alcohol Abuse and Alcoholism publication: <i>Helping Patients Who Drink Too Much: A Clinician’s Guide</i> for additional information regarding systematic screening methods.</p> <p>Reporting Instructions:</p> <ul style="list-style-type: none">• For all patients meeting the denominator criteria, report CPT Category II code 1119F, <i>initial evaluation for condition</i> <u>or</u> 1501F, <i>not initial evaluation for condition</i>.• When 1119F is reported, also report 3061F, <i>Patient screened for unhealthy alcohol use using a systematic screening method</i> <p>3016F Patient screened for unhealthy alcohol use using a systematic screening method 1119F Initial evaluation for condition 1501F Not initial evaluation for condition</p>
Denominator Exceptions	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p> <ul style="list-style-type: none">• Documentation of a medical reason for not screening the patient with a validated screening instrument for unhealthy alcohol use (eg patient diagnosed

with alcoholism)

- Append modifier to CPT II code: **3016F-1P**
- Documentation of a patient reason for not screening the patient with a validated screening instrument for unhealthy alcohol use (eg patient declines to answer questions/complete the screening)
 - Append modifier to CPT II code: **3016F-2P**

Measure #5: Querying about Pain and Pain Interference with Function

Distal Symmetric Polyneuropathy

Measure Description

Percentage of patient visits for patient age 18 years and older with a diagnosis of distal symmetric polyneuropathy who was queried about pain and pain interference with function using a valid and reliable instrument.

Measure Components

Numerator Statement	<p>Patient visits with the patient queried about pain and pain interference with function using a valid and reliable instrument (eg Graded Chronic Pain Scale).</p> <p>Note: Neuropathic pain can be assessed using one of a number of available valid and reliable instruments available from medical literature. Examples include, but are not limited to:</p> <ul style="list-style-type: none"> • Graded Chronic Pain Scale⁴⁹
Denominator Statement	<p>All visits for patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p>
Denominator Exceptions	<ul style="list-style-type: none"> • Documentation of a medical reason for not querying the patient about pain and pain interference with function (eg patient cognitively impaired and unable to respond) • Documentation of a patient reason for not querying the patient about pain and pain interference with function (eg patient declines to respond to questions)
Supporting Guideline & Other References	<p>The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines:</p> <ul style="list-style-type: none"> • Assessment of neuropathic pain (NP) should focus on identifying and treating the underlying disease processes and peripheral or central nervous system lesions, response to prior therapies, and comorbid conditions that can be affected by therapy. Particular attention should be paid to identifying coexisting depression, anxiety, sleep disturbances, and other adverse impacts of NP on health-related quality of life, and both pain and its adverse effects should be reassessed frequently. Patient education and support are critical components of the successful management of NP. Careful explanation of the cause of NP and the treatment plan are essential. Patient and provider expectations regarding treatment effectiveness and tolerability must be discussed, and realistic treatment goals should be established with patients.(Strength not available)³⁰

Measure Importance

Relationship to desired outcome

Treatment of chronic painful diabetic neuropathy remains a challenge for physicians as individual tolerability remains a major aspect in any treatment decision.¹ In the case of painful diabetic neuropathy it is a chronic disease that is often treated with analgesics, there is little data regarding the efficacy of any chronic treatment regimen. Improved patient outcomes and preventing complications such as neuropathic pain and complications such as microvascular diabetic neuropathy may significantly improve the quality of life in certain populations. Patients with severe pain may present with very few clinical symptoms which can lead often lead to a misdiagnosis or under-diagnosis, persistent pain over time can lead to disability and impaired quality of life.¹

The use of a valid and reliable assessment instrument for neuropathic pain may prevent complications and improve the patient's quality of life.¹

Opportunity for

At least one of four diabetic patients is affected by distal symmetric polyneuropathy¹, which

Improvement	represents a major health problem, since it may present with partly excruciating neuropathic pain and is responsible for substantial morbidity, increased mortality, and impaired quality of life.
IOM Domains of Health Care Quality Addressed	<ul style="list-style-type: none"> • Safe • Effective • Efficient • Patient-Centered
Exception Justification	In patients who are cognitively impaired, it may not be possible to obtain this information (medical exception). Patients may also refuse to answer questions about pain and function (patient exception).
Harmonization with Existing Measures	There are no other measures currently available that are similar to this measure or need to be harmonized with this measure.

Measure Designation

Measure purpose	<ul style="list-style-type: none"> • Quality improvement • Accountability
Type of measure	<ul style="list-style-type: none"> • Process
Level of Measurement	<ul style="list-style-type: none"> • Individual practitioner
Care setting	<ul style="list-style-type: none"> • Ambulatory care
Data source	<ul style="list-style-type: none"> • Electronic health record (EHR) data • Administrative Data/Claims (outpatient claims) • Administrative Data/Claims Expanded (multiple-source) • Paper medical record

Technical Specifications: Administrative/Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

The specifications listed below are those needed for performance calculation. Additional CPT II codes may be required depending on how measures are implemented in reporting programs versus performance assessment programs.

Denominator (Eligible Population)	<p>All visits for patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p> <p>ICD-9 –CM Diagnosis Codes: 250.60, 250.61, 250.62, 250.63, 356.4, 356.9, 357.1, 357.2, 357.3, 357.4, 357.5, 357.6, 357.7, 357.8, 357.89, 357.9</p> <p>AND</p> <p>CPT E/M Service Code: 99201, 99202, 99203, 99204, 99205 (office-new patient), 99212, 99213, 99214, 99215 (office-established patient), 99241, 99242, 99243, 99244, 99245 (outpatient consult), 99304, 99305, 99306, 99307, 99308, 99309, 99310 (nursing facility), 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337 (domiciliary), 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 (home visit)</p>
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Numerator

Patient visits with the patients queried about pain and pain interference with function using a valid and reliable instrument (eg Graded Chronic Pain Scale).

Note: Neuropathic pain can be assessed using one of a number of available valid and reliable instruments available from medical literature. Examples include, but are not limited to: Graded Chronic Pain Scale⁴⁹

Reporting Instructions:

- For all patients meeting the denominator criteria, report CPT Category II code **1502F**, *Patient queried about pain and pain interference with function using a valid and reliable instrument.*

1502F Patient queried about pain and pain interference with function using a valid and reliable instrument

Denominator Exceptions

All visits for patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.

- Documentation of a medical reason for not querying the patient about pain and pain interference with function (eg patient cognitively impaired and unable to respond)
 - Append modifier to CPT II code: **1502-1P**
- Documentation of a patient reason for not querying the patient about pain and pain interference with function (eg patient declines to respond to questions)
 - Append modifier to CPT II code: **1502-2P**

Measure #6: Querying about Falls for Patients with DSP

Distal Symmetric Polyneuropathy

Measure Description

Percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy who were queried at least once annually about falls within the past 12 months and the response was documented.

Measure Components

Numerator Statement	<p>Patients who were queried at least once annually about falls within the past 12 months</p> <p>Note: Participants are encouraged to use validated assessments. An example of this is the multifactorial falls risk assessment, which is to be performed once a year as part of an exam.³¹</p>
Denominator Statement	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p>
Denominator Exceptions	<ul style="list-style-type: none"> • Documentation of a medical reason for not querying the patient about falls within the past 12 months (eg patient is cognitively impaired and unable to communicate, patient is non-ambulatory) • Documentation of a patient reason for not querying the patient about falls within the past 12 months (eg patient declines to answer the query about falls)
Supporting Guideline & Other References	<p>The following evidence statements are quoted <u>verbatim</u> from the referenced clinical guidelines:</p> <ul style="list-style-type: none"> • An increased risk of falls is also probable among patients with Parkinson disease, peripheral neuropathy, lower extremity weakness or sensory loss, and substantial loss of vision (Level B).²⁶ • All of the patients with any fall risk factors described above should asked about falls during the past year (Level A)²⁶ • After a comprehensive standard neurologic examination, including an evaluation of cognition and vision, if further assessment of the extent of fall risk is needed, other screening measures to be considered include the Get-Up-And-Go Test or Timed Up-and-Go Test, an assessment of ability to stand unassisted from a sitting position, and the Tinetti Mobility Scale (Level B).²⁶ • An increased risk of falls is established among persons with diagnoses of stroke, dementia, disorders of gait and balance, and those who use assistive devices to ambulate (Level A).²⁶ • As for screening measures that may predict or further assess fall risk, a history of recent falls is an established predictor of future falls (Level A).²⁶ • Additional screening instruments of probable value include the Get-Up-And-Go Test or Timed Up-and-Go Test, an assessment of ability to stand from a sitting position, and the Tinetti Mobility Scale (Level B).²⁶ • Other screening instruments of possible utility are described in appendix e-4 (Level C).³¹ • Direct interventions customized to the identified risk factors, coupled with an appropriate exercise program should follow the multifactorial fall risk assessment.(Level A)³¹ • A strategy to reduce the risk of falls should include multifactorial assessment of known fall risk factors and management of the risk factors identified. (Level A)³¹

Measure Importance

Relationship to Diabetic peripheral neuropathy causes loss of distal strength and sensation with interruption

desired outcome of both afferent and efferent pathways. The postural instability associated with diabetic peripheral neuropathy is most apparent in unipedal stance and balance – both of which are critical in gait and activities of daily living such as changing clothes and climbing stairs.

No associated co-morbidities explained the high rate of falls among the elderly with peripheral neuropathy suggesting there is a risk factor for falls among the elderly with peripheral neuropathy.⁵⁰ Fall risk assessment and plan of care tools reduce the risk of falls among older adults in the community.^{26,51}

Opportunity for Improvement Fall risk assessments and plans of care reduce risk of falls among older adults. Falls are a recognized as an important cause of morbidity and mortality in the elderly – costing the health care system millions of dollars each year.⁵⁰ Almost one-third of those over age 65 and not in a nursing home fall each year. Much work has been done to identify risk factors that contribute to falls. An important risk factor that has been identified and is increasingly more prevalent is diabetic peripheral neuropathy.

One retrospective study by Cavanagh et al. found that diabetic neuropathic subjects were 15 times more likely to report injury and felt significantly less safe during standing and walking than non-neuropathic subjects.⁵² Another study by Richardson et. al. found diabetics with EMG-confirmed peripheral neuropathy were 23 times more likely to report instability resulting in a fall or injury.⁵³

- IOM Domains of Health Care Quality Addressed**
- **Safe**
 - **Effective**
 - **Efficient**
 - **Patient-Centered**

Exception Justification A patient that is non-ambulatory (eg wheel chair bound, amputee, or paralyzed) or patients that are unable to communicate or decline to communicate would be excluded from this measure as the querying of the patient is driven by their mobility condition or ability to communicate (medical exception) and willingness to communicate (patient exception).

Harmonization with Existing Measures The AAN attempts to harmonize with existing measures, this measure has been adapted to capture those patients with a diagnosis of distal symmetric polyneuropathy screened for falls. The measure has also been adapted to account for additional screening not captured in existing falls measures. This measure specifically does NOT have an upper age limit that is associated with other falls measures from the American Geriatrics Society.

Measure Designation

- | | |
|-----------------------------|--|
| Measure purpose | <ul style="list-style-type: none"> • Quality improvement • Accountability |
| Type of measure | <ul style="list-style-type: none"> • Process |
| Level of Measurement | <ul style="list-style-type: none"> • Individual practitioner |
| Care setting | <ul style="list-style-type: none"> • Ambulatory care |
| Data source | <ul style="list-style-type: none"> • Electronic health record (EHR) data • Administrative Data/Claims (outpatient claims) • Administrative Data/Claims Expanded (multiple-source) • Paper medical record |

Technical Specifications: Administrative/Claims Data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based

on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

The specifications listed below are those needed for performance calculation. Additional CPT II codes may be required depending on how measures are implemented in reporting programs versus performance assessment programs.

Denominator (Eligible Population)	<p>All patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy.</p> <p>ICD-9–CM Diagnosis Codes: 250.60, 250.61, 250.62, 250.63, 356.4, 356.9, 357.1, 357.2, 357.3, 357.4, 357.5, 357.6, 357.7, 357.8, 357.89, 357.9</p> <p>AND</p> <p>CPT E/M Service Code: 99201, 99202, 99203, 99204, 99205 (office-new patient), 99212, 99213, 99214, 99215 (office-established patient), 99241, 99242, 99243, 99244, 99245 (outpatient consult), 99304, 99305, 99306, 99307, 99308, 99309, 99310 (nursing facility), 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337 (domiciliary), 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 (home visit),</p>
Numerator	<p>Patients who were queried at least once annually about falls within the past 12 months.</p> <p>Note: Participants are encouraged to use validated assessment. An example of this is the multifactorial falls risk assessment, which is to be performed once a year as part of an exam.³¹</p> <p>Reporting Instructions:</p> <ul style="list-style-type: none">• For all patients meeting the denominator criteria, report CPT Category II code 6080F, <i>Patient (or caregiver) queried about falls</i> <p>6080F Patient (or caregiver) queried about falls</p>
Denominator Exceptions	<ul style="list-style-type: none">• Documentation of a medical reason for not querying the patient about falls (eg patient is cognitively impaired and unable to communicate, patient is non-ambulatory)<ul style="list-style-type: none">○ Append modifier to CPT II code: 6080F-1P• Documentation of a patient reason for not querying the patient about falls (eg patient declines to answer the query about falls)<ul style="list-style-type: none">○ Append modifier to CPT II code: 6080F-2P

EVIDENCE CLASSIFICATIONS / RATING SCHEMES

1. American Academy of Neurology^{4,23-26}

Classification of evidence for therapeutic articles

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required:

- a) Primary outcome(s) is/are clearly defined.
- b) Exclusion/inclusion criteria are clearly defined.
- c) Adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias.
- d) Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II: Prospective, matched, group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criterion a–d.

Class III: All other controlled trials including well-defined natural history controls or patients serving as own controls in a representative population, where outcome assessment is independently assessed or independently derived by objective outcome measurement (an outcome measure that is unlikely to be affected by an observer’s [patient, treating physician, investigator] expectation or bias [eg, blood tests, administrative outcome data]).

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

Classification of recommendations

A _ Established as effective, ineffective, or harmful for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)

B _ Probably effective, ineffective, or harmful for the given condition in the specified population. (Level B rating requires at least one Class I study or at least two consistent Class II studies.)

C _ Possibly effective, ineffective, or harmful for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U _ Data inadequate or conflicting given current knowledge, treatment is unproven.

2. American Diabetes Association evidence grading system for clinical practice recommendations²⁷

Level of Evidence	Description
A	<p>Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:</p> <ul style="list-style-type: none"> • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis <p>Compelling non-experimental evidence, i.e., “all or none” rule developed by Center for Evidence Based Medicine at Oxford</p> <p>Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:</p> <ul style="list-style-type: none"> • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	<p>Supportive evidence from well-conducted cohort studies</p> <ul style="list-style-type: none"> • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies <p>Supportive evidence from a well-conducted case-control study</p>
C	<p>Supportive evidence from poorly controlled or uncontrolled studies</p> <ul style="list-style-type: none"> • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls) • Evidence from case series or case reports <p>Conflicting evidence with the weight of evidence supporting the recommendation</p>
E	Expert consensus or clinical experience

3. United States Preventive Services Task Force (USPSTF) Ratings²⁸

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

- B. The USPSTF recommends that clinicians provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.
- C. The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.
- D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.
- I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing the service. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

4. National Quality Forum-National Voluntary Consensus Standards for the Treatment of Substance Use Conditions: Evidence-Based Treatment Practices²⁹

This project was conducted according to the NQF Consensus Development Process, and the 11 endorsed practices and their specifications have legal status as national voluntary consensus standards for the treatment of substance use conditions. For each endorsed practice, the target outcomes are identified, and additional specifications are provided for what a practice entails, for whom it is indicated, who performs it, and the settings where it is provided. Consistent with the priorities established, these practices are applicable across a broad range of populations (eg, adolescents and adults), settings (eg, primary care and substance use treatment settings), and providers (eg, counselors and physicians).

5. Oxford Centre for Evidence-Based Medicine³⁰

<http://www.guideline.gov/disclaimer.aspx?redirect=http://www.cebm.net/index.aspx?o=1025>

Rating scheme for strength of evidence

1a: Systematic review (SR) (with homogeneity) of randomized controlled trials

1b: Individual RCT (with narrow Confidence Interval)

1c: All or none (met when all patients died before the treatment because available, but now some survive on it; or when some patients died before the treatment became available, but none now die on it)

2a: SR (with homogeneity) of cohort studies

2b: Individual cohort study (including low quality RCT; eg, <80% follow-up)

2c: "Outcomes" Research; Ecological studies

3a: SR (with homogeneity) of case-control studies

3b: Individual Case-Control Study

4: Case-series (and poor quality cohort and case-control studies)

5: Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"

Source: Oxford Centre for Evidence-based Medicine. Levels of evidence and grades of recommendation. Available at:

http://www.cebm.net/levels_of_evidence.asp

Rating Scheme for strength of recommendations

A: Consistent level 1 studies

B: Consistent level 2 or 3 studies *or* extrapolations from level 1 studies

C: Level 4 studies *or* extrapolations from level 2 or 3 studies

D: Level 5 evidence *or* troublingly inconsistent or inconclusive studies of any level

Source: Oxford Centre for Evidence-based Medicine. Levels of evidence and grades of recommendation. Available at:

http://www.cebm.net/levels_of_evidence.asp

6. American Geriatrics Society³¹

A standardized format based on an evidence rating system used by the U.S. Preventive Services Task Force was used to critically analyze the literature and grade the evidence for this document.⁸ Based on overall quality of evidence and magnitude of benefit for each intervention, the committee assigned a rating of A, B, C, or D to each recommendation (A5a strong recommendation that physicians provide the intervention to eligible patients, B5a recommendation that clinicians provide this intervention to eligible patients, C5 that no recommendation for or against the routine provision of the intervention can be made, and D5 that the panel recommends against routinely providing the intervention to asymptomatic patients). If evidence was insufficient to come to a decision for or against the intervention, the panel assigned a rating of I.

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